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Development and optimization of a suspension system for lower limbs prostheses

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“Anything you can think of, you can create,”

Van Phillip

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ABSTRACT

The increasing rate of amputations reinforce the need to improve the prostheses currently on the market and develop new solutions, to provide a better quality of life for the amputees.

The suspension systems have a fundamental role in adapting to the prosthesis and amputee's rehabilitation. These systems guarantee a firm attachment between the residual limb and prosthesis. The suspension systems available in the currently market, do not provide the quality of life that the lower limb amputees deserve, since do not ensure the total safety and comfort enough to use the prosthesis in long term. These limitations are associated with the difficulties on donning and doffing the prosthesis.

This dissertation proposes a novel approach to solve some of these limitations. The proposed suspension system was obtained following the Design methodology, to understand the amputees' needs, define the statement-problem, create several alternative solutions, and prototyping and testing the selected solution. The new suspension system is a combination of a guiding and fixation mechanisms, that improves the donning and doffing of prosthesis and, consequently, increases the amputee's satisfaction.

Motion analysis, safety and functional tests were done to evaluate the performance of the prototype and ensure that the proposed solution is viable and follows all the requirements and specifications stablished.

Due to some technical issues, it was not possible to test all the functionalities of the prototype of the suspension system. However, the proposed suspension system presented an effective fixation of the serrated pin. Additional tests are still needed to evaluate the proposed system with the intention of being tested on amputees.

In short, the new suspension system is a good alternative system to improve the life quality of amputees with lower activity level on the daily basis.

With this dissertation, were published abstract for the Regional HELIX'17 conference and a paper for the International Journal of Mechatronics and Applied Mechanics, and a paper for the ICEUBI 2017 conference.

KEYWORDS: Lower limb prosthesis, suspension system, mechanical design, guiding system and locking system

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LIST OF ABBREVIATIONS AND ACRONYMS

D_A = diameter of arbor (mm)

Dc= inside diameter of spring cage (mm)

E = Young's modulus (MPa)

I= Moment of Inertia ($kg.m^2$)

L_a = active length of spring when torque is applied (mm)

L_b= length of free material in inner unpacked region of caged spring before torque is applied (mm)

L_F = line length from spring end attached to arbor to any element in free configuration (mm)

L_o = total length of material in spring (mm)

L_p = line length between end atattached to arbor and any element in packed zone before Torque (mm)

M = Torque (N.m)

N = number of turns

N_{max} = maximum number of turns available

N_s = number of turns at which all material in spring is active

PAD= Peripheral artery disease

$p_{A=}$ radius of arbor plus half of material thickness (mm)

p_b = radial distance from origin to center line of element at boundary between free and packed zones (mm)

p_c = radial distance from origin to center line of end attached to spring cage (mm)

p_F= radial distance from origin to center line of element of material in free of spring (mm)

p_v = radial distance from origin to center line of element of material in the outer packed zone (mm)

R_F = radius of curvature of an elemento of material in the free configuration (mm)

R_p = radius of curvature of an elemento of material in the outer packed zone (mm)

θ = angular coordinate of polar coordinate system (°)

t= thickness of material (mm)

U = shape factor constant of logarithmic spiral ($radians^{-1}$)

v = Poisson's ratio

1. INTRODUCTION

This chapter aims to introduce the central issue of the dissertation as well the motivation to pursue it. Hence, the objectives of the dissertation are underlined to clarify the thinking and intentions. It is also presented the dissertation outline to provide the reader enough information to understand what was accomplished with the dissertation.

1.1 Overview

This dissertation attempted to develop a new suspension system and to incorporate it in a transtibial prosthesis, in order to improve the quality of life of lower limb amputees and, at the same time, to increase amputees' satisfaction with the prosthesis. The study was developed in cooperation with Padrão Ortopédico company.

The novel approach was achieved following the subsequent objectives:

- Explore the commercially-available suspension systems;
- Identify the main user of lower limb prosthesis;
- Determine the perceived problems that the main user has with the suspension system, daily;
- Develop a new prosthetic suspension system for amputees with lower activity level;
- Investigate the mechanical performance of the new prosthetic suspension system;
- Evaluate the satisfaction with the new prosthetic suspension system in comparison with other existent suspension systems.

The next chapters deal with the conception, design, development, refinements and application of the new suspension system.

1.2 Motivation

Literature reports that lower limb amputations are increasing due to incidence of vascular diseases, such as diabetes, especially affecting the older population. So, the amputee is mainly an individual with lower level of activity and manual dexterity, also presenting difficulties in terms of adaptation and learning, since most of them have advanced age.

The proper suspension system is the key element in the amputee's rehabilitation since it securely connects the prosthesis to the residual limb to prevent excessive movements between the socket and residual limb. Several prosthetic suspension systems are commercial available, including pin/lock systems, lanyard system, straps and hinges, suction systems, and recently magnetic system.

No single suspension system was shown to be efficient in all aspects for all types of amputees. For instance, pin/lock systems are simple suspension system commonly used among the amputees. However, it can be challenging for amputees with poor hand dexterity in terms of inserting the pin correctly into the housing, which in the long term can cause deformation of the pin and housing, limb volume variations and pain at the end of distal limb.

Designing a new suspension system is deemed necessary to improve the positive qualities of the current systems. Therefore, the central focus of this dissertation relies on designing and developing of a new suspension system that provides an effective pin insert for amputees with lower activity levels, while offering comfort and an easy process of donning/doffing the prosthesis.

1.3 Dissertation outline

The dissertation’s outline can be summarized as follows:

Chapter 2 provides a concise overview of amputation and prosthesis background, prosthetic components and review of literature with the advantages and disadvantages of current suspension systems for transtibial prosthesis. The problem addressed in this research and the objectives are also presented.

Chapter 3 describe the design and development procedures of a novel prosthetic suspension system. It is also elucidated the suspension system mechanism.

Chapter 4 describes the development and specifications of the new suspension system and the prototyping process.

Chapter 5 provides a quantitative and qualitative evaluation of the new prosthetic suspension system in terms of loading conditions and satisfaction among the transtibial amputees.

At last, **Chapter 6** deliberates on the outcomes of the research and alleges the system limitations that still need to improve for future research.

2. PROSTHESIS: THE KEY FOR AMPUTEE'S REHABILITATION

This chapter intents to describe the information that refers to the lower limb prosthesis, to provide a background, so one can fully understand and respond to the stated problem. The literature review is crucial to deliver the ideal solution for the user.

2.1 Amputation

Amputation is one of the oldest known surgically performed procedures. Through the history, many surgical amputation techniques have been developed and improved with technological evolution [1].

Unfortunately, the amputation is still often viewed as a failure of treatment. Society should view the amputation as a treatment of choice for severe trauma, vascular disease, and tumors. Consequently, one of the difficulties for a person undergoing amputation surgery is overcoming the psychological stigma that society associates with the loss of a limb [2].

In general, there are several levels of lower limb amputation, including partial foot, ankle disarticulation, transtibial, knee disarticulation, transfemoral, hemipelvectomy and hip disarticulation. The lower-limb amputation levels are summarized in the figure 1. The most prevalent amputation levels are transtibial, the amputation below knee, and transfemoral, the amputation above-knee [3].

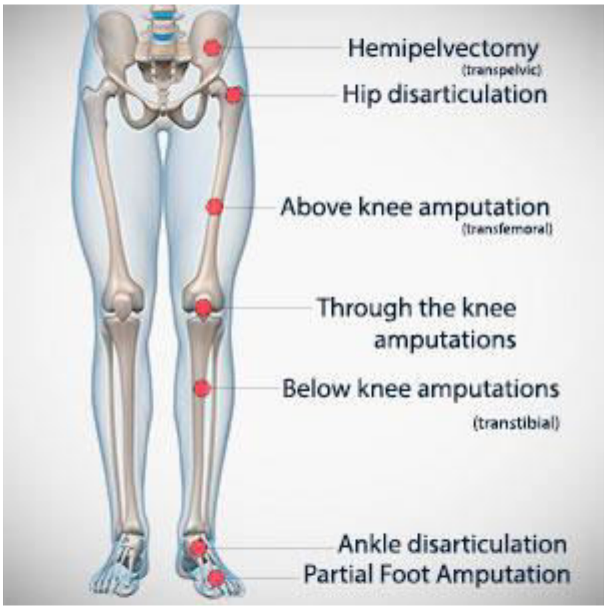

Figure 1. Illustration of amputation levels for lower limb amputation [53].

Lower limb amputation is mainly cause by peripheral artery disease, trauma, congenital malformations and tumors [2].

Peripheral artery disease (PAD) characterized by occlusive of the arterial of the body's extremities when the blood vessels are hardened such that causes an accumulation of plaque, eventually the blood is blocked from reaching tissues. It can cause ulcers, infections and gangrene, which can result in a limb loss [2]; [4]. Diabetes contributes to PAD, while at the same time triggers the nerve death, called neuropathy. Approximately 12 million people in the United States are affect by PAD, and about 20% to 30% of these patients have diabetes.

The incidence of amputation depends on the demographic location. In some of the developing countries, PAD have a lower incidence compared with developed countries, probably, because the rate of people with advanced age is lower. So, in some countries like Cambodia, Afghanistan, Mozambique, Burma, Somalia, Ethiopia and Angola, trauma is the predominant due to the injuries from accidents and war conflicts like land-mines and bombs [3]. Unfortunately, the majority of these amputees are unable to afford the technology they need to overcome their disability.

In the industrialized countries, PAD, especially from diabetes, have the major incidence of lower limb amputation due to the increase of the average lifespan of the population and improved the preventive surgery techniques [5].

In 2005, it was estimated that there are approximately 1.6 million amputees in the United States of America, and it is expected to growth to 3.6 million by 2050 [6]. These statistics shown that vascular problems are the highest cause of amputation by 54%, followed by 45% of trauma and less than 2% of tumors.

The risk of amputation increases among individuals with PAD and diabetes. The Bild *et al*. reported that diabetic individuals have 15 times higher probability to have an amputation than non-diabetic individuals [7].

The lower limb amputations population with is continually growing. There are more than 29 million Americans are living with diabetes in the United States of America. Indeed, about 60% of non-traumatic lower-limb amputations occur in people with diagnosed diabetes [7]. In Portugal, the prevalence of diabetes is 13,3% and 1250 lower limb amputations were performed in 2015 due to diabetes [8].

Most amputees in developed countries are elderly patients with vascular problems [9]. In Unites States of America, approximately 57% of the incident lost limb cases occurred among older adults 65 years and over [6]. So, the main patient is defined has an advanced age person with lower level of activity and hand function and presents difficulties in terms of adaptation and learning [10].

As an irreversible surgical procedure, lower limb amputation has profound economic, social and psychological impact. After amputation, it is important to restore the limb mobility to assist the rehabilitation and social reintegration of the amputee. The prosthesis helps to achieved the rehabilitation intentions of amputee, by replacing of limb loss functions, regain to the amputee autonomy and motor function [11][12].

2.2 Lower limb prostheses

The prosthetists role in the rehabilitation has become more significant after World War II. This following period brought prosthetic advancements. The massive number of amputees stimulated the research for prostheses that could replace the limb functions. Also, the introduction of new designs and materials revolutionized the design of prostheses, for instance the wood components change to plastics [1][13].

In recent years, have been developed new bionic technology that allows overcoming the prosthesis limitations impose by obstacle such as stairs and decline ground. For example, the Ottobock company developed the Genium knee, shown in figure 2 (a). Similarly, the Össur company launched the Power knee, illustrated in figure 2 (b). These two prosthetic knees provide propulsive energy in both flexion and extension phase of the Knee, revolutionizing the prosthetic industry.

During the rehabilitation, the patient needs to learn how to walk with a prosthesis, apply and remove the prosthesis (donning and doffing process) and care necessary to maintenance the prosthesis.

Figure 2. The Prosthetic knee (a) Genium knee from Ottobock company and (b) Power knee from Össur company [54][55].

Normally, since the residual limb volume, after the amputation, will continues variety with the wear of the prosthesis, the amputee uses a temporary prosthesis until the volume of residual limb stabilizes and the definitive prosthesis fits. This temporary prosthesis has a quick production and low cost. The definitive prosthesis takes longer time to produce and it is constituted by more expensive components than the provisional prosthesis, in order to be stronger and more durable [12].

Typically, the prosthesis production starts with the cast or a scan of the residual limb. To select the components that are most suitable for the individual amputee, the rehabilitation team evaluate the patient information and physical examination, including the current weight, level of activity, leisure activities, lifestyle, health status and the condition of the residual limb [14].

The prosthesis design looks to obtain the maximum of functionality, comfort, safety and aesthetic. The prosthesis can be classified as endoskeletal or exoskeletal.

The traditional exoskeletal prosthesis, illustrated in figure 3 (a), has a rigid laminated plastic

Figura 3. The (a) endoskeletal and (b) exoskeletal prosthesis [56].

shell or skin with a wood or urethane foam interior, that provides the weight-bearing support. It is more durable than endoskeletal prosthesis, however the choice of components is limited and the alignment of components cannot be changed [15].

The endoskeletal prosthesis, shown in figure 3 (b), has a tubular structure that constitutes the internal support, providing a wide range of movements. It is lighter than exoskeletal prosthesis and have modular joints and adaptors that allow an easy alignment and adjustment of components at any point of time [15][16].

Currently, the market offers different types of prosthesis according to the amputation level. The following subchapters are focus on transtibibial prosthesis. A variety of companies manufacture and sell various components of a prosthesis, highlighting companies such as Ottobock, Össur, Blatchford, Hanger and The Ohio Willow Wood.

Collaboration between health care physician, prosthetist, and therapist is essential in developing an appropriate limb prescription for each amputee.

2.3 Gait cycle of an amputee

The success of the prosthesis can be dictated by a gait similar or equal to the normal gait. For this, it is necessary to observe and interpret the amputee’s gait, using different evaluation tools, to detect the gait deviations and the associated causes. With this accomplished, it is possible to improve the prosthesis components in order to prevent gait cycle abnormalities.

Before understanding the biomechanics of the amputee gait, the terminology used in describing the different components of normal gait cycle must be understood.

Walking is a complex activity that requires muscular strength, joint mobility and coordination from the central nervous system. The human gait relies on the anatomical and physical condition of the subject and the ground [17].

Descriptions of walking are confined to the gait cycle. The gait cycle is normally assumption as sequence of limb movements that starts and ends when the heel of the same foot touches the ground.

Figure 4 illustrates the gait cycle divided into stages: stance phase and swing phase. The stance phase begins when the initial contact of heel with the ground occurs and ends at the toe-off position. The swing phase begins at the toe-off position and ends at heel contact.

The stance phase represents the period when the foot is on the ground which corresponds to 60 % of the gait cycle. The weight acceptance and single limb support tasks are accomplished during this phase [18] [17].

The swing phase is distinguished from the stance phase by the moment of the foot's take-off the ground, which represents 40% of the cycle. In this phase, the reference leg swings through in preparation for the next foot strike. The hip extension torques are translated into forward propulsion of the pelvis and swing limb, providing the forward push of the reference leg.

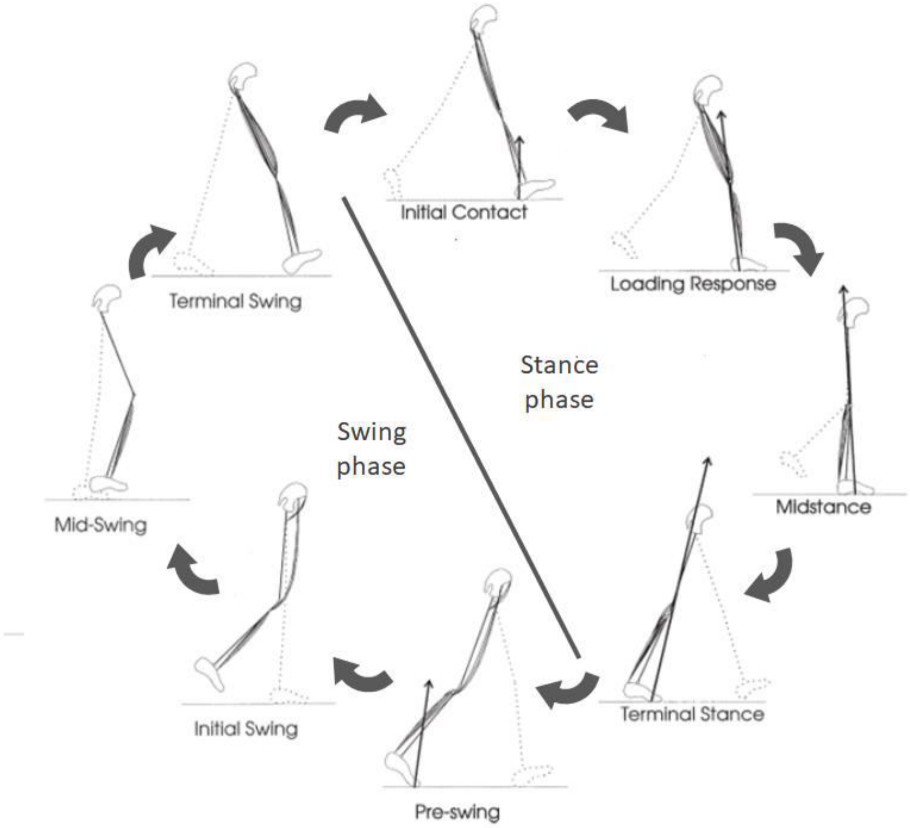

Figure 4. Illustration of the eight events of the gait cycle with the ground reaction force vector represented by a solid line with an arrow [17].

Both stance and swing phase are divided in events based on the movement of the reference foot. The nomenclature developed by Perry and her associates at Rancho Los Amigos Hospital in California divides the stance and swing phase in five and three events, respectively, which consist on:

- Initial contact: The moment that the heel of the reference limb touches the ground.

- Loading response: In this moment, the weight is transferred on to the referenced limb when the plantar surface of the foot touches the ground, to provide forward propulsion.
- Mid stance: Starts with lifted of the opposite foot from the ground and continues until body weight is aligned over the forefoot.
- Terminal stance: Begins with heel rise of reference limb and ends when the opposite foot strikes the ground, occurring the transference of body weight for the ahead of the forefoot.
- Pre-swing: Represents the moment of the transition from stance to swing phase. It begins with initial contact of the opposite limb and ends with toe-off.
- Initial swing: The moment that begins with the lifting of the reference foot from the floor and ends when the swinging foot is opposite to stance foot.
- Mid-swing: The moment when the opposite stance limb and the swinging reference limb intersect. It ends when the swinging limb is forward the opposite limb and the tibia is vertical.
- Terminal swing: Corresponds to the ending of the swing phase and the preparation for the stance phase. It begins with a vertical tibia and ends when the heel strikes the floor[17].

The knee, ankle and foot have an important role during the heel contact event by providing a smooth absorption of the shock of the heel contact and maintained the center of gravity of body.

Different parameters can characterize the gait, such as:

- Step Length: The distance, usually, measured from the midpoint of the back of the heel to the midpoint of the back of the other heel, also can be measure from the front of toe to the front toe of the other foot, is described as the distance traveled during one step.
- Stride Length: The distance between two successive placements of the same foot, is described as the distance traveled during one gait cycle.
- Step Width: The distance between the center of the feet during the double limb support portion of the gait cycle when both feet are in contact with the ground.
- Cadence: The number of steps taken in a specified period, commonly expressed as steps per minute.

- Walking speed: The distance covered in a given time. It is calculated as the cadence times the step length [17].

Walking biomechanics is altered with the use of prosthesis. The gait of person with a unilateral amputation is asymmetrical. The asymmetrical gait alters the load distribution of the body weight and consequently cause pain in the lower limbs. Thus, reestablishment of functional and symmetrical gait is one of the main focuses of amputee's rehabilitation [19][20].

Typically, clinicians observe in amputee's gait cycle, an increase of the period of stance phase and decrease of the period of swing phase. The stride width of the amputees is larger than normal and their successive step lengths tended to be uneven. Also, the walking speed is significantly lower as a result of the increased effort required to compensate for the loss of the limb, increasing the metabolic cost and consequently reduce the walking speed [21].

Some abnormalities are, commonly, observed in specifics events of the transtibial amputee gait, like the abrupt and prolonged heel contact during the initial contact, the rapid knee flexion and jerky knee motion in the loading response event, the heel rice too early or excessively delayed and early knee flexion during the terminal stance and the prosthetic foot drags during the swing phase. These abnormalities are may cause due to the poor alignment of the prosthesis, inadequate heel and foot lever, quadriceps weakness, prosthesis is too short or too long, gait insecurity, inadequate suspension and socket loose[12][22].

2.4 Prosthetic components for transtibial prosthesis

Transtibial prosthesis, represented in figure 5, consist of an assembly of several components such as: socket, pylon, prosthetic foot and suspension system. The liner that involves the residual limb is also considerate a component of the prosthesis, since it is a fundamental to the success of the replacement of the limb loss functions [15].

The recent technological advances have resulted in new materials that allowed the prosthesis to be stronger, more cosmetic, and lighter and reduce the amount of extra energy necessary to operate.

The alignment is an important aspect in designing a prosthesis since allows the amputee to have the correct posture and support. Therefore, all the components must be prefect connect and adjust in order to not occur any misalignment. The prefect alignment is possible through the adaptors [23].

Figure 5. Elements of transtibial prosthesis [57].

Prosthetist are focus on improving the prosthetic components and fitting technology in order to reduce energy consumption and to enhance the amputee's mobility.

2.4.1 Prosthetic foot

The prosthetic foot is designed to mimic the foot-ankle assembly, the interface between the ground and amputee's body. It provides the support during standing and walking, responsible for the shock absorption and push-off during walking. It is an important component for the locomotion of the amputee and alignment of the prosthesis, since it is replacing the ankle-foot articulation [12].

It's very difficult to reproduce the human foot and ankle functions. Ideally the foot need be lightweight, strong enough to support the amputee's corporal weight and to have a good energetic performance and good dynamic response.

The SACH (Solid Ankle Cushioned Heel), illustrated in figure 6, is a basic prosthetic foot and it has a rigid structure made of wood with a rubber outer cover. This foot is commonly used due to its simplicity, low cost, and durability. However, it is inappropriate for amputees with high level of activity since does not provide any flexion and cause moments of instability during the walk [24].

Figure 7. The prosthetic foot SACH [59].

The ESAR (energy storage and return) foot, shown in figure 7, also called dynamic-response foot is a passive-elastic prosthetic foot that is made of carbon fiber and it was designed to store energy after heel-strike and releasing this energy at push-off. This foot works like a spring and it is more flexible than SACH foot [25].

Figure 6. The prosthetic foot ESAR [58].

2.4.2 Pylon

The pylon or shank is a pole that connects the socket to the prosthetic foot, corresponding to the anatomical lower leg. This vertical structure is designed to support the amputee's weight and it is possible to adjust its height as well realignment [15].

2.4.3 Socket

Socket constitutes a critical interface between the residual limb and prosthesis. This personalized component is designed to properly involve the residual limb in order to achieve satisfactory load transmission, stability, and efficient control for mobility[15].

The fit and functionality of the socket can affect the gait and the blood flow and can cause pain, skin problems and discomfort. If the socket does not fit, the prosthesis will not function properly[23].

Socket shape influences the acceptability of a socket fit since it can produce different pressure levels between the socket and residual limb. Depends of different factors include residual limb's external and internal geometry, tissue viability (pain, vascular response, lymphatic supply, skin temperature, and abrasion) and tissue's mechanical properties [26].

The custom-designed socket is a difficult procedure due to the uniqueness of each amputee's residual limb. Plastic and carbon fiber are the common materials used to manufacture the socket. Fabrication of the socket involves several steps, including the measurements of residual limb, the creation of positive model of the residual limb, the modification of the positive model and, finally, the fabrication of the socket model [15].

Commonly, these steps are accomplished through conventional manual fabrication, the prosthetist aim to produce a suitable socket by using their experience and patient feedback. Thus, with conventional hand fabrication, the success of socket fitting dependents on the skill and experience of the prosthetist.

Although at present, Computer-Aided Design (CAD) and Computer-Aided Manufacturing (CAM) has emerged as an automated method that produce sockets directly without the need of any physic positive model.

The positive model is automatically generated with CAD techniques, then, the prosthetist can modify the three-dimensional computer model and the final model is created using a CAM techniques.

After the production of the socket, it is subjected to a test phase, in which the amputee uses the socket for analyze its performance. Check socket is used for short-term and can easily be modified to accommodate the changes of the residual limb that occur at the beginning, when the amputee is still adjusting to wearing a socket. It is necessary a careful analysis by the prosthetist during the check socket phase, before the optimal socket fit is obtained.

The check socket is replaced with the definitive socket once the fit has been optimized. The definitive socket is made with durable materials, normally, carbon or glass fibers impregnated in a resin.

However, during the daily basis the residual limb shrinks, causing the felling of loose and uncomfortable since the shape of the socket remains the same. To accommodate these changes, it is added prosthetic socks.

Over the years, several different socket shapes and styles have emerged. The type of sockets currently chosen is the Patellar Tendon Bearing (PTB) and Total surface bearing (TSB).

The patellar tendon bearing (PTB), shown in figure 8, was developed in the late 1950s and intended to be molded with specific areas with higher pressure to support the socket itself and relived the load over the sensitive areas of the residual limb. The standard PTB design has several variations such as PTB-Supracondylar (PTBSC) and PTB-Supracondylar/suprapatellar (PTBSCSP) [27].

Normally, the PTB socket is use with a liner of a softer material such as Pelite. The liner is used as a barrier between the socket and residual limb to provide comfort, reduce the friction between them and also can contribute to suspension of the residual limb inside the socket.

The PTB socket presents a lower cost of manufacture and great adjustability for the changes of the residual limb. However since the residual limb is different for each user, it may promote the excessive pressure in certain areas that can cause pain, skin abrasions and discomfort for some amputees. Also it can limit knee flexion range during sitting and walking [23].

Figure 8. Patellar tendon bearing (PTB) socket [60].

Later in 1993, appeared a new socket concept, the total surface bearing (TSB), in following the creation of the ICEROSS liner, a silicone gel that allows the distribution of the weight of the residual limb on the whole socket surface. The TSB socket, shown in figure 9, distributes the loads consistently all over the residual limb without any underload or relief areas [28].

Figure 9. Total surface bearing (TSB) socket [60].

The amputees with fragile skin and sensitivity benefit with this socket since has lower peak pressures.

The TSB socket incorporates modern gel liners and can be combined with various suspension systems in order to reduce the movement between the socket and residual limb [29].

2.4.4 Suspension system

Suspension system connects firmly the prosthesis to the residual limb in order to prevent the excessive movements between the socket and residual limb. These movements subjected the residual limb to forces that it is not physiologically designed to tolerate. The suspension system must hold effectively the prosthesis on residual limb and at the same time decrease the motion of the residual limb inside the socket [14].

An ineffective/poor suspension system can promote deterioration of the socket fitting that can lead to skin problems, pain, gait instability, shear stress and increase of pressure on residual limb due to the volume loss of the residual limb, since it cannot prevent the movement between the residual limb and the socket. So, selecting an appropriated suspension is crucial for amputee's rehabilitation [30][10].

Various systems were developed to suspend the socket securely on the residual limb. The common transtibial suspensions include sleeve with suction, supracondylar and suprapatellar cuff/strap, waist belt, thigh-lacer, gel liners with suction, vacuum systems or pin/lock systems and recently magnetic systems [31].

The PTB socket is usually suspension via supracondrylar cuff, waist belt, thigh-lacer or also use a sleeve to reproduce a suction effect.

The TSB socket, commonly, achieve suspension through a pin lock system, suction or vacuum suspension. This suspension systems are used in combination with gel or silicone liners [23].

Despite the technological progress, the selection of the most appropriate suspension system for each amputee is still difficult. The selection between the suspension system commercial available requires a careful ponderation that adequate to the needs of a person with LLA.

The studies by Coleman et al. (2004), Klute et al. (2011) and Sadeeq et al. (2012b) highlighted the preference for the pin/lock system due to the easy donning and doffing. Nevertheless, the study by Eshraghi et al. (2012) suggested some difficulties of donning and doffing with pin/lock system, because some patients experienced some trouble aligning the pin during donning.

2.4.5 Liner

Liner is the interface between the residual limb and socket that offers additional protection, comfort and reduces the movement between the skin and the socket.

This protective cover is fit over the residual limb and is made of a flexible, cushioning material such as Pelite, silicone, urethane, or thermoplastic elastomer [30].

The Pelite liner, shown in figure 10, is a conventional liner made of polyethylene foam sheet that is used, normally, with the PTB socket for improved comfort. Some strategies are used to achieve suspension with Pelite liner, including suprapatellar strap or cuff or supracondylar bulge or suspension with a sleeve worn over the socket and extending to mid-thigh.

Figure 10. Pelite liner [60].

Later silicone, urethane and thermoplastic elastomer liners were introduced in the market to improve the pressure distribution and lead to development of the TSB socket by helping maintain the total contact of the socket. It can be used with a PTB socket but are generally recommended for use with TSB socket. They are particularly convenient for amputees with sensitive skin since can provide greater comfort, better suspension and reduce localized skin tension and shear. Exist different methods to fix the silicone liner to prosthetic devices such as pin/lock systems, suction by hypobaric seals (seal-in liners) or sleeve, lanyard and recently magnetic system [32][19].

There are many different brands and types of liners with several properties that are commercially available. The selection of the appropriate liner depends on amputee’s needs and his characteristics.

Skeo liner from Ottobock company, represented in figure 11, is a silicone liner with a textile cover and features a distal connection to allow the attachment of the pin, that will create suspension when it is inserted into the locking system.

Figure 11. Skeo liner from Ottobock company [61].

Iceross Dermo liner from Össur company, shown in figure 12, is another example of a silicone liner available in the current market, this type of liner can provide suction suspension combined with a sleeve.

Figure 12. Seal-In X5 liners from Össur company [62].

Seal-In liner provides suction suspension without an external sleeve through a hypobaric sealing membrane around the silicon liner and an expulsion valve. The figure 13 represents the Seal-In X5 liners from Össur.

Figure 13. Iceross Dermo liner from Össur company [62].

Selecting the right liner helps to ensure that your prosthesis fits well since liners play an important role in the comfort and health for amputees.

Sleeve combined with liner helps to provide a vacuum or suction suspension. The sleeve, shown in figure 14, is attached around the external side of the socket and creates an airtight seal around the top edge of the socket. They are made from a variety of elastic materials to guarantee durability and flexibility.

Figure 14. Derma ProFlex sleeve from Ottobock [63].

2.5 Literature review of suspension systems for transtibial prosthesis

Suspension system is an imperative for the prosthesis since it connects firmly the socket to the residual limb in order to prevent the excessive movements between them.

Several systems use the atmospheric pressure, anatomical contour and straps and hinges as techniques to provide the proper suspension.

The suspension alternatives commercial available can be divided into four categories: Straps and Hinges, Locking/Lanyard systems, Suction systems and Magnetic systems. Each category has is disadvantages and advantages, which will be describe in more detail later in this subchapter.

A careful prescription of the suspension system is fundamental for a successful rehabilitation. To select the suitable suspension system, it should be take into account the activity level of the amputee, the amputee's needs and his satisfaction. A proper suspension must securely attach the residual limb to the socket, eliminate the pistoning without unduly complicating the donning and doffing process, and at the same time guarantee comfort [26].

2.5.1 Straps and hinges

Different types and shapes of straps can be attach to the sidewalls of the socket. These alternatives are easy to apply however cannot effectively minimize the pistoning and can reduce the knee flexion. Usually used for amputees who have difficulties or cannot tolerate other forms of suspension.

The suprapatellar cuff, shown in figure 15, circles the thigh over the femoral condyles and attaches to the socket with straps. It is most commonly used with a PTB socket. This suspension is inexpensive, easily applied and adequate suspension for the lower activity level amputees with limit hand function. It is normally used with a waist belt [33].

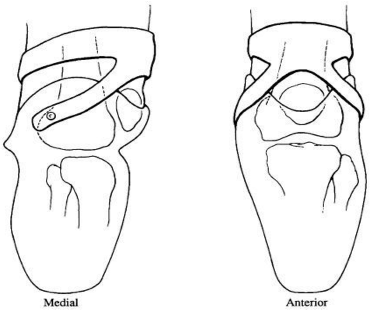

Figure 15. Suprapatellar cuff [64].

The waist belt, represented in figure 16, has an anterior fork strap that attaches to the socket. It is most frequently added to supplement another suspensory component. For instance, the waist belt is frequently use with a thigh corset and joints[34].

Figure 16. Waist belt [65].

The thigh corset and joints, illustrated in figure 17, is a combination of metal joints that extends from the medial and lateral surfaces of the socket and connects to a corset used around the thigh. It is used with PTB socket for patients who have very short residual limbs or poor control of the knee during the gait [28][34].

Figure 17. Thigh corset and joints [66].

2.5.2 Locking systems

This type of suspension is a combination of silicone and elastomeric gel liners with a lock mechanism. The distal end of the liner is usually fix to the bottom of the socket by a lanyard system or pin/lock system. For the first prosthesis or amputees with continuous volume fluctuations, rehabilitation professionals advise to use this type of system, since it can accommodate residual limb volume fluctuations through the use of socks [35][30].

Pin/lock system is a popular system, especially among the elderly population, that provides a secure attachment between residual limb and prosthesis through a pin attached to the distal end of the liner. The pin is insert, by the amputee, into a locking mechanism in the bottom of the socket, that guarantees the fixation of the pin. To remove the prosthesis, the amputee needs to press a button to release the pin. This suspension system has a good level of proprioception and minimizes the pistoning. Most of the lower activity amputees prefer this system since provides a quick and easy donning and doffing, a process determinant for amputee's satisfaction [14]. The figure 18 shows one example of Pin/lock system commercial available.

Despite of the overall satisfaction with pin/lock systems, some patients have reported to had some difficulty in the proper alignment of pin into the housing, due to lack of visual access or poor manual dexterity, which in the long-term can causes deformation of pin and housing and can lead to change of residual limb volume and pain at the end of distal limb [36].

Figure 18. Pin/lock system of Ottobock company [67].

Also, pin/lock system is associated with Milking phenomenon, the elongation and stretching of the distal tissues of the residual limb during swing phase that may lead to pain and change of residual limb volume [30].

The lanyard suspension system, represented in figure 19, has a lanyard cord, adaptd to extend and attach to the distal end of the liner and it is fed through a hole in the bottom of the socket and it is secured fix in place near the top of the socket [37].

This system ensures easy donning of the prosthesis especially for inexperienced or elderly amputees. It is often used with transfemoral prostheses, to reduce the rotation and shear of the residual limb inside the socket, however it presents more pistoning than pin/lock system [32].

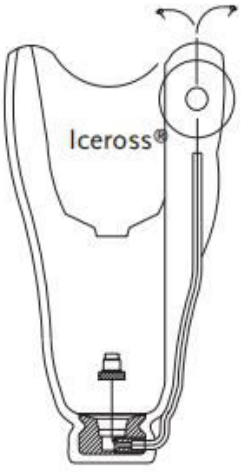

Figure 19. Icelock Lanyard 390 from Össur company [68].

2.5.3 Suction systems

The suction systems create and maintain a pressure lower than atmospheric pressure (negative pressure) by removing the air out of the socket, this difference of pressure between the outside and inside the socket cause adherence of the liner that involves the residual limb to the wall of the socket. This type of suspension offers a more intimate fit between the socket and the residual limb [38].

The knee sleeves provide suspension by creating a seal between the patient’s skin and the prosthesis. The knee sleeve is applied over the socket and ends a couple of millimeters above the top of the socket creating seal against the skin to prevent air infiltrations, so when the limb starts to move, a partial vacuum is created inside the socket and the residual limb is securely hold to the socket. Although, this alternative restricts the maximum knee flexion, it is difficulted for people with a very tapered thigh since the cone-shaped musculature tends to force the sleeve to roll down the leg and some amputees complain of an irritation at the top edge of the sleeve [10][39].

A socket with one-way valve permits the expelling of air automatically as the amputee walks. This system increases the vacuum significantly. This difference of pressure holds the socket more securely against the residual limb. This suction effect it is created in conjunction with the external sleeve and liner [39]. The figure 20 shows an example of a socket with one way valve.

Figure 20. Socket with one way valve [56].

The Seal-In liner presents a suction method without the necessity of using an external sleeve. A hypobaric sealing membrane is integrated around the distal part of the liner and creates vacuum on the lower portion of the socket in combination with one-way valve. This method simplifies the donning and doffing process and knee flexion is less restricted. Figure 21 shows a Seal-In liner X5 Wave by Össur as an example of a suspension based on a hypobaric seal.

Figure 21. Seal-In liner X5 Wave from Össur.

Figure 22. Harmony P3 from Ottobock company.

Another suspension variant uses a small vacuum pump to generate an elevated vacuum without depending upon the limb position to expelled the air, increasing surface contact with the socket wall. It is combine with the sleeve and liner. One example of the vacuum pump is the Harmony P3 from Ottobock company in figure 22. Some studies suggest that this negative pressure may help to control volume fluctuations of the residual limb [35]. This augmented vacuum system has higher level of proprioception compared to others suction system. Figure 23 shows the suspension system with vacuum pump of Ottobock company.

Figure 23. DVS - Dynamic Vacuum suspension system from Ottobock company.

Several studies have demonstrated that the suction suspension with one way valve or vacuum pump minimize more the pistoning compared to pin/lock systems [33][40][31]. However, these systems are more expensive, cause discomfort in terms of donning and doffing, especially for elderly amputees, than suspension alternatives and require a correctly fitting and maintenance since a leak of air can corrupted the vacuum.

Generally, suction suspension requires more time and effort to perform the donning and doffing process due to the additional sleeve. To apply this type of suspension, the amputee needs to have sufficient hand dexterity [41].

Additionally, suspension system is a good alternative for amputees with high activities levels.

2.5.4 Magnetic systems

The magnetic suspension systems introduce a magnetic-based coupling system to reduce the pressures within the socket particularly during the swing phase of gait. It is used with the silicone liners and consists in a cap that is matched both to the liner’s distal end and the main body of the coupling device, a magnetic assembly that remains outside of the socket between the prosthetic socket and the pylon and a switch to connects or disconnects the coupling device. When the switch is positioned in the "On" mode, the magnetic field will hold and retain the stump within the prosthesis. And the amputee can switch to the "Off" mode to the remove of the prosthesis. To reduce the risk of fall due to any failure of the coupling, an acoustic alarm system can be added for a better sense of security [36].

This system has an easy process of donning and doffing, decreases interface pressure and reduces pistoning. The MAGLOCK system, shown in Figure 24, is one of the few magnetic suspension systems available in the market [42].

Eshraghi *et al.* study demonstrated that donning and doffing were easier with the magnetic suspension system compared with the pin lock system and Seal-In suspension.

Figure 24. *The MAGLOCK* system from ST&G corporation [53].

2.5.5 Evaluation parameters of the suspension systems

Selecting an appropriated suspension is crucial for amputee's rehabilitation, since a poor suspension of the prosthesis can cause deterioration of the socket fitting and it can lead to skin problems, pain, gait instability, shear stress and volume loss of the residual limb [41].

The selection between the commercial solutions requires a careful evaluation in order to choose the suspension system that best adequate the amputee's needs. Normally, the selection of the components for the is a combination of the complete assessment of the patient with the knowledge and expertise of the professionals. The selection criteria mainly follows the clinician's subjective experience since does not exists a technical guideline or consensus over selection criteria [32].

The selected prosthetic suspension significantly affects the overall satisfaction and comfort of amputees with the prosthesis. However, amputee's satisfaction in regard to the suspension remains a complex issue to be evaluated, concerning the satisfaction with prosthetic suspension. So, it is important to investigate and define the main parameters that influence the patient satisfaction with the current suspensions, to better evaluate and select the adequate suspension system for each amputee[32].

Therefore, amputees’ satisfaction is a multifactorial issue that has been a topic of debate on several studies. On these studies, several measurements have been conducted (in terms of energy costs, interface pressure, pistoning) and as well questionnaires to evaluate the users’ satisfaction with different suspension systems. It is frequently used the Prosthetics Evaluation Questionnaire (PEQ) as a mean to evaluate the function, performance and satisfaction by rating the participants’ opinion about the satisfaction in different domains (fitting, walking on diverse surfaces, appearance, donning and doffing and sitting) and the perceive problems such as pistoning, sweating, skin irritations, residual limb pain, swelling, smell and sounds [43].

Hatfield and Morrison (2001) carried out a retrospective study to record the amputee’s opinion with Alpha pin/lock and Alpha cushion liner system. The results showed that both systems can improve the amputees comfort with the suspension. Nevertheless, eight out of forty amputees with Alpha pin/lock could not use it on a regular basis. However, the participants did not have the opportunity to experiment both and select the best one, instead, they gave their own experience with their suspension system [44].

Board et al. (2001) related the volume loss of the residual limb with the increase of pistoning. The vacuum system with an electric pump had slight increase of volume since more fluid was drawn into the residual limb. Contrary, the vacuum system with an expulsion valve had a decrease of volume. The participants referred that they had less pistoning with the vacuum system with an electric pump than with an expulsion valve. They concluded that a reduce of pistoning and a maintenance of the residual limb volume with an electric pump provided a more symmetric gait[45].

The Coleman et al. (2004) study evaluated the Alpha pin/lock and Pelite liner with neoprene sleeve in terms of satisfaction and activity level. The obtained feedback showed that the participants were more satisfied with the Pelite liner than with the pin/lock, since it provides a quick and simple donning and doffing and enabling good comfort in long use. Participants considered the pin/lock system more secure and with a better appearance, but they spend more consuming time in inserting the pin in the locking system [30].

Klute et al. (2011) found that the vacuum system with an electric pump (VASS) had less pistoning than pin/lock system and the activity level was also less significant, providing a better fit. However, the questionnaire results showed a preference for the pin/lock system over the VASS, assuring that the residual limb was healthier while wearing the pin/lock system. This study also confirmed that the pin/lock system for the patients was less frustrating [35].

Sadeeq et al. (2012a) investigated the amputee's satisfaction and perceived problems with Pelite liner, Seal-In liner and silicone liner with a pin/lock system. Through the use of questionnaires, a greater feedback from pin/lock was obtained in terms of donning and doffing and overall satisfaction with the suspension system. The Seal-In liner had the lower pistoning, the higher score in overall satisfaction and less wound and pain complaints, but the amputees found out that the donning and doffing procedure of this system was very difficult. Each participant did not have equal chance for comparing the systems considered in this study since it was not provided to all the amputees the three suspension systems [33].

Additional, Sadeeq et al. (2012b) compared the pressure interface and satisfaction between pin/lock system with dermo liner and Seal-In liner system. The Seal-in presented less pistoning, lower skin irritations, swelling, smell and pain in the residual limb. However, three users refused to use Seal-In liner on long term basis since they felt tightness and excessive pressures on the limb. The overall satisfaction was higher with pin/lock, as well as the donning and doffing procedure[39].

Datta et al. (1996) study the ICEROSS liner system advantages over the Pelite liner system. During the study, ten participants rejected the ICEROOS liner due to pain and skin problems. In overall rating, the ICERROS score was higher than the Pelite liner and as for comfort and donning and doffing almost the same score was obtained for both systems. The participant's opinion about both systems was not uniform [46].

Brunelli et al. (2013) compared the vacuum system with expulsion valve and Seal-In liner X5 ICEROSS with expulsion valve using pistoning and energy cost measurements, and self-questionnaire, that targeted various parameters, including appearance, ambulation, frustration, perceived response, residual limb health, social burden, sounds, utility and well-being. The participants experienced less pistoning with Seal-In liner than with the vacuum system with expulsion valve. They also improve the appearance domain with Seal-in. No significant difference between both systems was observed in terms of energy cost [47].

Eshraghi et al. (2012) conducted a study to compare the effects of the new magnetic suspension system with pin/lock and Seal-In system. The results from the questionnaire exhibited a higher satisfaction rate in terms of donning and doffing, walking and overall satisfaction. The Seal-In had the lowest pistoning [36].

Gholizadeh et al. (2013) conducted a retrospective study to evaluate the satisfaction and the perceived problems with vacuum system with expulsion valve and Seal-In liner system. They concluded that the overall satisfaction was higher with the Seal-In, providing a better fitting, as well as, donning and doffing. The normal vacuum system presented problems in terms of sweating, wounds, pain, sound, pistoning, smell and swelling. In turn, the Seal-In had lower durability [26].

Gholizadeh et al. (2014) introduced a new suspension system HOLO, a hook and loop system, and compared it with the pin/lock, Seal-In and magnetic system. They reported that the participants were more satisfied with the new system in comparison with the other three systems, particularly for donning and doffing. The Seal-in system had the lower pistoning but at the same time had the worst score in terms of overall satisfaction and donning and doffing. Although, the pin/lock presented more perceived problems, four of the nine participants select the pin/lock as their first choice and had the highest score in terms of overall satisfaction [48].

Some studies pointed out pistoning as a determinant factor to amputee’s satisfaction. Pistoning is a variable that characterizes the vertical displacement between the residual limb and the liner or between the liner and socket wall. The increased of pistoning inside the socket is associated with skin problems, shear stress and residual limb pain. The range of pistoning can be measured with various techniques including X-ray, spiral computerized tomography and photoelectro sensors [31].

The ease of donning and doffing also claims to be a factor that significantly affects amputee’s satisfaction. The donning and doffing techniques varies with the suspension used and it requires a proper hand function for a safety and adequate suspension. Some evidence shown that the donning and doffing can overpass the other domains such as pistoning, fitting, walking on diverse surfaces, appearance, sitting, sweating, skin irritations, residual limb pain, swelling, smell and sounds.

The research on the influence of subject characteristics on the overall satisfaction is in general of poor quality. The currently studies did not correlate the individual information of the participants with the evaluation parameters. In most of the case studies, the number of participants perhaps was not enough to make a detailed discussion about the influence of amputee's characteristics. The low numbers did not permit to have homogenous groups to perceive the effect of participant's characteristics, like activity level, amputation cause, age and skin quality of the residual limb, in the amputee's satisfaction. Instead, the study group on these studies, was heterogeneous and had different causes of amputation like diabetes, trauma, vascular diseases, congenital limb deficiency and tumors and had different function levels.

However, the amputee's characteristics can influence the outcomes of the studies, because most data were obtained by using a self-questionnaire to ask the amputee's opinion.

For example, in the Gholizadeh et al. (2014) study, even though the authors did not discuss the influence of the activity level of the amputee in the preference of the suspension system, it was possible to observe that the only amputee that preferred the Seal-In system was the amputee with higher activity level. Therefore, the activity level can influence the amputee's satisfaction with the suspension system, since the amputees with high activity level need a suspension system that guarantees an effective attachment of the prosthesis for the intensive movements on a daily basis. On the contrary, the amputees with lower activity level have, normally, more difficulty in donning and doffing the prosthesis, since they do not have a proper hand function, specially the elderly amputees.

Additional, the Baars et al. (2005) study shown that hand function is related with skin problems, revealed that an impaired hand function increased the risk for skin problems with the prosthesis. Subsequently, an improper hand function can influence the satisfaction of amputees with the suspension system [10].

To proper evaluate the current suspension system, amputee's characteristics such as age, activity level, duration of prosthetic use, skin quality of the residual limb and hand functionality need to be considered when it is analyzed different parameters of satisfaction: pistoning, donning and doffing, fitting, walking on diverse surfaces, appearance, sitting, sweating, skin irritations, residual limb pain, swelling, smell and sounds. For this purpose, it is important to extent the evaluation of the satisfaction between different groups of amputees to determine the real benefits and advantages of the available suspension systems.

Therefore, it is imperative a careful selection of the patients and a detailed discussion about the amputee’s satisfaction with the different suspension systems currently available on the market.

Further research is still needed to evaluate the most suitable suspension system for each amputee and to prepare a guideline for the selection of the most adequate suspension system. To obtain even more accurate results on the amputee’s satisfaction, a great number of experiments are needed to be carried out while testing different suspension systems.

3. DESIGN PROCESS

As the literature review indicated, the current suspension systems have certain problems that should be addressed in a new design in order to improve the life quality of amputees. Therefore, the main objective of this dissertation was to develop a new prosthetic suspension system that can enhance the suspension quality, especially for elderly amputees. In this chapter, the design of new suspension system is described, using Engineering Design tools.

3.1 Design solution

An essential part of the design process is the definition of the problem statement that the system is aimed to address. The design concept involves research to specify the main user and understand the user's need in order to develop an innovative system that brings benefits.

The design of the new suspension system was based on the difficulties that elderly population have with the pin/lock system during the daily basis, since it is one of the most used suspension solution for transtibial amputees.

While the commercially suspension systems are focused on lowering the pistoning effect, this new approach intends to increase amputee's satisfaction, by designing a simple suspension method that improves the donning and doffing process of the prosthesis.

The amputation due to vascular diseases represents a large percentage of overall amputations and vascular diseases are frequently linked to diabetes mellitus, that especially affects the older population. The mainly user was defined as a person with lower level of activity and manual dexterity and presents difficulties in terms of adaptation and learning, since most of them have advanced age.

The literature review pointed that despite the overall satisfaction with pin/lock systems in terms donning and doffing, some patients reported to had some difficulty in the proper alignment of pin into the housing, due to lack of visual access or poor manual dexterity. Consequently, in the long-term it can cause deformation of the serrated pin and ratchet and can lead to change of limb volume and pain at the end of the distal limb. Thus, the mechanical design of the suspension system was driven by the need to guide the pin and inserted correctly into the housing without colliding at the its ends and, at the same time, increases the amputee's satisfaction in terms of donning and doffing [33].

3.2 Conceptual Design Phase

The design is a bridge between a conceived idea and the final product. All the necessary information is collected and organized in order to transform a concept into a real form.

The following evaluation steps are crucial to reach the final solution. Decisions are necessary to make, to determine if it is worth carrying out the design, if it is attractive enough and what kind of restrictions can be imposed, regarding the human resources, cost and time.

The Design Process must be done properly, if one of the steps is skipped it will be difficult to achieved a viable solution. The final product needs to satisfy all the specifications and functions.

The conceptual design followed principles and practices to establish the objective tree and function diagram, represented in the next sections, in order to achieve the optimum solution

3.2.1 Objective tree

Through the objective tree is expressed the desired attributes and behaviors that the user wants to see in the final product. The objective tree is expressed in a diagram that allows to transform the vague design statements into more specific customer desires.

The established objective tree, shown in figure 25, highlighted, clearly and schematically, the objectives and the means to achieved the ideally suspension of the prosthesis. The objectives are: functionality, simplicity, comfort and low-cost. They related to each other, as well as their sub-objectives.

It is essential to develop a functional mechanism that ensures, without failure, the connection between the amputee and the prosthesis and that guarantees the fixing element is inserted correctly into the housing without colliding at its ends. So, the design includes a functional mechanism in terms of operation and safety.

During the development of the mechanism it is crucial the simplicity in the assembly, maintenance, manufacture and operation since, as mentioned before, most amputees have lower activity level and difficulties in prosthesis adaptation and learning. A simple mechanism allows the reduction of the existing barriers during the adaptation to the prosthesis and improves the amputee’s satisfaction in terms of donning and doffing and consequently the reduction of rejection rate.

It is also important that the system is comfortable and available at low-cost, to be accessible to all users at different socioeconomic levels.

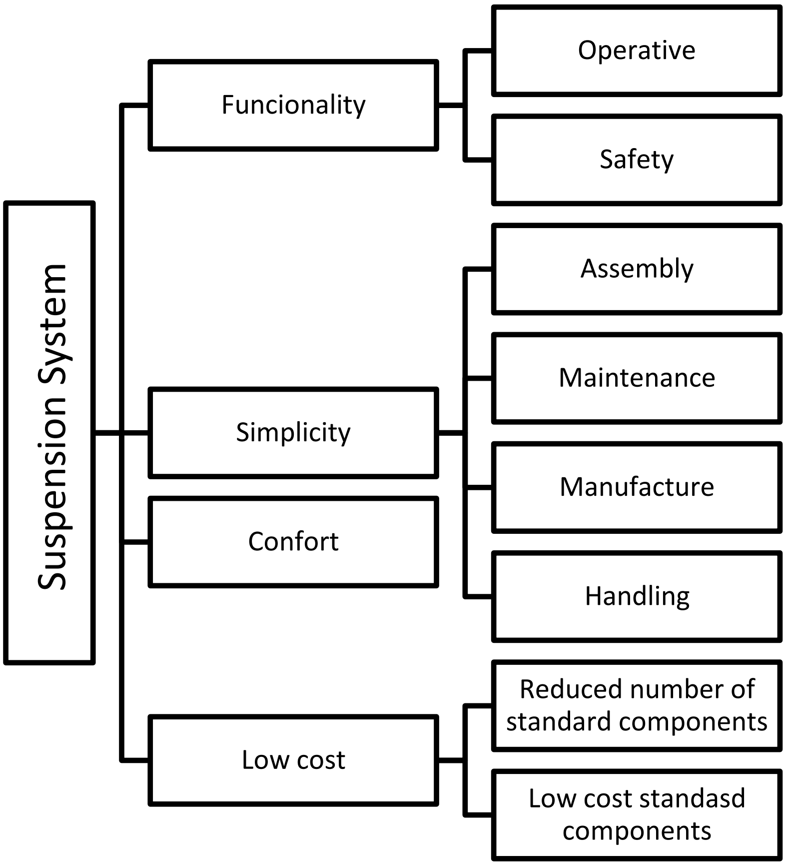

Figure 25. Objective tree diagram of the proposed mechanism.

3.2.2 Function diagram

In order to complement the objectives tree, the function diagram establishes the functions that the new suspension system must have, regardless of how they will be achieved. This allows the designer to evaluate the complexity of the problem and acquire a better understanding of the functionality of the system concept.

The function diagram, shown in figure 26, express the sub-functions “Insert the residual limb into the socket”, “Guide the fixing element to the housing”, “Insert the fixing element into the housing” and “Lock the fixing element” as the steps involved in the global function energy is accumulated with the spring turns. When it is reached the desired length of USB cable, the external torque is released and the stored energy causes revolution of the power spring to its initial position and, consequently, reverses the rotation of the spool in clockwise direction. The rotation in clockwise direction allows the USB cable to be involved around the spool.

In addition, the retractable device was designed with a locking mechanism, to control the USB cable length that it pulled out. It consists of a roller in the curved through of the top part of the spool. When the cable is being pulled, the roller moves in the curved through and, when the pulling is released, the roller moves into the cavity and locks the movement of the spool. To retract the cable, a slight pull of the cable is required, to clear the roller from the cavity and unlock the movement of the spool. So, this locking mechanism prevents the power spring from returning to its initial position without the user desire it.

Since the power spring dictates the rotation of the spool to wind and unwind the cable, it was specifically studied the power spring in the following section.

- **Power spring performance**

Power springs are commonly used in different industry fields such as robotic machines, vibration isolation systems, clocks, toys, door actuation or safety belts. Like other types of springs, the power springs are used to store and release the mechanical energy and they are particularly known for the low torque change, relatively large curvature variability and high security.

They are usually made of a spiral stainless-steel coil with a constant flat section. However, power springs can be produced from a variety of sizes, materials and coatings. Thus, designing a spring that perfectly fits the desired specifications can be a very complex process. The wrong choice of material or size can compromise the durability and reliability of the power spring and can cause a malfunction.

The performance of the power spring depends on the stablished design parameters, as well as, its durability and reliability.

With the purpose of understanding the design of the spring selected in the retractable wire mouse, a performance evaluation was carried out to determine the torque per turn during the pull and retraction phases. It was established an analytical model of power spring, as an effort to facilitate the design process for a specific application.

An analytical model permits the analysis of different variables affecting the performance of the power spring, which allows to have different types of torque–turns characteristic curves. The analytical model follows the equations of the model proposed by Queener and Wood.

Queener and Wood modeled a spring with the mathematical shape set out in figure 29, to numerically calculate torque-turn curve of a power spring. The configuration of figure 29, presents a spring confined in a cage, wherein a portion of its strip coils is wound down on the internal wall of the cage (packed portion) and the remaining strip coils are free (unpacked portion) [50].

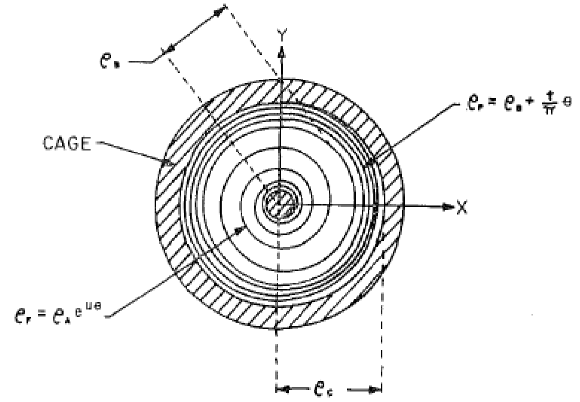

Figura 29. Power spring in a caged [50].

The model assumes that the unpacked portion as a geometry of a Logarithmic spiral, since the spring coils do not touch each other.

The packed portion of the spring as a geometrical configuration of an Archimedean spiral, with coils wounded down on the internal wall of the cage.

Nonetheless, when an external torque is imposed on the spring with the rotation of the inner shaft, the strip coils inside of the packed zone will peel away and become part of the unpacked zone. This way, the reserve strip length will be progressively removed from the packed portion and become part of active length (L_a) in the unpacked zone. Thus, the applied bending moment required to peel away any element of material from the packed zone can be calculated from the difference in curvature of Logarithmic and Archimedean spirals.

The theoretical torque-turn curve is represented in figure 30 as well as hypothetical experimental curve. The proposed model predicts that torque increases quickly during the firsts turns, and continues to increase at a lower rate until it is fully wound. The theoretical torque-turn curve is represented in figure 30, as well as, the hypothetical experimental curve. The graph of figure 30 shows that the unwinding torque is lower than the winding torque in experimental curve due to some friction or hysteresis. Although, friction was neglected in the proposed model since predicting the friction behavior of power springs is very complex.

Moreover, the proposed model divides the torque-turn curve of the power spring into two stages. The first stage, represents the torque-turn curve of the release of the strips coils clamped to the internal wall into the unpacked space until the entire length is released completely and becomes active. The torque-turn curve, during these state, behaves like a hairspring of increasing length. The applied torque is equal to the bending moment of the material in the unpacked region since the material in the unpacked region acts like a rigid body.

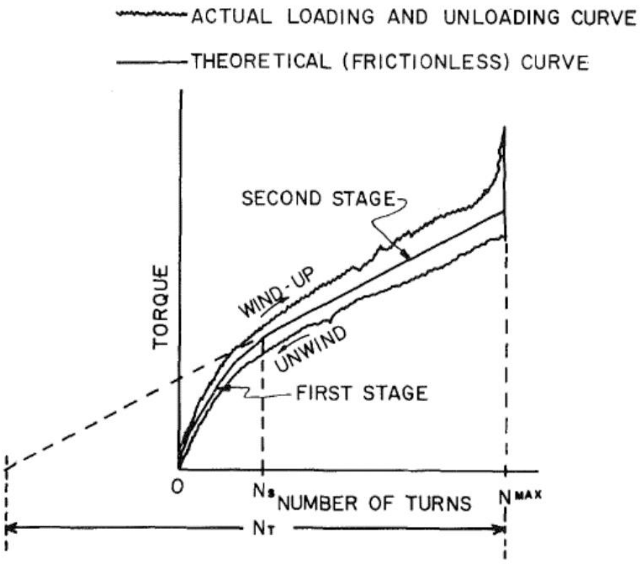

Figura 30. Theoretical and hypothetical experimental torque-turn curve of power spring [50].

The bending moment at this stage is given by the torque equation of the hairspring, using the difference in curvature of the element in the packed and unpacked configuration. Since the length of hairspring is constantly increasing, torque can be expressed as function of L_a by the equation (1).

$$M = \frac{EI}{(t - v^2)} - \left[\frac{1}{\sqrt{\frac{t}{\pi} L_a - \frac{t}{\pi} \sqrt{1 + \frac{1}{U^2}} \left(\rho_b - \frac{D_A}{2} - \frac{t}{A} \right) + {\rho_b}^2}} - \frac{1}{U L_a + \left(\frac{D_A + t}{2} \right) \sqrt{1 + U^2}} \right] \quad (1)$$

The number of turns (N) of the power spring for a given torque, during the unpeeling process of hairspring, can be calculated the equation (2):

$$\begin{aligned} N &= \frac{1}{2\pi U}\left[\frac{(D_A+t)\sqrt{1+U^2}}{(D_A+t)\sqrt{1+U^2}+2UL_a}-\frac{(D_A+t)}{2\rho_b}+ln\frac{\frac{\sqrt{1+U^2}(D_A+t)}{2}+UL_a}{\sqrt{1+U^2}\rho_b}\right] \\ &-\left[\frac{\frac{\rho_b^2}{t}-\frac{1}{\pi}\sqrt{1+\frac{1}{U^2}}\left(\rho_b-\frac{(D_A+t)}{2}\right)+\frac{1}{2\pi}L_a}{\sqrt{\rho_b^2-\frac{t}{\pi}\sqrt{1+\frac{1}{U^2}}\left(\rho_b-\frac{(D_A+t)}{2}\right)+\frac{t}{\pi}L_a}}-\frac{2\rho_b^2-\frac{1}{\pi}\sqrt{1+\frac{1}{U^2}}\left(\rho_b-\frac{(D_A+t)}{2}\right)}{2\rho_b t}\right] \end{aligned} \tag{2}$$

The torque-turn curve of the first stage has an increasing slope at the begging and it is expressed by the equations (3) and (4), with L_a as the parameter.

The boundary between stage 1 and stage 2 of torque-turn curve is defined by the number of turns at which the entire material of the spring is active (Ns). The Ns value can be found by evaluating equation (4) at L_a value which all the material of packed zone is completely released. This respective L_a can be less than L_0 ($0 < L_a < L_0$), if a maximum of equation (3) exists and if does not show such maximum, it is assumed that L_a is equal to L_0.

The second stage starts when the packed region of the spring is fully release and the entire length of the spring becomes active. This stage is defined by the progressively revolution of the strips coils around the arbor until it is completely wound down. The power spring, in this state, has the geometric shape of an Archimedean spiral.

The second state of the torque-turn curve is expressed by a straight line since the free length of spiral spring is constant. The bending moment at this stage is given by the torque equation of the hairspring with constant length and it is calculated by the equation (3) in function of the number of turns:

$$M = \frac{2\pi EI}{(1-v^2)L_b}\left[\frac{D_c-t}{2t}-\frac{\rho_b}{t}+\frac{1}{2\pi U}\ln\left(\frac{2\rho_b\sqrt{1+U^2}}{(D_A+t)\sqrt{1+U^2}+2UL_0}\right)+N\right] \tag{3}$$

The maximum number of available turns for a given power spring is proportional to the change in the number of coils between the configurations of logarithmic and Archimedean.

$$N_{max} = \frac{1}{t}\Bigg\{\Bigg(\left[\frac{1}{t}L_0 + \left(\frac{D_A + t}{2}\right)^2 - \frac{t^2}{2\pi^2} - \frac{1}{2}\sqrt{\frac{t^4}{\pi^4} + \frac{4t^4}{\pi^4}\left[\left(\frac{D_c + t}{2}\right)^2 - \left(\frac{D_A + t}{2}\right)^2 - \frac{t}{\pi}L_0\right]}\right]^{3/2} + \rho_b - \frac{D_A}{2} - \frac{D_c}{2} - \frac{t}{2\pi U}ln\left(\frac{2\rho_b}{D_A + t}\right)\Bigg\} \quad (4)$$

The maximum torque, that corresponds to the entire strip length wound down on the arbor, can be calculated from equation (5) to the point the where N = N_{max}.

Following this methodology, it is possible to describe the torque-turn curve behaviour of the power spring applying the equation (1) and (2) for the first stage and the equations (3) and (4) for the second stage where the Ns value defines the boundary between the two stages. The design parameters acquired from the study power spring are listed on Table 2, and are used for the for obtain the torque-turn curve.

Table 2- Design parameters of the studied power spring

Cage Diameter (D_C) (mm)	Arbor Diameter (D_A) (mm)	Width (w) (mm)	Thickness (t) (mm)	Length (Lo) (mm)	Shape Factor (U) (radians^{-1})	Young's modulus (E) (MPa)	Poisson's ratio (v)	Mandrel Diameter (mm)
20	4	0.3	0.12	60	0.035	190000	0.265	4

Since it was not provided the shape factor (U) information, it was calculated. The calculation steps are in appendix II. Figure 31 represents the predicted torque-turn curve, using the analytical model.

In short, the proposed analytical model will dictate the design of power spring by calculating the torque in function of turns of the power spring, as well as, the maximum torque and the maximum number of turns, using design parameters of power spring.

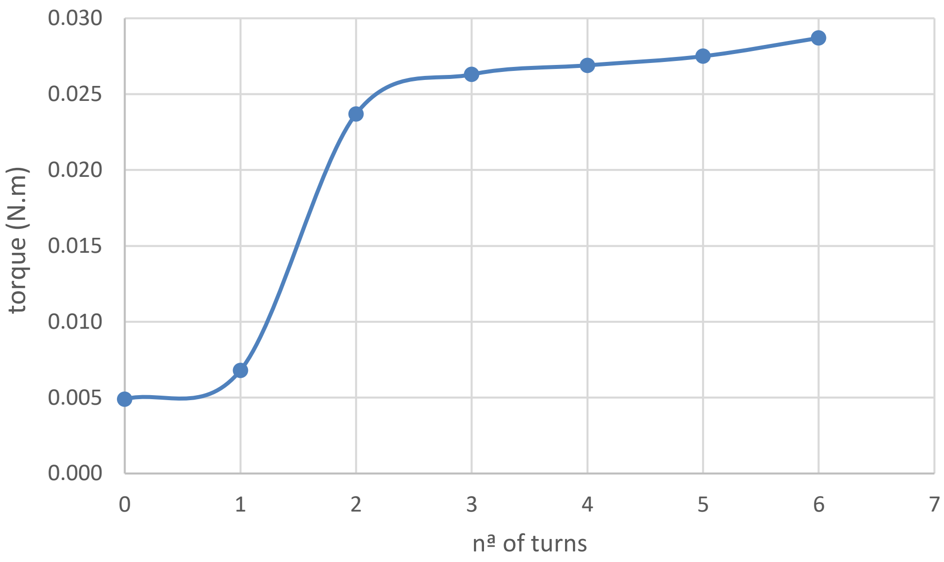

Figure 31. Predicte torque turn curve for the studied spring.

The analytical model permits to analyze the different variables affecting the performance of the power spring, which allows to have different torque–turn curves. The main design parameters are length, variation of curvature of the spiral, relation between the curvatures of shaft and housing, strip thickness and the variation of the bending stiffness along the length of the spring strip. Numerous spring parameters can influence the torque-turn curve. So, this model not only calculates the power spring turns and torque but also allows to adjust the design so that corresponds to the performance requirements.

The viability of the analytical model allows, in turn, the development of a systematic design procedure for obtaining the spring design based on the equations of the model.

- **Establishment of functions**

The guiding mechanism follows the objectives of the purposed suspension system, in figure 32. The functions define the mechanism as a functional system that effectively guides the serrated pin to the entrance of the housing without colliding at its ends. Also, it is desired a low-cost mechanism with simple assembly, maintenance, manufacture and operation, that guarantees it is possible to be incorporated easily in different commercially available housings, without modified its main dimensions. In addition, the guiding mechanism needs to have a long-life expectancy, the mechanism cannot degrade quick with the use, in order to not increase the cost of replacement.

demonstrate poor hand dexterity and recent amputees who are still adjusting to the process of donning and doffing the prosthesis.

- **Morphologic chart**

The morphological chart, represented in table 4, was created to identify and combine different possibilities of solutions to guide the serrated pin into the housing. The following morphological chart consists on listing the essential sub-functions of the guiding mechanism and the means to achieve each sub-function. The first column on the left represents the list of sub-functions: “Pull the wire from the housing”, “Connect the wire to the serrated pin” and “Retract the wire into the housing”. And each row represents the means for performing the sub-function of that column.

For the sub-function “Pull the wire from the housing” was proposed the following sub-solutions:

- Sub-solution (i): The roller moves on the arcuate through on the top of the spool with the release of the wire, keeping the wire in extension.
- Sub-solution (ii): The spool rotates around the shaft in the clockwise direction with the pull of the wire.
- Sub-solution (iii): Pinion gear assembly inhibits the movement of the spool in the opposite direction, keeping the wire in extension.

For the sub-function “Connect the wire to the serrated pin” was presented the following sub-solutions:

- Sub-solution (iv): The patient screws the wire to the distal part of the serrated pin.
- Sub-solution (v): Connect the serrated pin with the claw on the extremity of the wire.
- Sub-solution (vi): Application of a magnetic field between the serrated pin and the magnet at the end of the wire.

Finally, for the last sub-function “Retract the wire into the housing” the following sub-solutions:

- Sub-solution (vii): A slight pulling of the wire clears the roller from the cavity to unlock the movement of spring inside the spool.

3.2.5 Fixation mechanism

The design of suspension mechanism was based on the ALPS Lock™ S496-T commercial system, shown in figure 36. Although, the proposed mechanism can be applied to other marketed pin-lock systems since they use the pin-gear attachment as the suspension method.

Figure 36. ALPS LockTM S496-T commercial system.

The ALPS Lock™ S496-T consists of a one-way gear rotation mechanism. It is included a pinion gear, HFL0822 INA needle clutch bearing, glass reinforced nylon housing, serrated pin, a compression spring, a mounting case, and a button. This system is adapted to support the user weight until 100 kgf.

The pinion gear is constituted by a shaft portion and gear head with teeth projecting radially. The HFL0822 INA needle clutch bearing holds the shaft part of pinion gear and restricts the rotation of the shaft in clockwise direction. The button is screwed at end of the pinion gear and the compression spring is placed between the button and the HFL0822 INA needle clutch bearing. The housing has a receiving compartment with internal threads to assemble the mounting case. Additionally, the housing includes a central opening to receive the serrated pin and an axial hole that gives access to the receiving compartment, its where the engagement of the serrated pin with the pinion gear occurs. Figure 37 shows all the components of the ALPS Lock™ S496-T system.

The rotation of the pinion gear allows the serrated pin, that is screw at distal part of the residual limb, to get inside the housing and the teeth of the gear engage with the serrated pin. In turn, the HFL0822 INA needle clutch bearing in juxtaposition with the gear inhibits the rotation in the opposite direction. Since the gear mechanism only rotates in one direction, the pin keeps engaged and cannot be removed from the housing until the push button is pressed. To disengaged the pin and remove the prosthesis, the user needs to press the push

The fixation mechanism needs to fit perfectly inside the housing, without damage or interfering with the performance of other components. The system cannot modify the total length and height of the housing and it is required to store 400 mm of wire.

The materials, that constitute the fixation system, must be resistant to support the user's weight and at the same time must be lightweight to not interfere with the user's gait.

It is intended a universal system to apply on the numerous pin/lock systems available on the current market. Therefore, the assembly process of the fixation system needs to be easily adaptable to the different structures of housings of pin/lock systems. Also, the assembly process needs to be easy, inexpensive, low time-consuming, effortless, and at the same time, it cannot modify or damage the structure of the housing.

The mechanism must efficiently and safely engage the serrated pin to prevent the movement of the pin during the amputee's gait, and, at the same time, allows the patient to disconnect the serrated pin when desires it.

Also, the mechanism needs to present a simple, quick and easy performance, adequate for the elderly patients since most of them demonstrate poor hand dexterity and recent amputees who are still adjusting to the process of donning and doffing the prosthesis.

- **Morphologic chart**

The morphological chart, shown in table 7, presents a helpful resource to obtain different solutions for each of the sub-functions of the fixation system. On the first column of morphological chart is listed the established sub-functions of the fixation mechanism: "Unlock the rotation of the pinion gear", "Store the wire" and "Engage and lock the serrated pin with pinion gear". In each row is represented different means to achieved the sub-function of that column. By analyzing the morphologic chart is possible to combine different solutions to lock the serrated pin.

For the sub-function "Unlock the rotation of the pinion gear" was presented the following sub-solutions:

- Sub-solution (i): Rotation of the pinion gear is unblocked by compressing the spring that is connected with the button to move the pinion gear away from the claws.
- Sub-solution (ii): Pushing the button, gives energy to the spring move the pinion gear away.

- Sub-solution (iii): The rotation of the button, keeps the pawls disengaged from the ratchet system, that restrain the pinion gear rotation.
- Sub-solution (iv): Application of tension on the lateral pins of the mounting case compress the lateral springs to retract both half-retaining ring that is constraining the pinion gear rotation.

For the sub-function “Store the wire” was proposed the following sub-solutions:

- Sub-solution (v): The wire is involved around the spool in the parallel plan with the pinion gear head.
- Sub-solution (vi): The wire is wound down on the shaft of pinion gear.
- Sub-solution (vii): The wire is winded around the spool that is perpendicular to the shaft of pinion gear.

Lastly, for the sub-function “Engage and lock the serrated pin with pinion gear” the following sub-solutions:

- Sub-solution (viii): The HFL0822 INA needle clutch bearing fix the serrated pin engage with the pinion gear by inhibiting the rotation of the pinion gear in the clockwise direction.
- Sub-solution (ix): The rotation of the pinion gear-pin serrated assembly is prevented by constraining the shaft with half retaining ring.
- Sub-solution (x): The serrated pin keeps engage with the pinion gear by inhibiting the rotation of pinion gear with application of the ratchet system.
- Sub-solution (xi): Both claws are fixed with the ledges of the shaft to prevent the disengagement of the pinion gear with pin serrated.

All the proposals were analyzed to select the best combinations from the following alternative solutions: alternative solution 1 resulting from the combination of sub-solutions (iv), (v) and (xi); alternative solution 2 resulting from the combination of sub-solutions (ii), (vi) and (viii); the alternative solution 3 resulting from the combination between sub-solutions (iii), (vi) and (x) and the alternative solution 4 resulting from the combination between sub-solutions (i), (vii) and (ix).

dimensional limits. However, the solution 2 requires that the mounting case has a large diameter, to accommodate the guiding system, which can cause an impact in terms if appearance.

The viability of the solution determines if the idea is applicable or not. The system needs to function properly to ensure that the serrated pin is firmly attached. The alternative 3 is a viable solution to lock the serrated pin and do not presented any functional restrictions. The viability of solution 4 is uncertain, because the engagement of the claws with the pinion gear is unreliable, the claws can correctly engage with the protrusions of the pinion gear in just certain positions. The viability of alternative 2 is questionable due to the way that the wire is collected. The wire needs to pass through a curved path until is stored, which compromises the guiding of serrated pin and causes wear of the wire.

The fixation mechanism must ensure safety during the gait of the amputee, the failure can cause direct damages to the amputee such as fall, skin damage and pain. The alternative 4 is not safety, since the solution 4 do not ensure that the claws are complete engage with the pinion gear. So, it can occur the release of the serrated pin without desire. Although the solution 2 has a one-way-gear that is already used by the pin/lock systems, the safety of this system is not fully guaranteed, since have been reported failure cases about the one-way-gear mechanism, in which the debris that lodged inside the bearing bushes prevented its effective operation. The solution 1 and 3 are, theoretically, safe.

In comparison between solutions, solution 3 distinguished positively, obtaining the highest score in the table 8. This proposed system fits all the desired needs, functions and requirements and specifications. The other alternatives also presented innovated solutions but the solution 3 stands out for its simplicity and efficiency.

3.3 Final design mechanism

The proposed suspension system is the solution that best suits the objectives and functionalities previously established. Therefore, the final solution is a combination of the best alternative that for guiding and fixation mechanism.

The final design, illustrated in figure 43, presents a simple suspension system that improves the donning and doffing of prosthesis, by providing a better alignment of the pin into the housing.

respective torsion spring forcing the pawl into the cavity between the tooth, as it passes the edge of each tooth. Yet, if in some instance the pin serrated attempts to move in the release direction, both pawls look up the teeth motion of the ratchet gear. In this way, the proposed solution guarantees the serrated pin is fix with the teeth of pinion gear and cannot release until the patient desire it.

To detach the serrated pin from the locking device, the patient just need to rotate again the button to disconnect the pawls from the ratchet gear, to unlock the pinion gear rotation in counterclockwise direction with the release of the serrated pin, so that the patient can pull-out the serrated pin and remove the residual limb from the prosthetic limb.

4. DEVELOPMENT OF NEW SUSPENSION SYSTEM FOR LOWER LIMB PROSTHESIS

The proposed suspension system is specifically developed to easily guide and secure the serrated pin without any failure.

In general, the requirements and specifications of various components that constitute the proposed system are interrelated. The technical specifications of a component will reflect on the other incorporated components. Thus, this chapter is primarily concerned with the design and the technical considerations of the components to determine the optimal design of the suspension system.

In this chapter, the conceptual design is convert to the fully define configuration. Each component of the suspension system is described, as well as the materials suitable for their manufacture and the production process.

The solution can still be modified during its production process, since the combination of components will impose some constraints.

The fixation mechanism consists of a one-way gear rotation mechanism. The pinion gear rotates with the serrated pin movement, until is totally inside the housing, and the teeth of the pinion gear engage with the serrated pin. In turn, the ratchet system inhibits the rotation in the opposite direction. Since the pinion gear only rotates in one direction, the pin keeps engaged and cannot be removed from the housing until the button is pressed.

To disengaged the pin and remove the prosthesis, the user need to rotate the button to disconnected the pawls from the ratchet gear.

4.1 Components

This section describes, in more detail, the components include in the proposed suspension system, defined in the previous chapter, to give enough information to guide the production process. Solidworks^{R} v.2016 (Dassault Systemes^{R}) CAD tool was used to create the three-dimensional system of the proposed solution, to reduce efforts and understanding its structure configuration and construction.

The figure 44 shows an exploded view of the proposed suspension system. The technical drawings of the components are in appendix VI.

limit motion to a single direction. Each pawl has two openings, the inferior opening to receive the pin of the button and the superior opening to engage with the pin of the reel. Besides the two lateral openings, the pawls are projected with a middle opening to receive of one end of the torsion spring. The figure 51 and figure 52 illustrate, in greater detail, the ratchet gear and pawl, respectively.

An important consideration in ratchet system design is backlash, the small amount of backward rotation before the pawl is stopped by one of the teeth, since there is an opportunity for the serrated pin to release from the engagement with pinion gear, as the pinion gear rotates in counterclockwise direction. In fact, to the ratchet gear locks up a small amount of backward slippage occurs. The backlash is based on the number of teeth and maximum magnitude of the backlash of the ratchet gear is given:

$$backlash = \frac{2\pi}{6} = 1 \text{ rad}$$

The system can have some backlash when the pinion gear is still adjusting to the serrated pin. The ratchet system design just need to ensure that the backlash is small enough to prevent the movement of serrated pin in the release direction after the patient starts moving. So, it is possible to affirm that the efficiency of the ratchet mechanism depends on the number of teeth that the ratchet gear has.

The ratchet mechanism has a release mechanism coupled, which allows the engage and disengage of the pawl from the ratchet gear. This release mechanism uses two pins/levels to link with the pawls and rotate them. Therefore, the ratchet system is reversible system, where the pawl has two possible orientations. Each orientation corresponds to a different level of freedom of ratchet gear, as well as, the pinion gear. The "engaged" position of pawl prevents counterclockwise rotation of the pinion gear while clockwise rotation is precluded. The "disengaged" position permits free rotation of the ratchet gear in either direction, and thereby the rotation of the pinion in both direction.

4.1.9 Torsion springs

The torsion springs, as the one represented in figure 53, are positioned around the superior pin of the respective pawl, inside the middle opening of the pawl, with one end fitted into the inner wall of the mounting case and the other end in the pawl. The torsion springs were design in accordance with the dimensions of the pawl, such that have enough force to push the pawls into the depression between the teeth as it passes the tip of each tooth to maintain the pawl in communication with the ratchet gear.

Torsion Spring is subjected to bending stress whose ends are rotated in angular deflection on the direction of wind from free position.

The design specifications of torsion spring are described in table 10 and the design procedure is detail described in appendix V.

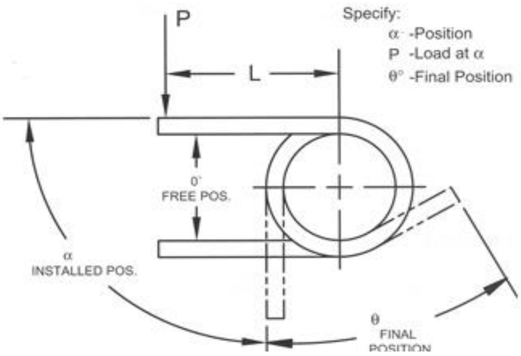

Figure 53. Main dimensions of torsion spring.

Table 10- Main dimensions of the torsion spring

Proprieties	
Wire Diameter	0.4 mm
Torque	3560 N.m
External diameter	3 mm
Leg Length	6.6 mm
Young's modulus	206 GPa
Number of coils	3
Inner diameter	2.2 mm
Deflection angle	21°
Force application	0.54 N
Direction of helix	counterclockwise

4.1.10 Pinion gear

The pinion gear allows the engagement of the serrated pin inside the housing. The pinion gear is made of stainless steel and has a cylindric/shaft portion combined with the gear head. The teeth of pinion gear engage with the serrated pin at axial hole when it is inserted through the central opening. The opposite side of the gear head has an internal thread

The principal dimensions of the housing are represented in figure 57 and correspond to the dimensions of the housing of the ALPS Lock S496-T model.

In figure 57 it is shown that the housing contains a vertical hole that slightly intersects with horizontal hole to receive the serrated pin.

The upper portion of the vertical hole has a cone-shaped form to accept the residual limb. The receiving compartment corresponds to the horizontal hole of figure 57 and it has internal threads to receive the mounting case. It has an axial hole that gives access to the receiving compartment to allow the engage and disengage of the serrated pin.

4.2 Prototyping

This section focuses on the representation of the final solution to properly test and evaluate the viability and the possible improvements of the conceptual idea.

Prototyping is an integral part of design process that brings the conceptual solution to life and allows to be tested quickly. Creating a prototype promotes the consolidation of the proposed solution.

With this intention, it was created a low-fidelity prototype model that offer a wealth of leeway without high costs, which is preferable in this early stage, since, after evaluation, changes can still be made without spending a lot of resources.

The prototype model, presented in figure 58, allows to better understand the dynamics of the final solution and its impact, more specifically, whether the guiding and fixation mechanisms work or not.

The shaft, power spring, stainless steel pins and torsion springs were purchased. The remaining components were produced using 3D printing, a fast and simple additive technique that creates a three-dimensional model by successive layers of material, homogeneously united.

Integrated in the product development chain, this technique allows to accelerate the development phase and facilitates the validation of the system without highly costs. It offers the possibility of obtaining, by a simple process, the components described in the previous section, from their respective 3D models.

After the components were created by the Sigma BCN3D machine, they were subjected to a grinding process to create the components finishes.

5. EVALUATION, DISCUSSION AND VALIDATION OF NEW PROTOTYPED OF THE SUSPENSION SYSTEM

This chapter focuses on evaluated the performance of the proposed suspension system and ensure that the suspension system design follows all the requirements and specifications stablished.

The motion analysis was done to study the viability of the solution, before spending resources on the prototype and to ensure that the mechanical performance of the system has no interference.

After the prototype was created, it was conducted safety and functional tests to evaluate its performance and the feasibility of the solution, and if necessary, identify possible improvements.

Finally, since amputee's satisfaction is imperative for the selection of suspension systems, it was proposed a method to rate the participants' opinion about the suspension system in different domains and in this way, evaluate the proposed suspension system.

5.1 Motion analysis

To better understand the required physical motion for the suspension system to attach the residual limb to the prosthesis, a simulation of the mechanical dynamics of the proposed system was performed with Motion analysis tool of SolidWorks.

Motion analysis is an economical way to know if the proposed solution works. This tool simulates a 3D CAD assembly and it is possible to incorporate mass and the effects of friction, forces, gravity, motor motions and spring action.

5.1.1 Methodology

For the proposed model, motion analysis using Solidworks Motion was performed. The motion analysis focused on the rotation of the pinion gear that drives the pinion gear and the relationship between the angular position of the pawl and the pins rotation of the button.

The motion analysis of the solution was divided in two moments. The first moment corresponds to the pulling process, where the button moves 45º and pinion gear rotates in counterclockwise direction. The second moment corresponds to the retracting process and fixation of the serrated pin, where occurs rotation of pinion gear in clockwise direction and the button goes to the first position.

The motion analysis the reel component was specified to be fixed and the torsion springs were defined with a constant of 0.169 N.m/rad. Both moments occurred at a pre-set time. In the first 20 seconds, the pinion gear was assigned with a constant motor of 35 RPM in counterclockwise direction and the button was assigned to rotate 25° in counterclockwise direction. After 20 seconds, the button was assigned to rotate back again the 25° and was assigned the torque imposed by the power to rotate the shaft in clockwise. Together, these conditions simulate the movements that the prototype will executed, in reality, to attach the residual limb with the prosthesis.

After running the motion analysis, was plotted the simulation results to analyze the displacements relative to each component.

5.1.2 Results and Discussion

The simulation of the movements require to fix the serrated pin inside the housing were observed in detail with Solidworks Motion.

It was possible to simulate the torsion springs effects and observe if the torque produced by the release of energy of the power spring it is enough to bend the torsions spring to be able to rotate in clockwise direction.

When was give the spring torque in retraction phase the ratchet gear was able to push the torsion spring leg and, in this way, the serrated pin can move to inside the housing without any interference.

The button was able to move the pawls away from the teeth of ratchet gear and the pinion gear rotate in counterclockwise direction without any interferences.

This simulation demonstrates that the proposed model can faultlessly guide and lock the serrated pin inside the housing.

5.2 Overall performance

In this section, a study was carried out to validate the prototype of the suspension system, which was divided into two phases: The first phase of the study aimed to evaluate the safety of the prototype, analyzing possible failures that may occur. The second phase of the study evaluated the performance of the prototype, in order to verify the prototype functionality, and if necessary, make modifications.

In this way, this study efforted to perform simple and repeatable experiments that prove the viability of the system and verify if it follows all the specifications and requirements.

The tests were carried out at the Automation Laboratory of the Department of Mechanical Engineering of Minho University.

5.2.1 Safety tests

In order to validate the developed prototype and proceed its revision to obtain the final suspension system, it was performed a safety analysis. The safety analysis consists of detecting possible failures and evaluating its effects for the system and patient. From the identification of possible failures, it is possible to intervene correctively in order to eliminate or reduce the probability that these events occur.

The safety analysis systematic analysis the potential failures and identify the corrective actions required to prevent failures and to assure the reliability of the system.

Each failure mode has a potential effect, and each potential effect has a relative risk associated with it. Failures can be classified as critical failure, major failure, and minor failure. The critical failure is when the user's safety is at risk, and it is necessary to take improvement actions urgently. The major failure affects the performance of the product but does not affect the user's safety, improvement actions must be taken. While minor failures do not affect product performance or put the user at risk, there is no need for improvement actions.

Potential failures for both guiding and fixation mechanisms of the system were identified and evaluated for possible corrective interventions. The following table specifies, in detail, the failures of the guiding and fixing mechanism, as well as, their evaluation.

extender and the spring can be damaged, so, it may not have enough energy to wind the entire wire. During the pulling and retraction process, if the applied forces reach the rupture point the wire will break and the serrated pin is not guided. Also, the nut or serrated pin may contain some debris that can jeopardize the wire connection with the serrated pin.

Since the fixation system provides the residual limb suspension, it has a directed influence on the movement between the residual limb and the socket, and a poor suspension can promote the symptoms of pain, residual limb swelling and a sense of instability. Therefore, it presents some failures that can be critical to the suspension system and compromise patient safety. If it occurs the disengagement of the pawls or if the pins, that support the pawls, break, the ratchet gear is no longer locked and pinion gear can rotate in counterclockwise direction, and consequently the serrated pin can release. The disengagement of the serrated pin with the teeth of pinion gear is a critical failure, if the serrated pin is able to release from this engagement, the residual limb is no longer effectively connected with the limb prosthesis. The probability of the rotation of the button be blocked, is presented as a major failure, since it prevents the release of serrated pin and the pulling the wire out.

Also, the table 11 suggests some improvements to prevent the occurrence of the mentioned failures. For the guiding system, it is proposed the lubrication of the power spring in order to avoid its failure. To avoid the wire breaking, it should be selected a wire with higher tensile strength. In order to avoid the serrated pin corrosion, it can be coated with a layer of chromium nitride (CrN) and the serrated pin should be clean daily. It is also possible to place a thin and small spongy layer that allows the entrance of the serrated pin and, at the same time, prevents the entrance of impurities inside the housing.

For the fixation system, besides the serrated pin coating and spongy layer proposals, to prevent the pin disengagement and button blocking, it is proposed the redesign of the ratchet gear with bigger number of teeth to ensure the pawls are correctly engaged with the teeth of ratchet gear.

To estimate the risk of the referenced failures a more detailed analysis should be carried out through the FMEA, the Failure Mode and Effects Analysis. The FMEA tool uses a specific worksheet for the systematic analysis of the potential failures and identification of the corrective actions required to prevent failures and to assure the reliability of the system. It involves the review of the process or product, identification of the failure modes, causes and effects and the assign the severite, occurrence and detection ranking to calculate the risk pulling of wire, it was measured the time to execute it, the mean force to pull, the length of the wire pulled out and the maximum force before rupture.

During the retracting process, should be evaluated the following features: the efficiency of the drive, the guide of the serrated pin without interference and the alignment of the serrated pin with the pinion gear head. Furthermore, it must be measured the length of the wire retracted, the pulling force require to set the retraction and the time to execute it.

The fixation processes it should be checked if the serrated pin engages with the teeth of pinion gear. To ensure that the serrated pin is secure and there is not any chance of release without the patient desire it, the pawls must perfectly fix up the rotation of the ratchet gear in counterclockwise direction.

The button actuation has an important role in guiding and fixation process because its rotation defines if the rotation of pinion gear in counterclockwise direction is prevent by the ratchet, and consequently dictates fixation of serrated pin.

The power spring performance is crucial for the overall performance, since it provides enough torque to rotate the pinion gear ten times in the wind direction. Therefore, it should be measured the minimum torque of the power spring to pull and retract the wire, using different weights connected to the outside end of the wire, to estimate the torque for each turn and obtain torque-turn curve, where the minimum torque to pull and retract corresponds to the torque at the tenth turn.

In addition, the ratchet system must be tested, separately, to ensure that the serrated pin is securely attached. The ratchet gear was rotated in both directions to evaluate the reaction of the pawls.

In order to facilitate the evaluation, it was stablished a check list, in Appendix VII, with all the parameters that influence the performance of the prototype.

5.2.3 Results and Discussion

Due to the lack of time and unavailability of spring companies to produce the power spring with the desired requirements, it was used the power spring of the commercial wire mouse. However, since it did not have the require dimensions for the prototype, the power spring failed during the functionality tests, preventing further tests. Therefore, it was not provided the proof-of-concept since it was not possible to evaluated the guiding of the serrated pin to the entrance of the housing.

During the pre-tests, the spring suffered damages that made it impractical for the functional tests. Since these springs are difficulted to obtain in a short period of time, it was impossible to continue the functional tests. However, during the pre-testing, it was possible to observe the power spring action causing the rotate the pinion gear to wound the wire around the pulley.

Damage caused by using a power spring that does not have the required design, emphasizes the importance of spring design to avoid similar damages. Before any prototype, the springs of the model must be design in accordance with the desired requirements and applied forces.

Even if, it was not possible to perform the process of pull and retract the wire, it was possible to evaluated the good fixation of the serrated pin with pinion gear teeth. It was possible to verify that the system of pawls effectively locks the ratchet gear and prevents its movement in the counterclockwise direction. The pawls perfectly fixed up the rotation of the ratchet gear in counterclockwise direction, even when it was tried to pull out the serrated pin. The ratchet gear was quickly locked up by the pawls when attempted to rotate in counterclockwise direction and the pinion gear did not release the serrated pin.

Furthermore, it is possible to increase the head of the pawls to increase the diameter of the torsion springs, to achieve smoother rotation of the ratchet gear in clockwise direction with the decrease in the force required to deform the torsion spring.

Also, the button should be more ergonomic for the patient, must have a length or shape that makes it easy to rotate the pins that will push the pawls away from the ratchet gear.

In addition, the material of the wire should be carefully reconsidered to reduce the length of wire store inside the housing, and thereby reduce the outside diameter of the mounting case.

Therefore, it is necessary to perform further tests on the new prototype with the desired spring, to evaluate the performance of the proposed system.

5.3 Satisfaction evaluation

The suspension system significantly affects the overall satisfaction and comfort with the prosthesis. Then, to study the performance and feasibility of the proposed suspension mechanism, a satisfaction evaluation study should be carried out to check the level of satisfaction and problems with it. However, this evaluation will be conducted at a future stage of the project, when all the conditions to produce a high-fidelity prototype are fulfilled.

Since the amputee’s satisfaction in regard to the suspension system is a complex issue to be evaluated, this section aims to present a method to evaluate, in the future, amputee’s satisfaction with the proposed suspension.

This method proposes to evaluate amputee’s satisfaction using questionnaires as an instrument to collect the feedback on the proposed suspension system and other commercial systems. For further analysis, the proposed suspension system should be compared with others commercially available pin/lock system. The propose questionnaire was based on the Prosthesis Evaluation Questionnaire (PEQ) to distinguish the perceptions of subjects regarding each suspension system.

5.3.1 Questionnaire

The questionnaire presented in Appendix VIII follows the Prosthetics Evaluation Questionnaire to record the satisfaction and perceived problems of the proposed suspension system as well the commercial pin/lock system.

Prosthetics Evaluation Questionnaire is the most common type of questionnaire use among the researchers to evaluate different prosthetics or components. PEQ evaluate different parameters such as: pain, satisfaction, transfer, self-efficacy, and prosthetic care.

To identify and describe the amputee type, the first section of the questionnaire consists of demographic variables (sex, age, height, and weight), amputation side, cause of amputation, years since amputation and activity levels of the participants

The second section of the questionnaire is focus on participant's satisfaction. It includes questions about participant's satisfaction and prosthetic related problems that the participant experienced with each suspension system. The participants are asked about the donning and doffing ability, functionality, design, innovation and overall satisfaction with the two suspension systems.

A scale 0–10 can be used to score the amputee’s satisfaction with the suspension system, with 0 indicating that a participant was “unsatisfied” and 10 being indicative of “completely satisfied”.

5.3.2 Participants

In order to understand the full potential of new proposed system a careful selection of patients should be carried out to determine the real benefits and advantages of the new system.

Amputee's characteristics such as age, activity level, duration of prosthetic use, skin quality of the residual limb and hand functionality can influence the amputee's opinion about the suspension system.

Therefore, to correctly measure the benefits of the proposed suspension system, it must be considered the above mentioned characteristics of the participants in satisfaction evaluation. The participants should be, systematically, categorized in different groups to study their influence in amputee's satisfaction.

In addition, the participants need to be transtibial amputees who currently use a pin/lock system.

Table 11 suggests a way of present the information about the participants, to facility the correlation between the amputee's characteristics and satisfaction level. The defined characteristics consists of demographic variables (age, height and weight), amputation side, cause of amputation, years since amputation, residual limb length and activity levels of the participants. The activity levels were defined according to the Medicare Functional Classification Level (MFCL): household ambulator (K1), limited community ambulator (K2), community ambulator (K3), and high-level user (K4) [52].

Table 8- Example of how to display the participant's characteristics data

Subject no.	Age	Height (cm)	Weight (kgf)	Amputation side	Cause of amputation	Time since amputation (years)	Residual limb length (cm)	Activity level
1								
2								
3								
4								
(….)								

5.3.3 Methodology

The testing of the proposed suspension system with amputees should succeed the steps of the following procedure to get their feedback in the standing and seating situation.

The participants will perform stand, the donning and doffing process with the new suspension system. After, the participants are asked to repeat the doffing and donning while they are seated.

After, the participants will perform the donning and doffing process with their original pin/lock system, while they are standing and again while they are seated, in order to compare with the new suspension system.

Participants should be encouraged to give verbal feedback while using the both suspension system and after the tests they will complete the questionnaire in appendix IV, to classify and share his/her experience about the suspension system.

5.3.4 Results and discussion

To assist the analysis of results, the obtained feedback from the questionnaire can be organized and categorize in the domains of donning/doffing, comfort, functionality, design and overall satisfaction. Table 12 exemplifies how the satisfaction results should be presented. The results are organized, in such way, to facilitate the comparison of results between the two suspension systems.

Table 12- Satisfaction results of the suspension systems

Participant	Questionnaire item									
	Donning/doffing		Comfort		Functionality		Design		Overall satisfaction	
	New system	Old system	New system	Old system	New system	Old system	New system	Old system	New system	Old system
1										
2										
(…)										
Mean										

6. CONCLUSIONS AND FUTURE WORK

This chapter presents the general conclusions of the developed dissertation as well as the directions for further development are suggested to expand the research outcomes.

6.1 Conclusions

The methodology presented provide the directions to obtained a more effective and efficient solution to improve the quality of life of amputees. Different fields of knowledge were duly studied and assimilated in order to define the problem statement and stablish user's needs.

A novel suspension system based on standard pin/lock system was developed in order to improve the quality of life of amputees who have lower activity level. By incorporating a guiding mechanism to drive the serrated pin until the housing, which will be held securely engaged with the fixation mechanism.

Conceptually, the model not only guides the pin into the housing without fail, it allows the amputee to perform the donning process without having to be stand, which removes a potential fall hazard. This design does not only provide a better suspension, but also promote the frequency of the use of prosthesis, by allowing a quick and simple process of donning and doffing the prosthesis.

Despite the creation of the prototype, it was not possible to achieve the proof-of-concept to confirm the feasibility of the proposed suspension system. Regarding the functional tests, the fixation system engages the pawls effectively with the teeth of the ratchet gear, which is extremely important to secure the serrated pin inside the housing.

The prototype must follow all the designs requirements to not occur more failures and further tests need to be done to evaluated the performance of the prototype.

The motion analysis results demonstrate the efficiency of the mechanical dynamics of the proposed model to attach the residual limb to the prosthesis.

In sum, the development of the suspension system for ease donning and doffing was a challenge, despite the failures, some of the results demonstrate that the system can be feasible and improved.

In the future, it is necessary to proof-of-concept and optimize the system and create the final prototype, in order to evaluate the feedback of the amputees on the suspension system to identify the positively effects of the novel system in the lives of amputees.

The development work during the dissertation, permitted the publication of an abstract and a paper for the Regional HELIX'17 conference and ICEUBI 2017 conference, respectively. Also, a paper for the International Journal of Mechatronics and Applied Mechanics. It is intended to apply another paper for the Regional HELIX’18 conference that will be realize in June. This paper will be focus on the performance results of the proposed model.

6.2 Future work

With the analysis of the results, it was concluded that there are still some improvements that should be implemented in order to optimize the performance of the suspension system. Even though it was not possible to evaluate the functional performance of the prototype, it was shown to be successful in the fixation of the serrated pin into the housing. However, it is still needed to improve the ratchet system design, so that the serrated pin can easily enter the housing without any effort and the button design to be easier to the user to rotate the button.

Also, the material of the wire should be carefully reconsidered to reduce the length of wire store inside the housing, and thereby reduce the outside diameter of the mounting case.

Due to the time constraints and power spring failure, it was not possible to performed the desired tests as a proof-of-concept. So, it is intended create another prototype with the redesign proposals to verify the feasibility of the proposed suspension system.

Besides that, further tests will be done in terms of pistoning, gait analysis and satisfaction. To this end, it is intended the creation of a high-reliable prototype for the clinical trials with the amputees.

To evaluate the amputee’s satisfaction, in the clinical phase, a large group of participants with different activities levels and currently using pin/lock system should be selected. The satisfaction evaluation will follow the methodology proposed in chapter 5, to determine the satisfaction and perceived problems with the new prosthetic suspension system in comparison with other suspension system.

The pistoning evaluation is fundamental, to ensure if the suspension system prevents the movement between the socket and the liner, to avoid any consequent for the amputee. The pistoning measurements will be compared with other existing suspensions.

The gait analysis is proposed as a complementary test to evaluate the adaptation of the amputee to the new suspension system. It will be verified if the amputee has any abnormality or improvement in his gait compared to his old suspension system.

It is also important to implement the proposed suspension system in other commercials pin-lock systems, to prove the concept of universality of the system.

There is still much to do to improve and evaluate the amputee’s satisfaction. Design refinement and prototype testing are proposed as future work.

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APPENDIX I – POWER SPRING MODEL

The proposed analytical model follows the equations of the model proposed by Queener and Wood.

The model assumes that the power spring, initially, consists of two zones: packed and unpacked. The center line (p_F) and the curvature of any element of the material in the unpacked region are expressed by the equations (1) and (2), using the center of the arbor as the origin:

$$p_F = p_A\, e^{U\theta} \tag{1}$$

$$\frac{1}{R_F} = \frac{1}{UL_F + \left(\frac{D_A + t}{2}\right)\sqrt{1+U^2}} \tag{2}$$

The length of the spring material in unpacked region (L_b) given by the equation (3) is the line length from the spring end attached to arbor to the boundary between unpacked and packed zones.

$$L_b = \sqrt{1+\frac{1}{U^2}} \tag{3}$$

The packed portion of the spring as a geometrical configuration of an Archimedean spiral, with coils wounded down on the internal wall of the cage. The center line (p_p) and curvature of any element of the material in the packed region are defined by the equation (4) and (5), respectively.

$$p_F = p_b + \frac{t}{2\pi}\theta \tag{4}$$

$$\frac{1}{R_p} = \frac{1}{\sqrt{\frac{1}{\pi}L_p - \frac{t}{\pi}\sqrt{1+\frac{1}{U^2}}\left(p_b - \frac{D_A}{2} - \frac{t}{2}\right) + p_b^2}} \tag{5}$$

The difference between the line length of an element in packed zone (L_P) and line length of the boundary (L_a), shown in the equation (6), gives the total length of material in the packed region (L_{TP}) by evaluating the equation at $p_p=p_c$, equation (7).

$$L_p - L_b \approx \frac{\pi}{t}\left(p_p^2 - p_b^2\right) \tag{6}$$

$$L_{TP} = \frac{\pi}{t}\left(p_c^2 - p_b^2\right) \tag{7}$$

So, the total length of the power spring (L_0) is a combination of the length of spring material in the packed and unpacked zones:

$$L_P = L_{TP} + L_b \tag{8}$$

Additional, p_b can be expressed in terms of the basic geometrical parameters of the power spring by substituting the equation (3) and (7) into the equation (8) and solving for p_b:

$$\rho_b = \frac{\frac{t}{\pi}\sqrt{1+\frac{1}{U^2}} + \sqrt{\frac{t^2}{\pi^2}\left(1+\frac{1}{U^2}\right) - 4\left[\left(\frac{tL_0}{\pi}\right) + \frac{t}{\pi}\sqrt{1+\frac{1}{U^2}}\left(\frac{D_A+t}{2}\right) - \left(\frac{D_c-t}{2}\right)^2\right]}}{2} \tag{9}$$

The bending moment at any point is given by the torque equation of the hairspring, using the difference in curvature of the element in the packed and unpacked configuration.

$$M = \frac{E\times I}{(1-v^2)}\left(\frac{1}{R_p} - \frac{1}{R_F}\right) \tag{10}$$

Since the length of hairspring is constantly increasing, torque can be expressed in function of L_a, by considering $L_o=L_a$ and $L_b=L_a$:

$$M = \frac{EI}{(t-v^2)^2} - \left[\frac{1}{\sqrt{\frac{t}{\pi}L_a - \frac{t}{\pi}\sqrt{1+\frac{1}{U^2}}\left(\rho_b - \frac{D_A}{2} - \frac{t}{A}\right) + {\rho_b}^2}} - \frac{1}{UL_a + \left(\frac{D_A+t}{2}\right)\sqrt{1+U^2}}\right] \tag{11}$$

The number of turns (N) of the power spring for a given torque, during the unpeeling process of hairspring, can be calculated the equation (12):

$$N = \frac{1}{2\pi U}\left[\frac{(D_A+t)\sqrt{1+U^2}}{(D_A+t)\sqrt{1+U^2+2UL_a}} - \frac{(D_A+t)}{2\rho_L} + ln\frac{\sqrt{1+U^2}(D_A+t)/2+UL_a}{\sqrt{1+U^2}\rho_b}\right] \quad (12)$$

$$-\left[\frac{\rho_b^2/t - \frac{1}{\pi}\sqrt{1+\frac{1}{U^2}}\left(\rho_b - \frac{(D_A+t)}{2}\right) + \frac{1}{2\pi}L_a}{\sqrt{\rho_b^2 - \frac{t}{\pi}\sqrt{1+\frac{1}{U^2}}\left(\rho_b - \frac{(D_A+t)}{2}\right) + \frac{t}{\pi}L_a}} - \frac{\rho_b^2 - \frac{1}{\pi}\sqrt{1+\frac{1}{U^2}}\left(\rho_b - \frac{(D_A+t)}{2}\right)}{2\rho_b t}\right]$$

The second stage starts when the power spring has the geometric shape of an Archimedean spiral and the center line of the material is described by equation (13):

$$p_{WD} = p_o + \frac{t}{2\pi}\theta \quad (13)$$

The length of the entire material wound down around the arbor (L_w) do not corresponds to the L_0, since the total length includes also the length of material (L_x) from end of wound-down spiral to cage wall. The wound length is given by the line length of the spring material from the innermost end to the end of wound-down spiral, for the Archimedean spiral of equation:

$$\frac{\pi}{t}(p_w^2 - p_A^2) \quad (14)$$

The bending moment at any point is given by the torque equation of the hairspring with constant length and it is calculated by the equation (15) in function of the number of turns:

$$M = \frac{2\pi EI}{(1-v^2)L_b}\left[\frac{D_c - t}{2t} - \frac{\rho_b}{t} + \frac{1}{2\pi U}\ln\left(\frac{2\rho_b\sqrt{1+U^2}}{(D_A+t)\sqrt{1+U^2}+2UL_0}\right) + N\right] \quad (15)$$

The maximum number of available turns for a given power spring is proportional to the change in the number of coils between the configurations of logarithmic and Archimedean.

$$N_{max} = \frac{1}{t}\left\{\Bigg(\left[\frac{1}{t}L_0 + \left(\frac{D_A+t}{2}\right)^2 - \frac{t^2}{2\pi^2} - \frac{1}{2}\sqrt{\frac{t^4}{\pi^4} + \frac{t^4}{\pi^4}\left[\left(\frac{D_c+t}{2}\right)^2 - \left(\frac{D_A+t}{2}\right)^2 - \frac{t}{\pi}L_0\right]}\right]^{1/2} + \rho_b \quad (16)\right.$$

$$\left. - \frac{D_A}{2} - \frac{D_c}{2} - \frac{t}{2\pi U}ln\left(\frac{2\rho_b}{D_A+t}\right)\right\}$$

The maximum torque, that corresponds to the entire strip length wound down on the arbor, can be calculated from equation (15) to the point the where N = N_{max}.

APPENDIX II – CALCULATION OF THE WIRE TURNS

The number of turns of wire around the spool for the 40 cm of length can be deduced by considering the length of the wire for one turn as the perimeter of the circle with the radius equivalent to the spool radius (r_s). For practical purpose, the wire is wound by two layers, thus, it is considerate the circle radius of the second layer as the spool radius plus the wire diameter.

The wind of the wire is limited by the width of the spool indentation and the maximum number of turns per each layer is calculated by the quotient of the spool length(l_i) by the wire diameter (D_f) (equation 17).

$$N_{max} = \frac{l_i}{D_f} \tag{17}$$

Therefore, the total length of the first layer is obtained by equation 18.

$$L_{1º} = 2\pi \times r_s \times N_{max} \tag{18}$$

The total length of the second layer ($L_{2º}$) is found by subtracting the length of the first layer ($L_{1º}$) to the total length (L_t) (equation 19).

$$L_{2º} = L_T - L_{1º} \tag{19}$$

These considerations result in equation 20, where the number of turns of the second layer ($N_{2º}$) is calculated.

$$N_{2º} = \frac{L_{2º}}{2\pi \times (r_s - D_f)} \tag{20}$$

The total number of turns (N_t) can be found be sum the number of turns of the two layers.

$$N_t = N_{1º} + N_{2º} \tag{21}$$

Calculations for a wire with a length of 400 mm and a diameter of 0.3 mm and it is involve around the spool with a diameter of 13 mm and receiving length of 3 mm:

$$N_{max} = \frac{3}{0.3} \approx 8$$

$$L_{1º} = 2\pi \times 6.5 \times 8 \approx 326.7mm$$

$$L_{2º} = L_T - L_{1º} = 400 - 326.7 = 73.3mm$$

$$N_{2º} = \frac{73.3}{2\pi \times (6.5 - 0.3)} \approx 2$$

$$N_t = 8 + 2 = 10$$

APPENDIX III – SHAPE FACTOR CALCULATIONS

The shape factor (U) is obtain from the equations:

$$U = \frac{\left[1 - nZ\left(\frac{Dm+t}{2}\right)^{1-n} - 2Y\left(\frac{Dm+t}{2}\right)^{3}\right]}{\left[1 - Z\left(\frac{Dm+t}{2}\right)^{1-n} + Y\left(\frac{Dm+t}{2}\right)^{3}\right]^{2}} \frac{t}{\pi(Dm+t)} \tag{22}$$

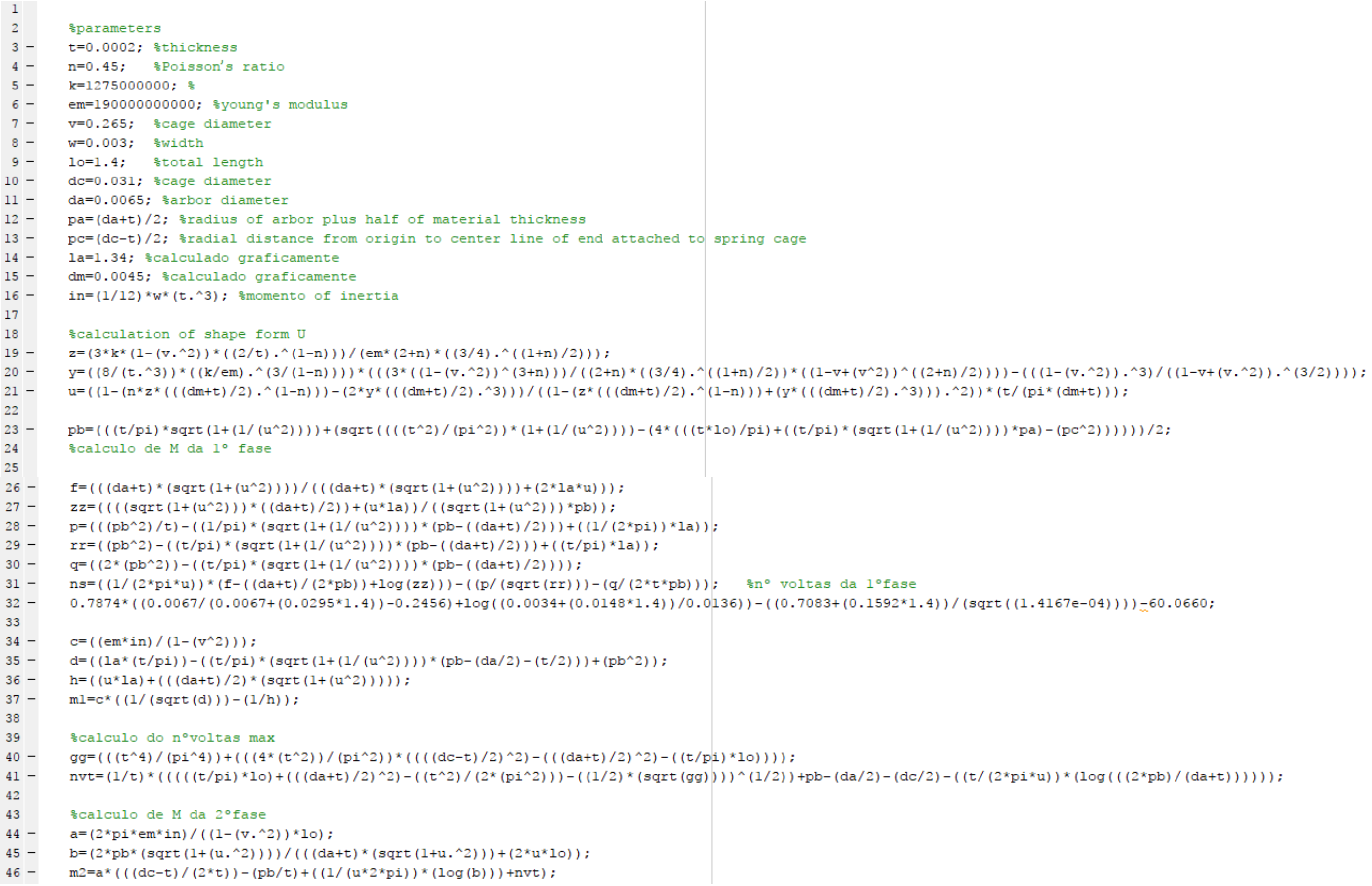
$$\text{And } Z = \frac{3\mathrm{K}(1-\mathrm{v}^2)\left(\frac{2}{\mathrm{t}}\right)^{1-\mathrm{n}}}{\mathrm{E}(1-\mathrm{n})\left(\frac{3}{4}\right)^{\frac{1+\mathrm{n}}{2}}} \tag{23}$$

$$\mathrm{Y} = \frac{8}{\mathrm{t}^3}\left(\frac{\mathrm{K}}{\mathrm{E}}\right)^{\frac{3}{1-\mathrm{n}}} \times \frac{3(1-\mathrm{v}^2)^{3+\mathrm{n}}}{(2+\mathrm{n})\left(\frac{3}{4}\right)^{\frac{1+\mathrm{n}}{2}}(1-\mathrm{v}+\mathrm{v}^2)^{\frac{2+\mathrm{n}}{1-\mathrm{n}}}} \tag{24}$$

Considering Dm=5 mm with material constants K and n of 19000MPa and 0.08 and v=0.265*:*

U=0,0015

APPENDIX IV – MATLAB CODE



```matlab

%parameters
t=0.0002; %thickness
n=0.45;   %Poisson’s ratio
k=1275000000; %
em=190000000000; %young's modulus
v=0.265;  %cage diameter
w=0.003;  %width
lo=1.4;   %total length
dc=0.031; %cage diameter
da=0.0065; %arbor diameter
pa=(da+t)/2; %radius of arbor plus half of material thickness
pc=(dc-t)/2; %radial distance from origin to center line of end attached to spring cage
la=1.34; %calculado graficamente
dm=0.0045; %calculado graficamente
in=(1/12)*w*(t.^3); %momento of inertia

%calculation of shape form U
z=(3*k*(1-(v.^2))*((2/t).^(1-n)))/(em*(2+n)*((3/4).^((1+n)/2)));
y=((8/(t.^3))*((k/em).^(3/(1-n))))*(((3*((1-(v.^2))^(3+n)))/((2+n)*((3/4).^((1+n)/2))*((1-v+(v^2))^((2+n)/2))))-(((1-(v.^2)).^3)/((1-v+(v.^2)).^(3/2))));
u=((1-(n*z*(((dm+t)/2).^(1-n)))-(2*y*(((dm+t)/2).^3)))/((1-(z*(((dm+t)/2).^(1-n)))+(y*(((dm+t)/2).^3))).^2))*(t/(pi*(dm+t)));

pb=(((t/pi)*sqrt(1+(1/(u^2))))+(sqrt((((t^2)/(pi^2))*(1+(1/(u^2))))-(4*(((t*lo)/pi)+((t/pi)*(sqrt(1+(1/(u^2))))*pa)-(pc^2))))))/2;
%calculo de M da 1º fase

f=(((da+t)*(sqrt(1+(u^2))))/(((da+t)*(sqrt(1+(u^2))))+(2*la*u)));
zz=((((sqrt(1+(u^2)))*((da+t)/2))+(u*la))/((sqrt(1+(u^2)))*pb));
p=(((pb^2)/t)-((1/pi)*(sqrt(1+(1/(u^2))))*(pb-((da+t)/2)))+((1/(2*pi))*la));
rr=((pb^2)-((t/pi)*(sqrt(1+(1/(u^2))))*(pb-((da+t)/2)))+((t/pi)*la));
q=((2*(pb^2))-((t/pi)*(sqrt(1+(1/(u^2))))*(pb-((da+t)/2))));
ns=((1/(2*pi*u))*(f-((da+t)/(2*pb))+log(zz)))-((p/(sqrt(rr)))-(q/(2*t*pb)));   %nº voltas da 1ºfase
0.7874*((0.0067/(0.0067+(0.0295*1.4))-0.2456)+log((0.0034+(0.0148*1.4))/0.0136))-((0.7083+(0.1592*1.4))/(sqrt((1.4167e-04))))-60.0660;

c=((em*in)/(1-(v^2)));
d=((la*(t/pi))-((t/pi)*(sqrt(1+(1/(u^2))))*(pb-(da/2)-(t/2)))+(pb^2));
h=((u*la)+(((da+t)/2)*(sqrt(1+(u^2)))));
m1=c*((1/(sqrt(d)))-(1/h));

%calculo do nºvoltas max
gg=(((t^4)/(pi^4))+(((4*(t^2))/(pi^2))*((((dc-t)/2)^2)-(((da+t)/2)^2)-((t/pi)*lo))));
nvt=(1/t)*(((((t/pi)*lo)+(((da+t)/2)^2)-((t^2)/(2*(pi^2)))-((1/2)*(sqrt(gg))))^(1/2))+pb-(da/2)-(dc/2)-((t/(2*pi*u))*(log(((2*pb)/(da+t))))));

%calculo de M da 2ºfase
a=(2*pi*em*in)/((1-(v.^2))*lo);
b=(2*pb*(sqrt(1+(u.^2))))/(((da+t)*(sqrt(1+u.^2)))+(2*u*lo));
m2=a*(((dc-t)/(2*t))-(pb/t)+((1/(u*2*pi))*(log(b)))+nvt);
```

APPENDIX VII- QUESTIONNAIRE

Informação sobre o paciente

Informação detalhada sobre os pacientes que se voluntariaram para o estudo do novo sistema de suspensão

1. Género
   - ☐ Feminino
   - ☐ Masculino

2. Idade

   ____

3. Peso

   ____

4. Altura (cm)

   ____

5. Educação
   - ○ 4º classe
   - ○ 9º ano
   - ○ 12º ano
   - ○ Licenciado
   - ○ Outro: ____________________________

6. Causa da amputação

   ____

7. Ano da amputação

   ____

8. Número de anos de utilização de prótese

   ____

9. Lado da amputação
   - ○ direito
   - ○ esquerda

.

10 Tipo de sistema de suspensão utilizado

____

11. Nível de atividade

- ○ K1 (ambulatório doméstico)
- ○ K2 (ambulatório doméstico limitado)
- ○ K3 (ambulatório doméstico)
- ○ K4 (usuário de alto nível)

Utilização

Esta secção foca-se na satisfação e adversidades que o paciente sente com o uso diário do seu atual sistema de suspensão. Utilizando uma escala de 0 a 5.

12. Quantas horas utiliza normalmente a sua prótese?

____

13. Sente-se satisfeito com o seu atual sistema de suspensão?

0	1	2	3	4	5
○	○	○	○	○	○

14. Sente dificuldade durante o alinhamento do pin no alojamento do sistema de suspensão?

0	1	2	3	4	5
○	○	○	○	○	○

15. Se sim, com que frequência?

0	1	2	3	4	5
○	○	○	○	○	○

Satisfação

Nesta secção é comparado o novo sistema de suspensão com o sistema utilizado pelo paciente, em termos de satisfação. Utilizando uma escala de 0 a 10 como classificação, em que 0 equivale a insatisfeito e 10 a completamente satisfeito.

16. O sistema permite uma conexão rápida e eficaz?

	0	1	2	3	4	5	6	7	8	9	10
Novo sistema	○	○	○	○	○	○	○	○	○	○	○
Pin/lock	○	○	○	○	○	○	○	○	○	○	○

17. O sistema é seguro?

	0	1	2	3	4	5	6	7	8	9	10
Novo sistema	○	○	○	○	○	○	○	○	○	○	○
Pin/lock	○	○	○	○	○	○	○	○	○	○	○

18. O sistema é confortável?

	0	1	2	3	4	5	6	7	8	9	10
Novo sistema	○	○	○	○	○	○	○	○	○	○	○
Pin/lock	○	○	○	○	○	○	○	○	○	○	○

19. O sistema é leve?

	0	1	2	3	4	5	6	7	8	9	10
Novo sistema	○	○	○	○	○	○	○	○	○	○	○
Pin/lock	○	○	○	○	○	○	○	○	○	○	○

20. o sistema é esteticamente agradável?

	0	1	2	3	4	5	6	7	8	9	10
Novo sistema	○	○	○	○	○	○	○	○	○	○	○
Pin/lock	○	○	○	○	○	○	○	○	○	○	○

21. Em pé, o sistema permite uma fácil aplicação?

	0	1	2	3	4	5	6	7	8	9	10
Novo sistema	○	○	○	○	○	○	○	○	○	○	○
Pin/lock	○	○	○	○	○	○	○	○	○	○	○

22. Sentado, o sistema permite uma fácil aplicação?

	0	1	2	3	4	5	6	7	8	9	10
Novo sistema	○	○	○	○	○	○	○	○	○	○	○
Pin/lock	○	○	○	○	○	○	○	○	○	○	○

23. Em pé, o sistema falhou durante a colocação do pin?
Neste caso 0= falhou sempre e 10= nunca falhou

	0	1	2	3	4	5	6	7	8	9	10
Novo sistema	○	○	○	○	○	○	○	○	○	○	○
Pin/lock	○	○	○	○	○	○	○	○	○	○	○

24. Sentado, o sistema falhou durante a colocação do pin?
Neste caso 0= falhou sempre e 10= nunca falhou

	0	1	2	3	4	5	6	7	8	9	10
Novo sistema	○	○	○	○	○	○	○	○	○	○	○
Pin/lock	○	○	○	○	○	○	○	○	○	○	○

.

25. Em suma, sente-se satisfeito com o sistema?

	0	1	2	3	4	5	6	7	8	9	10
Novo sistema	○	○	○	○	○	○	○	○	○	○	○
Pin/lock	○	○	○	○	○	○	○	○	○	○	○

26. O sistema facilita o seu dia-à-dia com a prótese?

	0	1	2	3	4	5	6	7	8	9	10
Novo sistema	○	○	○	○	○	○	○	○	○	○	○
Pin/lock	○	○	○	○	○	○	○	○	○	○	○

27. Utilizaria o novo sistema se estivesse disponível comercialmente?

○ sim
○ não

28. O novo sistema vem solucionar alguns dos problemas que sente com o seu sistema atual?

○ sim
○ não