Development and optimization of a new suspension system for lower limb prosthesis

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Abstract. The increasing rate of lower limb amputations reinforces the need to develop a new suspension system that provides a better quality of life for the lower limb amputees. This study aimed to present a novel suspension system that improves amputee's satisfaction in terms of donning and doffing process of the prosthetic lower limb. The design of the proposed suspension system was developed following the design methodology, to establish the amputee's needs, objectives, functions, requirements and specifications in order to optimize the final solution. The final solution is a combination of a guiding and fixation mechanisms that improve the donning and doffing process by driving the serrated pin to the fixation system. The proposed suspension system is a good alternative to improve the quality of life of amputees with lower activity level on the daily basis.

Keywords: Lower limb prosthesis, Suspension system, Amputee's satisfaction, Mechanical design, Guiding system and fixation system.

1 Introduction

Lower limb amputees perform daily the donning and doffing process to apply the prosthetic limb. The suspension system of prosthesis allows the firm attachment between the residual limb and the prosthetic limb and prevents excessive translation, rotation, and vertical movements between the residual limb and the socket [1][2].

Suspension systems have a fundamental role in the adaptation of the amputee to the lower limb prosthesis in order to replace the lost limb functions. Several prosthetic suspension systems are commercial available, including pin/lock systems, lanyard system, straps and hinges, suction systems and magnetic system [3][4]. Depending on the suspension system used, a different donning and doffing method is required, some of them are more time-consuming and require more hand strength than others. Each suspension system has disadvantages and advantages depending on the type of user [2][5][6].

The selection between the commercial solutions requires a careful evaluation in order to choose the suspension system that best fits the amputee's needs, since a poor

suspension can cause skin problems, pain, gait instability, shear stress and volume loss of the residual limb [2][7].

To select the most suitable suspension system, it is important to understand the overall satisfaction of amputees using the selected suspension system [3][8]. Several studies evaluated the satisfaction and functionality of the suspension systems available in the current market using a Prosthetics Evaluation Questionnaire (PEQ) [5][7][9]. PEQ rates the participant's feedback about the satisfaction in different domains (fitting, walking on diverse surfaces, appearance, donning and doffing and sitting) and perceives problems such as pistoning, sweating, skin irritations, residual limb pain, swelling, smell and sounds [1][10].

Some studies pointed out the ease of donning and doffing as an important factor to amputee's satisfaction since the donning and doffing technique differs according to the suspension used. Also, an impaired hand function increases the risk of skin problems and malfunction suspension [8][11][12]. Some suspension systems like suction systems requires a proper hand function during the donning and doffing process for a safety and correct suspension [3][6].

Some studies also highlighted the preference of amputees for the pin/lock system due to the easy donning and doffing process using a serrated pin attached to the distal end of the liner to suspend the prosthesis [13][14][15]. On the other hand, the study by Eshraghi et al. (2012) suggested some difficulties of donning and doffing with pin/lock system because some patients experienced a bit of struggle when aligning the pin with the locking system during donning process [8].

The authors claim that the suspension systems available in the current market, do not provide the quality of life that the lower limb amputees deserve, since they do not ensure the total safety and enough satisfaction to use the prosthesis in long term. These limitations are associated with the difficulties during the donning and doffing process, especially for amputees with lower activity levels. Therefore, this paper proposes a novel approach to solve some of the current limitations of the pin/lock systems in order to improve the quality of life of lower limb amputees and, at the same time, to increase amputee's satisfaction with the prosthesis. It is presented a new suspension system that ensures an effective serrated pin insertion, while providing comfort and an easy process of donning and doffing the prosthesis.

2 Suspension system design

The proposed suspension system was developed following the design methodology, to understand the amputees' needs, define the statement-problem, create several alternative solutions and prototyping the selected solution.

2.1 Design concept

The main user was defined as an individual with lower level of activity and manual dexterity, that also presents difficulties in terms of adaptation and learning, since the

literature reports that lower limb amputations are increasing due to the incidence of vascular diseases, such as diabetes, which especially affects the older population [16].

It was essential to develop a simple system that allows the reduction of the existing barriers during the adaptation to the prosthesis and improves amputee's satisfaction in terms of donning and doffing process. Therefore, the mechanical design was driven by the need to develop a simple and functional mechanism that ensures that the serrated pin is inserted and secured correctly into the housing without colliding at its ends. It was also intended to be a universal mechanism that could be easily adapted to the different types of pin/lock systems available in the current market.

The other parameters that were also taken into account during the conceptual design phase were safety, comfort, ergonomics, easy to assembly and maintenance, aesthetic appearance and costs.

2.2 Conceptual design solution

The proposed design, illustrated in Fig. 1, presents a guiding and fixation systems inside the mounting case, a serrated pin and a housing. It has two mainly functions: guide the serrated pin into the housing and establish a firm attachment between the residual limb and the prosthesis by fixating the serrated pin.

This solution proposes to guide the serrated pin into the housing with a retractable mechanism that winds and unwinds a wire connected to the serrated pin, with the energy release from a power spring. To achieve the fixation of the serrated pin with the pinion gear, it is proposed a ratchet mechanism, as the fixation system, to prevent the rotation in counterclockwise direction of the pinion gear.

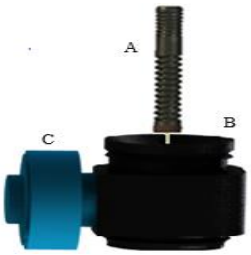

Fig. 1. The proposed suspension system: (A) serrated pin, (B) housing and (C) mounting case with the guiding and fixation systems inside.

Fig. 2 shows an exploded view of all the components of the proposed suspension system. The shaft, in which the ratchet gear is mounted, is fastened to the end of the pinion gear. The power spring is assembled inside the reel, that it is mounted on a shaft. The wire is wound around the spool, that it is mounted on the shaft portion of pinion gear. Each pawl has two openings, the inferior opening receives the pin of the button and the superior opening engages with the pin of the reel. The pawls also have a middle opening to receive one end of the torsion spring. Both torsion springs are connected to the respective pawls at one end and has its opposite end fitted into the inner wall of the mounting case. The button includes two pins and a central opening

to support the end of the shaft. The reel has two pins that hold the pawls and act as the center of the rotation of the pawls. All the components are assembled inside the mounting case that it is threaded to the receiving compartment of the housing with the pinion gear head positioned at the axial hole of the housing.

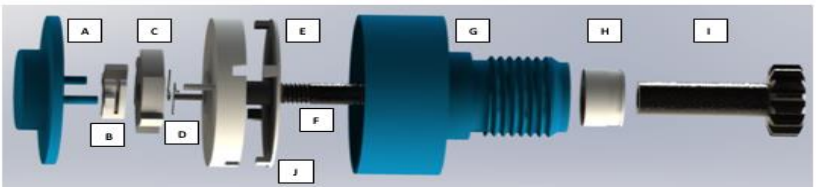

Fig. 2. Exploded view of the proposed model with the components: (A) button, (B) pawls, (C) ratchet gear, (D) torsion springs, (E) reel, (F) shaft, (G) mounting case, (H) spool with the wire, (I) pinion gear and (J) power spring.

To connect the residual limb to the prosthesis, the patient must first rotate the button to unlock the rotation of the ratchet gear backwards in order to pull out the wire. The pulling of the wire causes the rotation of the pinion gear in counterclockwise direction and the power spring is fully wound around the shaft. The wire connects with the serrated pin, which is attached to the distal part of the residual limb, through a nut. Then, the patient rotates again the button to the first position, where the pawls engage with the teeth of ratchet gear. Subsequently, the patient lightly moves the residual limb toward the socket direction. In turn, the power spring goes back to its initial position and its energy, stored during the pulling, is enough to wind the wire around the spool by the rotation of the shaft in the clockwise direction. This succession of events allows the serrated pin to be correctly guided into the housing. At this point, the serrated pin engages with the teeth of the pinion gear and the pinion gear rotates in the clockwise direction until the serrated pin is totally inserted inside the housing. Yet, if in some instance the serrated pin attempts to move in the release direction, both pawls lock up the rotation of the ratchet gear. In this way, the proposed solution guarantees that the serrated pin is fixed with the teeth of pinion gear and cannot be released until the patient desires it.

To remove the residual limb from the prosthetic limb, the patient just needs to rotate again the button to release the serrated pin. The pawls are disconnected from the ratchet gear with the rotation of the button to unlock the pinion gear rotation in the counterclockwise direction with the release of the serrated pin.

3 Prototyping and Validation

The final solution was prototyped to properly evaluate the viability and the possible improvements of the conceptual idea. A low-cost prototype model was created. The components were produced using 3D printing and they were assembled to create the prototype shown in Fig. 3.

A detail analysis was carried out to verify if the proposed solution follows all the established requirements and specifications. Safety and functional tests were conducted to evaluate the viability of the solution, and, if necessary, to identify possible improvements.

Fig. 3. Prototype model of the new proposed suspension system.

The safety analysis consisted on detecting possible failures and evaluating its effects for the system and patient in order to identify required corrective actions to prevent failures and to assure the reliability of the suspension system. Table 1 specifies possible failures, as well as the recommended actions to prevent these failures. They were classified as critical, major and minor failures. The critical failure is addressed when the user safety is at risk, and it is necessary to undertake improvement actions on the designed solution. The major failure affects the performance of the product but does not affect the user safety and again improvement actions must be undertaken. Minor failures do not affect product performance or put the user at risk and there is no need for improvement actions on the designed solution.

From the evaluation conducted on the prototype it was observed that it was possible to adapt the proposed solution to the different types of pin/lock systems, and, in turn, it can be applied in patients that already have the prosthesis with the pin/lock system.

It was also verified that there are still some improvements needed to optimize the proposed system. Besides the suggestions in Table 1, the ratchet system still needs to be improved, so that the serrated pin can easily enter the housing without any great effort to be developed by the user.

Due to the limitations imposed by the prototype of Fig. 3, it is still necessary further research to full evaluate the performance of the proposed system. Subsequently, in the future, it is intended to produce a new prototype to be tested on patients. The new system will be compared with prosthetic suspension systems available in the current market, in terms of patient's satisfaction to determine the real benefits and advantages of the proposed system. Besides that, further tests will also be carried out in terms of pistoning and gait analysis.

4 Conclusions

This study proposed a new suspension system that revealed to be a good alternative for amputees with lower activity level and bad hand function, since it facilitates the donning and doffing processes, and, at the same time, ensures a firm attachment be-

tween the residual limb and the prosthesis. The suspension system was developed to improve the quality of life of amputees and increase amputee's satisfaction. Not only it provides a better suspension but also promotes a frequent use of the prosthesis. However, further tests are still needed to determine the real benefits and advantages of the novel suspension system herein proposed.

Table 1. Potential failures for the proposed suspension system.

System	Potential failure	Type of failure	Cause	Effect	Recommended Action
Guiding	Spring failure	Major failure	Over extension of the spring coils	Serrated pin is not guided	Careful spring design
	Wire break	Major failure	High pulling force	Serrated pin is not guided	Select a wire with higher tensile strength
	Nut disconnec-tion	Major failure	Corrosion and debris	Serrated pin is not guided	Coating the serrated pin and ensure it is daily cleaned
	Button blocking	Major failure	Debris	The user cannot pull out the wire	Place a spongy layer on the entrance of the housing
Fixation	Ratchet gear rotates back-wards	Critical failure	Pawls are not correctly aligned with the ratchet gear	Release of the serrated pin	Design a ratchet gear with bigger number of teeth
	Button blocking	Major failure	Debris	The user cannot remove the ser-rated pin	Place a spongy layer on the entrance of the housing
	Serrated pin disengagement	Critical failure	Corrosion and debris	Poor suspension	Coating the serrated pin and ensures it is cleaned daily

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