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Selection of the most adequate suspension system for lower limb amputees: evaluation parameters

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Abstract

A proper suspension system influence the overall satisfaction of a lower limb ¬amputee on the daily basis. The present study aimed to establish the main parameters needed to evaluate and support the advantages of the new proposed suspension system by reviewing the literature related with amputee's satisfaction. Eleven studies were select and detailed analyzed. Most of the mentioned studies used Prosthesis Evaluation Questionnaire (PEQ) as a method to classify the amputee's satisfaction in different domains. Several studies pointed out pistoning and easy donning and doffing as the main parameters that addresses the amputee's satisfaction with the currently available suspension systems. Amputees had a general preference for suspension systems that have an easy donning and doffing. However, the current studies do not explore the impact of the amputee's characteristics on their satisfaction with the suspension system. The authors believe that amputee's characteristics such as age, activity level, duration of prosthetic use, skin quality of the residual limb and hand functionality can influence the selection of the suspension system. Further research is still needed to objectively define the clinical parameters for the selection of the most adequate suspension system. Therefore the research should be carried out using a homogenous study group to perceive the advantages, drawbacks and problems using different suspension systems and, consequently, to understand the full potential of the suspension system proposed by the authors.

Keywords

Suspension system; Mechanical design; Guiding system ; Locking system; Locking system

Review and evaluation of the most adequate suspension system for lower limb amputees

Introduction

Since the introduction of silicone liner ICEROSS by Össur, new suspension systems have been developed to provide a better suspension and overcome the problems of the conventional systems [1-2]. The most recent offers include the locking systems, vacuum systems, lanyard and magnetic systems [3].

The selection of the components for the prosthesis of an individual with lower limb amputation is a combination of the complete assessment of the patient with the knowledge and expertise of the professionals. The suspension method and fitting process significantly affects the overall satisfaction and comfort with the prosthesis [4].

A poor suspension of the prosthesis can cause 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. So, selecting an appropriated suspension is crucial for amputee's rehabilitation. 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 [3-5].

Amputees' satisfaction is a multifactorial issue and has been a topic of debate on several studies. On these studies measurements have been conducted (in terms of energy costs, interface pressure, pistoning) and the users' satisfaction with different suspension systems has also been evaluated through the use questionnaires [6].

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 [6, 7].

Some researches pointed out pistoning as a determinant factor to amputee's satisfaction. 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 photoelectric sensors [8, 9].

The ease of donning and doffing also claims to be a critical factor among prosthetic users. The donning and doffing techniques varies with the suspension used and it requires a proper hand function for a safety and adequate suspension [8]. An impaired hand function increase the risk of skin problems and mal-function suspension [10].

In Silveira *et al.* study, in 2017, it was presented a new concept design of a suspension system as an alternative to the available systems in the market. The authors proposed a system that overcomes the difficulties that the amputees with lower activity level have with the current systems and improves the quality life of the amputees [11]. But, in order to do that, it is necessary a full assessment of the system to ensure that it corresponds to the expectations of amputees.

Since the amputee's satisfaction in regard to the suspension remains a complex issue to be evaluated, this paper aims to review the literature concerning the satisfaction with prosthetic suspension to assist the evaluation of the new suspension system. The propose literature review is motivated to investigate the main parameters that influence the patient satisfaction with the current suspensions, as well as, the examination methods to better understand the evaluation system that should be used with the proposed suspension system.

New suspension system

The proposed suspension system, as shown in Fig. 1, consists in a stainless steel serrated pin, a guiding mechanism and a fixation mechanism.

Figure 1 – The proposed suspension system

The design of our suspension system was driven by the need to reduce the difficulties that amputees face on daily basis during donning and doffing process of the prosthesis. It presents a simple suspension method that increases amputee's satisfaction by promoting a quick and easy process of donning and doffing. Then, the proposed mechanism guides the fixing element into the housing, as a way of ensuring that the fixing element is inserted correctly into the housing without colliding at the ends of the housing.

This mechanism has two main functions: guiding the pin correctly into the housing and establishing a firm attachment between the residual limb and the prosthesis. To connect the residual limb to the prosthesis, first, the patient must screw a nut at the end of the wire into the pin. Then, must move the stump slightly to stretch the wire and allow the wire retraction. When the pin reaches the housing entrance, the patient must rotate the push button in order to engage the pin. To remove the pin, the patient simply must press the push button and disconnect the pin from the guide wire.

The guiding mechanism has a power spring inside the spool that allows pulling and retracting the nylon wire in order to guide the pin until the housing. The fixation mechanism is a one-way gear rotation mechanism and consists on a gear with teeth that engage with the serrated pin and a HFL0822 INA needle clutch bearing in juxtaposition with the gear. This clutch inhibits the rotation of the gear in the opposite direction, to keep the pin engaged until the push button is pressed. Other details regarding this new system were published elsewhere [11].

Methods

The approach used in this study to review the literature regarding the state of art is presented in the next sections.

Search

The following keywords were used in Medline, Science Direct and Embase databases as a search strategy to identify the most relevant papers: suspension system, lower limb amputation, amputee’s satisfaction, pistoning and donning and doffing.

Selection criteria

The method of selection excludes the studies performed with individuals with less than 1 year of prosthesis experience and a group study less than 3 participants. The non-writing English papers were also excluded.

It was preferably the prospective, retrospective and case series that give a clear information and have well-documented protocols. Both transtibial and transfemoral amputees were included in the review. It was also accepted clinical examination and questionnaires as research instruments.

Results

A total of eighty seven abstracts from the search results were analyzed. Although just twelve papers full correspond to the above-mentioned selection criteria, after reviewing each one of the full texts, one was excluded due to the fact that the study population was not defined. Eleven papers were identified and were published from 2001 to 2014. The earliest study was published by Board *et al.* in 2001 and the latest papers published by Gholizadeh *et al.* in 2014.

The age varied in the eleven studies considered, ranging from 42 to 56 years old, as it shown in table 1. The cause of amputation included trauma, infection, vascular disease and/or diabetes, congenital limb deficiency and other miscellaneous causes. Also, the time since amputation range from 8 to 25 years-old. Just one of the mentioned studies had participants with transfemoral, transtibial, knee disarticulation and symes amputation level; the others studies had transtibial amputees.

Table 1- Participants information

study	Mean patient age	Amputation etiology	Mean years since amputation	Level of amputation	Functional level
Board *et al.* (2001)[12]	45	Unknown	15.2	Transtibial	Unknown
Brunelli *et al.* (2013)[13]	44.9	Trauma, infection and vascular disease	8.7	Transtibial	K4 and K3*
Coleman *et al.* (2004)[14]	49.4	trauma	24.4	Transtibial	3.23**
Datta *et al.* (1996)[15]	48.35	Trauma, infection, vascular disease and/or diabetes, congenital limb deficiency and other miscellaneous causes	Unknown	Transtibial	Unknown
Eshraghi *et al.* (2013)[16]	42	Trauma and diabetes	Unknown	Transtibial	K2 and K3*
Gholizadeh *et al.* (2013)[17]	47.7	Trauma	23.8	Transtibial	K2 and K3*
Gholizadeh *et al.* (2014)[18]	42.2	Trauma and diabetes	9.7	Transtibial	K2, K3 and K4*
Hatfield and Morrison (2001)[19]	Unknown	Trauma, infection, vascular disease and/or diabetes, congenital limb deficiency and tumours	18.5	Transtibial, transfemoral, knee disarticulation and symes	Unknown
Klute *et al.* (2011)[20]	56	Trauma and vascular diseases	13	Transtibial	Unknown
Sadeeq *et al.* (2012a)[21]	44,02	Trauma	22.01	Transtibial	K2, K3 and K4*
Sadeeq *et al.* (2012b)[22]	49.3	Trauma, peripheral vascular disease and diabetes	Unknown	Transtibial	K2, K3 and K4*

*Activity level based on Medicare Functional Classification Level.
** Activity level based on Durable Medical Equipment Regional Carrier.

Table 2 presents the studies description, providing the methodology, outcome measurements and suspension system used.

Table 2-Studies information

Study	Sample size	Study design	Research instrumented	Suspension system	Location
Board *et al.* (2001)]12]	11	Case study	Pistoning, volume change, gait parameters and self-questionnaire	Vacuum system with expulsion valve and Vacuum with an electric pump	USA
Brunelli *et al.* (2013)[13]	10	Case study	Pistoning, energy cost and self-questionnaire	Vacuum system with expulsion valve and Seal-In liner X5 Iceross with expulsion valve	Italy
Coleman *et al.* (2004)[14]	13	Case study	Activity level and self-questionnaire	Alpha pin/lock and Pelite liner with neoprene sleeve	USA
Datta *et al.* (1996)[15]	54	Retrospective study	Self-questionnaire	Pelite liner system and ICEROOS liner with sleeve system	England
Eshraghi *et al.* (2012)[16]	10	Case study	Pistoning and self-questionnaire	Pin Icelock-clutch 4 with dermo liner, Seal-In X5 liner with expulsion valve and Magnetic system with Dermo liner	Malaysia
Gholizadeh *et al.* (2013)[17]	112	Retrospective study	Self-questionnaire	Vacuum system with expulsion valve and Seal-In liner system with expulsion valve	Malaysia
Gholizadeh *et al.* (2014)[18]	9	Case study	Shear stress and self-questionnaire	Pin/lock system, magnetic system (MPSS), Seal-In X5 and HOLO (hook/loop)	Malaysia
Hatfield and Morrison (2001)[19]	56	Retrospective study	Self-questionnaire	Alpha pin/lock and Alpha cushion liner system	England
Klute *et al.* (2011)[20]	5	Case study	Pistoning, activity level, volume change and self-questionnaire	Harmony vacuum pump system (VASS) and pin/lock system	USA
Sadeeq *et al.* (2012a)[21]	243	Retrospective study	Self-questionnaire	Pelite liner system, pin/lock system with silicone liner and Icerros Dermo Seal-In liner	Iran
Sadeeq *et al.* (2012b)[22]	9	Case study	Interface pressure and self-questionnaire	Seal-In X5 liner system with expulsion valve and pin/lock Icelock-200 series with dermo liner	Malaysia

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. In this study the participants gave their own experience with their suspension system. Nevertheless, they did not have the opportunity to experiment both and select the best one [19].

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 [12].

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 [14].

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.

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 [21].

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 [22].

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 [15].

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 costs [13].

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 [16].

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 [17].

Gholizadeh *et al.* (2014) introduced a new suspension system HOLO, a **h**ook and **l**oop 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 [18].

Discussion

Despite the importance of the suspension system, the main factors that influence amputee's satisfaction with the suspension has not been widely studied. 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.

From several studies is possible to observe that an easy donning and doffing has an important effect on the amputee's satisfaction using the suspension system. 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.

Studies did not correlate the individual information of the participants with the evaluation parameters; most of the obtained data was not related objectively with the amputee's characteristics. However, the amputee's characteristics can influence the outcome of the studies, because most data was obtained by using a self-questionnaire to ask the amputee's opinion. The study group considered on these studies, composed by individuals between 42 and 56 years-old, was heterogeneous and had different causes of amputation like diabetes, trauma, vascular diseases, congenital limb deficiency and tumours and had different function levels.

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.

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].

The research on the influence of subject characteristics on the overall satisfaction is in general of poor quality. 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. Nevertheless, the retrospective studies presented by Datta *et al.* (1996), Hatfield and Morrison (2001), Sadeeq *et al.* (2012b) and Gholizadeh *et al.* (2013) had a bigger number of participants, a number enough to evaluate various homogenous groups. However, the retrospective study by Sadeeq *et al.* (2012b) evaluated the feedback of the amputees with their currently suspension system: the participants gave their opinion for one of the systems, since they did not have the opportunity to use the systems considered in this study and referred previously. In addition, the feedback obtained in the studies by Hatfield and Morrison (2011), Datta *et al.* (1996) and Gholizadeh *et al.* (2013) were also based on the participant's experience with their currently suspension system and with their previous system. Therefore, 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.

The authors also believe that the amputee's characteristics such as age, activity level, duration of prosthetic use, skin quality of the residual limb and hand functionality can influence the results in terms of the amputee's satisfaction. However, there is still little evidence on literature to support the positive and negative effects on the satisfaction characteristics of the amputees. We therefore suggest a careful selection of the patients and a detailed discussion about the amputee's characteristics to study the different suspension systems currently available on the market regarding to clinical guidelines for suspension system prescription.

In order to correctly measure the benefits of the new proposed suspension system, as it was presented in [11], the above mentioned characteristics must be considered on its evaluation.

Conclusions

The objective of this study was to determine and evaluate the main parameters that address the amputee's satisfaction with the currently available suspension systems.

In general terms, the studies in this area do not explore the influence of the amputee's characteristics on their satisfaction with the suspension system. Subsequently, a further research is still needed to proper evaluate the most suitable suspension system for each amputee and to prepare a guideline for the selection of the most adequate suspension system.

Several studies pointed out that pistoning, difficulty in donning and doffing, sweeting, pain and skin problems are the main problems addressed to the current suspension systems available in the market. The alternative system proposed by the authors could solve some of these problems and increase the amputee's satisfaction, especially on elderly amputees. In order to understand the full potential of new proposed system it is important to extent the evaluation of the satisfaction between different groups of amputees to determine the real benefits and advantages of the new system.

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