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Research Paper

Comparing New Plunger-cylinder and Conventional Pin-luck Suspension Methods on Piston Movement and Satisfaction of Patients With Transtibial Prosthesis

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ABSTRACT

Background and Objectives: One of the factors affecting the time of using the prosthesis is the level of satisfaction of the amputee with the quality of the prosthesis. Choosing the right suspension system based on the functional needs and expectations of the amputee is a crucial step in the process of making the prosthesis and as a result, prosthetic rehabilitation. The critical side effects caused by "a weak suspension system" are pain and skin sores due to piston movement between the socket and stump and as a result, abnormal walking, reducing the amputee's satisfaction and comfort.

Methods: This study was conducted using a simple quasi-experimental method on six unilateral below-the-knee amputees. For each person, two prosthetic sockets were made with different suspension systems, one socket with a conventional pin-lock suspension system and the other socket with an innovative suspension system with a plunger cylinder. In this study, the level of satisfaction with the suspension system with a questionnaire and the amount of piston movement between the remaining limb and the prosthetic socket with the method of photography and the use of an indicator during 5 stages of a constant loading test, including full weight bearing, half weight bearing, no weight bearing, 30 N and 50 N were measured.

Results: The photography method did not show a significant difference in the amount of piston movement between the socket and the stump. However, the satisfaction level of the participants with the pin-lock suspension system was higher than with the plunge cylinder.

Conclusion: The use of a plunger-cylinder suspension system can be useful for below-the-knee amputations with a low activity level.

Keywords: Lower limb prosthesis, Suspension system, Satisfaction

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What is "already known" in this topic:

One of the vital components of the transtibial prosthesis is its suspension system, which plays an essential role in adapting the amputee to the prosthesis.

What this article adds:

Identification and evaluation of a new plunger cylinder suspension method for below-knee prostheses is useful especially for low activity level.

Introduction

In 2015, the World Health Organization (WHO) estimated the population of amputees to be around 40 million [1]. It is expected that this statistic will increase due to the increase in life expectancy and high prevalence of diabetes and vascular diseases [2]. Lower limb amputation is the most common type of limb amputation and causes a severe reduction in physical activity and mobility of a person [3]. In developed countries, the largest number of amputations is performed on people who are middle-aged and at the beginning of old age (55 to 64 years old) [4].

Amputation causes permanent disability and the amputee needs a prosthesis for stability, mobility, and daily activities [5]. One of the critical concerns of prosthetics is the non-use of prostheses by amputees or their limited use [2, 6, 7].

One of the vital components of the transtibial prosthesis is its suspension system, which plays an essential role in adapting the amputee to the prosthesis [6, 8-13]. Due to the importance of this part of the prosthesis, the selection of the appropriate suspension system based on the functional needs and expectations of the amputee is considered a crucial step in the process of making a prosthesis and as a result, prosthetic rehabilitation [6, 14].

The main function of the suspension system in the transtibial prosthesis is to create integration between the remaining limb and the prosthesis. The critical side effects caused by a "weak suspension system" are pain and skin sores due to the movement of the piston between the prosthetic socket and the remaining limb, and as a result, abnormal walking, and decreased satisfaction and comfort of the amputee [15-19].

Just one standard locking system is not defined for all amputees; because the needs of amputees are diverse and a specific type of suspension system cannot include all of them [8, 14]. In other words, the mentioned suspension systems have advantages and disadvantages, and each of them is suitable for a range of amputees with specific characteristics and expectations [6, 20, 21]. To choose the most suitable suspension system for each person, it is necessary to get information about the individual conditions and characteristics of the amputee's stamp and his expectations from the prosthesis [9, 22]. The results of some studies showed that one of the main criteria for amputees to choose a suspension system is the ease of wearing and removing the prosthesis. In other words, the ease of wearing and removing the prosthesis has always been considered a crucial factor for the satisfaction of the amputee [23-26].

Various suspension methods are used in transtibial prostheses, which are divided into four main groups based on their functional characteristics: 1) Atmospheric pressure suspensions, 2) Anatomical suspensions, 3) Suspensions with straps, and 4) Suspensions with joints.

Atmospheric pressure suspensions (or suction suspensions)

They are often used in sockets that are molded and made by the total surface bearing (TSB) method. In this type, prosthesis suspension is provided through surface tension, negative pressure, and muscle contraction. Vacuum-based systems can reduce gait asymmetry, stump pain, and skin ulcers, but manufacturing prosthesis with this method is a difficult process. They provide the strongest external connection to the stamp; therefore these suspensions are preferred over other types wherever possible. These types of sockets include suction sockets, liners, and elastomeric knee sleeves.

Anatomic suspensions

When the use of suspensions based on atmospheric pressure is not practical, it is the best option to connect the prosthesis using anatomical suspensions. Although anatomic suspensions create more local pressure than suction suspensions, most patients tolerate these pressures well after the first period of wearing the prosthesis. The advantages of this method can be mentioned easily in wearing and removing and internal-external stability. Prevention of full knee flexion and local pressure in the place of suspension is one of the disadvantages of this type of system.

Strap suspensions

It is one of the old methods of suspension, whose advantages include strength and simplicity. Adjusting the suspension with a strap is easier for amputees and suitable for stamps with daily volume changes, but allows significant piston movement due to the loosening of the strap when the knee is bent.

Suspension with lateral joints

The meaning of suspension with lateral joints in transtibial prostheses is to use a thigh corset and connect it to these joints. This suspension provides more internal-external stability, which is especially crucial for short stamps. Articulated suspensions, even with a very precise and optimal fit, still allow piston movement during the swing phase of the gait. Due to the volume, weight, and discomfort during the use of these suspensions, their use has been greatly reduced. Loose thighs cause atrophy of thigh muscles.

One of the most common suspension systems used for transtibial amputees who use various liners is the pin-lock suspension system [6]. Despite the simplicity of the mechanism of the shuttle lock suspension system, wearing and removing the prosthesis equipped with this system can be troublesome for people with upper limb disability [27]. In addition, some amputees have reported difficulty in wearing and removing the prosthesis with the pin-lock suspension system due to difficulty in fitting the pin inside the lock [22, 26].

In this research, a new suspension system has been introduced, which is used for the first time in lower limb prostheses. This study was conducted to design and construct a new method to overcome the limitations of the pin-lock suspension system and to investigate its impact on the quality of life, the person's satisfaction with the prosthesis, and the piston movement between the remaining limb and the prosthesis in transtibial amputees.

Materials and Methods

This study was conducted using a simple quasi-experimental method in the Department of Orthotics and Prosthetics, Faculty of Rehabilitation Sciences, Iran in 2022. The inclusion criteria included unilateral below-the-knee amputees who used a shuttle lock suspension prosthesis with an age range of 18 to 60 years, activity level K2 or higher, at least one year passed since receiving the first prosthesis, and a residual stump length of 5 to 7 inches, absence of knee flexion contracture, absence of wound in the stump. The number of participants in this research was considered to be six people based on similar articles. Before starting the work, the stages and objectives of the research were explained to the qualified people. Then, each of the people who volunteered to participate in the study completed the consent form. The information needed to enter the study was collected through clinical examination and face-to-face questions.

In summary, the current study included three stages:

1. Designing and manufacturing a new suspension system known as the plunge-cylinder suspension system

2. Making two similar prosthetic sockets with different suspension systems

3. Executing the test

The first stage: Designing and manufacturing the suspension system of the plunger-cylinder

The purpose of designing the new suspension system is to increase the ease of inserting and removing the prosthesis compared to the pin-lock suspension system. To achieve this goal, changes were made to the pin-lock suspension system, which will be explained below. The new suspension system had to be designed in such a way that the piston was smooth and easily placed inside the cylinder. So that even if the piston is tilted in relation to the cylinder, due to the deviation of the liner during wear, the piston is guided into the cylinder, and safety suspension is provided. In addition to the above, the suspension system of the plunger-cylinder should be such that it occupies the least space between the socket and the claw. Also, sufficient strength along with low weight and the ability to adjust the socket pyramid at any point of the socket were other criteria for designing and manufacturing the new suspension system. Figure 1 shows

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Figure 1. Different components of the plunge-cylinder suspension system

the various components of the plunge-cylinder suspension system. The advantages of this suspension system include its lightness, waterproofness, and no need for high perceptual power to maintain the alignment of the pin while wearing the liner, and no need for fingers to release the pin.

The second stage: Making two similar prosthetic sockets with different suspension systems

To carry out the molding stage of the remaining limb of the participants in the research, first, based on the end circumference, a suitable stamp liner was covered on it, and the molding was done by the prosthetic in a two-step supracondylar method. Then, the negative mold (obtained by performing the previous step) was turned into a positive mold by filling it with plaster, and the usually required corrections by a prosthetic were applied to it. After going through the mentioned steps, using polyester resin composite and prosthetic sock, a check socket was made from the modified positive mold. In the next step, the prosthetic parts were installed and adjusted to the socket, then the people participating in the research were asked to use the prosthesis for two weeks. During this period, the desired element was adjusted and possible necessary changes were made in the socket volume. After making these changes and obtaining the desired element and fit, the final prosthesis was made.

The final prosthesis was made with a pin-lock suspension system in the conventional way. Prosthesis with cylinder plunger suspension system was made according to the following steps:

First, a layer of polyvinyl acetate (PVA) was drawn on the plaster mold. The inside of the cylinder was filled with paste and the end of the mold was fixed with instant glue in line with the stamp. Eight layers of socks were stretched on the mold and carbon was used in the necessary areas to increase the resistance, then the second

Figure 2. Below knee prosthesis with plunge-cylinder suspension system

folio was stretched and the materials were laid. Then the socket was removed from the plaster mold and its edges were trimmed and the paste inside the cylinder was emptied and cleaned. Sealing rubbers were placed inside the cylinder and its cap was placed. The location of the valve door was drilled and the valve door was glued in the corresponding place by Ziegel glue. The piston was bolted to the end of the liner through an interface. Other parts were connected to the socket and the prosthesis element was adjusted (Figure 2).

The third stage: Test execution

The participant walked with each of the prostheses, the desired settings were made, and after two weeks of using the prosthesis, the questionnaire was filled out by the participant, and the amount of piston movement between the socket and the stump was measured in the following way. In this study, to measure the piston movement between the stamp and the socket, the connection between the skin and the liner was assumed to be one, and the amount of movement between the liner and the socket was measured [28]. Two marked points and a reference ruler were used for measurement. Before the test, the reference ruler was stuck on the outer part of the socket and the desired points were marked with a marker at a known distance, one on the outer upper edge of the liner and the other in line with the reference ruler on the outer part of the socket. After marking the points, from a certain distance so that the marked points and the reference ruler can be clearly seen, the amputee was asked to perform the five stages of the static test and the photos were recorded. Three and five kg weights were used to simulate the forces causing the piston movement between the remaining member and the socket at the end of the swing phase [13, 14, 28-32]. The validity and accuracy of this task have been evaluated in previous studies [30].

Ten tests were performed on each person. The tests were in two modes of use, "prosthesis with conventional pin-lock suspension system" and "prosthesis with designed plunger-cylinder suspension system", and each mode included five tests, which are explained below:

Test in full weight-bearing mode

At this stage, the amputee stands on a platform that is 50 cm above the ground and bends the knee of his healthy leg and puts all his weight on the prosthesis.

The stage of bearing half the weight on the prosthesis

At this stage, to apply 50% weight on the prosthesis, a weighing scale was placed under the prosthetic leg of the amputee, and to equalize the height of the healthy leg, a wooden board was placed at the height of the scale.

The stage of not bearing weight on the prosthesis

At this stage, the amputee was asked to hang his prosthetic leg from the platform with the knee completely straight.

The step of applying a load of 30 N to the prosthesis

At this stage, a weight of 30 N was hung along the prosthesis to the prosthetic paw. The knee should be completely straight at this point. For this reason, we had to ensure the absence of knee flexion by taking pictures before recording the data.

The step of applying a load of 50 N to the prosthesis

As in step 4, apply a force of 50 N.

All the test stages were performed 3 times and the state of full weight bearing was considered as the baseline state and other test states were compared with it. After performing the static test stages, the difference in the distance between the marked points in each stage compared to the base condition was obtained using the reference ruler installed on the outer part of the socket in Photoshop software, and the average of three test executions in each stage for the statistical analysis of the case was used.

In this study, to record the level of satisfaction, the comprehensive lower limb amputee socket survey (CLASS) questionnaire, which specifically examines the suitability of lower limb prosthesis sockets, was used to evaluate the prosthesis by the amputee himself in four cases, stability, suspension, comfort, and appearance of the prosthesis. The questions of each section are different and the options consist of simple movements, such as sitting, standing, walking, and going up and down the stairs. Answers can include completely disagree, disagree, agree, completely agree, and have no opinion, whose scores are 1, 2, 3, 4, and 0, respectively. The scores of different questions are added and the scores are calculated from 16, then the obtained number is converted into a percentage. Naimeh Rouhani in 2020 translated and psychometrically analyzed the above questionnaire [33].

Data were analyzed using SPSS software, version 26 and considering the significance level of 05. Due to the lack of normal distribution of the data, the Wilcoxon test was used to check and compare the data.

Results

Table 1 presents the demographic characteristics of the participants in the study.

Based on the analysis of the data obtained from the CLASS questionnaire, no significant difference was observed in the level of stability, comfort, and appearance of the prosthesis. According to the results of the CLASS questionnaire, the satisfaction level with the suspension of the prosthesis with the pin-lock suspension system is higher than with the plunger-cylinder, and the difference is significant ($P<0.05$). The amount of vertical displacement was 15 mm in the pin-lock prosthesis and 18 mm in the plunger-cylinder prosthesis, but this difference was not significant ($P>0.05$) (Table 2).

Discussion

Results showed that the satisfaction in terms of stability and appearance in the pin-lock suspension system was higher than the plunger-cylinder system, but this difference was not significant, which seems to be the reason for its stability in the field of stability, the high reliability of the pin-lock suspension and lack of the release of the pin during intense activities, and in terms of appearance, the small dimensions of the pin-lock suspension system.

Table 1. Demographic characteristics of the participants in the study

Sample	Gender	Age (y)	Weight (kg)	Height (m)	Amputation Side	Amputation Reason	Duration of Amputation (y)	K Activity Level	Using an Assistive Device
1	Male	54	86	1.73	Left	Diabetes	10	K3	Yes
2	Male	55	68	1.66	Left	Trauma	20	K3	No
3	Male	63	82	1.64	Right	Trauma	7	K3	Yes
4	Male	43	64	1.57	Right	Trauma	4	K4	No
5	Male	53	76	1.61	Left	Trauma	2	K4	No
6	Female	57	78	1.63	Left	Diabetes	2	K3	No

Table 2. The results of the CLASS questionnaire

Sample	CLASS Questionnaire Satisfaction With								Amount of Piston Movement by Photography Method*	
	Stability		Suspension		Comfort		Appearance			
	Pin-lock	Plunge-cylinder	Pin-lock	Plunge-cylinder	Pin-lock	Plunge-cylinder	Pin-lock	Plunge-cylinder	Pin-lock	Plunge-cylinder
1	81.25	68.75	81.25	68.75	68.75	62.5	66.6	58.6	13	18
2	75	75	75	68.75	68.75	68.75	41.6	50	13	19
3	75	75	75	50	75	56.25	75	75	21	23
4	87.5	87.5	87.5	81.25	87.5	93.75	66.6	50	15	13
5	56.25	43.75	87.5	75	68.75	81.25	50	58.3	18	25
6	56.25	56.25	62.5	56.25	56.25	81.25	66.6	66.6	11	13

CLASS: Comprehensive lower limb amputee socket survey.

*The amount of piston movement is in millimeters.

In the field of suspension satisfaction, a significant difference was observed between the two investigated suspension systems, and the pin-lock suspension system had a higher suspension satisfaction than the plunge-cylindrical suspension which seems to be the reason for the inherent feature of the pin-lock suspension, which does not allow the pin to move and come out of the lock if the pin is locked inside the lock chamber.

In the field of satisfaction with the comfort of using the prosthesis, the plunge-cylinder suspension system was higher than the pin-lock, but this difference was not significant, which was probably due to the small number of samples.

In this research, we measured the piston movement between the residual limb and the socket in static and dynamic situations using a ruler, and no significant difference was observed in the use of two suspension systems, pin-lock, and plunge-cylinder.

Despite the non-significance of the piston movement, the displacement of the markers in the socket with the plunger-cylinder suspension was more than that of the pin-lock. Considering that the largest difference in displacement was created during the measurement using a 50 N weight, this appears to be ensuring that the pin does not move after locking the suspension system.

Due to the innovativeness of the plunge-cylinder suspension method, no research has investigated the comparison of these two suspension systems; however, several similar studies have reported the problem of not being comfortable in inserting the pin into the lock in the pin-lock suspension system and by making changes in the mechanism. The lock and the use of a cable to guide the pin into the lock have tried to solve this problem.

The studies conducted in this field have not investigated the effect of individual characteristics of amputees on their satisfaction with the suspension system. In this study, although the authors did not investigate the effect of an amputee's activity level on the level of satisfaction with the suspension system, it is observed that only amputees with a high activity level prefer using the pin-lock system. Therefore, the level of activity can affect the amputee's satisfaction with the suspension system because amputees with a high level of activity need a stronger suspension system that provides high confidence to perform intense activities. On the other hand, amputees with a lower activity level usually have difficulty wearing and removing the prosthesis due to the poor function of the upper limb, and comfort in wearing and removing the prosthesis is a higher priority for them.

Conclusion

The use of a plunger-cylinder suspension system can be useful for amputations with low activity levels. The limitations of this study were the small number of samples and the impossibility of blinding the samples.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the Ethics Committee of Iran University Medical Sciences (IR.IUMS.REC.1401.348).

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Authors' contributions

Conceptualization, review & editing: All authors; Methodology: Vali Gholipour, Behnam Hajiaghaei; Investigation and data analysis: Vali Gholipour and Hassan Saeedi; Writing the original draft: Vali Gholipour; Review & editing: All authors; Supervision: Behnam Hajiaghaei.

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مقاله پژوهشی

مقایسه دو نوع روش تعلیق: پلانج-سیلندر جدید و پین-لاک مرسوم بر میزان حرکت پیستونی و رضایتمندی در بیماران استفاده‌کننده از پروتز ترنس‌تیبیال

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چکیده

مقدمه یکی از عوامل اثرگذار بر زمان استفاده از پروتز، میزان رضایت فرد آمپوته از کیفیت پروتز می‌باشد. در این راستا انتخاب سیستم تعلیق مناسب براساس نیازهای عملکردی و انتظارات آمپوته، گام مهمی در روند ساخت پروتز و درنتیجه توان‌بخشی پروتزی در نظر گرفته می‌شود. مهم‌ترین عوارض ناشی از «سیستم تعلیق ضعیف» ایجاد درد و زخم پوستی در اثر افزایش نیروهای برشی به سبب حرکت پیستونی، راه رفتن غیرطبیعی، کاهش رضایت و راحتی فرد آمپوته می‌باشد. در مطالعه حاضر سیستم جدید تعلیق پلانج- سیلندر برای کاهش این مشکل بررسی شد.

مواد و روش‌ها این مطالعه بر روی ۶ فرد قطع عضو یک‌طرفه زیر زانو انجام شد. برای هر فرد دو سوکت پروتزی با سیستم‌های تعلیق متفاوت ساخته شد که یکی از سوکت‌ها با سیستم تعلیق پین-لاک مرسوم و سوکت دیگر با سیستم تعلیق ابداعی جدید دارای پلانج-سیلندر ساخته شد. در این مطالعه میزان حرکت پیستونی از طریق عکس‌برداری در ۵ حالت مختلف و میزان رضایت از سیستم تعلیق با پرسش‌نامه انجام شد.

یافته‌ها تنها اختلاف معنادار در مطالعه حاضر در میزان رضایت از تعلیق می‌باشد که این اختلاف در اندازه‌گیری حرکت پیستونی با استفاده از روش عکس‌برداری معنادار نبوده و رضایت از تعلیق تنها در پرسش‌نامه CLASS معنادار بوده است. شرکت‌کنندگان رضایت از تعلیق بیشتری از سیستم تعلیق پین-لاک نسبت به سیستم تعلیق پلانج-سیلندر داشتند.

نتیجه‌گیری استفاده از سیستم تعلیق پلانج-سیلندر برای افرادی با سطح فعالیت پایین مناسب بود؛ به‌ویژه برای افراد دیابتی با مشکل تکرر ادرار شبانه به‌دلیل راحتی در جازدن پروتز، می‌تواند مفید باشد.

کلیدواژه‌ها:
پروتز اندام تحتانی،
سیستم تعلیق،
رضایتمندی

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