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Effectiveness of Suspension System in Transfemoral Prosthesis

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ABSTRACT

Background: Suspension was considered to be one of the most critical aspects of the prosthetic design and it's a method by which the artificial limb attached to a body. Suspension not only prevents the prosthesis from falling off, but it also avoids pistoning, minimizes shear forces on the skin of stump and enhances axial and rotational stability.
Objective: There were no such studies available for Indian population; therefore, the purpose of this study was to evaluate the effectiveness of suspension systems mostly used in Indian conditions (Hip joint and pelvic band, Total Elastic Suspension (TES) and T-Belt).
Methods: Ten unilateral Transfemoral amputees participated in this study, and the patients were asked to use three different suspension systems. All the suspension systems were tested in terms of active range of motion at the hip joint, rotational stability/axial rotation, axial pistoning (Radiographic findings of vertical displacement) and the patient's comfort.
Results: The results revealed that there was significantly more Range of motion on T-belt whereas less on Hip joint and pelvic band, rotational stability was more stable in TES, higher level of prosthetic satisfaction was on TES and pistoning was very less during the use of hip joint and pelvic band.
Conclusions: It can be concluded that even though TES was more stable suspension system for Transfemoral amputees, but overall satisfaction was higher with the hip joint and pelvic band suspension system as it helps to control the axial rotation and pistoning of the stump inside the socket.

Key words: *Transfemoral prosthesis, suspension system, hip joint and pelvic band, TES, T-belt, PEQ.*

INTRODUCTION

There is meager data regarding the overall incidence and etiological background of lower limb amputations in India. According to WHO (World Health Organization), India has the highest number of road accidents in the world with 16.8 fatal injuries per 100,000 population, and 38.9 non-fatal injuries per 100,000 populations as per the data from 2006. [(1)] Amputation of the lower extremities continues to be a major problem due to vascular impairments e.g. diabetes.

Suspension is considered to be one of the most critical aspects of the prosthetic design and it is a method by which the artificial limb is attached to a body. Suspension not only prevents the prosthesis from falling off, but it also avoids pistoning, minimizes shear forces on the skin of stump and enhances axial and rotational stability. [(2-5)] A number of prosthetic suspension systems are available for lower or upper limb amputees. [(6, 2, 7- 8)]

The best suspension is the one that minimizes pistoning without unduly complicating donning and doffing of the artificial limb. Numerous means to suspend the prosthesis have been developed. Diversity has resulted from the attempt to fit individuals of differing physical characteristics and life styles. Factors such as age, sex, and environmental condition, duration of amputation or time since amputation occurred, any medical condition, activity level, type of employment, sports, previous type of suspension used patient’s goals, residual limb shape, distal cushioning, skin problems and condition of pelvic and trunk control affect the choice of suspension systems for above knee prosthesis. Improper suspension results in poor gait, decreased safety, and increased skin problems. Secure and dependable suspension enhances proprioception and provides the feeling that the prosthesis is more a part of the wearer.

There have been many designs of suspension systems for transfemoral amputees, from which we have used hip joint and pelvic band, T-belt and Total Elastic Suspension (TES).

There are no such studies available for Indian population; therefore, the purpose of this study is to evaluate the effectiveness of above mentioned suspension systems in Indian conditions.

The main purpose of this study was to compare the effects of the above mentioned three suspension systems on various parameters (active range of motion, axial rotation, PEQ and axial pistoning) in unilateral transfemoral amputees. The main hypothesis of the study was that the T-Belt may allow more active Range of Motion at the hip and more axial rotation of the stump in the socket. Prosthesis related Quality of Life may be better in case of TES. Furthermore, Hip joint and pelvic band can provide better suspension and can reduce the pistoning compared to any other type of suspension systems used in the study.

Fig 1: Hip join and pelvic band suspension system

Fig 2: Total Elastic Suspension (TES)

Fig 3: T –belt suspension system

METHODS

Subjects:

Ten unilateral transfemoral amputees ranging in age from 21 to 50 years were found eligible to participate in this study as a sample of convenience. The anthropometric data were collected from the patients. A detailed explanation of the study was given to all the subjects, after they signed on an informed consent form. The subjects’ characteristics are shown in Table 1. The study was approved by the AIIPMR, Mumbai and Ethics Committee of Maharashtra University of Health Sciences.

Table 1: Characteristics of the subjects

Subject No.	Age	Height (in cm)	Weight (in Kg)	Amputated side	Residual Limb Length (in cm)
1	50	162	57	Right	17
2	48	168	69	Right	28
3	24	165	50	Right	23
4	46	161	46	Left	24
5	21	172	60	Right	25
6	47	172	60	Right	26.6
7	40	167	56	Right	22.8
8	49	172	75	Left	27
9	48	165	43	Right	18.3
10	21	177	41	Right	25.4

Procedures:

As the subjects were using different suspension systems (such as hip joint and pelvic band, TES and T-belt) prior to the study, we designed and aligned Endoskeletal transfemoral prosthesis for each subject. Only the suspension systems were different while all other components including feet, knee joint and socket design (quadrilateral) was similar for all prostheses. All the participants for this study were old users and who were using transfemoral prosthesis with hip joint and pelvic band previously. All subjects were given Trans-femoral Endoskeletal prosthesis with four bar linkage knee joint with suspension system and SACH foot approved by the Prosthetic and Orthotic clinic of the institute (AIIPMR, Mumbai).

Assessment:

The subjects were assessed and these parameters (active range of motion, axial rotation, PEQ and axial pistoning) were ta taken for knowing the effectiveness of the suspension systems.

1. Active Range of Motion at hip joint:

Active ROM at hip was measured using a Goniometer for each type of suspension with prosthesis.

For measurement of hip flexion and extension, center of the Goniometer was placed over the greater trochanter, and movable arm was placed along the midline of stump. Hip flexion was taken in supination position and extension in pronation position. Patient should be lying on a bed or table. Normal hip flexion angle is 135° and extension is 30°.

For measurement of hip abduction and adduction, center of the Goniometer was placed over the ASIS, and movable arm was placed along the midline of stump with supination position and patient should be lying over a bed or table. Normal hip abduction angle is 45° and adduction is 30°.

Fig 4: Rang of motion of hip joint pelvic band suspension

2. Axial Rotation:

Axial rotation in prosthesis occurs around a vertical axis passing from central line of pylon of the prosthesis. Inferiorly (at the bottom of the patient's shoe) this axis is thought to be passing from the midpoint of the anterior portion of the heel of the shoe (also called as heel breast). For the purpose of the study, side rail was placed on one side of the bed as shown in figure; which is adjustable in height. Then a pulley was placed having its axis parallel to the shoe. The amputee was asked to keep his leg straight. Rope was secured to the patient's forepart of the shoe with the help of elastic (figure 5) and allowed to pass through the pulley.

First, external rotation of the prosthetic foot with vertical was measured. To measure this, the center of the Goniometer was placed on the midpoint of the anterior portion of the heel of the shoe. The rigid arm is kept along the long axis of the shoe and the movable arm was kept vertical, whatever may be the rotation of the shoe. The angle subtended by the arms of the Goniometer was the initial external rotation of the prosthetic foot in relation with socket. Then a kilogram weight was added to the free end of rope. The prosthetic foot (along with prosthesis) was rotated to the side of pulley. Same procedure is followed for 2 to 4 kgs of weight. Precaution was taken to keep the rope always horizontal so that all the force exerted by the weights gets transferred to forepart of the shoe (pulling force).

Data was collected on the other side of the prosthesis (by keeping prosthesis straight and changing the side rails along with the pulley from one side to other, changing the rope's position) in the similar way as mentioned above. For example, if data had been collected from medial side of the prosthesis then for data collection of the other side, keep above mentioned assembly on lateral side of the prosthesis. Distance between rope and the point where center of Goniometer was placed, was measured in centimeters with the help of measuring tape as shown in figure, this was moment arm (M.A.). Then the torque was calculated by multiplying mass (m), gravitational force (g, which is 9.8 m/s) and moment arm (M.A.) (Because here, F=m×g and T=F×M.A.). This was the amount of torques acting to rotate socket over the stump. Similarly all the torques acting after addition of weights was calculated.

Then angular displacements on one side are added together (e.g. angular displacements on medial side). Then the sum of all the torques was divided by the sum of angular displacement. This was amount of torque acting to rotate the prosthesis over the stump per degree of angular displacement (ATRPS/DAD). Using above mentioned procedure ATRPS/DAD was calculated for each kind of suspension for both the sides. More the amount of ATRPS/DAD more was the rotational stability of that particular suspension system.

Fig 5: Pulley system and side rails for bed edge

3. Prosthesis related Quality of Life:

To evaluate the effect of these three suspension systems on patients' satisfaction, parts of the PEQ questionnaire were utilized. The PEQ questionnaire consists of 82 items grouped into nine subscales. Based on Legro et al., each question in the scales could be used separately. [9]

The questions from utility section and satisfaction were found relevant to suspension. Therefore, prosthesis related quality of life for this study was assessed using utility section and satisfaction question of the Prosthesis Evaluation Questionnaire (PEQ).

4. Axial Pistoning:

Effect of suspension on residual limb pistoning was checked with the help of X-rays. [10-11]

To take radiographic image in either full weight bearing or in non-weight bearing condition certain arrangements has to be done as shown in figure. First radiographic image with no loading (as in swing phase of gait) on the prosthesis was taken. This image was intended to mimic standing with single leg stance with full body weight on the prosthesis. Total two images were collected per subject for each suspension. So total 6 no. of X-rays were collected for each subject.

Fig 6: X-ray view with weight bearing position
Fig 7: X-ray view with non-weight bearing position

The distal end of femur bone and the bottom of the prosthetic socket or proximal end of adaptor are marked, and a vertical measurement was taken. Then, amount of the vertical distance in full weight bearing was subtracted from the amount of vertical distance in non-weight bearing condition. The measurement obtained was the amount of pistoning occurred with given kind of suspension. More the amount of pistoning means less effective.

Statistical Analysis:

Statistical data was analyzed using SPSS 21.0 and *p*-values of 0.05 or less reflected statistical significance. Paired-samples t-test was employed to compare the effect of three suspension systems. The statistical tests were applied like this hip joint and pelvic band vs. T-belt, hip joint and pelvic band vs. TES and T-belt vs. TES.

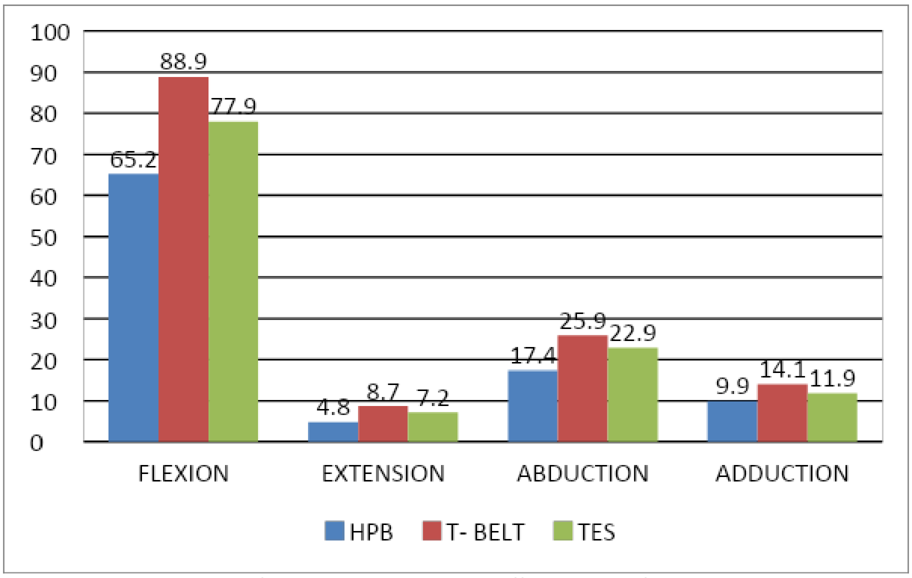
RESULTS

The mean age, height, and weight of the participants were 39.4 (SD, 11.69) years, 168.1 (SD, 4.8) cm, and 55.7 (SD, 10.45) kg, respectively. The mean stump length was 23.71 (SD, 3.43) cm.

1. Active Range of Motion at hip joint:

Table 2: Range of Motion at hip joint with different types of suspension system

Range of Motion at Hip Joint	Mean ± Standard Deviation			t-value			Remarks
	HPB	T-Belt	TES	HBP - T-Belt	HPB - TES	T-Belt - TES	
Hip Flexion	65.20±6.250	88.20±15.697	77.90±13.568	5.686	5.040	3.732	
Hip Extension	4.80±1.874	8.70±1.16	7.20±1.549	9.585	6.000	5.582	
Hip Abduction	17.40±8.127	25.90±7.795	22.90±7.385	8.044	5.009	4.881	
Hip Adduction	9.90±1.149	14.40±3.784	11.90±3.071	4.523	3.254	4.296	P<0.05



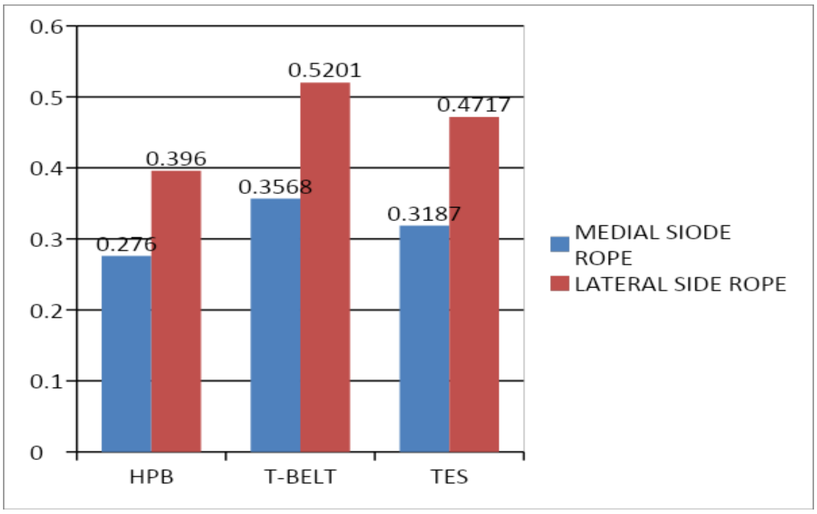
Graph 1: Range of Motion at hip joint with different types of suspension system

The study results showed that Active range of motion at the hip flexion, extension, abduction and adduction was found greatest with prosthesis with T-belt which is 88.20° (+/-15.697), 8.70° (+/- 1.16), 25.90° (+/- 7.795) and 14.40° (+/- 3.784) respectively whereas least with hip joint and pelvic band (Table 2). Also, there was a significant difference between the suspension systems ($p<0.05$).

2. Axial Rotation in Newton meter:

Table 3: Axial rotation of different types of suspension systems with medial and lateral side rope

Axial Rotation with	Mean ± Standard Deviation			t-value			Remarks
	HPB	T-Belt	TES	HBP - T-Belt	HPB - TES	T-Belt - TES	
medial side rope	0.276±0.054	0.3568±0.109	0.3187±0.0544	3.498	3.125	2.298	
Lateral side rope	0.396±0.078	0.5201±0.1341	0.4717±0.1007	4.270	3.944	2.338	P<0.05



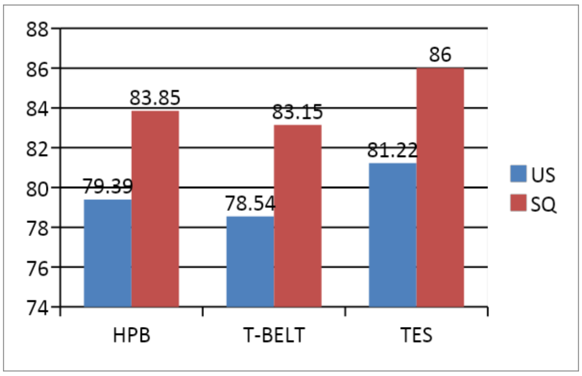
Graph 2: Axial rotation of different types of suspension systems with medial and lateral side rope

Rotational stability was found more on lateral side of the socket than medial side for all the three suspensions. It was found increased in T-belt medially 0.3568 (+/- 0.109) and laterally 0.5201 (+/- 0.1341) as compared to other suspensions used for the study (Table 3).

3. Prosthesis related Quality of Life:

Table 4: PEQ scale score for different types of suspension systems

PEQ Scale & Question	Mean ± Standard Deviation		
	HPB	T-Belt	TES
Utility Scale	79.34±7.74	78.54±8.02	81.22±6.804
Satisfaction Question	83.85±7.28	83.15±7.51	86±4.34



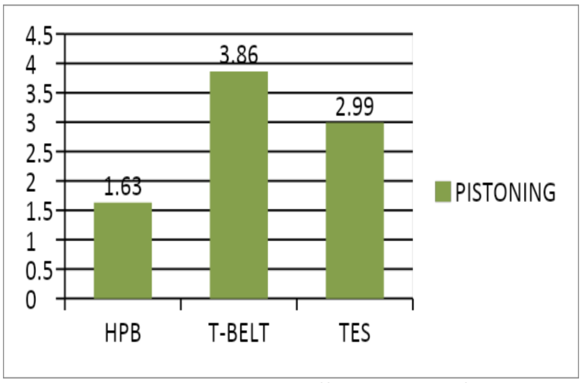
Graph 3: PEQ scale score for different types of suspension systems

Prosthesis Evaluation Questionnaire score for utility scale and satisfaction question was found more in TES.

4. Axial Pistoning:

Table 5: Amount of Axial Pistoning at different types of suspension systems

	Mean ± Standard Deviation			t-value			
	HPB	T-Belt	TES	HBP - T-Belt	HPB - TES	T-Belt - TES	Remarks
Amount of Axial Pistoning	1.63±1.02	3.86±1.27	2.99±0.91	3.784	3.507	2.298	P<0.05



Graph 4: Axial Pistoning at different types of suspension systems

Amount of pistoning for hip joint and pelvic band was 1.63 (+/- 1.02), with T-belt were 3.86 (+/- 1.27) and with TES were 2.99 (+/- 0.91). The amount of pistoning was more effective with Hip joint and pelvic band.

DISCUSSION

Prosthetist need to decide whether a suspension system is suitable or not for residual limb length, shape (i.e., cylindrical or conical), muscle strength, soft tissue, bony prominence, pain, aspiration of amputee, level of activity, upper limb strength and amputee's financial situation. In this study, we compared three suspension systems to examine the effectiveness.

Analysis of Range of motion at hip joint with different types of suspension system:

In this study, the range of motion was tested for residual limb and transfemoral prosthesis with 3 types of suspension system at hip joint with the help of Goniometer. The ROM was tested for hip flexion, hip extension, hip abduction and hip adduction on various subjects. The ROM has been shown to be affected by the residual limb length of the subject. [12] From, the means of ROM in the sample size, it was observed that that there was significantly more ROM on T-belt. However, ROM of different movements of hip was different. Active range of motion at the hip flexion, extension, abduction and adduction was found greatest with prosthesis with T-belt which is 88.20°, 8.70°, 25.90°and 14.40° respectively. But active range of motion at the hip flexion, extension, abduction and adduction was found less with prosthesis with hip joint and pelvic band which is 65.20°, 4.80°, 17.40°, 9.90°respectively.

Analysis of Rotational stability within the prosthesis with different types of suspension system:

Rotational stability in the prosthesis improved significantly after the use of correct suspension system. In this study as all the subjects were experienced users of prosthesis, socket comfortness and good experience about walking pattern and rotation of stump inside the socket, clearly obtained that rotational stability was found more on lateral side of the socket than medial side for all the three suspensions. It was observed that rotational stability found increased in T-belt medially 0.3568 NM and laterally 0.5201 NM as compared to other suspensions used for study. More stable in TES whereas less rotational stability at hip joint and pelvic band i.e. medially 0.276 NM and laterally 0.396 NM.

Self-assessment outcomes of the subjects after the successful use of transfemoral prosthesis with three types of suspension:

Prosthesis Evaluation Questionnaire is a population specific, validated and reliable method. [13] PEQ was used to collect subjective data mainly for capturing participant input and preference. It evaluates Prosthesis satisfaction, Prosthesis related quality of life and Pain related question. Questions were asked to the participants as it was strongly believed that patients own views should be an important and integral part of the evaluation of any prosthetic technology. Though PEQ compared of 9 validated scales and many additional individual questions, but only one scale and one individual question was studied due to the small acclimatization period with each systems. From the result, it was evident, that subjects rate higher levels of perceived Prosthesis satisfaction, Prosthesis related quality of life and pain related question, during the use of Transfemoral prosthesis with TES.

Analysis of Axial pistoning/Vertical displacement within the prosthesis with different types of suspension system:

According to Jason E. Tanner and Narita et al., [10-11] X-rays method is a successful method in finding amount of pistoning and the results were similar to dynamic methods of finding the amount of pistoning in case of Trans-femoral prosthesis also but they studied over transtibial prosthesis. As reported by them take X-ray at the time of non-weight bearing on prosthesis, also take X-ray at the time of full weight bearing on prosthesis. After subtracting the weight bearing value from non-weight bearing value we find out the amount of pistoning. From the results, it was evident, that axial pistoning was less during the use of Transfemoral prosthesis with hip joint and pelvic band i.e.1.3 cm. Less axial pistoning means that suspension system is more effective.

Study Limitations:

This study was conducted on a small sample size and this may have impact on the statistical relevance of the results. The allotted time period for this research seemed to be short which led to difficulties in maintaining follow up. Additionally, more suspension alternatives should be studied in future to deepen insights into the effectiveness and comfort of suspension systems.

CONCLUSION

From the outcome of this study, it can be concluded that amputee's were more stable with TES because range of motion, axial rotation and axial pistoning for this suspension was always less than T-belt and more than hip joint and pelvic band. Many amputees liked T-belt because of ease with which it can be donned and doffed as compared to hip joint and pelvic band and TES. Some patients preferred this suspension because it produces less perspiration than other systems, which can be great concern when patient lives in humid environmental conditions. Nevertheless, overall satisfaction with prosthesis was higher with the hip joint and pelvic band suspension system as it helps to control the axial rotation and pistoning of the stump inside the socket. Good prosthetic suspension system must secure the residual limb inside the prosthetic socket. Further research is needed to evaluate more amputees, and to offer a guideline for proper selection of suspension system.

Conflict of Interest: The author does not have any conflict of interest regarding research, authorship and publication of this article.

Authors' Contributions: The entire clinical course of Transfemoral prosthesis service delivery was done by Ms. Minakshi Behera towards the fulfillment of Master's degree research project under the supervision of Mr. Ashok G. Indalkar. Subsequent data collection and manuscript preparation is done by Ms. Minakshi Behera. All the clinical service delivery to patient and research study was carried out in the premises of AIIPMR, Mumbai.

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