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A Comparative Study between Patella Tendon Bearing-Supracondylar (PTB-SC) and Total Surface Bearing (TSB) Socket on Energy Expenditure in Subject with Transtibial Amputees on Two Surface Walking

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ABSTRACT

Background: Amputation is a procedure where a part of the limb is removed through one or more bones. Lower extremity amputation is the most common amputation surgery. Limb amputation can be considered as both life saving and life changing event. As per Census 2011, the population of persons with disabilities in our country is about 2.68 crore which is 2.22% of total population of the country. World Health Organization (WHO) estimated that there are 40 million amputees throughout the developing world. Approximately 200–500 million major amputations are performed each year worldwide. Incidence rate is every year 23,500 amputees are added to the amputee population in India, of which 20,200 are males and 3,300 are females.

Material & Methodology: Thirty adults who had a unilateral transtibial amputation participated in this study. Energy expenditure was measured with a Cosmed K4b2 oxygen analysis telemetry unit (Rome, Italy) as the participants walked over level ground for 30 meters at a self-selected speed. The variables that were analyzed were Tidal Volume, VO2 rate (ml/min), VO2 cost (ml/kg/m), Heart Rate (bpm), and Energy Expenditure per minute (Kcal/min).

Results: It is observed that the pre data result of VT, VO2, VCO2, HR, PaO2 and EE was found significant ($p<0.05$) while O2 cost was non-significant ($p>0.05$) and post data result shows that VT, VO2, O2 cost, HR, PaO2 and EE found significant ($p<0.05$) while VCO2 was non-significant ($p>0.05$) when comparing two prosthetic design variants, that is PTB and TSB socket design on plane surface. This suggests that the change in VCO2 uptake can directly affects the EE/min values and vice versa. It was observed that in pre data result of all outcome parameters were non-significant except HR and post data result found all outcome parameters are non-significant except VO2 and EE when comparing two prosthetic design variants, PTB and TSB socket design on inclined surface. This suggests that the change in VCO2 and VO2 uptake can directly affects the EE/min values and vice versa.

Conclusion: This study concluded that the subject (transatibial amputees) with PTB-SC socket spends more energy than subjects with TSB socket. So, this study demonstrated that people with transtibial amputation may be benefited from using prostheses with TSB socket compared with PTB-SC with respect to reduced energy expenditure and functional walking ability.

Keywords: *Transtibial Amputee, Energy Expenditure, TSB and PTB-SC Socket Design.*

1.0 Introduction

Amputation is a procedure where a part of the limb is removed through one or more bones. Lower extremity amputation is the most common amputation surgery.

Limb amputation can be considered as both life saving and life changing event [1]. As per Census 2011, the population of persons with disabilities in our country is about 2.68 crore which is 2.22% of total population of the country.

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World Health Organization (WHO) estimated that there are 40 million amputees throughout the developing world [2].

1.1 Prevalence of transtibial amputation in world and India

Approximately 200–500 million major amputations are performed each year worldwide. Amputation of the lower extremities approximately 85% of those [3]. Incidence rate is every year 23,500 amputees are added to the amputee population in India, of which 20,200 are males and 3,300 are females. According to the National Sample Survey Organization, the Condition 1valence rate of amputees in India out to be 0.62 per 1,000 populations, the state of West Bengal ranks second in terms of prevalence rate and third in incidence rates of disability among the major Indian states. In our present study in Kolkata, 94.8% of the amputation population consisted of lower limb amputees, the most common age group affected by amputation being those age between 20- 30 years [4].

1.2 Medical complication of transtibial amputation etiology

The major causes of amputation are vascular disease, Diabetes, Trauma, Tumor and Congenital deformity [5]. The cause of amputation varies from country to country. In developing country trauma is the leading cause of amputation caused by inadequately treated fracture, motor vehicles accidents and other motorized machinery. In developed country vascular complication of diabetes is the most cause of amputation. [6]. The most common cause of amputation was trauma (70.3%), the second most common cause being peripheral vascular disease (27.7%) [4].

The condition leading to amputation are peripheral disease (atherosclerosis, thromboangitis obliterans, thrombosis and embolism, trauma, raynaud’s phenomenon arteries, leg ulcer), diabetes mellitus, congenital malformation, malignant disease, infection, trauma [5]. The main associated risk factors are, diabetes mellitus, arterial hypertension, smoking, dyslipidaemia, advanced age, chronic renal failure, hypercoagulability and genetic factors.

Major amputation are generally defined as those performed above the level of ankle, whether transtibial, transfemoral, knee disarticulation or hip disarticulation, while minor amputation are those restricted to the toes or at the level of foot whether trans-metatarsal, tarso-metatarsal or lisfranc disarticulation, mid tarsal or chopart amputation.

Minor amputations are generally better accepted because they do not necessarily impose a need for prosthesis to enabling walking. The mortality rate is 22% within 1 year for minor amputation to 21% within 1 month up to 52% within 1 year for major amputation. The lower limb amputation accounts for 85% of this total and have major socioeconomic impact, with loss of capacity to work of socialization and quality of life, in addition to complication such as hematoma, infection, necrosis, contracture, neuroma, phantom pain and re-admission, making them a considerable public health problem [7].

1.3 Classification of amputation

Closed Amputation: This is done most of the times as an elective procedure and may be above knee or below knee, above elbow and below elbow, etc.

Open Amputation: The wound is left open over the amputation stump and is not closed. This is done as an emergency procedure in the face of life threatening infections.

1.4 Prosthetic clinical approaches of PTB-SC and TSB socket

The PTB-SC Socket first developed by Kuhn in Muenster, Germany in 1968[8]. The major difference between PTB-SC and the PTB-SCSP socket is that the patella is not enclosed. The medial and lateral brims purchase over the femoral condyles, but anteriorly they dip downward to form a more traditional trim line near the distal end of the patella.

The quadriceps bar and its knee extension control are thus eliminated. This suspension may be indicated when a patient wishes to do a lot of kneeling or cannot tolerate the quadriceps bar or encapsulation of the patella. The patient must have a stable cruciate ligament with no need for an extension stop at the knee. It is contraindicated for patients with moderate to severe ligamentous laxity that requires more stability [9].

In PTB-SC the weight bearing takes place below the patella, at the patellar tendon. The suspension is generated at the medial and lateral areas of the femoral condyles. Compared to the PTB socket with belt suspension, this design does not produce problems of blood circulation or atrophy. For the moment, this type is used worldwide as most basic design for prosthetic fitting of medium and long stumps (8,10). The Supracondylar suspension system employs high medial and lateral socket walls to encompass fully the medial and lateral aspects of the femoral condyles. If these proximal extensions were flexible enough, one could easily don the prosthesis by expanding them and then allowing them to retract over the condyles.

Since the laminate used in the socket walls is generally not that flexible and no liner is normally used in the socket, the Supracondylar suspension of the PTB now being introduced uses a prefabricated wedge of a flexible material which can be inserted between the socket and the medial condyles to obtain a locking fit over those condyles. The wedge has to be carefully fitted with special attention given to the construction of its seat in the medial socket wall. Properly fitted over the condyles, the wedge provides very adequate suspension. The amputee removes his prosthesis by first removing the wedge and puts the wedge back in after donning the limb. With this type of suspension, there is probably less restriction to knee flexion in comparison to the circumferential strap, and medial-lateral stabilization of the knee is provided. Significant in the fitting of this device is the care that must be taken in the medio-lateral dimensioning over the condyles.

Figure 1: PTB-SC Socket Design (Anterior and Posterior View)

A description of the Supracondylar suspension is given by Fillauer. This design has sometimes been called the Condylar clip, the KBM, or the STP, but terminology recommended will be addition of the letters SC (Supracondylar) to the PTB, such as PTB-SC (11).

2.0 Materials and Methodology

The study was conducted in Department of Prosthetics and Orthotics, National Institute For Locomotors Disabilities (DIVYANGJAN), B.T. Road, Bon-Hooghly , Kolkata – 700090. After the approval of synopsis by the ethical committee of the institute, the subjects reported to the N.I.L.D/ OPD thoroughly examined by registered medical practitioner& a prosthetist. The participants (n=30) with unilateral trans-tibial amputation fulfilling the inclusion criteria were included in the study by convenient sampling method. The individuals was explained the study procedure. The informed consent was obtained from the individuals prior to the study participation.

2.1 Inclusion criteria

- Activity level- K2 and K3
- Unilateral transtibial amputees.
- Traumatic amputee
- Age 20-40
- Height- 150-170 cm
- Weight 50-70 kg
- Stump length- 15-25 cm
- Amputee with full ROM of hip as well as knee and absence of any contracture and deformity that may hinder successful prosthetic fitting.
- Previous user of transtibial prosthesis.

2.2 Exclusion criteria

- Amputee with any neurological disorder that may change the outcome of study.
- Any musculoskeletal disorder associated to sound side.
- Mental retardation and visual impairment (26).
- Transtibial amputee with contra-lateral joint instability (26).
- Balance disorder
- Volume fluctuation of stump.
- Bad skin condition of stump

2.3 Procedure

After registration for the study, participants were conveniently divided into two groups A and B each with 15 subjects in each group. Group A patients were measured for TSB socket design and Group B patients were measured for PTB-SC socket design. The measurement and casting were taken as per the standard practice. After modification of positive mould the socket was fabricated. Each subject in the two groups was provided with Endoskeletal trans-tibial prosthesis with SACH Foot and auxiliary suspension.

Energy expenditure data was taken during plane and inclined surface walking by K4b2 instrument duringcondition 1- after initial gait training of the patient with the Prosthesis; and condition 2- after 3 months of adaptation period of the patient with Prosthesis. Then data was analysed for two groups in each condition using statistical test.

3.0 Statistical Analysis

Raw data were exported from K4b2 machine into Microsoft Excel, and final data analysis was performed in SPSS version 24.0. The data were explored using appropriate descriptive and graphic techniques. Each data set was examined for a normal distribution prior to conducting any inferential analysis. At first, Graph representation is done for all the nominal data such as gender and amputation side. Using the SPSS software tool, F-test was used to test the variability of age, weight and height between the two groups (Group A & Group B). Un-paired t-test was used to analyze the K4b2 data from the two groups of Transtibial Prosthesis users (group A& Group B) at two times, condition 1: After initial gait Training of the patient with the Prosthesis; and Condition 2: After 3 months of adaptation period of the patient with Prosthesis.

With the help of t-value, p value was found using a table from student’s t-distribution. If the calculated p-value is below the threshold chosen for statistical significance, then the null hypothesis is rejected in favor of the experimental hypothesis. The threshold value for significant level was kept at 0.05 levels. So that if p value < 0.05; then there will be significant difference between group A and Group B for the particular outcome parameter

4.0 Results

All the participants were informed that participation in the research was totally voluntary and if they refused to participate it would be not have any future negative consequences for them. In addition, all aspects regarding confidentiality were explained to the participants, i.e. no name would be written on the questionnaires and that their names would not e mentioned in the reports. Patients have been explained that nobody other than researcher & research supervisor will have access to the information they share.

Table 1: Distribution of Mean Age between two Groups

Age (years)	Mean	Standard Deviation (SD)	F- Value	P- Value
Group A	31.46666667	4.969430359	1.030194676	0.478201533
Group B	30.4	4.896062558		

The mean age mean + Standard deviation of group A patients was (31.466666 + 4.969430) and group B patients was (30.4 + 4.896062558) with range of 20-40 years and median age was 30 years. Using F-test on the data above (F=1.32958, df = 28) the result were found to be non-significant with p=0.300612, therefore there is no significant difference between two groups.

The Mean height mean +Standard deviation of group A patients was (166.73333333 + 3.594970031) and group B patients was a (164.06666667 + 3.261609302) with range of 150-170 cm and median height was 160 cm. Using F-test on the data above (F=3.954341987, df=28) the result were found to be non-significant with (p>0.360394828461645), therefore there is no significant difference between two groups.

The Mean weight mean + Standard deviation of group A patients was (59.46667+ 7.347173088) and group B patients was a (61.2+ 6.371813) with range of 50-70 kg and median weight was 60 kg. Using F-test on the data above (F=3.954341987, df = 28) the result were found to be non-significant with (p>0.300612), therefore there is no significant difference between two groups.

Result for Different Outcome Measures

		Test of significance for outcome parameters	
	Condition	**Significant**	**Non-significant**
Plane Surface	Condition 1: after initial gait	VT, VO2, VCO2, HR, PaO2 and EE.	O2 Cost.
	Condition 2: after 12 weeks of adaptation period	VO2, HR, O2 Cost, PaO2 and EE.	VCO2
Inclined Surface	Condition 1: after initial gait	HR	VT, VO2, VCO2, O2 Cost, PaO2 and EE.
	Condition 2: after 12 weeks of adaptation period	VO2 and EE.	VT, VCO2, HR, O2 Cost and PaO2.

5.0 Discussion

The purpose of the study was to find the impact compare between patellar tendons bearing Supra-Condylar (PTB-SC) versus total surface bearing (TSB) socket on energy expenditure to quantify prosthetic gait.

Through statistical test, it has been found that, there was no significant difference in mean age, height and weight between group A and group B as f- value = 1.030194676 & p- value = 0.478201533, f-value = 3.954341987 & p- value = 0.3603948284, f-value = 1.32958 & p- value = 0.300612 respectively. It can therefore be said that these co-variable should not cause any bias to estimate of association between main variable of the hypothesis.

The main objective of the study was to compare the gait energetic parameters between patella tendon bearing Supra-Condylar (PTB-SC) versus total surface bearing (TSB) sockets. Among all gait energetic parameters Heart rate, VO2, VCO2, PaO2, O2 cost, VT and EE were measured using Cosmed K4b2 for all subjects.

Statistical analysis indicates that for the plane surface walking, all of Energy parameters observed for patellar tendon bearing Supra-Condylar (PTB-SC) and total surface bearing (TSB) sockets are significantly different for all parameter, except for O2 cost after initial gait training (condition 1). Whereas, all of Energy parameter observed for patellar tendon bearing Supra-Condylar (PTB-SC) and total surface bearing (TSB) sockets are significantly different for all parameter, except for VCO2 after three months of adaptation period (condition 2).

Similarly, statistical analysis indicates that for inclined surface walking, the energy parameters observed for patellar tendon bearing Supra-Condylar (PTB-SC) and total surface bearing (TSB) sockets shows significant differences only for HR after initial gait training (Condition 1), whereas the energy parameters observed for patellar tendon bearing Supra-Condylar (PTB-SC) and total surface bearing (TSB) sockets shows significant differences for VO2 and EE after three months of adaptation period (Condition 2).

The hypothesis of this study that there is significant difference between PTB-SC and TSB socket design with respect to energy expenditure on two different surfaces in subject with TT amputation. So, the result found that on VO2, HR, PaO2 and EE per minute clearly indicated that all transtibial amputee groups-A walk with less effort by using prosthesis on plane surface. So that a well-fitted transtibial prosthesis with TSB socket design results in reduced physiological energy demand when compared to PTB-SC.

Although some amputee may prefer to use the transtibial prosthesis with PTB-SC socket design to perform his activities where the increased EE can be compromised for small distance walking, the use of transtibial prosthesis can be undertaken for activities requiring long distance walking, there PTB-SC design provide more exertion than walking with TSB design prosthesis.

In a study by K. Yiğiter et al in 2002 state that socket volume was found to be smaller in TSB than PTB when two types of prosthetic fitting were compared. Performing ambulation activities, a statistically significant difference was observed between the two socket types in favour of the TSB socket. It was found that shorter time is required by the amputee to complete the ambulation activities, except sitting and standing up from a chair and crossing an obstacle, using the TSB prosthetic socket ($p<0.05$). TSB sockets were lighter than the prostheses with PTB sockets and better suspension was obtained from TSB prosthetic socket ($p<0.05$) (11). TSB socket is having lesser volume, and more activity providing and temporal-spatial gait parameters than compare to PTB socket. However in present study in EE parameters so therefore further finding out the difference between the TSB and PTB-SC socket design and it is found that the lesser energy expenditure in TSB socket design compare to PTB-SC socket design.

So therefore the present study is supported by the previous study which also says that the TSB socket design is better in compare to PTB socket design in terms of energy efficient with respect to volume, activity and temporal spatial parameters and the present study it is PTB-SC socket design.

In a study by H. Narita et al in 1996 state that the suspension effect of the TSB prosthesis with an ICEROSS silicone socket is superior to that of the PTB prosthesis evaluated both by static x-ray and dynamic cineradiography. Thus, antero-posterior stability of the TSB prosthesis was superior to that of the conventional PTB prosthesis. The translation for the TSB prosthesis was significantly lower ($p< 0.05$) and the suspension effect of the TSB prosthesis consequently superior to that of the PTB prosthesis (12).

TSB socket is using interface material which is ICEROSS silicone having more suspension, stability and translation providing than compare to PTB-SC i.e. this study represents physical or temporal-spatial differences, however in present study in EE parameters so therefore further finding out the difference between the TSB and PTB-SC socket design and it is found that the same interface materials (ethaflex) was using in both socket design which was lesser energy expenditure in TSB socket design compare to PTB-SC socket design.

So therefore the present study is supported by the previous study which also says that the TSB socket design is better in compare to PTB socket design in terms of energy efficient with respect to suspension, stability and translation and the present study it is PTB-SC socket design.

In old study Molen N H et al (1973) state that the energy / speed relation of below-knee prosthesis users of rehabilitation program, on the ground of the O2-consumption during walking. They found the relation between O2 consumption and the walking speed of 54 users of below-knee prostheses, all but a few disabled in consequence of a trauma. Thirty-seven subjects could reach and maintain walking speeds of 50 to 90 m/min for a prolonged period, for this range of speed equations for gross and net VO2/kg were determined. The conclusion is that otherwise healthy users of below-knee prostheses are consuming approximately 20 % more oxygen at all speeds than normal subjects (13). Oxygen consumption is related to the speed of walking, the present study providing evidence to that and therefore present study where found energy consumption between two different socket design is very much related to the speed of walking with two types of patients. So therefore the present study is supported by the previous study which also says that the TSB socket design is better in compare to PTB socket design in terms of energy efficient with respect to oxygen consumption, speed walking and temporal spatial parameters and the present study it is PTB-SC socket design.

In a study by Marco Traballesi et al (2011) state that energy cost of walking in transfemoral amputee comparison between MAS socket and IC socket. Seven long term trans-femoral prosthesis users were taken in study and the test were performed first using IC socket and then after 30 days of MAS use, the last test was carried out after 60 days of MAS. The result shows the energy cost walking with MAS was significantly lower than with the IC socket (14).

However in the present study below knee socket design are compared but it is related with the above study because there also two socket design have compared. The MAS socket has got lower trim line compared to IC which influences the walking speed and there for the EE. In the present study the TSB socket trim line is lower compared to PTB-SC, which also influences the walking speed of transtibial amputee and therefore EE.

In a study by R.K. Mohanty, P. Lenka, A. Equebal, R. Kumar et al (2012) found that there is significant difference between prosthesis and crutches without prosthesis walking in adults with transtibial amputation ($P<0.025$). There was significant difference between prosthesis walking and crutches without prosthesis walking in terms of VO2 uptake rate ($P < 0.005$) and EE/min ($P < 0.00001$).

It was found the adults with transtibial amputation using prosthesis walked with 21% more efficient in terms of VO2 uptake rate and 92% more efficient in terms of EE/min as compared to crutches without prosthesis. The data on energy cost indicates that all below knee amputee groups walk with less effort by using prosthesis (15). However in the present study the outcome measure of VO2 uptake and EE were compared between PTB-SC and TSB were also found to be significantly low.

In a study by John G. Buckley, PhD, Steven F. Jones, BSc, Karen M. Birch, PhD et al (2002) found that on oxygen consumption during ambulation: Comparison of Using a Prosthesis Fitted With and Without a Tele-Torsion Device, the results indicate that inclusion of a TT Pylon into the prosthesis of a group of transtibial amputee patients.

Result found that VO2 during walking with the prosthesis fitted with the TT Pylon was 5.4% and 9.1% lower than when using the prosthesis without the TT Pylon, at the speeds 130% and 160% of normal, respectively. Findings at the speed 160% greater than normal were significant ($P < 0.05$). Two of the subjects perceived no difference in prosthetic comfort between Pros-With and Pros-Without. The other 4 subjects preferred the TT Pylon at all speeds. As per this study the amputee should be provided by the TT pylon in both groups of patients while there is no difference found in TT pylon on two different groups. In present study utilize only TT pylon for two groups of patients, so that there should not be any difference because of the TT pylon.

In a study Mohammad Reza Safari, PhD, Margrit Regula Meier, PhD et al (2015) found that the traumatic amputees, uses two types of sockets where TSB socket provide greater satisfaction than PTB socket were associated with fewer problems than the PTB socket. Interestingly, more sweating was reported when wearing the PTB socket with Pelite liner (36%) than the TSB socket with silicone liner (21%) or polyurethane liner (24%).

The results may be due to the fact that most patients were the previous prosthesis users by which they acquainted themselves in its use with a moderate evidence level measured the energy cost of walking of users fitted with TSB sockets and different liners. As per this study the amputee was provided the interface material (ethaflex liner) in both groups of patients while there is no difference found in ethaflex liner on two different groups. In present study utilize similar interface materials for two groups of patients, so that there should not be any difference because of the ethaflex liner. So therefore this present study is supported by the previous study in terms of interface materials which is using in both socket design.

6.0 Conclusion

The study concluded that subjects with trans-tibial amputation using endoskeletal trans-tibial prosthesis with PTB-SC socket design spends more energy than subjects with trans-tibial amputation using endoskeletal prosthesis with TSB socket. However prosthetic design, components and anatomical structures may influence the energy expenditure. Energy expenditure is a vital parameter for efficient gait and the number of subjects in this study was less, more numbers of studies are required with transtibial endoskeletal prosthesis with TSB and PTB-SC socket. When a comparison was made over suspension, subjects with TSB socket design were more satisfied than PTB SC socket design. Similarly the subjects with TSB socket design found to be more comfortable at basic ambulation activities in shorter period during walking than PTB SC.

As per the discussion it clearly said that there is no other cause of energy differences between two groups rather than the socket design. Hence, it can be concluded that there is no other differences between the two groups of patients (group-A TSB and group-B PTB-SC). So that we can conclude that when the socket design really affects the energy expenditure of the patients and TSB has better energy efficiency than PTB-SC socket design. This study demonstrated that people with transtibial amputation may be benefit from using prostheses with TSB socket compared with PTB-SC with respect to reduce energy expenditure and functional walking ability.

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