Original Article

To compare the effect of vertical ground reaction force in conventional below knee prosthesis versus modular below knee prosthesis on unilateral transtibial amputee patients

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Received: 19-06-2016
Revised: 29-07-2016
Accepted: 06-08-2016

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ABSTRACT

Background: *Proper prescription of prosthetic device and potential rehabilitation increases the quality of life for subjects with amputations.*

Objective: *To compare the effect of vertical ground reaction force (Fz) on unilateral Transtibial amputees those who are using conventional and modular patellar tendon bearing (PTB) prosthesis with stump exercises.*

Material and Methodology: *A sample of 120 persons with below knee amputees who were trained to wear prosthesis were studied with an comparative follow up study design with purposive sampling technique. The 120 adult amputee patients were divided in to two groups having 60 samples in each group, group A patients were given conventional patellar tendon bearing (PTB) prosthesis with intensive stump exercises and group B patients were given modular PTB prosthesis with intensive stump exercises respectively. Data analyzed statistically.*

Results: *The unilateral transtibial amputees who trained with modular prosthesis along with stump exercises group patients Fz-force in newton were increased as compared to the unilateral transtibial amputees who were trained with conventional PTB prosthesis along with stump exercises. There was no significant difference seen in both the groups while giving stump exercises alone.*

Conclusion: *The unilateral transtibial amputees who were trained with modular PTB prosthesis along with stump exercises group patient's Fz-force in newton (VGRF) has increased drastically compared with conventional PTB prosthesis.*

Keywords: *VGRF, amputation, Fz-force, PTB prosthesis, stump exercise*

Introduction

Lower-limb amputation is prevalent, with approximately 1,027,000 people in the United States. The number of people with lower-limb amputations is expected to double by the year 2050, unilateral transtibial amputees are primarily due to dysvascular disease and diabetes. [1,2] Diabetes is an independent predictor of limb amputation (versus revascularization) for the treatment of critical limb ischemia[3] patients with diabetes are 20 times more likely to undergo a LEA than those without diabetes. [4] There is strong, consistent evidence that men are more likely to undergo diabetes-related LEAs [5] and are younger at the time of amputation than women. In 2001, men had a rate of 55 LEAs per 100,000 diabetes patients, compared to women with 28 LEAs per 100,000 diabetes patients. [6] Amputation is a triple offence that results in loss of function, body image, and sensation. [7] Amputation should be considered as a treatment but not necessarily a tragedy. Due to amputation the patient becomes physically, socially and psychologically impaired. [8] Amputation of the lower limb can result in a permanent impairment and disability in all age group. [9] The amputees experience the following four themes: 'lost in the dark woods', 'emotional collapse', 'difficulty in passing through the shadow' and 'ignition a gleam of hope'. [10] The loss of a body part primarily can cause physical, psychological and social disturbance, the majority of previous researches in this area focused on the effective rehabilitation program [11]. People with amputations will receive a new prosthetic limb once every 2 years throughout their lifetime, and will see their prosthetist between 4 and 9 times per year. [12,13] Proper prescription of prosthetic device and potential rehabilitation increases the quality of life for subjects with amputations. Advances in prosthetic technology, includes specialized gel and silicone liners to improve the interface with the residual limb. [14] Methods of computer assisted design (CAD) and computer assisted manufacturing (CAM) of prosthetics have been available since the 1980s though acceptance has been slow (Brncick 2000). CAD/CAM techniques are just beginning to be widely used to design and manufacture sockets. As a general rule applicable to both upper and lower extremities, the more distal the level of amputation, better are the results with regard to overall function and efficiency of walking. [15,16,17] Further patients who have a lower extremity amputation, can be maintained at a transtibial level will have more efficient gait and better weight bearing(vgrf) function compared to those who have a transfemoral amputation. Therefore an adequate soft tissue envelope with proper skeletal length is important to maintain optimal physiotherapy outcomes and weight bearing. [18] Below knee amputation affects almost all the aspects of amputee patient's life style. The vertical ground reaction force (Fz-Force) is very important functional outcome which is measured through the kistler force plate to understand the gait and weight bearing on the patient's prosthetic foot (Engsberg et al 2003). According to world health organization, the ability to change body position and the ability to walk are the key components of mobility. [19] Vertical ground reaction force will be increased gradually in below knee amputees due to vigorous stump exercises and routine prosthetic rehabilitation program. The prosthetic socket is most important part of the prosthesis, if the socket fits well the individual's ability to function is much like a person with an able body. [20] The acceptable alignment of the below knee prosthetic device showed highest symmetries of the vertical ground reaction force, which include the fixed multi-component force generated at the sole of the prosthetic foot on the top of force plate induced by the stump end. (sin et al 1999, Isakov et al 2000) [21] The top plate of the force plate has three pairs of quartz plates, one sensitive to pressure in the Z-direction and the other two sensitive to shear force in the X- and Y-directions respectively, the force plate measures the static and dynamic vgrf in newton on a graphical wave form represented by BIOWARE software to measure the three orthogonal components of a force (Fx Fy Fz). The force plate is particularly suitable to measure slow and medium actions where centre of pressure accuracy is important.

Transtibial amputees with an adequate fit of the prosthesis socket are more likely to function better in daily life than those with fitting problems of their prosthetic sockets. To determine the right range of movement after fitting the first prosthesis, it's necessary to know when the stump volume has stabilized. Fluctuations in stump volume may hinder an adequate prosthetic fit. Therefore, accurate measurement of the stump volume is important in prosthetic care. A study was therefore planned to compare the VGRF while using the conventional and modular patellar tendon bearing prosthesis with stump exercises.

Material and methods

The study was a hospital / rehabilitation centre based comparative follow up study from the day of prosthetic fitting to 8 weeks. Sample for the study comprised of 150 amputee patients out of which the 120 adult (male and female) amputees aged between 40 years to 55 years who underwent unilateral below knee amputation between December2009 to December2015 were selected on purposive sampling method. Samples of the study comprised of unilateral transtibial amputees at Kempegowda Institute of Medical Sciences Bangalore and Kshema Hospital Mangalore. The study was conducted and the individual subject data (VGRF- Fz in newton) were collected from the 1st day of 1st prosthetic fitting to 8 weeks of post prosthetic limb fitting. The study samples were selected based on inclusion and exclusion criteria. The 120 adult amputee patients were divided in to two groups having 60 samples in each group, group A patients were given conventional patellar tendon bearing (PTB) prosthesis with intensive stump exercises and group B patients were given modular PTB prosthesis with intensive stump exercises respectively.

In this study all the 120 male and female unilateral below-knee amputees underwent 30 minutes of intensive physiotherapy exercises (starting with isometric stump exercises progressed to resisted exercises of the hip extensor, hip abductor, knee extensor muscle groups bilaterally and for the ankle plantar flexors on the sound side limb.) from the day of surgery, on the day of first prosthesis fitting to till 8 weeks post prosthetic fitting. All the subjects were given physiotherapy treatment for 5 visits per week for 8 weeks. All the patients were explained about the use of prosthesis, type of prosthesis and its weight bearing status according to the surgical procedure. The main criterion for selection of each subject with ideal stump, would be at least two months post-surgery to assure that the surgical wounds were well healed and non-tender. Residual limb length as measured from the medial tibial plateau to the distal tip of the tibia was required to range from 12 to 20 cm (4.7 in-7.9 in) to provide adequate muscle bulk for intensive physiotherapy for stump along with other joints and muscles on the amputated limb and sound side limb. All the subjects were required to be available for complete evaluation about one hour every two weeks over an eight-week period from the time of prosthesis fitting. The main goal of the intensive rehabilitation program for people with a lower extremity amputation is to assist them in returning to and maintaining normal living activities with prosthetic devices which in turn helps to increase the walking speed as well as the vertical ground reaction force (Fz-force) at the sole of the prosthetic foot.

Inclusion Criteria: Gender of subjects: Male/ Female, Etiology of amputation (trauma/ PVD/DM), Level of amputation (unilateral transtibial amputees), All subjects immediately after the prosthetic fitting with ideal stump, Patients who don't have phantom limb pain and other associated problems, Patients who don't have cardio respiratory and renal problems.

Exclusion Criteria: Level of amputation other than unilateral transtibial amputees, Patients without ideal stump, Patients with cardio respiratory and renal problems, Patients with major associated psychological problems, Patients who didn't want to participate in the study after being explained about the nature and purpose of the study, Patients with associated physical disabilities other than amputation were excluded.

The BK Amputee patients having well healed surgical wound with good and snuggy prosthetic fitting includes the subjects those who had proper prosthetic socket were participated in the walk test to assess the weight bearing at the sole of the prosthetic foot (VGRF-Fz-force in newton). For this study the subjects were selected (Central Ethical committee clearance was issued by NITTE university dated 29/05/2009 reference: NU/CEC/01/2009) from the day of surgery, first day of first prosthetic fitting and 8 weeks of post prosthetic fitting treatment sessions. Informed consent was taken from each and every patient. The data of first day of first prosthetic fitting, at the end of 4th week and at the end of 8 weeks end weight bearing (Fz –force in newton) mean average of six trials were recorded with the help of kistler force plate with BIOWARE software while using conventional and modular prosthesis in unilateral transtibial amputees.

Conventional prosthesis also known as exoskeletal limb, the outer visible skin is the main structural element and such limbs are hollow attached with socket and joint. In this the weight bearing of the stump takes place at the boundary of the socket mainly 60% of the weight borne to patellar tendon and 40% of the weight borne to supracondylar region of the socket.

In the last decade the design, material and prescription of the prosthesis have changed dramatically leading to modular prosthesis.

Modular prosthesis also known as endoskeletal limb, this type of prosthesis now most widely used for lower extremity amputee. It has a central structural tube to which the socket and joints are attached, and this is usually covered with shaped foam to match the contour of the contralateral limb as closely as possible. The advantage of this prosthesis allows comfortable end weight bearing.

After amputation, gait speed, end weight bearing usually declines and the energy cost of walking speed increases. Although regaining the strength on the amputated side and the sound side limb musculature have been emphasized to increase VGRF. Increased VGRF would have been emphasized by traditional rehabilitation programs which in turn increases the muscle strength and coordination to facilitate successful prosthetic weight bearing. The end weight bearing would have been calculated with the help of kistler force plate which have been mounted on the walk way measures the Fz- force-in newton (VGRF) of the subjects who are walked on a kistler force plate. In this study measurements were collected from six trials of Fz-force in newton to calculate their mean and standard deviation for the outcome.

The principal investigator described dynamic vertical ground reaction force in newton at the post-operative prosthesis fitting day 1 including stump exercises, post-operative prosthesis fitting with stump exercises at the end of 4th week and 8th week respectively, Data of each group are evaluated using means and SDs for all variables in the study. The researcher used parametric and non-parametric tests based on the outcome measure. Un-paired t test to compare the age groups. Mann Whitney 'U' test used to compare the differences between two independent groups. Friedman test was used to detect differences in treatments across multiple test attempts. Wilcoxon signed rank test was used to evaluate the differences between two treatments.

Results

The age group of conventional and modular below knee prosthesis was 47.1±4.2 and 47.9±4.5 respectively. The unpaired t= 0.946 and the p=0.346. (Table 1) There were 25(41.7%) conventional below prosthesis users and 18(30.0%) modular below knee prosthesis in the age group of 40 to 45 years. They were 17(28.3%) conventional below prosthesis users and 21(35.0%) modular below knee prosthesis in the age group of >45 to 50 years. They were 18(30.0%) conventional below prosthesis users and 21(35.0%) modular below knee prosthesis in the age group of >50 to 55 years. The Chi-square value=1.791 and the p=0.408. (Table 2) There were total 120 right and left side unilateral below knee amputees. In right side there were 31(51.7%) conventional below knee prosthesis users and 31(51.7%) modular below knee prosthesis users. In left side there were 29(48.3%) conventional below knee prosthesis users and 29(48.3%) modular below knee prosthesis users. The chi-square value=0.000 and p=1.000. (Table 3) There were total 120 male and female unilateral below knee amputees. In male gender there were 53(88.3%) conventional below knee prosthesis users and 51(85.0%) modular below knee prosthesis users. In female gender there were 7(11.7%) conventional below knee prosthesis users and 9(15.0%) modular below knee prosthesis users. The chi-square value=0.288 and p=0.591. (Table 4) Repeated measures ANOVA reveal significant difference in VGRF score measured at 3 different times, at day 1, at the end of 1st month and at the end of 2nd month.

Table 1: Age group between Conventional and Modular below knee prosthesis

Group	N	Minimum	Maximum	Mean±SD
Conventional below knee Prosthesis	60	40.00	55.00	47.1±4.2
Modular below knee Prosthesis	60	40.00	55.00	47.9±4.5

Unpaired t = 0.946, p = 0.346

Table 2: Age group distribution between Conventional and Modular below knee prosthesis

		Group		Total
		Conventional below knee Prosthesis	Modular below knee Prosthesis	
Age Group	40-45yrs	25	18	43
		41.7%	30.0%	35.8%
	>45-50yrs	17	21	38
		28.3%	35.0%	31.7%
	>50-55yrs	18	21	39
		30.0%	35.0%	32.5%
Total		60	60	120
		100.0%	100.0%	100.0%

Chi-square = 1.791, p = 0.408

Table 3: Side distribution between Conventional and Modular below knee prosthesis

		Group		Total
		Conventional below knee Prosthesis	Modular below knee Prosthesis	
Side	Right side	31	31	62
		51.7%	51.7%	51.7%
	Left side	29	29	58
		48.3%	48.3%	48.3%
Total		60	60	120
		100.0%	100.0%	100.0%

Chi-square = 0.000, p = 1.000

Table 4: Gender distribution between Conventional and Modular below knee prosthesis

		Group		Total
		Conventional below knee Prosthesis	Modular below knee Prosthesis	
Sex	Male	53	51	104
		88.3%	85.0%	86.7%
	Female	7	9	16
		11.7%	15.0%	13.3%
Total		60	60	120
		100.0%	100.0%	100.0%

Chi-square = 0.288, p = 0.591

Table 5: Vertical Ground Reaction Force (VGRF) in Newton in both groups

N=60 each group		VGRF on Day 1	VGRF at the end of 1 month	VGRF at the end of 2 months
Conventional below knee Prosthesis	Mean±SD	579.20±40.52	735.86±30.15	799.28±40.28
Modular below knee prosthesis	Mean±SD	376.52±83.21	578.33±46.85	833.41±18.07
	Unpaired 't' test value	16.962	21.897	5.987
	p value	<0.001	<0.001	<0.001

Since the patients are given conventional PTB ($F = 553.33$, $p < 0.001$) further Tukey Kramer multiple comparison test, the post-hoc test, revealed there was significant increase in VGRF score at the end of 1 month in comparison to HADS score on day 1 ($p < 0.001$). Also there was significant increase in the VGRF score at the end of second month in comparison to VGRF score at the end of 1st month ($p < 0.001$). The increase in VGRF score at the end of 2 months was significantly higher than the VGRF score at day 1 ($p < 0.001$).

The comparison of VGRF score of patients received conventional PTB prosthesis and modular PTB prosthesis revealed significant difference in the VGRF score on day 1 as well as at the end of 1 month. However there was significant increase in mean and median VGRF score of the patients who received modular prosthesis as compared to the patients who received conventional prosthesis (unpaired t test = 5.987, $p < 0.001$). (Table 5)

The Comparison of VGRF score on day 1, (Unpaired t test value = 1.275, p=0.207) at the end of 1 month, (t=2.290, p=0.026) at the end of 2nd month(t=0.203, p=0.840) with right side conventional PTB prosthesis and left side conventional PTB prosthesis revealed no significant difference. The Comparison of VGRF score on day 1 (Unpaired t test value=0.553, p=0.583), at the end of 1 month (t=1.919, p=0.060), at the end of 2nd months (t=0.455, p=0.651) with male subjects using modular PTB prosthesis and female subjects using modular PTB prosthesis revealed no significant difference.

The Comparison of VGRF score on day 1 (Unpaired t test value = 0.122, p=0.903), at the end of 1 month (t=1.547, p=0.127), at the end of 2nd months (t=0.590, p=0.558) with male subjects using conventional PTB prosthesis and female subjects using conventional PTB prosthesis revealed no significant difference. The Comparison of VGRF score on day 1 (Unpaired t test value=0.560, p=0.393), at the end of 1 month (t=1.197, p=0.236), at the end of 2nd months (t=1.047, p=0.299) with male subjects using modular PTB prosthesis and female subjects using modular PTB prosthesis revealed no significant difference.

Discussion

One of the primary goals of rehabilitation program for subjects with unilateral transtibial amputees was to increase the vertical ground reaction force (Fz) to assist and maintain their normal weight bearing at the sole of PTB prosthesis. According to the World Health Organization, the ability to change body position and the ability to walk are key components of mobility. In general the patient mobility depends on the types of PTB prosthesis would be given, further the types of prosthesis should allow the safe household ambulation, set of transfers, level walking and turns.

There are several tools were used to measure the vertical ground reaction force (Fz-in-newton) induced at the sole of the PTB prosthesis in BK amputees. The highly sensitive tool for measuring the dynamic weight bearing (VGRF) of prosthetic foot in PTB prosthesis was done using kistler force plate, which measures Fz, Fx, Fy respectively. [22,23] In the various research Studies the researchers have showed that the prosthetic socket is the most important part of the prosthesis, If the socket fits well, the individual's ability to function is much like a person with an able body. If the socket fits poorly, the results are chafing, bleeding, bruising, pressure sores and pain which reduce the vertical ground reaction force. [20] In the present study the researcher also considered the Fz -in –newton to measure the dynamic VGRF As a main objective to measure the properties and predict future dynamic VGRF of the amputees.

The prosthetic alignment was quantified by a special alignment jig designed by Sin et al. (1999) Alignment of the prosthesis was set according to Radcliffe and Foort (1961), such that the socket anterior and mediolateral tilts were both 5^0, and the socket was set 38 mm ahead of and 13 mm lateral to the centre line of the shank of the tube adapter. Alignment of lower limb prosthesis is the three-dimensional orientation of the socket with respect to the prosthetic foot, and it is an important factor in optimizing the gait of subjects with amputation. A misaligned prosthesis affects the gait pattern and dynamic VGRF (Hannah et al. 1984; Sanders et al. 1993; Pinzur et al. 1995; Rossi et al. 1995), may results abrasion and irritation at the interface of the socket and the stump. In the present study the researcher also found that the subjects used the exoskeletal and endoskeletal PTB prosthetic sockets were fitted with a solid ankle cushion heel (SACH) foot with proper alignment prevented the abrasion and irritation which inturn improved the dynamic VGRF-(Fz Force).

Winter and Sienko (1988) pointed out that the prosthetic and contralateral limbs constitute two distinct biomechanical systems, the gait pattern on the prosthetic side is therefore not a truly symmetric image of the sound limb (Bagley and Skinner 1991; Isakov et al. 2000). In the present study the researcher also found that the subjects used the exoskeletal and endoskeletal PTB prosthetic sockets were fitted with a solid ankle cushion heel (SACH) foot with proper alignment were also not a truly symmetric image compared to the sound limb. Further the researcher concluded that it is almost impossible to walk without producing a dynamic ground reaction force on one side. [24]

After amputation, gait speed and dynamic VGRF (Fz- Force) usually declines and the energy cost of walking speed increases. A Correct prosthetic prescription derived for functional benefits of prosthesis and the prosthetic user. [25] Many factors influence the gait of individuals who have had a dysvascular amputation. Burgess EM et al 1982 [26] concluded that the traditional rehabilitation programs emphasized the increased muscle strength and coordination to facilitate successful prosthetic gait and dynamic VGRF (Fz-Force). The gait analysis and the dynamic VGRF (Fz-Force) of lower limb amputee patients depends on the muscle power of the hip extensor, abductor and knee extensor muscle groups bilaterally, and the ankle plantar flexors on the sound side may result in greater ambulation ability. Renstrom et al 1983 [27] found a significant correlation (P<.01) between knee extensor and flexor strength and step length, as well as a relationship between strength and maximal walking speed and weight bearing, in a group of individuals with below-knee amputations. Winter and Arendt Nielsen et al [28] found that the increase in knee flexion during initial stance progressively faster the gait speed and weight bearing. In the present study researcher also found statistically significant improvement in the subjects gait speed and dynamic weight bearing(VGRF-Fz Force) of those who are used the modular PTB prosthesis with stump exercises, further the researcher concluded that the post-operative rehabilitation include the intensive stump exercises of the quadriceps, hamstrings, hip abductors, hip adductors, hip flexors and hip extensors of the residual limb reduces the stump oedema, promote the stump healing, prevent stump contracture, complications of bed rest and increases the stump muscle strength which in turn helps the subject to get out of the bed. Human locomotion is the dynamic process for transferring the body weight from one place to another without loss of equilibrium. Prosthesis is an integral part to share load for locomotion. Power et al studied on the gait and indicated that the sound limb takes more load than amputated limb in unilateral transtibial amputees. [29] Authors in previous study concluded that the weight bearing on the sole of the amputated foot, Increased gait speed in young transtibial amputees using PTB prosthesis with SACH foot than elderly amputee (P<0.0001). [30] The results showed that stride length of young amputee was 36% greater than elderly and a statistical significant difference was found (P<0.006) and similar findings were indicated by Elbel et al. 1991, Murray et al, 1969 and Winter et al. [31-33] In this study the researcher had more male patients aged between 40 to55 years(P=0.408), having right sided (P=1.000) unilateral transtibial amputees wearing the PTB prosthesis with SACH foot showed the statistically significant difference in their gait speed and weight bearing (P<.001) while using the modular PTB Prosthesis. Further the author concluded that the young subjects walking and weight bearing on the sole of the prosthetic foot showed greater improvement in modular PTB prosthesis then the conventional PTB prosthesis (P<.001).

The study population was small. The long term follow up of the new system (modular prosthesis) may further prove its potential as an alternative prosthetic limb. Further the non-availability of the female samples and drop outs of female samples limits the study.

It is suggested that the below knee amputees weight bearing at the sole of prosthetic foot can be evaluated ideally by kistler force plate, it is the major intervention for the overall management of amputees. The study has emphasised the role of orthopaedic surgeon, physiotherapist and prosthetist and orthotist as a part of the team in managing the cases. Further attempts may be made to evaluate patients with long term clinical follow up.

The present study concluded that the subjects those who used modular prosthesis showed drastic increase in the Fz-force (VGRF-IN-NEWTON) at the end of 8 weeks of stump exercises compared with those who used conventional below knee prosthesis. The male unilateral transtibial amputee subjects are more in number than female subjects. The right side unilateral transtibial amputee subjects are more in number when compared to left side unilateral transtibial subjects. Due to the advancement in modular PTB prosthesis along with regular stump exercises increased the Fz-VGRF IN NEWTON in transtibial amputees compared with conventional PTB prosthesis. All these changes are due to prosthetic advancements in modular PTB prosthesis such as light weight prosthesis.

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Cite this article as: Raja R, Rai HR, Sridharamurthy JN, Madhouraj B, Balaji R, Raja V, Somasundaram. To compare the effect of vertical ground reaction force in conventional below knee prosthesis versus modular below knee prosthesis on unilateral transtibial amputee patients. Int J Med and Dent Sci 2017;6(1):1398-1406.

Source of Support: Nil
Conflict of Interest: No