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Original Research Article

Comparative Study between Indigenously Developed Multi-Axis Prosthetic Foot and SACH Foot in Terms of Gait Parameters and Energy Expenditure in the Patients with Unilateral Transtibial Amputation

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ABSTRACT

Background: There are a large number of commercially available, prosthetic feet. Properly selecting prosthetic foot-ankle components with appropriate design characteristics is critical for successful amputee rehabilitation. However, currently developed prosthetic foot designs are high performance, dynamic response, energy restoring, and multi-axial motion properties. These are all made from carbon composite material, with superior strength and weight ratio. In fitting an artificial limb, the goal of the prosthetist is to restore the ability of the amputee to perform everyday activities in an easy, natural, and comfortable manner, all prosthetic foot attempt to return some of the lost gait function. But for the average individual in a developing country like India, amputees cannot afford such types of feet, which are more expensive. There is a need for a new prosthetic foot in economically developing countries that is technically simple yet functionally more equivalent to a dynamic response foot. The new design of a multi-axial prosthetic foot has been developed in this study, mechanically tested with 5000 cycles, and its effectiveness is compared with a time-tested SACH foot. The multi-axial prosthetic foot is the most effective and significant prosthetic foot design. The anatomical foot has multi-axial motion property, which is cautiously accommodated in this design characteristics deemed necessary by patients in achieving natural gait motion, including dorsiflexion, plantarflexion, inversion, and eversion mimics biomechanical characteristics of the prosthetic foot.
Study Design: Experimental interventional prospective study
Objective: To design and develop a multi-axis prosthetic foot that allows the same triplanar motion as a normal human ankle and foot and compare its effectiveness with the SACH foot in terms of gait parameters and energy expenditure by calculating the Physiological Cost Index.
Methods: 30 participants with unilateral transtibial amputation were recruited randomly and evaluated with SACH foot and multi-axial foot. The primary outcomes were gait parameters and energy expenditure.
Results: The multi-axial prosthetic foot has to be found to be more efficient than the SACH foot; at the $p<0.05$, there was a significant difference in the patient's gait parameters and energy expenditure.
Conclusion: Multi-axial prosthetic foot improved patient's gait as they covered more distance than SACH foot while walking on level ground. A newly designed multi-axis prosthetic foot mimics the normal human anatomical ankle. It helps to increase step length, stride length, cadence, and speed; hence subjects walk more efficiently with less energy consumption.

Keywords: amputee, dorsiflexion, eversion, foot, gait, inversion, multi-axial, parameters, plantarflexion, SACH, physiological cost index

INTRODUCTION

The task of walking is an important activity of daily life. The anatomic foot is dynamic, flexible in the initial stance phase, and as a rigid lever just before the terminal stance. The function of the anatomic foot can be appreciated as dynamic impact force attenuation at initial contact, smooth rollover at midstance, and active push-off at terminal stance phases. Incorporating an anatomic foot's characteristics into a simple mechanical design has never been easy. Though many individuals consider the movement effortless, the task can be much more complex for others. In particular, individuals who undergo a unilateral trans-tibial amputation must learn to adapt to the loss of musculature and the altered sensation from a lower leg while, at the same time, compensating for the properties of their prosthetic foot.

During the past decade, technology and research have considerably increased the functionality and aesthetics of prosthetic feet. The options for prosthetic feet have grown to more than 50 different models. Nowadays, amputees have numerous feet designed for walking, dancing, cycling, golf, swimming, snow skiing, and running. Lightweight plastics, aerospace alloys, and carbon-fiber composites have replaced heavier wood and steel materials. As with the human foot, many prosthetic feet today can store and return some of the energy generated during walking. Other key attributes include toe and heel springs that permit more natural movement at the ankle, shock absorption, multi-axial rotation, adjustable heel heights, and impermeable materials.

The future of prostheses has led to the development of very advanced components with a technology that closely biomimetics the anatomic human limb. Regarding the prosthetic foot, research has focused on augmenting energy storage and return properties and upgrading the technology to reproduce anatomical foot dynamics. One problem with the current research and development focus is that advanced prosthetic feet are only realistically available to consumers in developed countries and are very costly. While cost alone is prohibitively expensive, these designs are also improbable for developing countries due to their required maintenance, inadequate adaptation to advanced environments, and inability to obtain and maintain a reliable required supply. [1]

A significant issue with current prosthetic foot development is that it does not target most prosthetic users. About 80% of individuals with amputations worldwide reside in developing countries.[2] In 2013, the World Health Organization estimated about 30 million amputees lived in developing countries and that up to 95% lacked access to the prosthetic device.[2] In developing countries, many limb-deficient individuals are farmers, herdsmen, nomads, or refugees who rely on physical labor for survival. Thus, affordable, functional, and readily available prosthetic limbs are essential. The most common low-cost prosthetic foot used is the solid ankle cushion heel (SACH), designed for household or limited community ambulation. [1, 3]

Current prosthetic foot designs do not replicate the characteristics of a normal human foot. A human foot is a multi-functional device that can perform many activities: however, a prosthetic foot is limited to only a few. The SACH foot has been used in India for a very long time for transtibial amputees because it is available in the Indian market and is economical. Since the invention of the multi-axis prosthetic foot, which is made from carbon fiber, there has been a choice for amputees and prosthetists for using this foot. Still, these multi-axis prosthetic feet are not affordable for the average individual in a developing country like India. Amputees cannot afford such type of foot. It has been studied that using a multi-axis foot allows for improved performance and confidence in SACH foot users in Transtibial Amputees. As technology increases, human needs also increase, and the expectations of amputees are also high because of improved version is already on the market. The improved multi-axial ankle has all the functions and is designed to be fitted to all prosthetic users and even walk on uneven surface smoothly and comfortably. According to Prosthet Orthot Int (POI), several factors should be considered for constructing a prosthetic foot for developing countries. These factors include durability, low cost, local availability, manual fabrication capability, local climate, working conditions, simple repair, simple processing capability using local production, reproducibility by local personnel, technical functionality, biomechanically appropriate, and lightweight as possible.[4] This study aimed to develop a new design of multi-axis prosthetic feet that provides the same triplanar motions as a normal human foot and ankle using plastic material, which is high in strength and may be affordable to the average individual in a developing country like India. The efficacy of this newly designed multi-axis prosthetic foot was tested by clinically comparing it with the existing SACH foot on the patients with unilateral transtibial amputation (UTA) reporting to the tertiary rehabilitation center, All India Institute of Physical Medicine and Rehabilitation (AIIPMR) with respect to gait parameters and the Physiological Cost Index (PCI).

Walking with a fixed-ankle SACH foot, patients with unilateral transtibial amputation (UTA) often experience socket pressure and discomfort. When surveyed, patient rate socket comfort as the most important factor, [5] and socket pressure-related skin complications frequently limit prosthesis use.[6] A fixed-ankle SACH foot exposes the residual limb to higher pressure when ambulating on stairs and slopes, and uneven terrain.[7] The limited ankle motion and lack of slope accommodation in fixed-ankle SACH feet cause high socket pressure experienced in these conditions.

Over level ground, fixed-ankle SACH feet do not provide shock absorption and controlled plantarflexion during the first rocker of the stance phase.[8]This causes a delay in achieving foot flat and an unstable heel-only foot contact.[8] SACH feet are shown to disrupt the forward progression of the center of pressure and negatively affect body weight acceptance of the amputated limb. Uneven terrain can pose an environmental barrier for patients with UTA due to the interstep variability in the slope of the ground. Patients using a fixed-ankle SACH foot on a simulated uneven walkway exhibit a destabilized gait pattern.[9] Also, walking with a fixed-ankle prosthesis on a nonflat road causes increased pressure on the residual limb.[7] With a fixed-ankle SACH foot, the reaction forces and pressure experienced by the residual limb are increased, and the patient requires greater strength and balance to traverse uneven terrain.

Descending a hill, fixed-ankle SACH feet cannot normally accommodate the slope to achieve foot-flat. This results in unstable heel-only support when transferring weight onto the prosthesis, an increased knee flexion moment, [10] and an increased pressure experienced by the residual limb through the socket. The combination of torque and stress becomes too great for the residual limb to tolerate, and patients are forced to compensate by allowing their knees to flex rapidly. Patients fall forward onto their sound limb, causing a short prosthetic step duration and asymmetrical step length.[10] The sound limb experiences greater loads and increased negative work at the hip and knee in lowering the body mass in a controlled manner. Ascending a slope can be as difficult for patients using fixed-ankle

SACH feet. The lack of slope accommodation at the ankle causes knee hyperextension of the residual limb and increased socket pressure. The knee hyperextension and strains become too much for the residual limb to tolerate. Patients with UTA compensate by taking short step length and duration on the prosthesis, along with other gait deviations.[11] The increased loads, gait deviations, and instability experienced while ascending and descending slopes with fixed-ankle SACH feet limit mobility in the community for patients with UTA.

MPF was developed to address the above-described limitations of fixed-ankle SACH prosthetic feet by providing articulation in the sagittal plane and adapting to changes in terrain. Commercially available MPF has been studied since 2009 in 13 published research articles involving laboratory kinematic and kinetic analyses, inter-socket pressure measurement, energetic evaluation, and patient-reported and performance-based outcome measures.[12] Previous investigations include small sample sizes, with 16 participants accounting for the largest sample size, and most studies enrolled 10 participants or less. This low sample size limits the statistical power of these studies. In addition, the existing evidence consists mainly of investigations completed in controlled laboratory environments and focusing on instrumented gait analysis and energy expenditure.

There is a need to perform clinical research to examine the effectiveness of MPF against traditional fixed-ankle SACH prosthetic feet. Patient-reported and patient-performed outcome measures (PROMs) are standardized survey instruments used to quantify domains of prosthetic rehabilitation from the patient's perspective and often address effects not observable in the clinical environment (e.g., balance, mobility, socket comfort, health-related quality of life).[13] This study examined differences in gait parameters and energy expenditure between a fixed-ankle SACH foot and a newly designed MPF following a 4-week accommodation period. It is hypothesized that the MPF will have a more efficient gait, lesser energy expenditure, and be preferred more often when compared with the SACH foot. The study's results will inform patients and practitioners and impact clinical decision-making regarding MPF by focusing on patient-reported outcome measures and benefits experienced in a real-world setting.

MATERIALS & METHODS

The primary elements of the MPF framework include the following: (1) Making a three-dimensional (3D) model of MPF using computer-aided design (CAD) software, (2) Performing an engineering analysis using finite element methods (FEM) to assess the structural integrity of the MPF during normal loading conditions, (3) fabricating the MPF prototype, and (4) mechanically testing the MPF to verify stiffness characteristics.

The performance of the MPF was validated with testing on 30 UTA. Each component of the MPF framework is described below in detail.

Creation of MPF CAD Model: 3 D CAD model of the MPF was created in the CATIA V5 CAD software. 2 D profile of the prosthetic foot was created with the help of sketch tools. A fillet tool was used to add round edges for the anatomical resemblance. The closed sketch loop was then extruded to the proper width and trimmed appropriately. The sketch and extrude tools also created other necessary components of the foot. All the parts were assembled by using the assembly tool in the CATIA V5.

FEM Analysis of MPF's CAD Model:

The stiffness and structural integrity of the MPF was verified using FEM analyses in VON MISES software. Virtual TO, HO, and FF loading conditions were created by constraining the appropriate portions of the foot model and applying external loads. The mesh elements used were 3D parabolic tetrahedral solid elements with four corner nodes and six mid-side nodes per element. The mesh generator automatically adjusted the size of the elements if the local mesh was too large for a smooth transition between geometric features. To achieve the desired stiffness, an iterative design process was used. Locations of stress concentration were noted, and the material was added to ensure the maximum stress did not exceed the yield strength of the material.

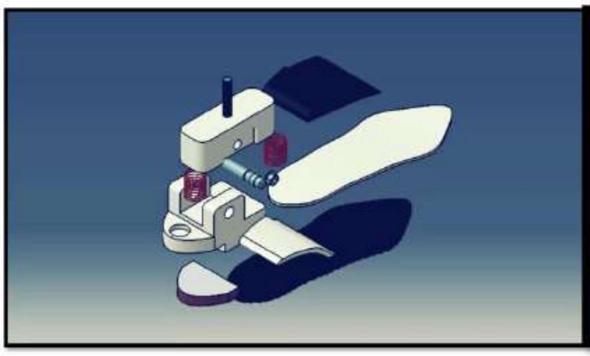


Fig. 1: Exploded view of MPF Design

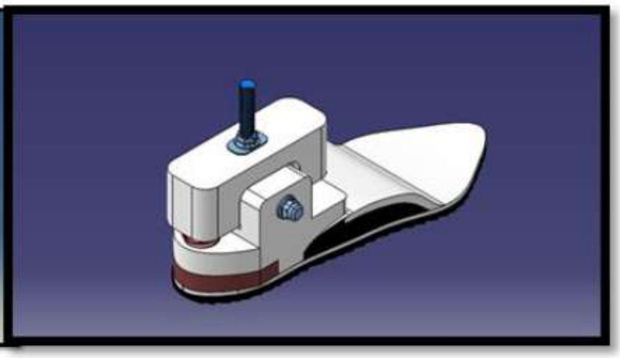


Fig. 2: 3D CAD Model of MPF Design

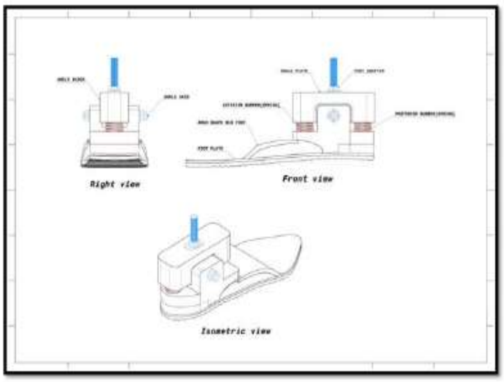


Fig.3: CAD Views of the MPF

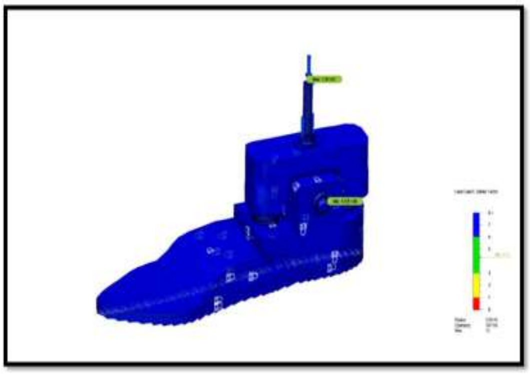


Fig.4: FEA of MPF

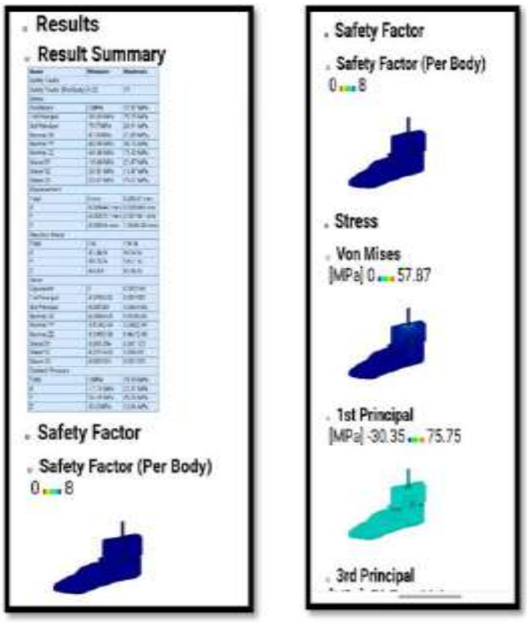
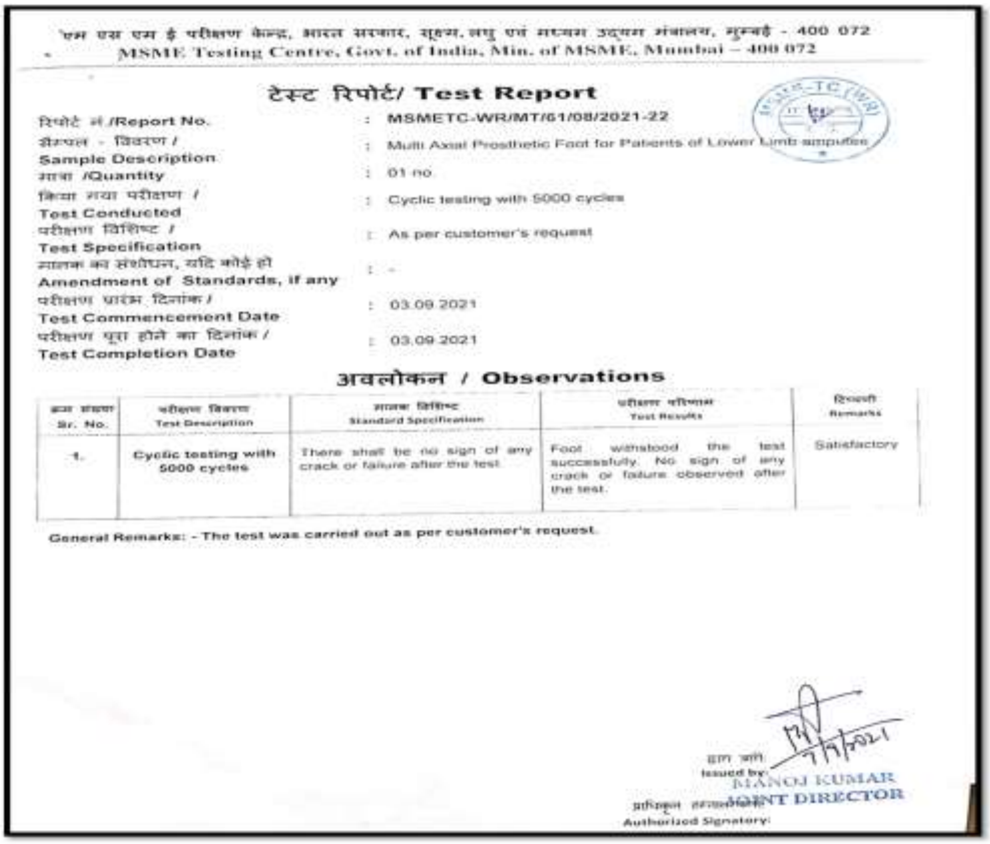


Fig. 5: (a) Result of FEA of MPF (b) Safety factor

Fig. 6: Construction of MPF

Fig. 6 (a) & (b) mechanical cyclic testing procedure of MPF



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MSME Testing Centre, Govt. of India, Min. of MSME, Mumbai – 400 072

टेस्ट रिपोर्ट/ Test Report

रिपोर्ट नं./Report No.	:	MSMETC-WR/MT/61/08/2021-22
सैम्पल - विवरण / Sample Description	:	Multi Axial Prosthetic Foot for Patients of Lower Limb amputee
मात्रा /Quantity	:	01 no.
किया गया परीक्षण / Test Conducted	:	Cyclic testing with 5000 cycles
परीक्षण विशिष्ट / Test Specification	:	As per customer's request
मानक का संशोधन, यदि कोई हो Amendment of Standards, if any	:	-
परीक्षण प्रारंभ दिनांक / Test Commencement Date	:	03.09.2021
परीक्षण पूरा होने का दिनांक / Test Completion Date	:	03.09.2021

अवलोकन / Observations

Sr. No.	Test Description	Standard Specification	Test Results	Remarks
1.	Cyclic testing with 5000 cycles	There shall be no sign of any crack or failure after the test.	Foot withstood the test successfully. No sign of any crack or failure observed after the test.	Satisfactory

General Remarks: - The test was carried out as per customer's request.

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MANOJ KUMAR
JOINT DIRECTOR
Authorized Signatory

Fig.7: Result of mechanical cyclic testing of MPF

Fabrication and Testing of MPF:

An ideal prosthetic foot should have dorsiflexion movement of an angle of 20°, eversion movement of an angle of 20° (both subscribed at the ankle), and 117% energy return efficiency. These considerations depend not only on the material's mechanical properties but also on the design of the foot and the manufacturing process. Due to changes in the human body over time, due to growth, or change in height, body weight, etc.; the prosthetic limbs need to be changed or adjusted occasionally.

The present prosthetic foot includes various structural features that give the foot an advantageous rollover prosthesis. This low-cost prosthetic foot includes a foot plate with a connection mechanism embedded within the ankle blocks to provide triplane motion. Ankle block consisting of proximal and distal heel blocks, which are attached to the footplate with the help of an ankle bolt, constituting the prosthetic foot axis and providing movement in the sagittal plane. The prosthetic foot includes a gap between proximal and distal ankle blocks, facilitating mediolateral movement in response to the wearer's gait and providing an enhanced transverse plane gait. A foot bolt is attached to the top of the proximal ankle block and gives attachment to the pyramid adapter for connecting the prosthetic foot to a prosthesis. A distal foot plate is shaped to provide a toe spring to the prosthetic foot for foot clearance in wearers. A foot shell for cosmesis is designed to enclose the prosthetic foot components.

Dynamic cyclic testing of 5000 cycles on the forefoot and heel was successfully achieved. The foot was designed, fabricated, and then tested mechanically for strain and displacement in a cyclic testing machine according to a component of the ISO-10328 testing protocol. The result of the cyclic testing showed that the foot withstood the test successfully, and no sign of any crack or failure was observed after the test. [Software – Von Mises (Safety Factor (Per Body) 0- 8 S, Ultimate Tensile Strength – {MPa} 0 57.87]

These considerations depend not only on the material's mechanical properties but also on the design of the foot and the manufacturing process. Due to changes in the human body over time, growth, or change in height, body weight, etc., the prosthetic limbs need to be changed or adjusted occasionally. This need for replacement or adjustment of prosthetic devices may become expensive if the material is costly. The commonly used materials for prosthetic feet are Carbon Fiber, Polypropylene, Reinforced Carbon Fiber, Kevlar, etc. which meet the required properties. The newly designed multi-axial prosthetic foot materials were nylon-6, polypropylene with copolymer sheet, microcellular rubber, and spring steel springs.

PROTOCOL:

The Institute ethical committee of AIIPMR approved a non-randomized convenient protocol of two prosthetic foot configurations used during a 4- week accommodation period. A convenience sample of patients with UTA was recruited from the Prosthetics and Orthotics department of the Institute. Informed consent was taken from all the patients who participated in this study. Inclusion criteria were as follows, UTA, age 18 to 60 years, body weight less than 100 kg, the current user of a prosthesis with SACH foot for at least 1 year, wears prosthesis 8 hours a day or more, has an activity level of K3 or higher, well-fitting and functioning prosthesis, does not require an ambulatory aid, and able to tolerate testing protocol including the ability to walk on slopes. Exclusion criteria were as follows: a presence or history of any condition that, in the view of the investigator, placed the participant at high risk of poor compliance or of not completing the study, or if a neurological impairment known to cause gait and balance dysfunction was present. Before the intervention fulfillment of inclusion criteria was verified; anthropometric, anamnestic, and demographical information was also collected.

INTERVENTIONS:

A pilot study was performed with four participants. The results from the pilot sample motivated the undertaking of the current research study; however, the data from the pilot subjects were not included in the current study sample.

A certified prosthetist performed the fitting and alignment of the research foot configuration using each participant's current well-being prosthetic socket. Each participant's currently prescribed habitual SACH prosthetic foot configuration was disassembled and maintained to be reassembled to the prosthetic socket after the study. During the research visit, participants were instructed on how to utilize the MPF to accommodate a slope and provided an opportunity to walk on a ramp in the clinic.

Participants were tested with each research foot following a 4-week accommodation period. The participant's SACH foot was reassembled to their prosthetic socket as participants completed the study.

Outcome Measures and Tools:
To investigate the three clinical aspects, we chose the following outcome measures. The patient's ambulatory skills on the floor, ramps, and stairs by the gait parameters, including step length, stride length, cadence speed, six-minute walking test (6 MWT), and Physiological cost index, were assessed for mobility. Finally, we considered the participant's feedback concerning comfort with each foot.
Temporospatial gait parameters and energy expenditure were assessed with two types of prosthetic feet.

Gait Analysis:
Three methods were adopted to determine the outcome measures: paper walk, 30-meter walkway test, and 6-minute walkway test. Spatiotemporal parameters like step length, stride length, and cadence were assessed by use of the paper walk with these two types of feet. A 30-meter walkway test was conducted for the physiological cost index and speed. Fixed distance walk test has proven to be a tool of excellent reliability, validity, and responsiveness when it comes to the evaluation of gait speed in prosthetic technology. Its coherence and convenience to carry out the procedure make it a tool of choice in less resource-deprived setups. The entire procedure is carried out in a long corridor of the facility, and elapsed time is taken to complete the 30-meter walk test.

Energy Expenditure:
The physiological cost index (PCI) is the indirect energy efficiency measure and correlates well with the total oxygen uptake in individuals with amputation. The physiological cost index was calculated with both types of prosthetic feet for assessing energy expenditure. It was calculated by taking the resting heart rate, and after that, the patient was asked to walk 30 meters. After each data collection session, 5 minutes of rest was given to the patient. After 30 meters walk, the heart rate was calculated by using a stethoscope. The PCI is calculated as the difference between walking heart rate and resting heart rate upon gait speed. Thus, the unit of PCI is expressed in beats per minute.

STATISTICAL ANALYSIS
The study design resulted in a paired sample dataset, with each participant having PROM results with both prosthetic feet. The difference in PROM measures was inspected for normality and found to be normally distributed. A traditional t-test was selected over other nonparametric statistical approaches due to the normal distribution of the data. A two-tailed paired t-test (with the participant being the pairing variable) was performed to compare whether there was a difference in the mean PROM scores between the SACH foot and MPF. All calculations were performed using the Graph pad Prism 4.82 software. All statistical tests used $\alpha = 0.05$.

RESULT
Newly designed MPF tested mechanically for strain and displacement in a cyclic testing machine according to a component of the ISO-10328 testing protocol. The result of the cyclic testing showed that the foot withstood the test successfully, and no sign of any crack or failure was observed after the test.

Fig.8: Clinical trial of MPF on UTA

Thirty participants with UTA were enrolled with mean age (35.56 years), body mass (65.43 kg), and years since amputation (10.53 years) depicted in Table 1. The cause of amputation was primarily trauma (n=24), with other causes, including dysvascular (n=6). The demographic information of the participants, as well as their activity level, is depicted in Table 1.

The differences in means between SACH and MPF were found to be satisfactorily significant in all PROMs. The mean, standard deviation (SD), and p-values for all measures are summarized in Table 2. Results from spatiotemporal gait parameters, physiological cost index, and distance covered in 6 minutes are depicted in Figures (1,2,3,4,5&6)

Spatiotemporal parameters were the primary quantitative measures for gait measurements. Data showed that there is a distinct increase in the cadence when patients walk with the MPF. The dorsiflexion movement provided by the MPF provides ground clearance during the terminal stance of the gait cycle. So, the patients could easily clear the ground and take more steps in a minute with a more normal and safer gait. Increased cadence (Fig.3) helped in increased speed (Fig.4), and that leads to fast walking of the patient with a substantially increased step length (Fig.1). This accounts that MPF is superior and the gait parameter increase is statistically significant when compared with the SACH foot. The walking speed with MPF was found to be significantly faster than the SACH foot (p=0.0029) (Fig.4). The physiological cost index (PCI) also showed a positive result in favor of MPF (Fig.5) and is statistically significant while comparing it with SACH foot (p = 0.0001). Significant differences were found in step length and stride length between both prosthetic feet. (Fig.1&2) (p=0.0001)

Table 1. Participant demographic characteristics

Subjects	Gender	Age	Body Weight, kg	Time since amputation, years	Amputation Cause	Activity Level
1	Female	38	58	2.5	Trauma	K3
2	Male	28	68	8	Trauma	K3
3	Male	39	98	10	Trauma	K3
4	Male	28	64	5	Trauma	K3
5	Male	40	80	12	Trauma	K3
6	Male	27	54	7	Trauma	K3
7	Male	29	59	8	Trauma	K3
8	Male	48	62	25	Dysvascular	K3
9	Male	40	50	15	Trauma	K3
10	Male	19	62	1	Trauma	K4
11	Male	48	65	18	Dysvascular	K3
12	Male	24	72	4	Trauma	K4

Table 1 To Be Continued…						
13	Male	47	65	17	Dysvascular	K3
14	Male	44	87	6	Trauma	K3
15	Male	45	58	12.5	Trauma	K3
16	Male	48	55	23	Dysvascular	K3
17	Male	23	62	3	Trauma	K4
18	Male	24	54	2	Trauma	K4
19	Male	37	75	7	Trauma	K3
20	Male	40	78	8	Trauma	K3
21	Male	26	80	3.5	Trauma	K4
22	Male	22	72	1.5	Trauma	K4
23	Male	50	64	30	Trauma	K3
24	Male	24	75	2.5	Trauma	K3
25	Female	21	60	2.5	Trauma	K4
26	Male	28	50	6	Trauma	K3
27	Male	38	48	16	Trauma	K3
28	Male	47	58	25	Dysvascular	K3
29	Male	49	52	19	Dysvascular	K3
30	Male	46	78	16	Trauma	K3
Mean		35.56	65.43	10.53		
SD		10.12	11.76	7.98		

Table 2. p-value of spatiotemporal gait parameters, PCI, and 6 MWT in the analysis of the efficacy of SACH Foot and MPF with mean and standard deviation, compared using two-tailed paired t-test (* significant at p<0.05)

Gait Parameters	SACH Foot		Multi-axial Foot		t value	p-value
	Mean	SD	Mean	SD		
Step length (meter)	0.5903	0.06547	0.6377	0.7440	8.172	P- 0.0001*
Stride length (meter)	1.148	0.1156	1.211	0.1230	5.552	P- 0.0001*
Cadence (steps/ minute)	94.03	8.062	97.33	8.907	7.056	P- 0.0001*
Speed (meter/second)	0.9633	0.1235	1.025	0.1513	3.256	P- 0.0029*
Physiological Cost Index (beats/meter)	0.4630	0.1623	0.4200	0.1485	5.873	P- 0.0001*
6-minute walk test (Distance covered in 6 min- in meters)	309.1	47.46	318.5	50.26	3.609	P - 0.0011*

Fig. 1: This chart signifies the effective role of MPF in contrast to SACH foot in step length gait variable

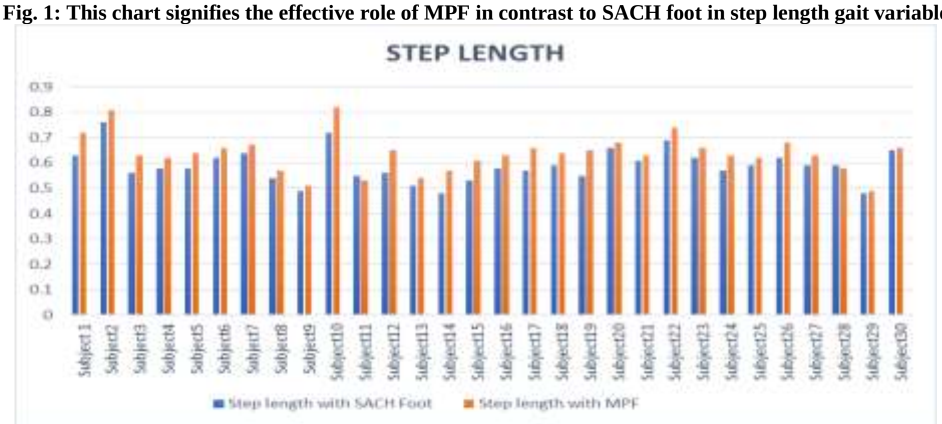


Fig.2: This chart signifies the effective role of MPF in contrast to SACH foot in the stride length gait variable

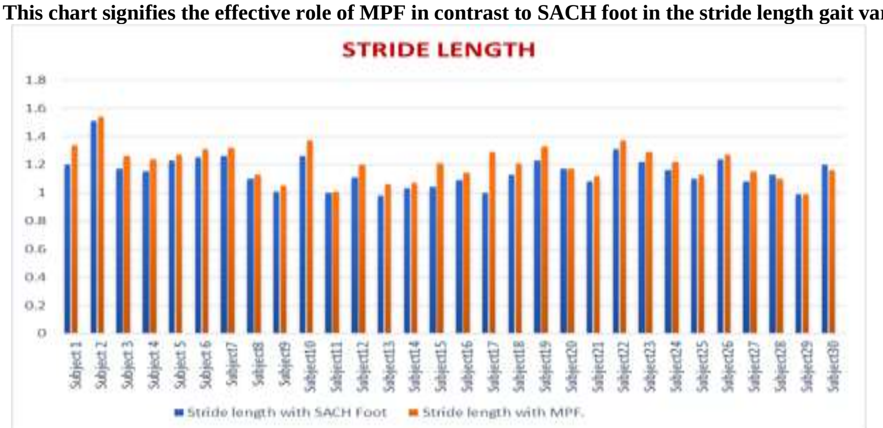


Fig.3: This chart signifies increased cadence because of ease of ground clearance in MPF

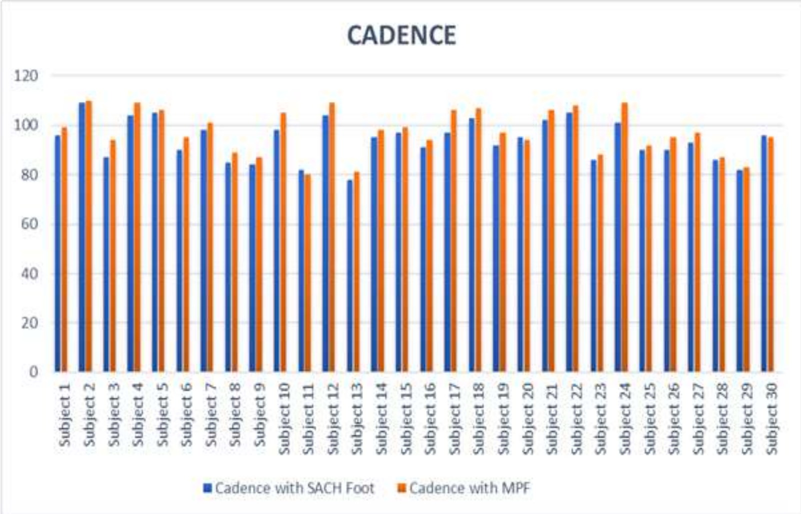


Fig. 4: This chart signifies the increased cadence enhanced the speed of PMF user

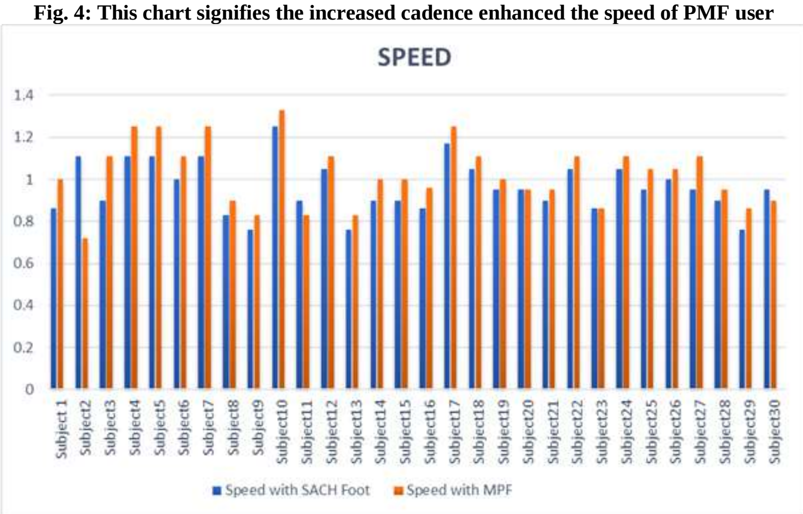


Fig.5: This chart of PCI signifies less energy consumption in MPF because it provides motion at the ankle joint

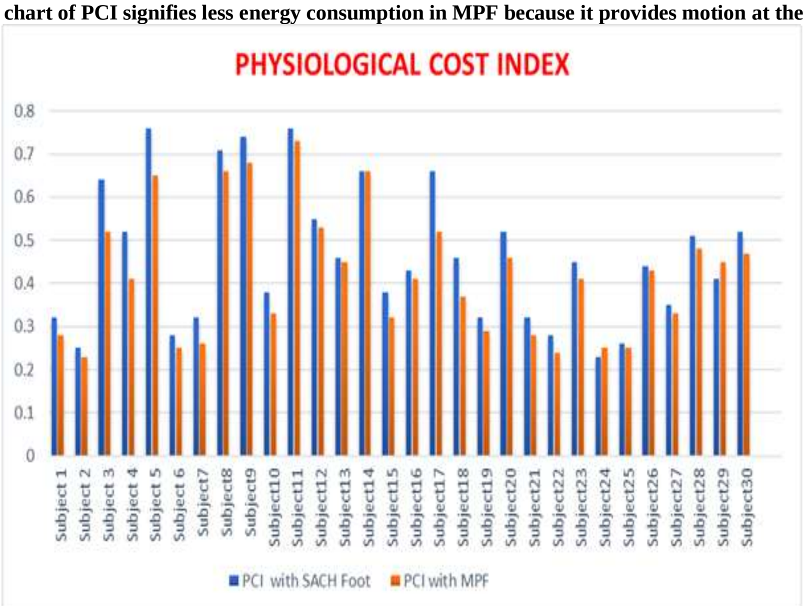
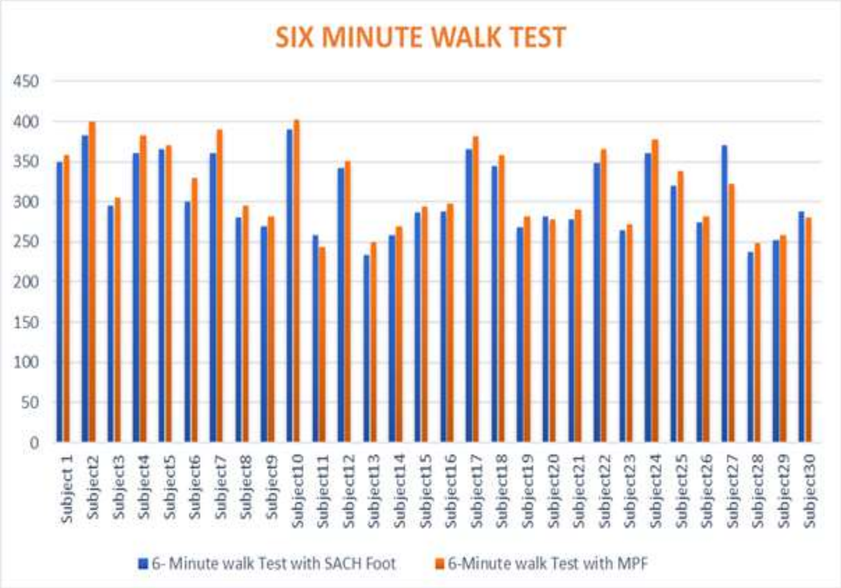


Fig. 6: The chart shows that patients covered more distance in 6-minute when they walked with MPF



DISCUSSION

This experimental interventional cross-sectional study aimed to develop a new prosthetic foot that provides multi-axial movement, and it may be beneficial for Indian amputees in terms of improving their natural gait pattern and reducing energy expenditure. Then it is compared with the SACH foot to check its walking effectiveness.

The selection of the subjects was made according to the convenience sampling method. During the study period, significantly, few female amputees reported to the department. Sometimes, they did not fit the inclusion criteria; hence, only two female amputees were in this study. The age criteria for selecting the candidate are between 18-60 years, in which 13 candidates are from the age group 18-30 years, seven candidates are from the age group 30-40 years, and the other ten candidates are from the age group 40-60 years. The mean age of the patients recruited for this study was 35.56 years. The youngest entrant was 19 years of age and the oldest was 50 years of age. The most common cause of Transtibial amputation was trauma. Lower extremity amputations are common in men. The amputation side for 18 candidates is right, and the remaining 12 are left.

All the transtibial amputees with prosthetic limbs fitted with the SACH foot could also walk with the multi-axis foot. The minimum use of a multi-axis prosthetic foot was 2 to 3 hours per day for one week. It was found that most young amputees were more comfortable with a newly designed multi-axial prosthetic foot; they walked more distance with a better natural gait pattern and less energy consumption. Some amputees aged 40-60 years and have been habitual of SACH foot for a long-time experience fear of falling initially because of ankle dorsiflexion movement in the multi-axial foot. However, later they felt that walking with the multi-axis foot was easy and comfortable, especially on stairs and slopes. It was observed that more amputees were ready to accept this newly designed foot and to switch over from the SACH foot to the multi-axial prosthetic foot, and a lesser number of amputees were not comfortable changing their existing foot. Lower limb amputees must learn to manage their prosthesis to optimize mobility relating to walking performance and negotiating ramps and stairs, balance performances, gait stability, and general comfort. The prosthetic componentry may significantly affect these aspects, which are vital indicators of the amputee's autonomy in activities of daily living. In this study, we have investigated more aspects of prosthesis usage as overall mobility, balance, and general satisfaction in a group of transtibial amputees fitting the SACH foot and, after an adequate period, a multi-axial one. Multi-axial foot with a multiaxiality feature gives a comparable or more adaptable gait with respect to the SACH foot in the selected sample.

Comparisons between the two prosthetic feet showed that when using the multi-axial foot, there was a significant increase in step length, stride length, cadence, and speed, a difference in distance covered in 6- minutes are also seen, and a significant enhancement in overall clinical response with respect to the SACH foot.

Results showed that the subject walked faster using the multi-axial foot ($p< 0.05$) than the SACH foot. These values are consistent with the previous research. After statistical analysis,

it is seen that in both studies, the p and calculated t value is identical in some spatiotemporal gait parameters, so our findings demonstrate that the multi-axial foot represents an alternative solution with respect to the SACH foot in the prescription of the prosthetic foot for active amputees where dynamic movement is needed.

Unilateral transtibial amputations often lead to reduced walking speed, gait asymmetries, and altered residual leg muscle activity relative to non-amputee walkers. The main contributing factor is the absence of the ankle plantar flexor muscles, which provide needed body support, forward propulsion, and swing initiation during non-amputee walking. A multi-axial foot is developed to acquire the functions of the ankle plantar flexor muscles, which provides multi-axial movement and reduces the user's energy consumption.

The researcher observed that all the subjects felt that there was no restrictive movement at the ankle because of articulation which provides dorsiflexion and plantarflexion on an uneven surface, and inversion and eversion on uneven surfaces, which facilitates natural gait to the amputees. It also provides dorsiflexion movement during stair and slope climbing, reducing all forces acting on the distal end of the stump, it also provides spring action and easy dynamic moments as it mimics all three rockers of the foot, enhancing its acceptance by amputees.

This study was able to enroll 30 participants and administer the research protocol in an outpatient clinical practice environment. To our knowledge, this sample size is larger than previous studies performed in research laboratories.[3,9,11-21] The sample consisted of primarily males (n=28) and persons with amputation secondary to trauma (n=24). The mean age of all participants (35.56 years) is comparable to the age range from other published research studies.[3-9, 11-21] Actively level of the participants was distributed between K3 (n=24) and K4 (n=6). The age and Activity level of the study sample are generalizable to the larger population of persons with lower-limb loss; however, the limited enrollment of female participants and those with dysvascular amputation cause are not representative of the typical patient population who may benefit from MPA technology.

LIMITATIONS:

Inclusion criteria of Activity level K3 or higher and the nature of the convenience sample recruited for this study can explain the higher prevalence of males with traumatic amputation cause and younger age exhibited in this study sample. Future studies may seek to limit the recruitment of male participants and those with traumatic amputation cause to enroll a more generalizable sample that includes representative levels of female participants and those with amputation from dysvascular cause. This study focused on patients classified as activity level K3 or higher (unlimited community ambulators);

however, the assistive functions of MPF may be beneficial for patients classified in lower functional levels (limited community and household ambulators). Future studies should evaluate MPF benefits in patients with mobility limitations and may rely more on their prosthetic technology for balance and mobility.

CONCLUSION

This study's aimed primarily to determine the efficacy of the multi-axial Prosthetic foot for improving gait and dynamic movement compared with the SACH foot in unilateral transtibial amputees. For the assessment of gait, spatiotemporal parameters were studied and analyzed.

According to data analysis of this study, multi-axial prosthetic foot improved patients' gait as they covered more distance than SACH foot walking on level ground. Patients were more confident with multi-axial Prosthetic foot while walking on uneven terrain, ascending and descending stairs, and on a ramp. The patient's compliance with the multi-axial foot was more satisfactory than with the SACH foot.

The subjects reported an increase in comfort level as a multi-axial prosthetic foot provides dynamic movement, which is absent in the SACH foot.

All the persons recruited were already using a SACH foot. Initially, there were no observable changes in the gait pattern of some subjects using the SACH foot for a long time. Still, after the training with a newly designed multi-axial Prosthetic foot, their gait improved as they walked more naturally due to dorsiflexion and plantar flexion movement in the sagittal plane and mediolateral movement in a frontal plane provided by multi-axis foot.

A newly designed multi-axis prosthetic foot mimics the normal human anatomical ankle. It helps to increase step length, stride length, cadence, and speed; hence subjects walk more efficiently with less energy consumption.

This study protocol was performed in a prosthetic outpatient clinic environment and recorded patient-centric outcome measures, which can readily be administered in routine practice and large-scale clinical trials. The results manifest evidence of several benefits that multi-axial prosthetic foot provides to patients with UTA. The MPF showed significantly better patient-reported mobility when walking and standing on sloped surfaces. These benefits should be considered by patients and practitioners when making a clinical decision. Future research on MPF should examine the effects of the type of habitual SACH prosthetic foot, the type of socket suspension mechanism, longer accommodation times, training in physical therapy, and benefits in mobility-limited patients.

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