# CHARACTERISTICS OF CONTRALATERAL PLANTAR PRESSURE DISTRIBUTION IN DIABETIC PATIENTS POST BELOW KNEE AMPUTATIONS, WITH AND WITHOUT A PROSTHETIC FOOT: AN OBSERVATIONAL STUDY

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**A dissertation submitted in partial fulfillment of the requirements of MS General Surgery Branch I examination of the Tamil Nadu Dr. MGR University Chennai to be held in 2018.**

**Declaration certificate**

This is to certify that the dissertation titled "Characteristics of contralateral plantar pressure distribution in Diabetic patients post below-knee amputation, with and without a prosthetic foot – An observational study" which is submitted by me in partial fulfilment towards M.S. Branch I (General Surgery) Examination of the Tamil Nadu Dr. M.G.R. University, Chennai to be held in 2018 comprises only my original work and due acknowledgement has been made in text to all material used.

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**Acknowledgements:**

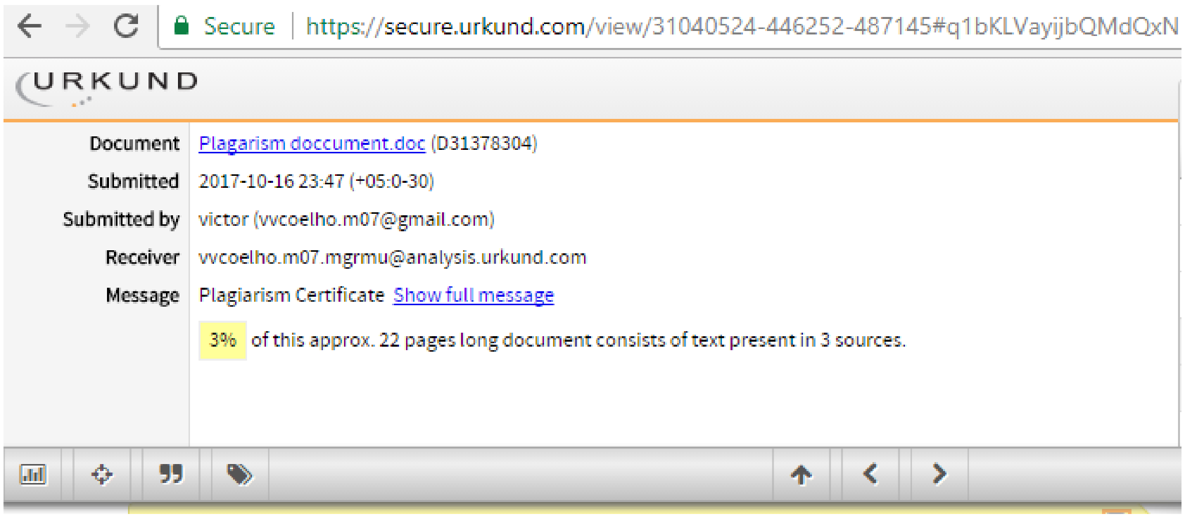
I am grateful to a number of people who have guided and supported me throughout my research process and provided assistance for my venture. First and foremost, praise and thanks to God, Almighty, for His showers of blessing throughout the journey of my research work to complete the research successfully. I would like to thank my advisors, Dr. John C Muthusami and Dr. Amit Tirkey who have guided me in selecting the final theme for this research. My advisors were there throughout my preparation of the proposal and the conceptualization of its structure. I would not have been able to do the research and achieve learning in the same without their help. Their recommendations and instructions have enabled me to assemble and finish the dissertation effectively.

I am immensely grateful to the patients for their participation and co-operation in my research work.

To Dr. Jayaprakash Muliyil , Dr. George Tharion and Dr. Suresh Devasahayam I will always be indebted to.

My family has always been a source of continuous encouragement and support throughout the course of this dissertation. To them, I am eternally grateful.

# PLAGIARISM REPORT



## CERTIFICATE - II

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1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

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**The Committee reviewed the following documents:**

1. IRB Application format
2. Proforma
3. Information Sheet and Informed Consent Form (English, Tamil, Telugu, Hindi)
4. Cvs of Drs. Nihal Thomas, AmitJiwanTirkey, John C. Muthusami, Deepak Thomas Abraham, Prasanna Samuel, George Tharion, . Jayaprakash Muliyil, Suresh Devasahayam.
5. No. of documents 1 - 4

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on October 20th 2015 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

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We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Characteristics of contralateral plantar pressure distribution in Diabetic Patients post below-knee amputation, with and without a prosthetic foot" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in)

*Fluid Grant Allocation:*

*A sum of Rs.96,940/- INR (Rupees Ninety Six thousand nine hundred and forty Only) will be granted for 2 years. 50,000/- INR (Rupees Fifty Thousand only) will be granted for 12 months as an Ist Installment. The rest of the 46,940/- INR (Rupees Forty six Thousand nine hundred and forty only) will be released at the end of the first year as 2 nd Installment*

Yours sincerely

Dr. Nihal Thomas
Secretary (Ethics Committee)
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Ref: IRB Min. No. 9682 dated 20.10.2015

The Institutional Review Board at its meeting held on October 20th 2015 vide IRB Min. No. **9682** accepted the project for *Rs. 96,940/- (Rupees Ninety six thousand nine hundred and forty Only) will be granted for 2 years. 50,000/- INR (Rupees Fifty Thousand only) will be granted for 12 months as an Ist Installment. The rest of the 46,940/- INR (Rupees Forty six Thousand nine hundred and forty only) will be released at the end of the first year as 2 nd Installment following the receipt of the Interim progress/Annual report and subsequent submission of it to the IRB. If overspent the excess should be debited form the respective departmental or Special funds.*

Kindly arrange to transfer the sanctioned amount to a separate account to be operated by Dr. Coelho Victor Vijay Frederick and Dr. John C Muthusami (jcm@cmcvellore.ac.in)

Yours sincerely,

Dr. Biju George,
Secretary (Ethics Committee)
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CC: Dr. Coelho Victor Vijay F, Dept. of Surgery, CMC, Vellore
Dr. John C Muthusami, Dept. of Surgery, CMC, Vellore.
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## ABSTRACT

The characteristics of contralateral plantar pressure distribution in Diabetic patients with and without a prosthetic foot.

**Aims and objectives**

**Aim**: To study the characteristics of static plantar pressure distribution after a major amputation in the contralateral foot of diabetic patients with and without a prosthetic device.

**Primary Objectives:** To compare the relationship between plantar pressure distribution in the contralateral leg with and without a prosthesis in diabetic patients who have undergone a lower limb amputation and have been rehabilitated.

**Secondary objectives**: To identify areas of high pressure over the contralateral leg and suggest appropriate modifications in the prosthetic foot wear so as to reduce the plantar pressure in those high-pressure regions.

**Methods**

This was designed as an observational study, approved by the Institutional Review Board with financial grant for the same. A total of 48 diabetic patients who had undergone either an elective or emergency transmetatarsal amputation and had been rehabilitated with a Jaipur foot prosthesis were recruited to the study. The precious limb was the main focus of the study and static plantar pressure distribution was measured over the precious limb with and without the prosthetic limb. The Harris Mat was used as the tool to assess the static plantar pressure distribution. The following parameters were also assessed.

a) Sensory testing assessment.

b) Vibration testing assessment.

c) Temperature testing assessment.

The routine diabetic profile assessment was also done which included, fasting blood sugar profile, post-prandial sugar profile and glycosylated hemoglobin levels.

## Results

A total of 48 diabetic patients who had undergone a transmetatarsal amputation were analyzed in this study. The static plantar pressure distribution was found to be significantly higher without the prosthetic device over the $1^{st}$, $2^{nd}$, $3^{rd}$, $4^{th}$, and $5^{th}$ metatarsal. The ratio of the forefoot pressure versus the hind foot pressure was also significant.

# Contents

# INTRODUCTION

This study is designed as an observational study. The main aim of this study is to prevent an amputation in the contralateral lower limb, once the patient has already undergone a below-knee amputation over one limb. In our routine clinical practice, it has been a common association that patients who have undergone a below-knee amputation over one limb, present to us at a later date with a plantar ulcer over the contralateral leg, requiring some form of either a major or minor amputation. There is no available data regarding this information in India and the data from the western countries is not too conclusive. To understand this more thoroughly, we will be aiming to study the characteristic distribution of contralateral static plantar pressures in diabetic patients who have already undergone a below-knee amputation and have been rehabilitated with prosthetic device.

## AIMS AND OBJECTIVES

1) To study the characteristics of static plantar pressure distribution after a major transmetatarsal amputation in the contralateral foot of diabetic patients with and without a prosthetic foot.

2) Primary objective was to compare the relationship between plantar pressure distribution in the contralateral leg with and without a prosthesis in diabetic patients who have undergone a transmetatarsal amputation and have been rehabilitated.

3) Secondary objective was to identify areas of high pressure over the contralateral leg and suggest appropriate modifications in the prosthetic footwear so as to reduce the plantar pressure in those high-pressure regions.

## JUSTIFICATION OF THE STUDY

In India there are nearly 62 million people currently diagnosed with diabetes mellitus. The complications arising from this potentially epidemic disease pose a significant problem to the quality of life. There are two population based studies that have been carried out, with regards to the complication of diabetes in the southern part of India, Chennai urban rural epidemiological study(CURES) and Chennai urban population study (CUPS). 50% of the population affected with diabetes mellitus over 20 years will develop some form of neuropathy. It could be either central, peripheral, or autonomic neuropathy, and causing impairment in this order particularly, results in foot injuries, ulcer formation and subsequently amputations. Sinnock et al proved that diabetic patients have a 15-fold higher rate of lower limb amputations than those without diabetes . Reiber et al proved that there is nearly a 6%-30% chance of the amputees of undergoing a contralateral lower limb amputation within 1 -3 years of the initial amputation . Within our institution, we have had similar data. Hence the main aim of this study was to prevent an amputation of the contralateral limb.

# LITERATURE REVIEW

## Causes and epidemiology of amputations

Amputations can be the outcome of unforeseen disasters like trauma, road traffic accidents, chronic or acute medical illnesses where the limb cannot be salvaged, natural calamities, accidents at the work place, sports injuries, congenital deficiencies, terrorism, and war. The incidence varies from country to country. The leading cause of amputations in developed countries are arterio-occlusive disease diabetes and tumors accounting for 68% of amputations annually. In developing countries, trauma related accidents including motor vehicle, industrial or farming accidents are the leading causes of amputations accounting for 30% of new limb amputations (1).

## Incidence and prevalence

The worldwide prevalence of amputation is difficult to ascertain as many countries do not keep tabulated records of amputation cases. The incidence of amputation increases steeply with age above 60 years, the major cases being trauma and cancer and is higher in men than in women (2). The incidence of amputation rose steeply with age; most amputations occurred in patients over 60 years. In most centers the incidence was higher in men than women and the incidence of major amputations was greater than that of minor amputations (3).

## Impact on diabetes mellitus and lower limb amputations

Currently, 135 million people around the world have diabetes mellitus and more than 62 million people (more than 7.1% of the adult population) of Indians are affected by it (4). By the year 2030 AD, India (the current diabetic capital of the world) is expected to have the largest number of diabetic patients surpassing the 92 million of China. Diabetes related lower extremity amputation rates have been found to be 12.5 to 31.6 times that of a person without diabetes (5). Diabetic foot is one of the common diabetic complications found in India (5). Each year, 40,000 individuals undergo lower limb amputations due to diabetic complications (2). However, it is second only to traumatic accidents as the major cause of lower limb amputations in India. In a multi-centric study done in India, the leading cause of amputations in diabetic patients was found to be infections. Among those who underwent major amputations, more than 50% were found to be trans-tibial amputations and 11.9% were found to be trans-femoral amputations.

In the western world, peripheral vascular disease with or without diabetes accounts for 80-90% of all amputations (2). In a study done in the Indian population

(6), the overall prevalence of peripheral vascular disease was found to be considerably lower compared to the western population.

## Surgical principles of amputations

**Importance of nutritional status and amputation level.** Studies done by Dickhaut et al. and Kay et al. reported uneventful healing of amputations in 15 of 16 patients with normal nutritional parameters, whereas 11 of 25 malnourished patients had post-operative complications including ulcers. It was concluded that lower healing rates and higher post-operative complications will be seen in patients with a serum albumin level of less than 3.5 gm/dl and total lymphocyte count of at least 1500 cells/ml (7). Waters et al studied the energy cost of walking for patients with amputations at different levels. On comparing with controls without amputations, they confirmed that the lower the level of amputation, the better the performance. It is understood that amputation should be performed at the lowest possible if preservation of function is the chief concern (8).

**Technical aspects.** The ideal stump length is between 12.5 cm to 17.5 cm. As it may vary according to height, allowing 2.5 cm bone length for every 30 cm of height gives a satisfactory measurement. The most acceptable length is 15 cm distal to the medial tibial articular surface (9). With the modern total contact prosthetic sockets which are now in use, the location of the scar is not of major importance as long as the scar does not adhere to the underlying bone. This is because an adherent scar causes difficulty in fitting the prosthesis and often breaks down after prolonged prosthesis use. Redundant soft tissues or “dog ears” also create problems in prosthetic fitting. Muscles after resection from their origin are usually stabilized by myodesis (suturing muscles or tendons to bone) or myoplasty (suturing muscle to periosteum or to fascia of opposite musculature). The preferred method if possible is myodesis as it provides a stronger insertion which in turn maximizes strength and minimizes muscle atrophy, maximizes residual limb function and is more effective for preventing contractures. Its use in limb ischemia however, is contraindicated because of increased risk of wound breakdown (9).

**Staged amputations**

Staged (two staged) amputations are done in cases on infection and severe trauma. In such cases, debridement or stump preparation in the form of an open ‘guillotine” amputation is the first of at least two operations. This is always followed by a secondary closure, re-amputation, revision or plastic repair (10) (11).

**Techniques specific to below knee amputations**

1) **Posterior flap technique-** This is the most common technique preferred for transtibial amputation. The advantage of this flap is placement of the scar in a non-weight bearing surface (12). A study done in 1976 by Mooney V et al. also confirmed that this technique offered a significant advantage in healing rate (13). The disadvantage however is the potential for ischemia in the flap area.

2) **Skew technique-** This is based on equal anteromedial and posterolateral fasciocutaneous flaps. Useful if there is inadequate skin to create a posterior flap (14).

3) **Saggital-** In this technique, equal medial and lateral myocutaneous flaps are created (15).

4) **Medial-** This technique constructs a long medial and short lateral flap (14).

5) **Medial Fish-mouth-**This method is based on equal anterior and posterior flaps.

**Complications**

Complications following amputation include medical complications like cardiac and pulmonary conditions and can also be local complications related to the residual limb including infections, incessant pain, post-operative pain, and others which may need re-exploration. Some of the most common complications we see according to their frequency are stated below:

Ulcers: Bony edges which are not rasped or smoothened out can be one of the major causes of ulcer complications especially in bony prominences such as anterior aspect of the tibia for transtibial amputations and lateral aspect of the femur for trans-femoral amputations (10). Residual limb skin conditions are also another major aspect determining the development of ulcers. Levy in 1956 was one of the earliest researchers in this field where he emphasized that skin problems (folliculitis, contact dermatitis, skin edema syndrome, epidermoid cyst) and stump hygiene should not be overlooked in an amputee patient. During weight bearing, the skin is exposed to shear forces which cause repeated ulcerations at the stump prosthesis interface. This can be exaggerated with poor nutritional status, vascular insufficiency, poor stump hygiene, and inadequate pressure relieving points of an ill-fitting prosthesis (16).

A study done by Berridge DC et al, on a hundred amputees with ischemia reported that 13-40% of the patients with pre-operative infections, low nutritional status, advanced age, and wound hematomas developed infections. There was no significant difference in wound sepsis rates of diabetic patients (15).

**Phantom limb pain.** It is defined as burning, aching, electric-type pain on the amputated limb. In a questionnaire for 5000 American veterans done in 2005, 78% reported phantom pain. Of those receiving treatment only 1% reported any long last benefit (16). It was reported that 10-20% of patients who had undergone below knee amputation needed re-amputation at the femoral level. Diabetic patients were more prone to higher level reamputations than on diabetic patients (17).

**Neuroma**. A neuroma is formed when a nerve has been divided. It becomes painful when it is located in an area which exposes it to repeated pressure and trauma. Different methods of isolating and burying the nerve are being practiced. Strong tension and crushing should be avoided.

## Characteristics of transtibial residual limbs

It is imperative that residual limbs have certain characteristics which make them adaptable to transtibial prostheses. The residual limb characteristics, length of residual limb, range of motion at the adjacent joint/presence of any contractures or deformities, individuals‟ goals and activities, individuals‟ geographic location are some of the important factors needed for determining the prosthetic socket fitting and suspension methods (18). Characteristics of the residual limbs include skin condition, volume (edematous changes), location and condition of surgical scar.

Residual limb length may vary between long (more than 80% of the normal limb), medium (50% of the normal limb) or short (less than 30% of the normal limb).

An ideal stump should have the following characteristics:

- an ideal length and shape.

-all bony margins should be well covered by muscle and skin

-it should be free from any open wound or infection.

-neuromas should be absent.

-there should not be any joint contracture or deformity.

There should be a full range of movements of the joint above it.

**Transtibial prosthesis**

When lower limb prostheses are prescribed, the following principles should be

remembered:

- The mobility needs of the particular patient are met
- Maximal comfort with no pain caused by the socket on the residual limb. A poorly fitting prosthesis with an uncomfortable socket will lead to limited mobility and higher chances of rejection of the prosthesis
- Correct choice of components for achieving maximal independence and functional mobility
- Acceptable cosmetic appearance

Transtibial prostheses comprise the following components:

- A socket with silicone liner system which maximizes the comfort and minimizes chances of ulceration at the area of the residual limb which comes in direct contact with it. The patellar tendon bearing (PTB) socket is the most commonly used socket design. Variations of it are the PTB-SC (Supracondylar) and PTB-SCSP (Supracondylar Suprapatellar) sockets. They are most useful for patients with short residual limbs. Other alternative sockets such as the total surface bearing (TSB) and hydrostatic sockets are being increasingly accepted (19).
- The suspension system includes straps (most commonly Supracondylar cuff strap),

prosthetic sleeves, suction and gel liners with locking mechanisms (19). Sleeve suspension consists of elastic sleeves, rubber or neoprene which are pulled up over the thigh after donning the prosthesis (20). Gel liners reduce shear which make them the option of choice in residual limbs with compromised skin integrity or those with skin grafts. The suction suspension system works through a partial vacuum which is created by an air valve present at the bottom of the prosthesis with an air tight sleeve (21).

- An endoskeletal pylon is most commonly used. It allows further alteration if needed after fabrication of the prosthesis. It absorbs shock on impact and helps reduce energy expenditure.
- A suitable prosthetic foot completes the transtibial prosthesis. It can be basic, articulated, or dynamic response. Solid Ankle Cushion Heel (SACH) foot is the most commonly and widely accepted basic prosthetic foot. Articulated prosthetic feet come as single axial or multi-axial joints. Dynamic response feet help in push off and decrease force of impact of the other foot with the ground (20).

All the transtibial amputees in this study were fitted with a Jaipur foot prosthesis. This prosthetic leg was designed to be inexpensive, water resistant, easy to manufacture and designed to fit well. It is made of polyurethane, which at the time of its innunciation was the new material used in the production of prosthesis. The idea of the Jaipur Foot was conceived by Ram Chander Sharma under the guidance of Dr. P K Sethi (22).

## STUDY BACKGROUND

Individuals with diabetes mellitus have a fifteen-fold higher rate of lower extremity amputations than those without diabetes as proved bby Most and Sinnock. A total of 6-30% of the amputee populations undergo contralateral lower extremity amputations within 1 to 3 years of the initial amputation. After major amputation, 5.7% and 11.5% have a contralateral major amputation at 1 and 5 years, respectively. After minor amputation, 3.2% and 8.4% have a contralateral major amputation at 1 and 5 years while 10.5% and 14.2% have an ipsilateral major amputation at 1 and 5 years, respectively (23). The scene in our country is not very different. According to the RSSDI textbook of diabetes mellitus, the mean age of amputation in the Indian population is 61.25 years as opposed to the 75 years in the Western population. The mortality rate following this amputation is 14.28% in an Indian scenario, versus a 50% mortality in the Western population. The high rate of mortality in the western population is mainly due to older age, atherosclerosis, and multisystem disease involvement. The rate of contralateral amputations in the Indian population after two years is 8.92%.

Despite this disconcerting rate of contralateral limb loss, this problem appears to be in adequately addressed by various rehabilitation and institutional centers all around the world. The World Health Organization (WHO) has described Type II diabetes mellitus as an international epidemic. Current estimation suggests that the number of persons with diabetes will reach 30 million by 2025 (24). A total of 50% of patients who have suffered from diabetes for more than 20 years develop peripheral neuropathy which affects nerve function from the periphery to the proximal region (25)(26). Peripheral diabetic neuropathy is one of the most insidious complications in the chronic evolution of diabetes mellitus (27). It can affect and cause dysfunction in the central, peripheral and autonomic nervous system and by causing impairment in this same order makes the patient more susceptible to progressive foot injuries, ulcer formation and eventually amputations (28). One of the first impairments arising from diabetic neuropathy is the progressive loss of tactile sensation, followed by pain and loss of thermal proprioceptive and vibration sensitivity, which is classified as restrictive neuropathy. Motor neuropathy and atrophy of the distal musculature of the lower limbs especially intrinsic to the feet occurs progressively and leads to foot deformities and loss of function. Autonomic neuropathy leads to impairments in the sympathetic and parasympathetic innervations of various organs and result in a reduction in sweat production that leads to dryness and fissuring of the skin. Autonomic neuropathy also leads to decrease in joint mobility, of the foot (29).

**Need for plantar pressure measurements**.

Foot plantar pressure is the pressure field that acts between the foot and the support surface during everyday locomotor activities.

Feet provide the primary surface of interaction with the environment during ambulation. It is very essential to identify foot problems at an early stage for injury prevention, risk management and general wellbeing. One approach to measuring foot health, widely used in various applications, is examining foot plantar pressure characteristics. It is, therefore, important that accurate and reliable foot plantar pressure measurement systems are developed. One of the earliest applications of plantar pressure was the evaluation of footwear. Lavery *et al.* (30) in 1997 determined the effectiveness of therapeutic and athletic shoes with and without viscoelastic insoles using the mean peak plantar pressure as the evaluation parameter. Since then there have been many other studies of foot pressure measurement; for example, Mueller (31) applied plantar pressure to the design of footwear for people without impairments (i.e., the general public). Furthermore, Praet and Louwerens (31) and Queen *et al.* (32) found that the most effective method for reducing the pressure beneath a neuropathic forefoot is using rocker bottom shoes and claimed the rocker would decrease pressure under the first and fifth ray (metatarsal head). The metatarsal heads are often the site of ulceration in patients with cavovarus deformity. Queen *et al*. indicated that future shoe design for the prevention of metatarsal stress fractures should be gender specific due to differences in plantar loading between men and women.

**Plantar pressure assessment**

Pressure (p) (also called “stress”) is defined as force (f) per unit area (a) (i.e., p5f/a). Force, when measured using a force platform, is the net result of the 3 components of the ground reaction or resultant force acting on the foot. The 3 components of the ground reaction force are in the fore-aft, medial-lateral, and vertical directions. When assessing plantar pressure, a discrete sensor or a matrix of multiple sensors is used to measure the force acting on each sensor while the foot is in contact with the supporting surface. The magnitude of pressure is then determined by dividing the measured force by the known area of the sensor or sensors evoked while the foot was in contact with the supporting surface. The System International (SI) unit of force is the newton, and the SI unit of pressure is the pascal. A pascal is defined as the pressure experienced when a force of 1 N is distributed over an area of 1 $m^2$. Pressure values can be reported in newtons per square centimeter, pounds per square inch, or kilograms per square inch, but kilopascals or megapascals are the preferred units of measurement.

**Method of measurement of plantar pressures in diabetics**

Several methods of measuring and reducing foot pressures are available. Extra-depth footwear, jogging shoes, hosiery, insoles, and orthoses have been shown to decrease plantar foot pressures. Furthermore, these devices can prevent the occurrence and recurrence of foot ulceration. However, when using orthoses or other inserts care must be taken not to increase pressures over another region of the foot.

In the last two decades, the development of intricate computerized systems has revolutionized diabetic foot pressure measurements and made their application possible for daily clinical practice. Foot pressure measurements obtained from out-of-shoe and in-shoe methods may have far-reaching consequences for both research and clinical applications. Moreover, these systems can potentially identify at-risk patients and provide a basis for the implementation of either footwear modifications or surgical intervention. Foot pressure measurement systems are still being developed. Currently, research is in the initial phase of developing methods of measuring in-shoe shear forces. Piezoelectric transducers are currently being evaluated which may be able to measure both vertical and shear forces. In the future, computer systems will hopefully become more widely available and may be employed routinely for diabetic foot management and a variety of foot conditions.

**Out- of- shoe- method**

One of the earliest studies to examine foot pressures was that of Beely in 1882 (33). Subjects ambulated over a cloth-filled sack filled with plaster of Paris to produce a footprint. Beely postulated that the plaster would capture the plantar aspect of the foot with the highest load, representing the deepest impression. However, this primitive technique was limited because it represented a crude measurement the total force of the foot creating the impression rather than the dynamic pressures underneath the foot during gait. Moreover, this method was strictly qualitative and therefore susceptible to both inter and intra observer unreliability. In 1930, Morton (33) described a ridged, deformable rubber pad, termed the kinetograph. This pad made contact with an inked paper placed underneath the foot as the subject ambulated over the pad. The kinetograph examined the relationship between the static and rigid foot deformity and was the first documented attempt to measure foot pressures rather than forces. Elftman (33) further developed a system that allowed for the observation of dynamic changes in pressure distribution as the subject ambulated. This device was called the barograph and consisted of a rubber mat that was smooth on top yet studded with pyramidal projections on the bottom. The mat was placed on a glass plated, and as subjects ambulated over the mat, the area of contact of the projections increased according to changes in the pressures under the foot. A video camera recorded the deformation pattern of the mat from below as the subject walked on the mat.

## HARRIS–BEATH MAT

In 1947, Harris and Beath (34) used a similar method to study foot problems and related foot pressure changes in a large group of Canadian soldiers. Their device used a multilayered inked rubber mat that allowed contact with a piece of paper below. When pressure was applied to the mat with ambulation, the ink escaped from it, thereby staining the paper. Thus, the density of the inked impression was dependent on the applied pressure. By using this technique, Barrett and Mooney (35) found high loading under the feet of subjects with diabetes. The major problem with this device, however, was that it could not be calibrated to various degrees of foot pressures and therefore the Harris–Beath Mat would saturate at levels within the normal limits of foot pressures. Furthermore, the amount of ink placed onto the mat could not be standardized. Silvino and associates (35), however, calibrated the Harris–Beath mat by using a contact area of known size and weight, thereby producing both qualitative and semiquantitative data.

In 1947, they published a monumental survey of the foot and its disorders in which they developed their own foot printing technique to record plantar pressures. This technique employed a rubber mat stretched across a support frame. The mat has a rough side which consists of ridges of three different heights lined up in two planes. A light pressure is indicated by only the large ridges printing, whereas a heavier pressure will progressively print the smaller and then the smallest ridges in addition to the large ridges.

At a very high pressure, a blotting of ink will obliterate the squares formed by the ridges.

This mat is inexpensive to use and very practical for the clinician. It provides a permanent record of the distribution of pressures under the foot in an analog mode. A drawback of the Harris mat is that although it records the shape of the contact area, it has provided only qualitative information regarding the pressures involved (35).

We have used this Harris Mat for determining the plantar pressures over the precious limb in our study. There is a major drawback in this method of measurement, in that it can measure only the static plantar pressures and does not aid in the dynamic pressure measurement.

Figure 1

## Applied anatomy of the foot

There are three main arches of the foot. They are the medial longitudinal, the lateral longitudinal and the transverse arches. These three arches play a very pivotal role in the standing, walking, and running.

## Medial longitudinal arch

The medial margin of the foot arches up between the heel proximally and the medial three metatarsophalangeal joints to form a visible arch. It is made up of the calcaneus, talar head, navicular, the three cuneiforms and the medial three metatarsals. The posterior and anterior pillars are the posterior part of the inferior calcaneal surface and the three metatarsal heads, respectively. The bones themselves very little to the stability of the arch, whereas the ligaments contribute significantly. The most important ligamentous structure is the plantar aponeurosis, which acts as a tie beam between the supporting pillars (Hicks, 1954). Dorsiflexion, especially of the great toe, draws the two pillars together, thus heightening the arch: the so called “windlass” mechanism. Next, in importance is the spring ligament which supports the head of the talus. If this ligament fails, the navicular and calcaneus separate, allowing the talar head, which is the highest point of the arch to descend, leading to a flat-foot deformity. The talocalcaneal ligaments and the anterior fibers of the deltoid ligament, from the tibia to the navicular, also contribute to the stability of the arch.

Muscles play a role in the maintenance of the medial longitudinal arch. Flexor hallucis longus acts as a bowstring. Flexor digitorum longus, abductor hallucis and the medial half of the flexor digitorum brevis also contribute but to a lesser extent. Tibialis posterior and anterior invert and adduct the foot, and so help to raise its medial border. The importance of tibialis posterior is manifest by the collapse of the medial longitudinal arch that accompanies failure of its tendon.

**Lateral longitudinal arch**

The lateral longitudinal arch is much less pronounced arch than the medial one. The bones making up the lateral longitudinal arch are the calcaneus, the cuboid and the fourth and fifth metatarsals, they contribute little to the arch in terms of stability. The pillars are the calcaneus posteriorly and the lateral two metatarsal heads anteriorly. Ligaments play a more important role in stabilizing the arch, especially the lateral part of the plantar aponeurosis and the long and short plantar ligaments. However, the tendon of fibularis longus makes the most important contribution to the maintenance of the lateral arch. The lateral two tendons of flexor digitorum longus (and flexor accessorius), the muscles of the first layer (lateral half of flexor digitorum brevis and abductor digiti minimi), and fibularis brevis and tertius also contribute to the maintenance of the lateral longitudinal arch.

## Transverse arch

The bones involved in the transverse arch are the bases of the five metatarsals, the cuboid, and the cuneiforms. The intermediate and lateral cuneiforms are wedge shaped and thus adapted to maintenance of the transverse arch. The ligaments, which bind the cuneiforms and the metatarsal bases, mainly provide the stability of the arch, as does the tendon of the fibularis longus, which tends to approximate the medial and lateral borders of the foot. A shallow arch is maintained at the metatarsal heads by the deep transverse ligaments, transverse fibers that tie together the digital slips of the plantar aponeurosis, and, to a lesser extent, by the transverse head of adductor hallucis.

## Muscles acting over the foot

The muscles acting over the foot could be divided into extrinsic and intrinsic muscles. The extrinsic muscles are further classified into the anterior group, lateral group, posterior group, and the superficial group.

The extensors arise in the anterior compartment of the leg and their tendons pass anterior to the ankle, where they are bound down by the extensor retinacula.

The lateral group arises in the relatively narrow lateral compartment of the leg and their tendons pass posterior to the lateral malleolus, bound down by the fibular retinacula. The flexors arise in the posterior compartment of the leg and their tendons pass posterior to the ankle, where the tendons of the superficial group of flexors are inserted into the calcaneus, and the tendons of the deep group of flexors are bound down by the flexor retinaculum.

**Anterior group.**

The tibialis anterior, extensor hallucis longus, extensor longus and fibularis tertius belong to the anterior group of muscles.

**Lateral group.**

Fibularis longus and fibularis brevis belong to the lateral group of muscles.

**Posterior group.**

The posterior group of muscles are divided into superficial and deep groups. The gastrosoleus, calcaneal tendon, and plantaris are included in the superficial group of muscles, whereas the popliteus, flexor hallucis longus, flexor digitorum longus and tibialis posterior comprise the deep group of muscles.

**Intrinsic muscles**

The intrinsic muscles, i.e., those contained entirely within the foot, follow the primitive limb pattern of plantar flexors and dorsal extensors.

The plantar muscles may be divided into medial, lateral, and intermediate groups. The medial and lateral groups consist of the intrinsic muscles of the great and fifth toes, respectively, and the central or intermediate group includes the lumbricals, interossei and intrinsic digital flexors. It is customary to group the muscles into four layers because this is the order in which they are encountered during dissection. In clinical practice and in terms of function, however, the former grouping is often more useful.

**Plantar muscles of the foot: first layer**

This superficial layer includes abductor hallucis, abductor digiti minimi and flexor digitorum brevis. All three extend from the calcaneal tuberosity to the toes, and all assist in maintaining the concavity of the foot.

**Abductor hallucis.**

Attachments: Abductor hallucis arises principally from the flexor retinaculum, but also from the medial process of the calcaneal tuberosity, the plantar aponeurosis, and the intermuscular septum between this muscle and flexor digitorum brevis. The muscle fibers end in a tendon that is attached, together with the medial tendon of flexor hallucis brevis, to the medial side of the base of the proximal phalanx of the great toe. The clinical application of the abductor hallucis is that its fascia is strong and can be used in soft tissue augmentation following correction of hallux valgus deformity. Rarely, persistent, exaggerated tonus in the muscle maybe a case of varus deformity of the foot, necessitating surgical correction.

**Flexor digitorum brevis.**

Flexor digitorum brevis arises by a narrow tendon from the medial process of the calcaneal tuberosity, from the central part of the plantar aponeurosis, and from the intermuscular septa between it and adjacent muscles. It divides into four tendons, which pass to the lateral four toes, the tendons enter digital tendinous sheaths accompanied by the tendons of flexor digitorum longus, which lie deep to them. At the bases of the proximal phalanges, each tendon divides around the corresponding tendon of flexor digitorum longus, the two slips then reunite and partially decussate, forming a tunnel through which the tendon of flexor digitorum longus passes to the distal phalanx.

**Abductor digiti minimi.**

Abductor digiti minimi arises from both processes of the calcaneal tuberosity, from the plantar surface of the bone between them, from the plantar aponeurosis and from the intermuscular septum between the muscle and flexor digitorum brevis. Its tendon glides in a smooth groove on the plantar surface of the base of the fifth metatarsal and is attached, with flexor digiti minimi brevis, to the lateral side of the base of the proximal phalanx of the fifth toe.

**Plantar muscles of the foot: second layer.**

The second layer consists of the flexor accessorius and the four lumbrical muscles. The tendons of flexor hallucis longus and flexor digitorum longus run in the same plane as the muscles of the second layer.

**Flexor accessorius (quadratus plantae).**

The flexor accessorius arise by two heads, with the long plantar ligament, situated deeply in the interval between the two heads. The medial head is larger and is attached to the medial concave surface of the calcaneus, below the groove for the tendon of the flexor hallucis longus. The lateral head is flat and tendinous, and is attached to the calcaneus distal to the lateral process of the tuberosity, and to the long plantar ligament. The muscle belly inserts into the tendon of flexor digitorum longus at the point where it is bound by a fibrinous slip to the tendon of flexor hallucis longus and where it divides into its four tendons.

### Lumbrical muscles.

The lumbrical muscles are four small muscles that are accessory to the tendons of flexor digitorum longus. They arise from these tendons as far back as their angles of separation, each springing from the sides of two adjacent tendons, except for the first lumbrical, which arises only from the medial border of the first tendon. The muscles end in tendons that pass distally on the medial sides of the four lateral toes and are attached to the dorsal digital expansions on their proximal phalanges.

## Plantar muscles of the foot: third layer

The third layer of the foot contains the shorter intrinsic muscles of the toes, i.e., flexor hallucis brevis, adductor hallucis, and flexor digiti minimi brevis.

### Flexor hallucis brevis.

Flexor hallucis brevis has a bifurcate tendon of origin. The lateral limb arises from the medial part of plantar surface of the cuboid, posterior to the groove for the tendon of the fibularis longus, and from the adjacent part of the lateral cuneiform. The medial limb has a deep attachment directly continuously with the lateral division of the tendon of tibialis posterior, and a more superficial attachment to the middle band of the medial intermuscular septum. The belly of the muscle divides into medial and lateral parts, the twin tendons of which are attached to the sides of the base of the proximal phalanx of the great toe. The medial part blends with the tendon of abductor hallucis, and the lateral with that of adductor hallucis, as they reach their termination.

**Adductor hallucis.**

Adductor hallucis arises by oblique and transverse heads from the bases of the second, third, and fourth metatarsals, and from the fibrous sheath of the tendon of fibularis longus. The transverse head – a narrow, flat fasciculus-arises from the plantar metatarsophalangeal ligaments of the third, fourth and fifth toes, and from the deep transverse metatarsal ligaments between them. The oblique head has a medial and lateral part. The medial part blends with the lateral part of flexor hallucis brevis and is attached to the lateral sesamoid bone of the great toe. The lateral part joins the transverse head and is also attached to the lateral sesamoid bone and directly to the base of the first phalanx of the great toe.

**Flexor digiti minimi brevis.**

Flexor digiti minimi brevis arises from the medial part of the plantar surface of the base of the fifth metatarsal, and from the sheath of fibularis longus. It has a distal tendon that inserts into the lateral side of the base of the proximal phalanx of the fifth toe; this tendon usually blends laterally with that of abductor digiti minimi.

**Plantar muscles of the foot: fourth layer**

The fourth layer of the muscles of the foot consists of the plantar and dorsal interossei and the tendons of tibialis posterior and fibularis longus.

**Dorsal interossei.**

The dorsal interossei are situated between the metatarsals. They consist of four bipennate muscles, each arising by two heads from the sides of the adjacent metatarsals. Their tendons are attached to the bases of the proximal phalanges and to the dorsal digital expansions. The first inserts into the medial side of the second toe, and the other three pass to the lateral sides of the second, third, and fourth toes.

**Plantar interossei.**

There are three plantar interossei They lie below, rather than between, the metatarsals, and each is connected to only one metatarsal. They are unipennate, unlike the dorsal interossei; they arise from the bases and medial sides of the third, fourth, and fifth metatarsals, and insert into the medial sides of the bases of the proximal phalanges of the numerically corresponding toes.

## THE BIOMECHANICS OF THE FOOT IN DIABETES MELLITUS

The aim of this section is to provide a biomechanical framework on which an understanding of the cases, treatment and prevention of foot injury in patients with diabetes mellitus can be built. Diabetes related distal symmetric polyneuropathy results in a loss of protective sensation, and subsequently, a number of biomechanical risk factors conspire to cause the injury. Thus biomechanics has a great relevance to neuropathic injury (36)(37). Most skin injuries that are seen on the feet of patients with diabetic neuropathy occur in the forefoot, with approximately equal distribution on the dorsal and plantar surfaces. Those on the plantar surfaces are frequently at the sites of high pressure under the foot (38). Subsequent developments have shown that biomechanics can make a can make a significant contribution to managing the foot in diabetes.

**Forces at the foot**

Although the likelihood of high pressure between a region of the foot and the ground can be inferred from an analysis of movement, neither the eye nor the most sophisticated video system analysis can measure these forces and pressures, because it is only the consequences of force that can actually be "seen." The area of mechanics in which the forces that cause movement are studied is called kinetics, whereas the label kinematics is applied to studies in which the movement per se is measured. The most frequently measured and studied forces are the external forces between the foot and either the ground or the footwear. Less frequently, internal forces in tissues or forces between the articulating surfaces of joints can be measured, estimated, or modeled.

When the foot strikes the ground in gait, Newton's third law tells us that equal forces will be experienced by both the foot and the ground. Because it is more convenient to measure the force with an instrument mounted on the ground than on the foot, a device called the "force platform" is frequently used in gait laboratories.

## Pressure: The harm done by force

The late Paul Brand so aptly once said, "Pressure is the critical quantity that determines the harm done by the force" (38). The link between force and pressure is, of course, the area of force application. Much more danger can be done by a force transmitted through a few plantar prominences than by the same force distributed over a larger area of the plantar surface. Consequently, plantar pressure measurement is a topic of critical interest in the field of diabetes-related foot injury.

## Is there a threshold pressure for injury?

Plantar ulceration has been linked to high plantar pressures in several retrospective studies and in one prospective study (39). However, there is no clear agreement yet on the pressure threshold for ulceration. This lack of accord maybe a consequence of several factors. It was found that results that were obtained by using one pressure platform were not extrapolated to other platforms. Also, the different regions in the foot may have different pressure thresholds for breakdown. Third, the pressure threshold for tissue breakdown may vary depending on the health of the tissue related to vascular supply, tissue perfusion, amount of glycosylation of the tissues and scarring (40). Fourth, shear, although not measured by any of the currently available platforms, may interact with normal forces in ways that are not fully understood. Fifth, the integral or time-pressure product, currently not often calculated could be more relevant than simple peak pressure (41). Sixth, and perhaps the most important, barefoot pressures that are measured during a few steps across a pressure platform do not predict the load experienced by the foot. Actual cumulative load during normal daily living depends on each patients' activity level and footwear.

**Conventional Approach to defining abnormal values**

It is not possible to take the foot pressure distribution of a healthy population and assume that similar values are safe for patients with insensitive feet. Healthy individuals remain ulcer free not because they have lower plantar pressures but because they can feel pain. Plantar pressures can and do occur in the feet of neuropathic patients at sites where peak plantar pressure is as low as 500kPa, as measured on the EMED SF platform (42).

# MATERIALS AND METHODS

The hypothesis of this study was that there is an equal spatial redistribution in static plantar peak pressures in the precious limb following a rehabilitation with a prosthetic device in a diabetic patient who has undergone a below knee amputation.

This trial was approved by the Institutional Review Board and Ethics Committee of Christian Medical College, Vellore. The cases were recruited from three areas:

-The General Surgical wards i.e., P1, P2, P3

-The Diabetic Foot Clinic –Medical Endocrinology

-The Physical Medicine Rehabilitation Centre–PMR.

The precious limb following the amputation was the main focus during this study.

The study will commence by recruiting diabetic patients who have undergone either an elective or emergency below knee amputation due to a non-traumatic, diabetic cause.

The patients received an information sheet and consent form prior to recruitment for the study. Those patients who have undergone an amputation due to a traumatic cause and not primarily due to an underlying diabetic ulcer and those patients with peripheral occlusive arterial disease requiring any surgical intervention, as well as those patients with a musculo-skeletal or spinal disorder were excluded from the study.

The patients underwent four sets of clinical evaluation and investigations

-Sensory assessment of the precious limb involved

-Plantar pressure assessment of the precious limb

-Biochemical assessment of the general Diabetic status of the patient.

-Photographic assessment of the precious foot using a smart phone

**Sensory assessment: Evaluated four main areas**

**Sensation testing.** Patients with foot ulcers were observed to have less pressure sensation than those without foot ulcers. In 1898 Von Frey attempted to standardize the stimuli for testing the subjective sense of light touch by using a series of horse hairs of varying thickness and stiffness. Weinstein used nylon monofilaments mounted on Lucite rods. The Semmes-Wienstein monofilament has been consolidated for testing the insensate foot. The 4.17 monofilament supplies 1 g of force and is indicative of normal sensation. If the patient cannot feel the next monofilament (5.07), he or she does not have the protective sensation level of 10 g and cannot sense trauma to the foot to cease weight bearing. Failure to sense the 10 g monofilament is used as the determining factor for use of protective footwear and accommodative orthotics. Inability to feel the largest monofilament indicates a sensation loss at 75 g. This monofilament tests the single point perception test. The monofilament was placed on the skin, until the monofilament bends. The diameter of the monofilament controls the point of bend. The monofilaments are tested and determined to be reliable at the 95% confidence interval.

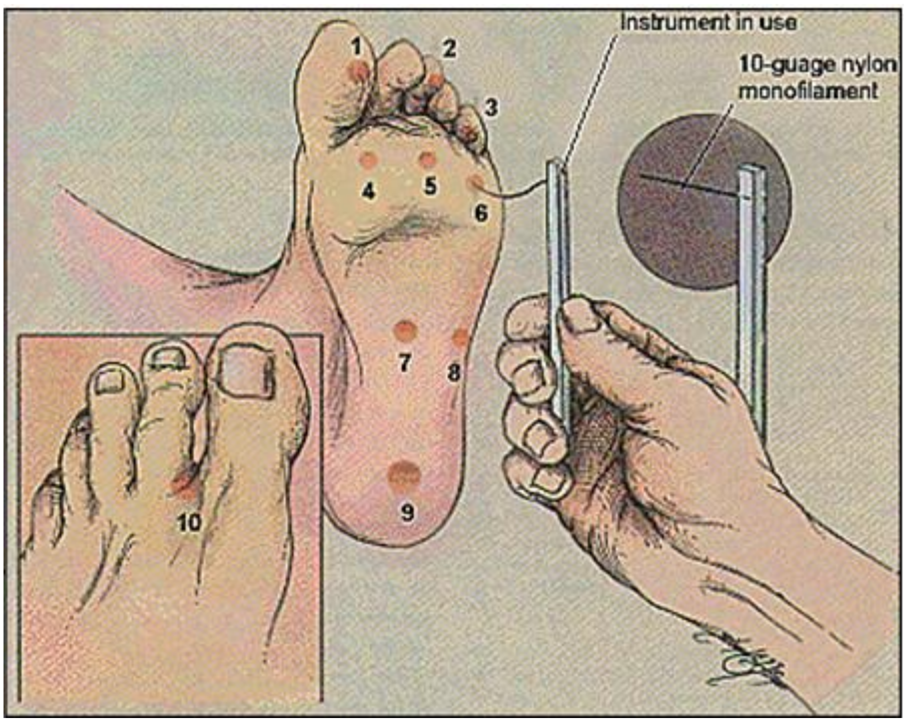



Figure 2

**Vibration testing.** Testing for vibratory sensation maybe accomplished by using the biothesiometer. This instrument is essentially an electrical tuning fork that uses repetitive mechanical indentation of skin delivered at a prescribed frequency and amplitude. The simple graduated tuning fork is a rapid means of sensory testing. The main purpose of sensory testing is to identify those areas at risk of developing an ulcer in the precious limb.

**Temperature testing. S**urface sensing temperature devices (infrared), temperatures are recorded in pre-determined areas usually in those common areas related to breakdown. When there is one definite area with a temperature 3 degree Farenheit, higher than the adjacent area, it can be assumed to be an area of high pressure or stress. If there is no current breakdown, this area must be relieved of pressure and the pressure must be adequately distributed over the remaining weight bearing surface.

**Achilles Tendon Reflex Pin Prick Sensation.** This will be carried out over the precious foot. The Neuropathy Disability scoring system (NDS) will be used to term the precious foot as being neuropathic or not.

**Plantar pressure measurement.** A rubber mat was developed by R.I Harris, that would print light foot pressures in large light squares (formed by tall grid ridges) and heavier pressures in smaller squares (deep ridges). This is the tool that was used to measure static plantar pressures. The subject was initially seated on a chair. He then rose up from the chair with the temporary support of a quadripod walker. The same walker was used to standardize the procedure. Thus, from sitting to standing the static laboratory peak plantar pressures will be measured over the precious limb with and without the prosthetic device. There were three such readings taken, for the sake of the patient understanding the procedure and the final of the three readings will be chosen for the final analysis. The two ink prints of the precious limb (one supported with the prosthetic limb on the contralateral side and one without the prosthetic limb) were scanned and the pressure over the different areas of the foot was analyzed using Kody's podometer analyser. This software provided us with a color coded graphic representation of the plantar pressure distribution over the precious limb. The foot wear on the precious limb could then be modified in order to off load the pressures at the specific high-pressure zones. This we believe, will prevent an ulcer formation over the precious limb in the future which will in turn prevent the need for an amputation of the precious limb. Also, we do realize that dynamic pressure measurements will be more reliable and accurate. We will attempt to extrapolate our study to measure the dynamic pressures, using in-house built insole with a number of microsensors attached to the base. This will be a part of another study at a later date.

To assess the degree of diabetic polyneuropathy we used the Revised Neuropathy Disability Score It includes the ankle reflex, vibration, pin-prick, and temperature (cold tuning fork) sensation at both sides of the great toes.

Figure 3


**Figure 4**

**This pictoral representation depicts areas of high pressure over the sole of the precious foot on the right side, without the prosthetic over the amputated limb.**

## STATISTICAL METHODS

### Sample size

The formula that was used was the Paired t-test. This formula compares the means in the same population.

The Standard deviation of Peak plantar pressures was found to be 17.5kPascal.

The difference of Peak plantar pressures of patients with and without a prosthetic device were found to be 10kPascal.

The formula used for sample size calculation was

$$N = \frac{(Z\alpha + Z\beta)^2 \times (\text{Standard deviation})^2 \times 2}{(\text{Difference in plantar pressures with and without prosthesis})^2}$$

Where $Z\alpha$=Type I error =1.96

$Z\beta$=Type II error= 0.84

Standard deviation=17.5kPascal

Difference in plantar pressures with and without prosthesis =10kPascal.

$N = (1.96+0.84)^2 \text{ X } (17.5)^2 \text{ X } 2 \div 10 \text{ X } 10$

$= (7.84) \times (306.25) \times 2 \div 100$

$= 4802 \div 100$

$= 48.02$

$= 48$

Sample Size 48 patients.

**Inclusion and exclusion criteria**

The inclusion criteria will include any known diabetic patient who has undergone either a below knee  amputation and has been rehabilitated with an appropriate prosthetic device for over 30 days.

Only those patients will be included who give a written consent for the study.

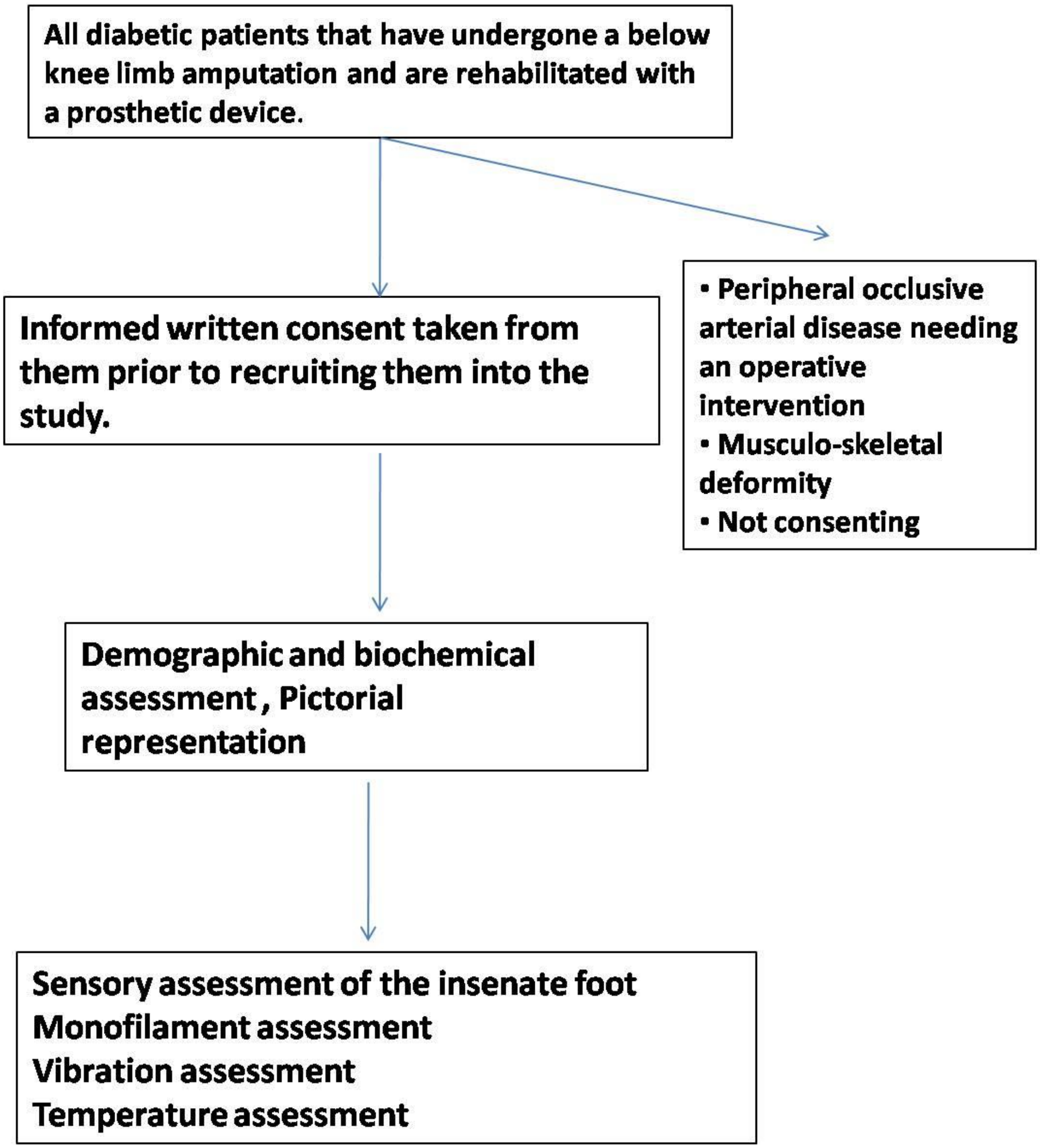
The exclusion criteria will include any patient who has undergone an amputation for a non-diabetic cause ; for example  a traumatic cause.

Those patients who have undergone an amputation , but have a peripheral arterial disease , requiring a surgical intervention.

Those patients with a known spinal or musculoskeletal deformity .

Those patients not giving a consent for the study .

## STUDY ALGORITHM



**Plantar pressure assessment of precious limb with Harris mat**

↓

**Analysis of the plantar pressure by Kody's Software programme**

↓

**A graph will be plotted showing the change in plantar pressures over the hallux and the 1st to 5th metatarsal head and calcaneum with and without the prosthesis**

↓

**Appropriate recommendation of change in the prosthetic footwear to reduce the areas of high pressure over the precious limb.**

Data entry was done using EpiData 3.1 and the data was analysed using SPSS Version 18.

# RESULTS

A total of 48 patients were analyzed from October 2015 to August 2017, thus reaching the target sample size. Results are presented in order of the objectives of the trial.

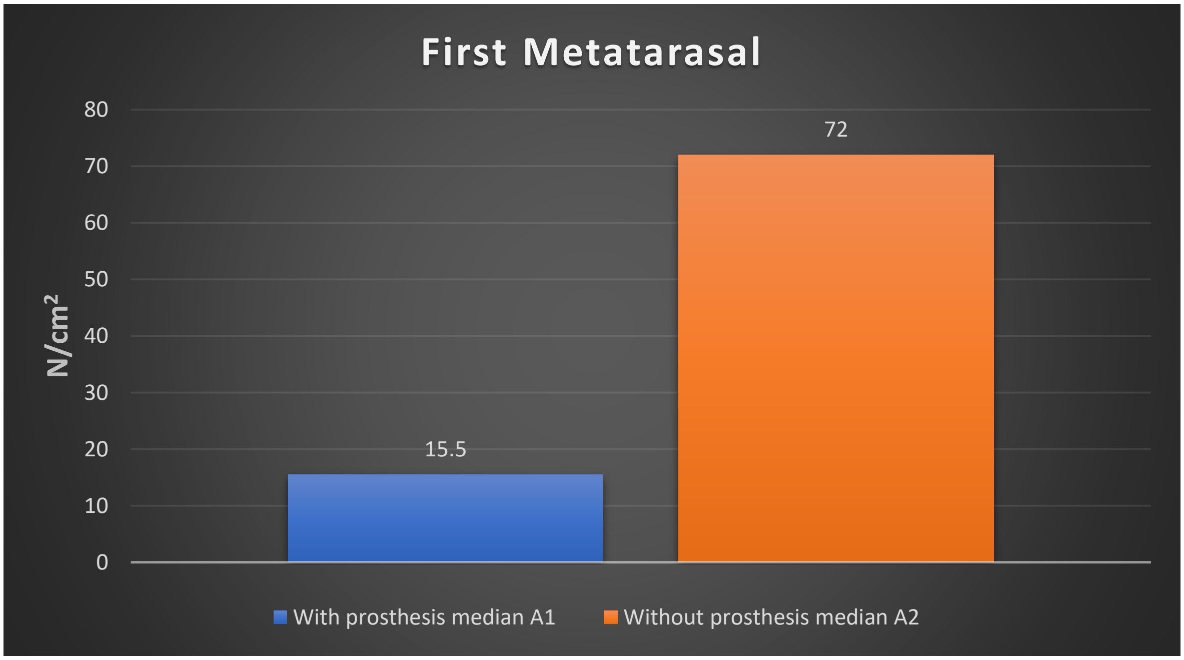
## Results of the primary objectives

**Primary.** To compare the relationship between plantar pressure distribution in the contralateral foot with and without the prosthesis in diabetic patients who have undergone a below-knee amputation and have been rehabilitated.

| Variable | With prosthesis Median (min, max) N/cm2 | Without prosthesis Median (min, max) N/cm2 | Difference (with-without) | P-Value |
|---|---|---|---|---|
| First Metatarsal | 15.5 (7, 30.5) | 72 (27, 101) | -40 (-65, -14.5) | <0.001 |
| Second Metatarsal | 16.5 (6, 34.5) | 65 (22.5, 97) | -39 (-61, -7) | <0.001 |
| Third Metatarsal | 14.5 (8, 57) | 71 (33.5, 94) | -40 (-61.5, -20) | <0.001 |

| | | | | |
|---|---|---|---|---|
| Fourth Metatarsal | 14.5 (5.5, 29) | 73.5 (32.5, 93.5) | -46.5 (-66, -24.5) | <0.001 |
| Fifth Metatarsal | 9.5 (4, 30.5) | 84 (24.5, 103) | -53 (-82, -15) | <0.001 |
| Ratio of Forefoot Pressure versus hindfoot pressure | 16 (7, 42) | 43 (24, 78) | -17 (-32, -6) | 0.0020 |

Figure 5




The mean pressure over the first metatarsal with the prosthesis was 15.5N/cm2 and without the prosthesis the mean pressure was 72N/cm2.

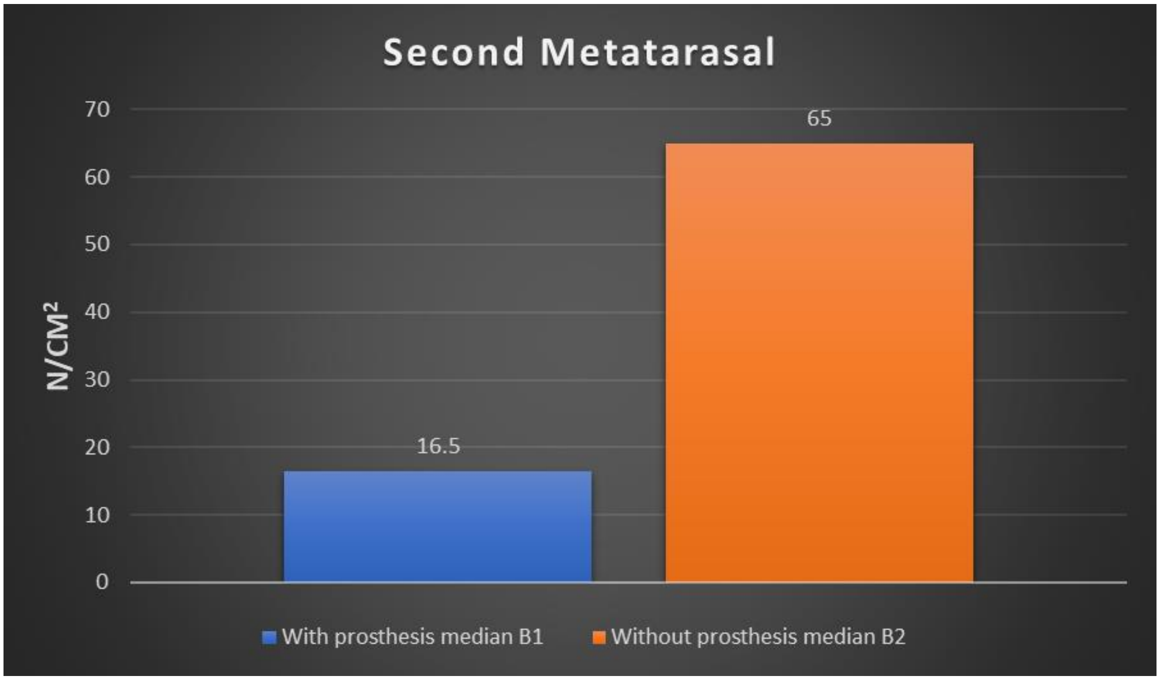



Figure 6

The mean pressure over the second metatarsal with the prosthesis was 16.5N/cm2 and without the prosthesis the mean pressure was 65N/cm2.

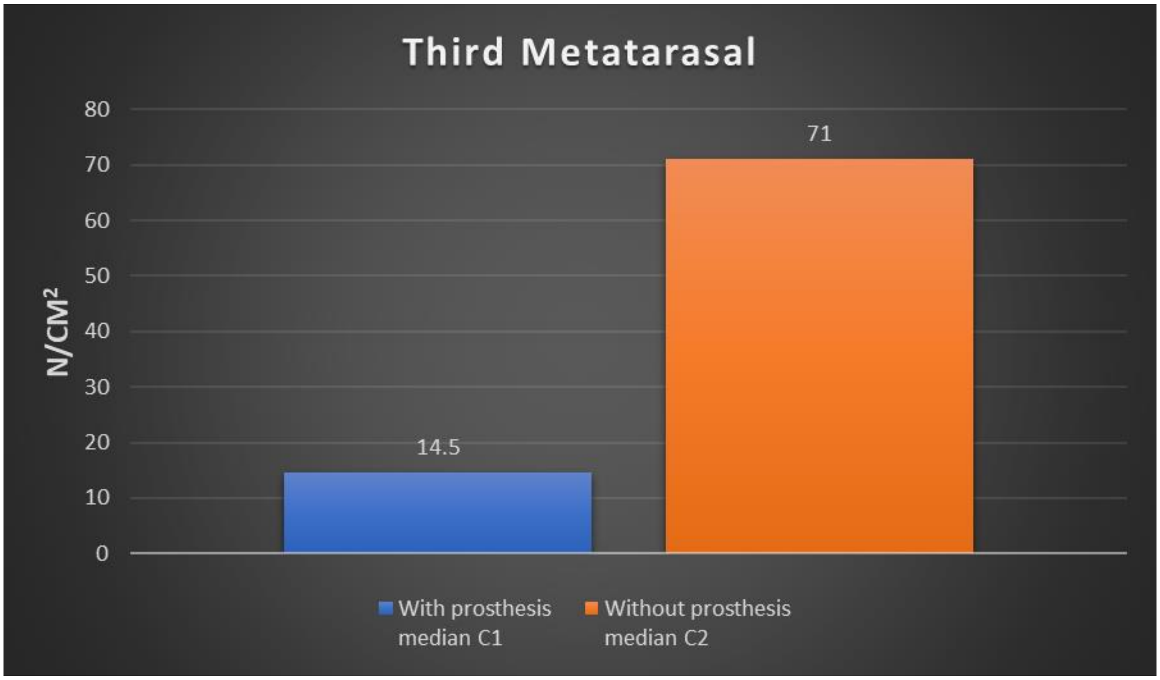



Figure 7

The mean pressure over the third metatarsal with the prosthesis was 14.5N/cm2 and without the prosthesis the mean pressure was 71N/cm2.

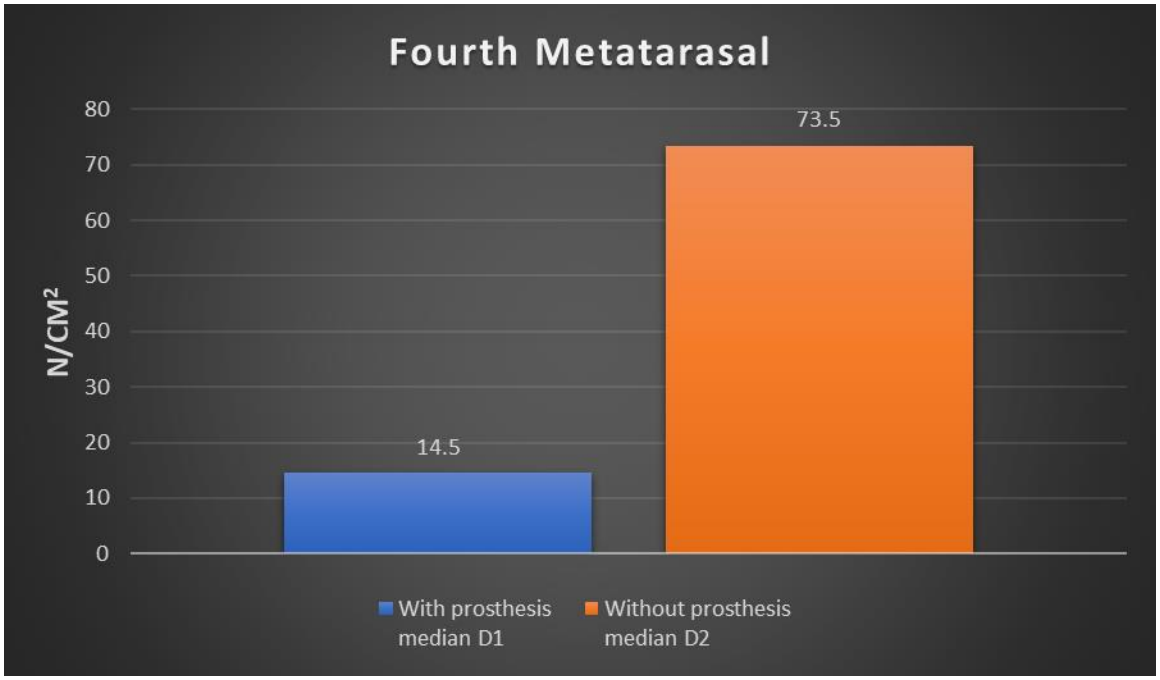



Figure 8

The mean pressure over the fourth metatarsal with the prosthesis was 14.5N/cm2 and without the prosthesis the mean pressure was 73.5N/cm2.

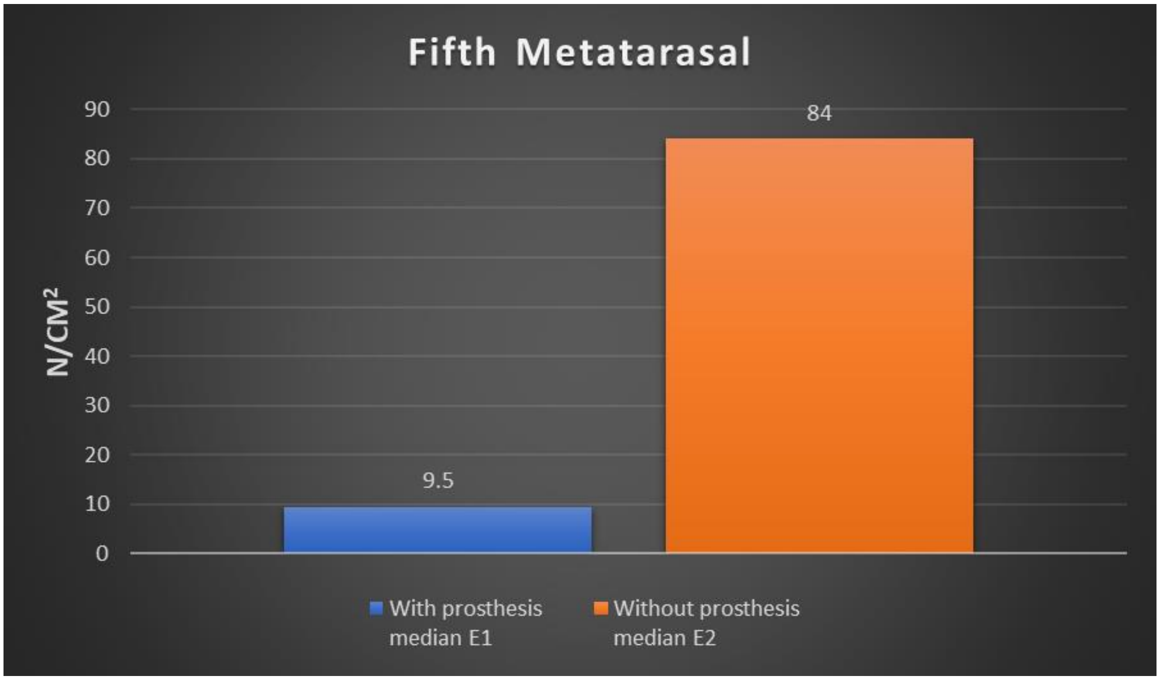



Figure 9

The mean pressure over the fifth metatarsal with the prosthesis was 9.5N/cm2 and without the prosthesis the mean pressure was 84N/cm2.

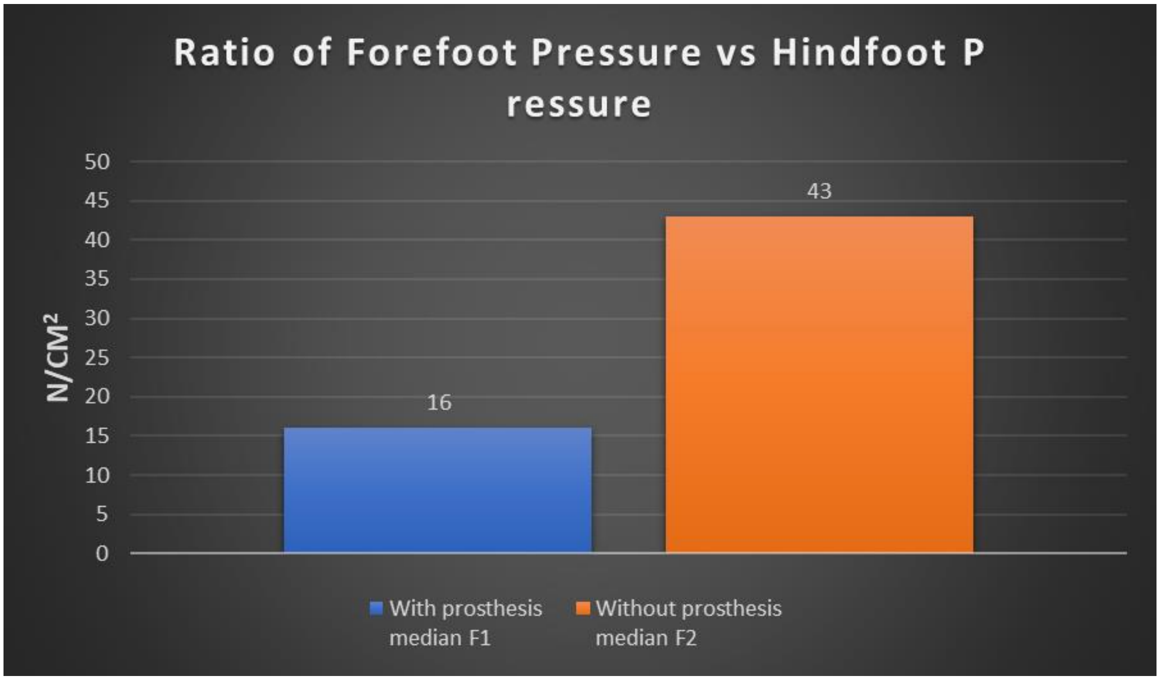



**Figure 10**

**Secondary.** To identify areas of high pressure over the contralateral foot and suggest appropriate modifications in the prosthetic foot wear so as to reduce the plantar pressure in those high-pressure regions.

We found that that the ratio of the forefoot versus hindfoot pressures were higher over the hindfoot. With the prosthesis the mean pressure was 16 N/cm2 and without the prosthesis the pressure was 43 N/cm2.

**Demographic details**

There was a total of 48 patients that were recruited in this study. There were 40 male patients and 8 female patients. The mean age distribution of the patients in the study was 57.1 years. The mean height and weight of the study population group was 168.2 cm and 69.60 kilograms, respectively.

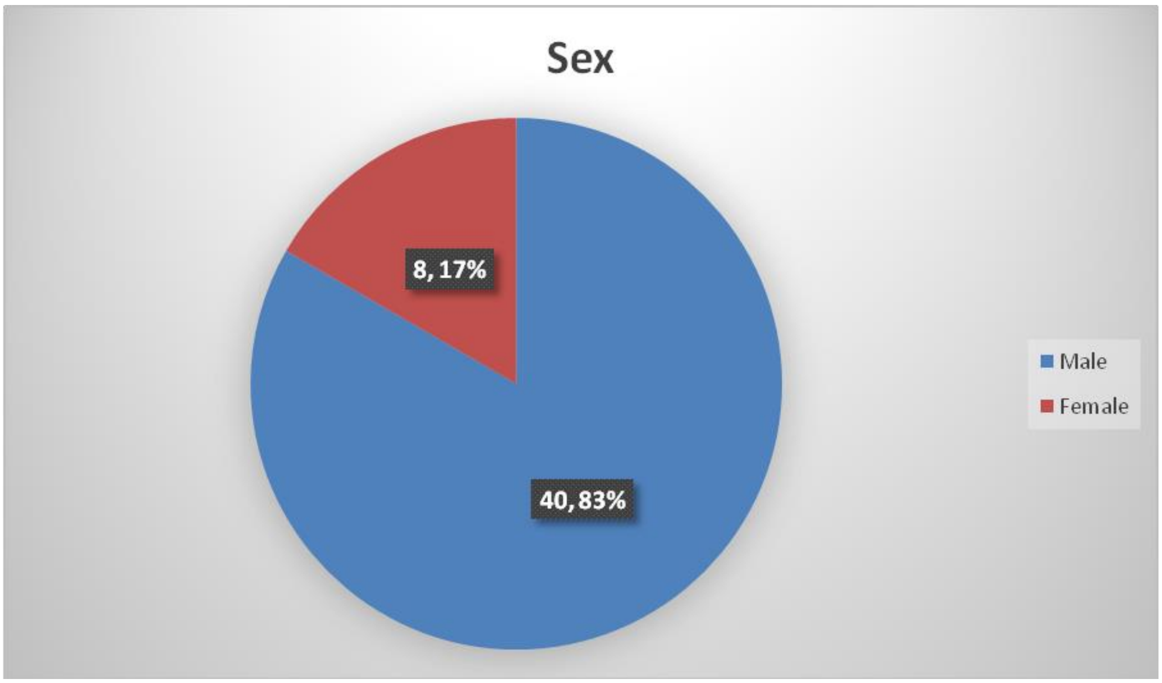



Figure 11

The population that was studied in this study was on varied medications which included only oral hypoglycemic agents, insulin and a combination of the two. There were 21 patients who were only on oral hypoglycemic agents, 15 who were only on insulin and 12 patients who were on a combination of oral hypoglycemic agents along with insulin.

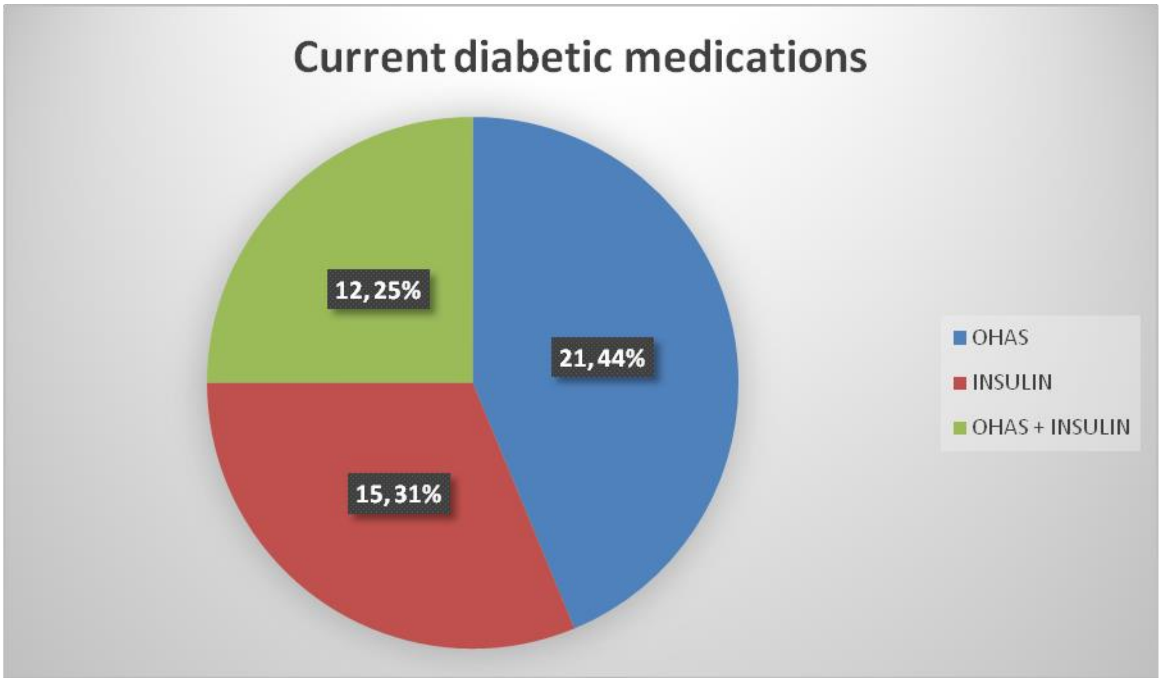
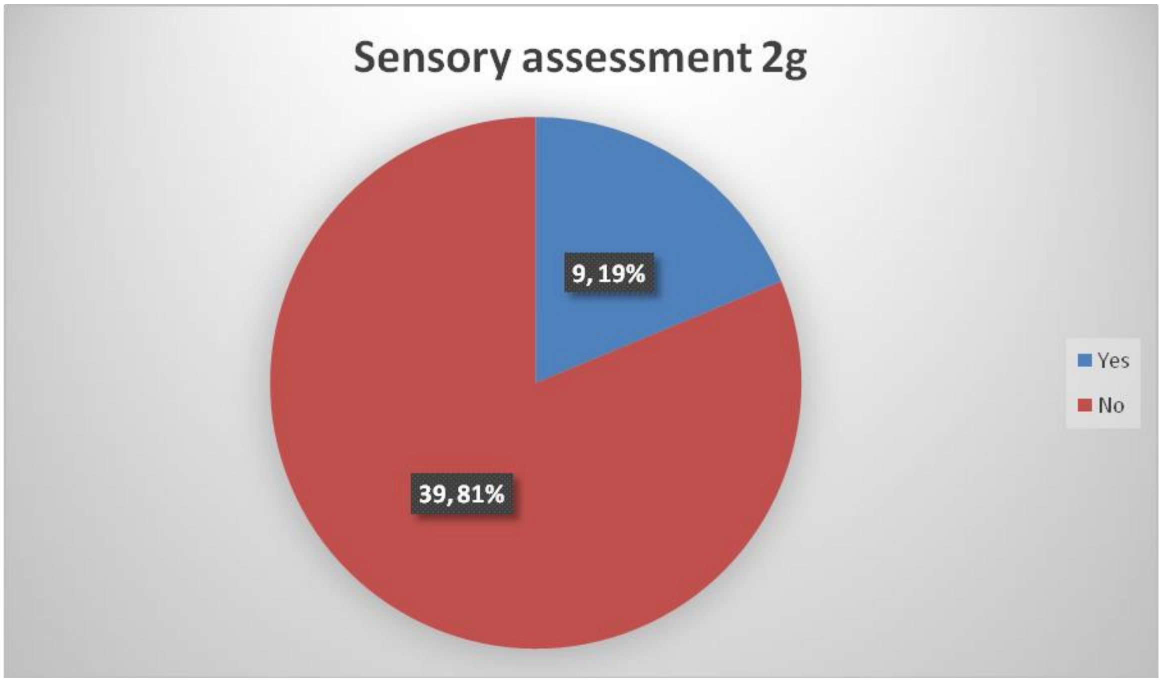
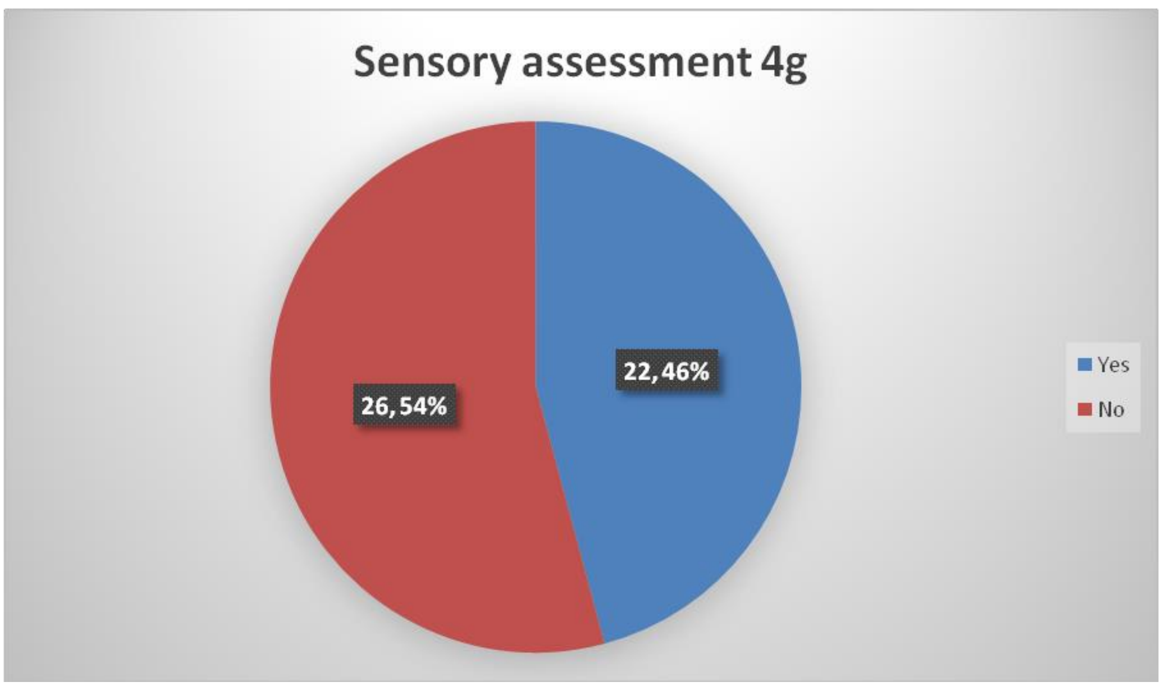



Figure 12

The neuropathic status of the precious foot was assessed with Semmes-Wienstein monofilament has been consolidated for testing the insensate foot. Sensory assessment was achieved with 2 g, 4 g, and 10 g monofilament. There was a total of 9 patients who were able to identify 2 g monofilament and 39 who were not able to sense the 2 g monofilament. There were 22 patients who were able to appreciate 4 g monofilament and 26 were not able to appreciate the same. There were 29 patients who were able to sense the 10 g monofilament and 19 patients who were not able to sense the same.


Sensory assessment 2g
9, 19%
39, 81%
Yes
No


Sensory assessment 4g
22, 46%
26, 54%
Yes
No

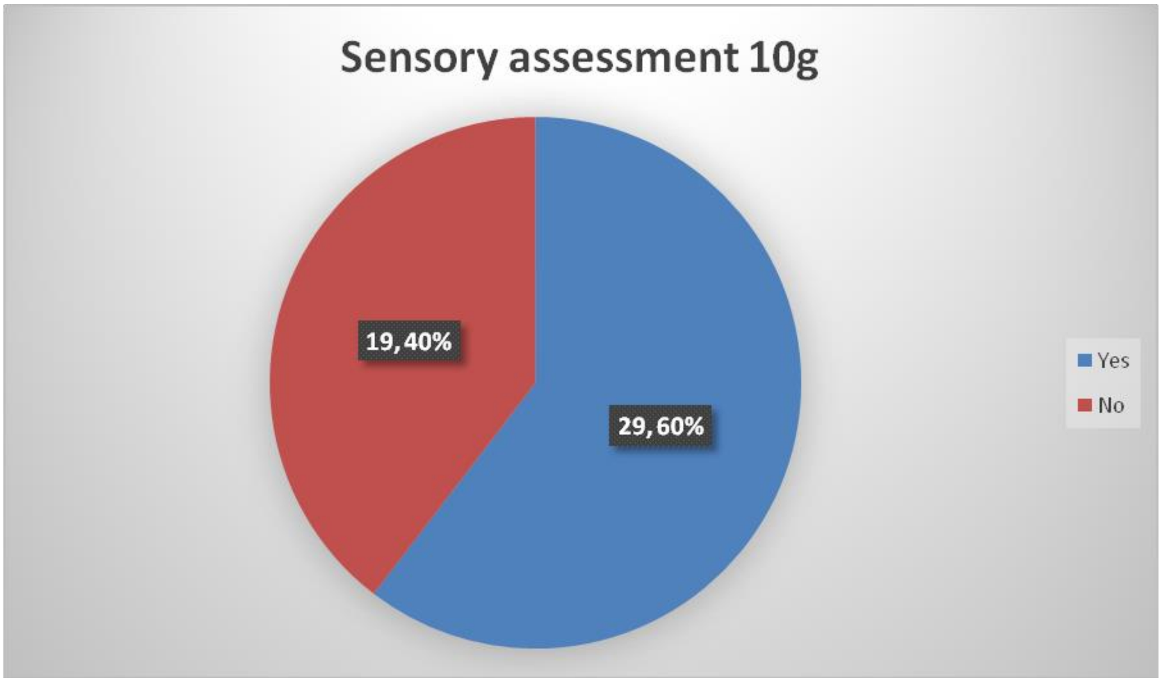



Figure 13

**Vibratory assessment**

The vibratory sensation maybe accomplished by using the biothesiometer. There were 23 patients who were able to appreciate the vibratory stimulus and 25 that were unable to appreciate the vibratory stimulus. The main purpose of sensory testing is to identify those areas at risk of developing an ulcer in the precious limb.

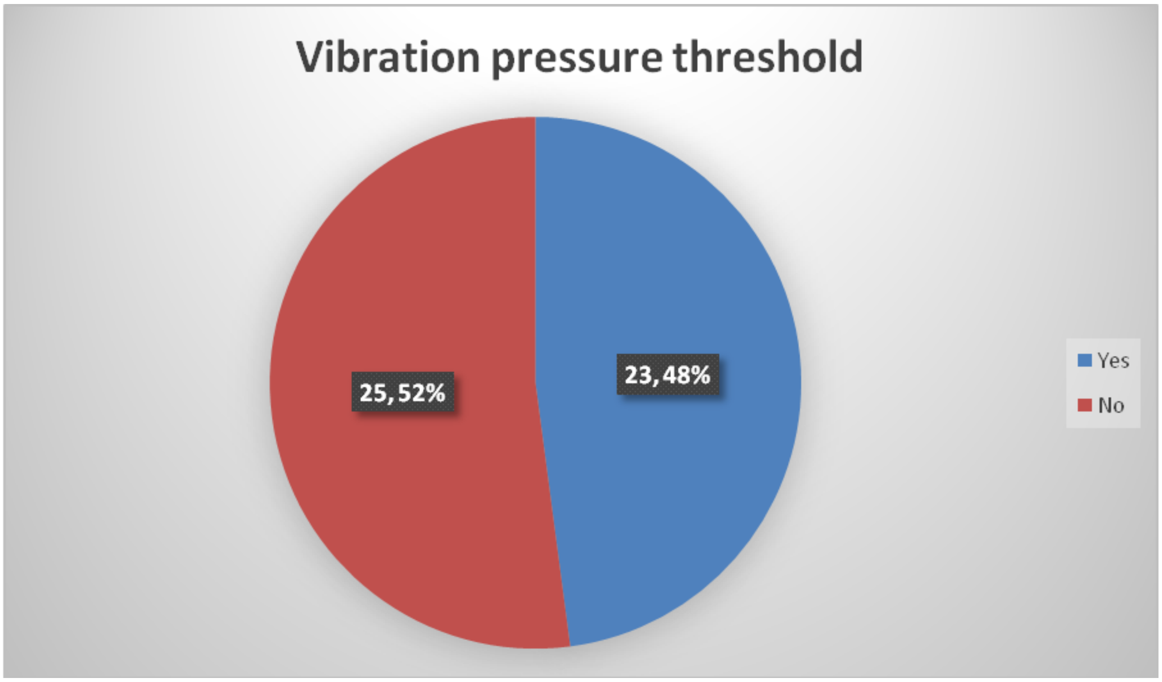



**Figure 14**

**Temperature assessment**

When there is one definite area with a temperature 3 degree Farenheit, higher than the adjacent area, it can be assumed to be an area of high pressure or stress. If there is no current breakdown, this area must be relieved of pressure and the pressure must be adequately distributed over the remaining weight bearing surface. The temperature assessment for the 48 patients in the study revealed that 22 patients had areas of higher pressure distribution compared to the corresponding area. A total of 26 patients on the other hand had a normal perception of temperature.

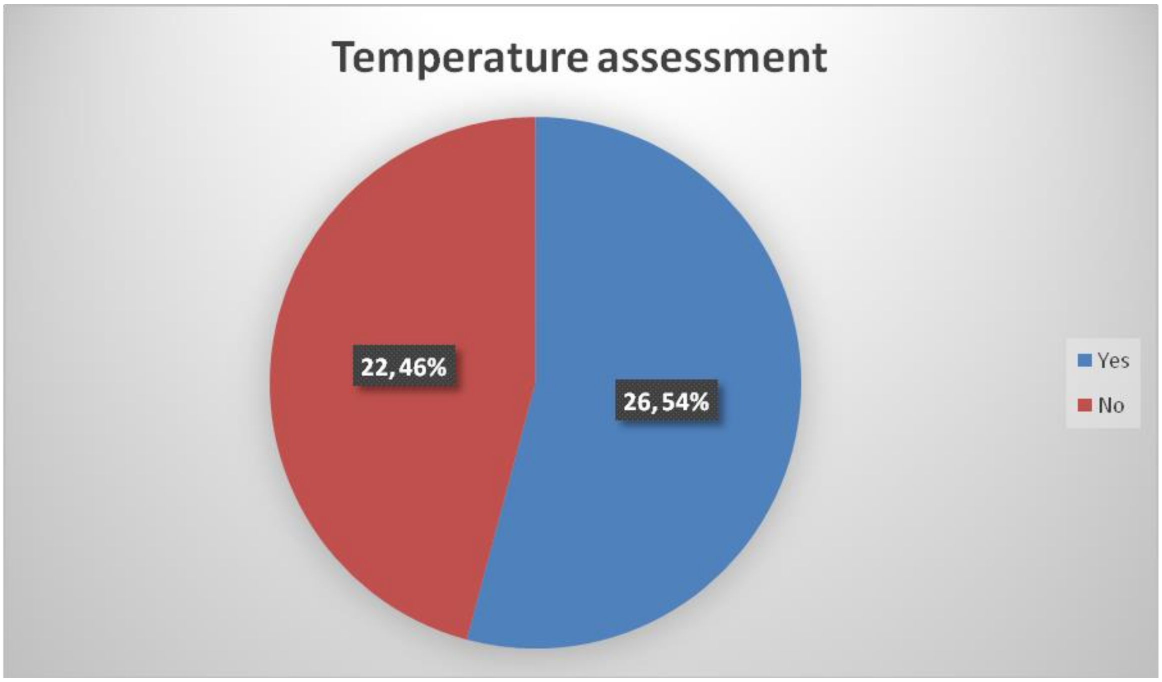


Figure 15

**Achilles reflex assessment**

**Achilles Tendon Reflex Pin Prick Sensation.** This will be carried out over the precious foot. The Neuropathy Disability scoring system (NDS) was used to term the precious foot as being neuropathic or not. There was a total of 11 patients in whom the reflex was absent, 28 of them who had the reflex present of re-enforcement and 9 patients in whom the reflex was present.

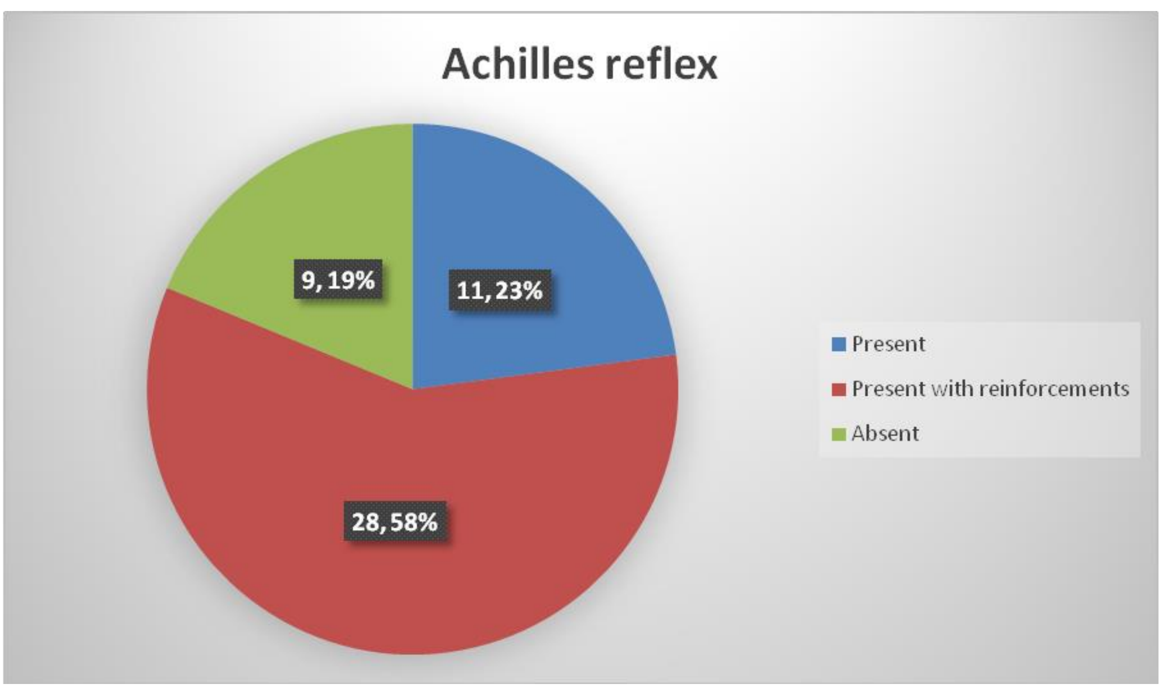


Figure 16

| **Variable** | **N (%)** |
|---|---|
| **Sex** | |
| Male | 40 (85.11) |
| Female | 8 (14.89) |
| Age, Mean (SD) | 57.1 (9.8) |
| Height, Mean (SD) | 168.2 (7.7) |
| Weight, Mean (SD) | |
| BMI, Mean (SD) | 24.5 (4.1) |
| **Current diabetic medications** | |
| 1 Only on oral hypoglycemic agents | 21 (43.75) |
| 2 Only on insulin | 15 (31.25) |
| 3Combination of the above two | 12 (25) |
| **Sensory assessment PT** | |
| 0 Normal | 7 (14.58) |
| 1 Abnormal | 41 (85.42) |
| **Sensory assessment n2g** | |

| | |
|---|---|
| 0 Able to sense | 9 (18.75) |
| 1 Unable to sense | 39 (81.25) |
| **Sensory assessment n4g** | |
| 0 Able to sense | 22 (45.83) |
| 1 Unable to sense | 26 (54.17) |
| **Sensory assessment n10g** | |
| 0 Able to sense | 29 (60.42) |
| 1 Unable to sense | 19 (39.58) |
| **Vibration pressure threshold** | |
| 0 Able to sense | 23 (47.92) |
| 1 Unable to sense | 25 (52.08) |
| **Temperature assessment** | |
| 0 Able to sense | 26 (54.17) |
| 1 Unable to sense | 22 (45.83) |
| **Achilles Reflex** | |
| 0 Normal | 11 (22.92) |
| 1 Present with re-enforcement | 28 (58.33) |
| 2 Absent | 9 (18.75) |

## DISCUSSION

The primary objective of this study was to compare the relationship between plantar pressure distribution in the contralateral foot with and without the prosthesis in diabetic patients who have undergone a below-knee amputation and have been rehabilitated. The static plantar pressures over the precious foot were found to be significantly lower with the prosthesis as compared to without the prosthesis. The changes were observed in peak plantar pressure over the precious foot with and without the prosthesis over the rehabilitated limb were in agreement with the earlier studies (43). The difference in static plantar pressures with and without the prosthesis was found to be highest in the fifth metatarsal in our study. In a study done by DV Rai et al, they had found that the highest forefoot pressures were located under the second and third metatarsal heads. This study included subjects with Hansen's disease. The pressure difference may be due to their standing posture of the patient which has become part of their daily habit. Cavanagh et all had showed that peak plantar pressures did not show a significant relationship to the body weight of subjects (44). Even in our patients there no significant relationship between the weight of the patient and the peak plantar pressures.

There was a wide range of variation in the plantar pressure of pathological subjects was in agreement with the sensory, motor, and other clinical evaluation that we had conducted in our group of patients.

The study suggests that the bipedal standing of an amputee patient who has been rehabilitated with a prosthesis does not guarantee equal plantar pressure distribution on the precious limb. The human foot attenuates potentially harmful impact shocks, and provides a sensory information regarding the contact with the ground. Pressure distribution measurement techniques are useful in the analysis and understanding of the biomechanics of human foot in bipedal standing. Orthotics are useful for the uniform distribution of plantar pressure. It was found that orthotics attenuated the peak pressure and distributed it normally on the plantar area of the foot. Plantar pressure distribution instrumentation could be used as a standard clinical tool for diagnostic and therapeutic interventions.

# CONCLUSION

The static plantar pressures were higher without the prosthesis compared to with the prosthesis and it was found to be statistically significant ($p < 0.001$). The highest pressure difference was noted over the fifth metatarsal which was 53 $N/cm^2$. The ratio of the forefoot versus the hind foot pressures with and without a prosthesis was also noted to be significant ($p = 0.002$). Even once the patient has undergone a below knee amputation and has been rehabilitated, regular inspection of the precious foot is of paramount need. This variation in the pressure distribution over the precious foot thus disproves our hypothesis that there is an equal spatial redistribution in static plantar peak pressures in the precious limb following a rehabilitation with a prosthetic device in a diabetic patient who has undergone a below knee amputation.

## Limitations

In this study we have measured only the static pressures over the precious foot with and without the prosthesis. A more accurate method to understand the pressure distribution over the precious foot will be the monitoring of dynamic plantar measurements. Long term follow up for these patients is essential.

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## ANNEXURE

**<u>Proforma for the Dissertation topic</u>**

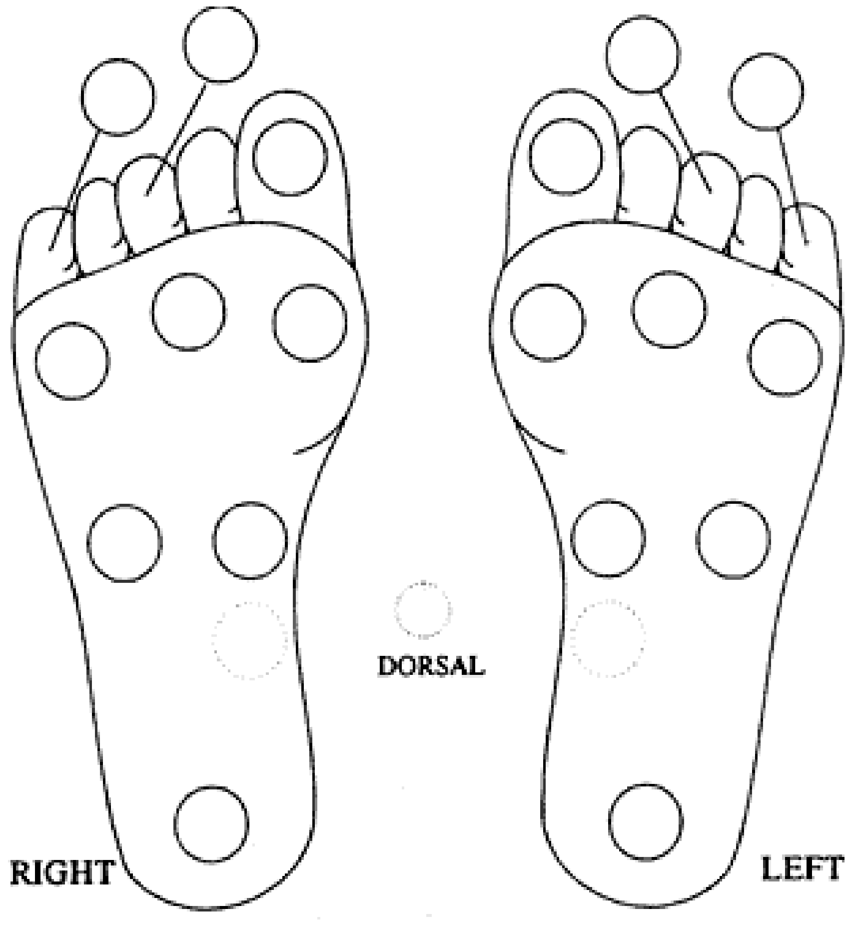
To study the characteristics of contralateral plantar pressure distribution in diabetic patients who have undergone an amputation and have been rehabilitated with a prosthetic device.

### 1) Demographic details

a) Name:
b) Age:
c) Sex:
d) Hospital number:
e) Address:
f) Contact number:
g) Duration of diabetes:
h) Current diabetic medications:
i) Height:
j) Weight:
k) Body mass Index:

### 2)Sensory assessment of the precious foot

a) Sensory assessment:
b) Vibration pressure threshold:
c) Temperature assessment:
d) Achilles Reflex:




**PICTORIAL REPRESENTATION OF THE SENSORY ASSESSMENT OF THE PRECIOUS FOOT.**

**3) Plantar pressure assessment**

| Sites of assessment | Plantar pressure assessment with prosthesis in kPa | Plantar pressure assessment without prosthesis in kPa |
|---|---|---|
| | | |
| a) First metatarsal | | |
| b) Second metatarsal | | |
| c)Third metatarsal | | |
| d)Fourth metatarsal | | |
| e) Fifth metatarsal | | |
| | | |
| f) Ratio of forefoot pressure versus hindfoot pressure | | |

**4)Biochemical assessment**

a) Fasting blood glucose level:

b) Post prandial blood glucose level:

c) $HbA_1C$ value:

**5) Photographic representation of the precious foot**

**Signature of primary investigator:**

**Signature of Guide:**

**Date:**

**INFORMED CONSENT**

**Christian Medical College, Vellore**

**Department of General Surgery**

***An observational study to study the characteristics of the plantar pressure distribution in diabetic patients in the contralateral limb who have undergone an amputation over the other limb and have been rehabilitated with appropriate prosthetic footwear***

**Information sheet**

You are being requested to participate in a study to determine the characteristics of the plantar pressure distribution in the contralateral limb following an amputation in one limb and compare these pressures with and without a prosthetic device. You have recently undergone a lower limb amputation secondary to a diabetic foot ulcer. There is 5-14% chance of you having to undergo another amputation over the contralateral limb over the next four years. This study is designed to identify that risk and prevent the subsequent amputation.

**What is the purpose of the study?**

Diabetes accounts for a majority of lower-limb amputations in the adult population. Once the patient undergoes an amputation the center of gravity of the patient automatically shifts to the contralateral lower limb. Due to this reason, it is imperative to protect the contralateral limb from going in for plantar ulcer formation and subsequent need for an amputation. After a major amputation it was found that, 5.7% and 11.5% have a contralateral major amputation at 1 and 5 years. After minor amputation, 3.2% and 8.4% have a contralateral major amputation at 1 and 5 years. The main aim of this study is to prevent this disconcerting rate of bilateral limb loss in patients with diabetes mellitus.

**What is the relation between diabetic foot amputations and prosthetic devices?**

It has been shown that the use of prosthetic devices not only protects the limb that has undergone some form of amputation, but also redistributes the plantar pressure of the contralateral limb to prevent ulcer formation over the precious foot and the need for a subsequent contralateral amputation.

**If you take part what will you have to do?**

If you agree to participate in this study, you will be asked a few questions about your age, duration of diabetes and the medications that you are using for diabetes and your height and weight will be measured. We will also be checking your feet for signs of nerve damage along with the plantar pressure assessment of the precious limb with and without the prosthetic device. We will also be collecting a single blood sample using standard precautions, to measure the fasting and post- prandial blood glucose levels and the glycosylated blood sugar levels. We will also be collecting information regarding some blood tests previously performed in this hospital, from the medical records system.

All other treatments that you are already on will be continued and your regular treatment will not be changed during this study. No additional procedures or blood tests will be conducted routinely for this study.

**Can you withdraw from this study after it starts?**

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

**What will happen if you develop any study related injury?**

We do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at no cost to you. We are unable to provide any monetary compensation, however.

**Will you have to pay for the blood test?**

The blood test taken from you will be performed free of cost for the purpose of this study.

Any other treatment that you usually take will continue but the usual arrangements that you have with the hospital will decide how much you pay for this.

**Will your personal details be kept confidential?**

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

**If you have any further questions, please ask Dr. COELHO VICTOR VIJAY F, (Tel: 0416 2282082/ +91 9943422313) or email: vvcoelho.m07@cmcvellore.ac.in/ vvcoelho.m07@gmail.com**

**CONSENT TO TAKE PART IN A CLINICAL TRIAL**

**Study Title**: *An observational study to study the characteristics of plantar pressure distribution in the contralateral limb in diabetic patients who have undergone a below knee amputation and have been rehabilitated with a prosthesis.*

**Study Number:**

**Participant's name:**

**Date of Birth / Age (in years)**:

I_______________________________________________________________

___________, son/daughter of____________________________________

(Please tick boxes)

Declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ]

I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]

I understand that I will NOT receive free treatment for any study related injury or adverse event but I will not receive and other financial compensation [ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]

I understand that my identity will not be revealed in any information released to third parties or published [ ]

I voluntarily agree to take part in this study [ ]

Name:

Signature:

Date:

Name of witness:

Relation to participant:

Date: