# ASSESSMENT OF RESIDUAL FUNCTIONAL STATUS AND QUALITY OF LIFE IN FOOT AMPUTEES AT A TERTIARY VASCULAR SURGERY CENTRE – AN INSTITUTIONAL BASED PROSPECTIVE STUDY

By

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**Regn No : 333-27112-202-230563**

Dissertation submitted to the National Board of Examinations, New Delhi

in partial fulfilment of the requirements for the degree of

**DOCTORATE OF NATIONAL BOARD (DrNB)**

In

**PERIPHERAL VASCULAR SURGERY**

**(ACADEMIC YEAR 2020-2023)**

under the guidance of

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Dissertation submitted to the National Board of Examinations, New Delhi, in partial fulfilment of the requirements for the award of the Doctorate of National Board (DrNB) in the super specialty of Peripheral Vascular Surgery

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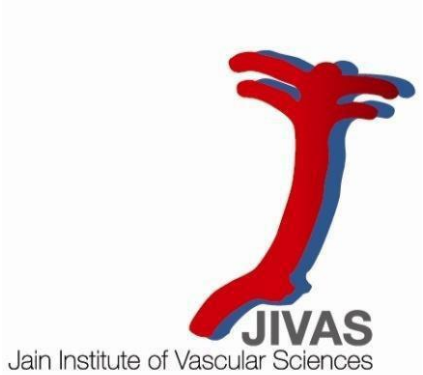


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The interpretations put forth are based on my reading and understanding of the original texts and they are not published anywhere in the form of books, monographs or articles. The other books, articles and websites, which I have made use of are acknowledged at the respective place in the text.

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Place : Bengaluru

August 2023

## TABLE OF ABBREVIATIONS AND ACRONYMS

| | | |
|---|---|---|
| 2MWT | - | 2 Minute Walk Test |
| 6MWT | - | 6 Minute Walk Test |
| 12MWT | - | 12 Minute Walk Test |
| ABI | - | Ankle-Brachial Index |
| AKA | - | Above Knee Amputation |
| AMC LDS | - | Amsterdam Academic Medical Centre Linear Disability Score |
| AP | - | Ankle (systolic) pressure |
| BKA | - | Below Knee Amputation |
| COPD | - | Chronic Obstructive Pulmonary Disease |
| CKD | - | Chronic kidney disease |
| CLI | - | Critical limb ischemia |
| CLTI | - | Chronic limb-threatening ischemia |
| CV | - | Cardio-Vascular |
| CVA | - | Cerebrovascular Accident (also known as Stroke) |
| CVD | - | Cardiovascular disease |
| DAMA | - | Discharge against Medical Advice |
| DFI | - | Diabetic Foot Infection |
| DFU | - | Diabetic foot ulcer |
| DM | - | Diabetes Mellitus |
| DVT | - | Deep Vein Thrombosis |
| FS | - | Functional Score (in AMC LDS) |
| GVG | - | Global Vascular Guidelines (in Vascular Surgery) |
| IC | - | Intermittent claudication |
| IHD | - | Ischaemic Heart Disease |
| LCI-5 | - | Locomotor Capability Index – 5$^{th}$ version |
| LOPS | - | Loss of Protective Sensation |
| MACE | - | Major Adverse Cardiovascular Event |
| MALE | - | Major Adverse Limb Event |
| MI | - | Myocardial Infarction |
| PAD | - | Peripheral artery disease |
| PAOD | - | Peripheral Arterial Occlusive Disease |
| OHA | - | Oral Hypoglycaemic Agent |
| OM | - | Osteomyelitis |
| OPD | - | Out Patient Department |
| SD | - | Standard Deviation |
| SIRS | - | Systemic Inflammatory Response Syndrome |
| SSG | - | Split Skin Grafting |
| SVS | - | Society of Vascular Surgery |
| SVT | - | Superficial Venous Thrombosis |
| TcPO2 | - | Transcutaneous oximetry |
| TMA | - | Trans Metatarsal Amputation |
| TUG | - | Timed Up-and-Go Test |
| UGI | - | Upper Gastro-intestinal |
| VasQOL | - | Vascular Quality of Life Index Questionnaire |
| WHO | - | World Health Organisation |
| WIFI | - | Wound, Ischemia, Foot Infection |

# ABSTRACT

**Title**: Assessment of residual functional status and quality of life in foot amputees at a Tertiary Vascular Surgery Centre – An Institutional based Prospective Study.

**Aims and Objectives**:

1. To evaluate and follow up patients undergoing foot amputation at JIVAS, Bengaluru

2. To evaluate the pre-op (baseline) condition of the wound at presentation, patient factors and ambulatory status and foot condition.

3. To follow up and regularly assess during the post-operative period; the ability of the patient to balance, stand and walk (with or without support) and evaluate any difficulties, gait disturbances and walking speed with comparison to the pre-operative status under the same parameters.

4. To compare the post-operative wound status and foot condition during the postoperative follow up visits and correlate the same with the ambulatory status of the patient, ability to balance and other indices of ambulation.

5. To ultimately create a standard institutional protocol and rehabilitation program for all foot amputees and predict / avoid complications in postoperative / follow up period.

**Materials and Methods**:

This is a Single Centre, Prospective Observational Study carried out at Jain Institute of Vascular Sciences (JIVAS), Bhagwan Mahveer Jain Hospital Bengaluru. It followed the progress and recovery of 366 patients (Study Population) who underwent foot amputation at this Centre from 1st Jan 2021 to 31st Dec 2021. They were evaluated at presentation for their comorbidities and standard Tests of Ambulation (Bergs Balance Test, AMC Linear Disability Score and LCI-5 Index, TUG Test and 2MWT) were conducted to determine their baseline ambulatory / performance status. Following admission and Amputation Surgery the patients who fulfilled the Inclusion Criteria (Sample Size = 311) were followed up at 1 week, 1 month, 2 months, 3 months and 6 months during which they were again subjected to the Tests of Ambulation.

At each stage of the Study follow up period the patients' standing and walking capability were assessed and compared. This was done to compare level of amputation and wound status to the performance Scores of the Ambulatory Tests for assessment for overall improvement in function at the relevant follow up period.

**RESULTS**

The Study followed up 311 patients - 317 (84.08%) men and 60 (15.92%) women following their foot amputation at JIVAS. Diabetes Mellitus (344, 91.25%), Hypertension (230, 61.01%) and IHD (135, 35.81%) were the most common comorbidities. They were subdivided into CLTI / ischaemic (281, 74.54%) and non ischaemic / DFU (96, 25.46%) wounds however the groups were arbitrary and not

significant in the follow up period (since all CLTI patients underwent revascularisation). The results of Berg Balance Test over the course of follow up revealed significant association between the level of toe amputation (whether the 1st toe was amputated or not and TMAs) in follow up improvement in the Scores. Similarly the TUG, LCI-5 scores and AMC LDS was also significantly associated with the level of amputation as well as independently associated with the rate of wound healing and foot condition (presence of wound calluses and deformities). 1st Toe amputation (for Ray amputations) and TMAs had the most significant association with post op return to functional status. Similarly the patients' gait was also evaluated (as a part of the 2MWT and independently) and was shown to be significantly related to the level of amputation, wound healing and foot deformity. The Study had a large number of Adverse events and loss to follow up at all stages, confirming with the natural history of CLTI and foot sepsis.

**CONCLUSIONS**:

The level of foot amputation (number of toes) and especially involvement of the 1st Toe was found to be significantly associated with delayed return to functional ambulatory status in the early postop period. The Berg Balance Test was the mainstay of assessment during the Study and had excellent sensitivity, specificity and predictive value in assessing the patients' functional status at all points of follow up. Majority of patients graduated from walker to walking stick to even able to walk without support by the end of the Study. The progressive assessment of gait also showed improvement over follow up. This rate of recovery was significantly and directly related to the level of amputation (including which toe was amputated), rate of wound healing, and development of foot complications.

# TABLE OF CONTENTS

# INTRODUCTION

# INTRODUCTION

The specialty of Vascular Surgery deals with diseases of the circulatory system, primarily arterial and venous disorders. Occlusion or reduction of the blood flow in the arteries leads to ischaemia in the distal vascular beds.

The most common vascular bed dealt in Vascular Surgery is the lower limbs. Chronic Limb Threatening Ischaemia (CLTI) – earlier known as Critical Limb Ischaemia (CLI) is defined as Peripheral Arterial Disease (PAD) in association with rest pain and / or tissue loss in the form of ulceration or gangrene. Majority of these patients need major or minor amputations for the control of foot sepsis which is then followed by a revascularization procedure.

Diabetes Mellitus is an extremely common disorder among large proportion of the world population. One of the most common presentations of its many complications is a non-ischaemic Diabetic Foot Ulcer (DFU). DFUs are notoriously difficult to treat due to their multifactorial aetiology, and foot amputations are a very common end stage surgical procedure in infected DFUs.

Control of foot sepsis in the form of removal of the unhealthy and / or gangrenous tissue is the first step in preparing a threatened limb for preservation / revascularisation and healing. Surgical debridement of the infected (wet gangrene) tissue freshens the otherwise chronic and stunned wound and creates an acute fresh wound bed.

However, any amputation no matter the extent - whether minimal or major results in functional as well as psychological setback to the patient who usually at this point is already dealing with multiple comorbidities at the time of presentation. Early rehabilitation of the patient with ambulation and confidence in walking even with support is vital in improving the confidence of the amputee. Hence amputation should not be considered a failure of treatment, but a step toward rehabilitation and treatment of the patient and his / her symptoms.

This study aimed to follow up to-forefoot-only amputees managed at our institution and evaluate their recovery, return to ambulant status and quality of life parameters during their follow up period.

# AIMS AND OBJECTIVES

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1. To evaluate and follow up patients undergoing foot amputation at JIVAS, (BMJH, Vasanth Nagar) Bengaluru

2. To evaluate the pre-op (baseline) condition of the wound at presentation, patient factors and ambulatory status and foot condition.

3. To follow up and regularly assess during the post-operative (post amputation) period; the ability of the patient to balance, stand and walk (with or without support) and evaluate any difficulties, gait disturbances and walking speed with comparison to the pre-operative status under the same parameters.

4. To compare the post-operative wound status and foot condition during the follow up visits and correlate the same with the ambulatory status of the patient, ability to balance and other indices of ambulation throughout follow up period.

5. To evaluate the patients' recovery and return to daily living functional status.

6. To eventually create a standard institutional protocol and rehabilitation program for all foot amputees and predict / avoid complications in postoperative / follow up period.

# REVIEW OF LITERATURE

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## HISTORY

Amputations and foot debridement procedures form a major proportion of Vascular Surgery operations. The Specialty of Vascular Surgery involves management of the peripheral vasculature, primarily arterial and venous disorders.

Amputations are one of the oldest surgical procedures, with records dating back to the Egyptian and ancient Indian texts. The earliest confirmed evidence of an amputation is the skeletal remains of a child discovered in Borneo, Indonesia who underwent a forearm amputation almost 31000 years ago [(1)]. Amputation as a definite treatment for non-salvageable gangrene was first described by Celsus in the 1st Century AD [(2)]. The operative techniques were refined over the years. With the advent of anaesthesia the field of surgery also underwent a sea change with drastic fall in mortality and morbidity. The introduction of specialised instruments (vascular clamps and ligatures instead of boiling oil cauterisation) by the great Ambroise Pare [(3)]; and the use of tourniquets by the French surgeon-barber Morell during injured limb amputations in the battle of Besancon (1674) [(4)] led to even further improvement in perioperative mortality rates following major amputation.

## ETIOPATHOGENESIS OF VASCULAR DISEASES:

Atherosclerosis forms the major etiological process in the arterial tree which constitutes the deposition of fibrofatty plaques within the vessel wall. Advanced atherosclerosis leads to progressive reduction in the diameter of the arterial lumen, with resultant paucity of distal blood flow into the distal tissues [(5)]. Primarily atherosclerosis related Cardiovascular disease (CVD) - Myocardial Infarction (MI) and Stroke / Cerebrovascular Accidents (CVA) are the major causes of mortality and morbidity, representing the first and third most common causes of all-cause mortality [(5)]. With the advent of and recent advances in modern medical management, there is an overall reduction in number of deaths due to these CVDs.

However, this has simultaneously translated into the overall increase in the proportion of other Cardiovascular (CV) bed symptomatic involvement. The next important CV bed to be affected are the arteries of the limbs – constituting Peripheral Arterial Occlusive Disease (PAOD) which is nowadays known as Peripheral Arterial Disease (PAD). Other CV beds are the gastrointestinal tract (Mesenteric vessels causing Mesenteric Ischaemia) and Renal arteries.

Involvement of the limb vasculature and reduced blood flow results in Critical Limb Ischaemia (CLI); now known as Chronic Limb Threatening Ischaemia (CLTI) [(6)]. Conversely, CLTI is defined as presentation of PAD in the form of rest pain and / or tissue loss (ulceration or gangrene) [(7)]. Lower extremity PAD affects more than 200 million people worldwide, and up to 10% of people with PAD have CLI/CLTI. Over five years, between 5-10% of patients with asymptomatic PAD or minimal symptoms with intermittent claudication, may progress to CLI/CLTI [(8)].

The Rutherford classification [(9)] was one of the first systems to systematically divide (as it was then known) CLI based on symptoms as well as reproducible clinical examination parameters. It is the most used classification system today. It sub-divides the spectrum of presenting signs and symptoms in PAD from asymptomatic (Category 0) to major tissue loss (Category 6) and is described in Table 1 below:

**Table 1 : Rutherford Classification of Ischaemic Wounds**

| Grade | Category | Clinical description | Objective criteria |
|---|---|---|---|
| 0 | 0 | Asymptomatic—no hemodynamically significant occlusive disease | Normal treadmill or reactive hyperemia test |
| | 1 | Mild claudication | Completes treadmill exercise; AP after exercise > 50 mm Hg but at least 20 mm Hg lower than resting value |
| I | 2 | Moderate claudication | Between categories 1 and 3 |

| | | | |
|---|---|---|---|
| | 3 | Severe claudication | Cannot complete standard treadmill exercise, and AP after exercise < 50 mm Hg |
| II | 4 | Ischemic rest pain | Resting AP < 40 mm Hg, flat or barely pulsatile ankle or metatarsal PVR; TP < 30 mm Hg |
| III | 5 | Minor tissue loss—nonhealing ulcer, focal gangrene with diffuse pedal ischemia | Resting AP < 60 mm Hg, ankle or metatarsal PVR flat or barely pulsatile; TP < 40 mm Hg |
| | 6 | Major tissue loss—extending above TM level, functional foot no longer salvageable | Same as category 5 |

Gangrene is defined as tissue damage secondary to infection, ischemia, or both. It is a clinical condition of ischemic and necrotic tissue, often circumferential around a digit or extremity. It is identified by discoloured or black tissue and associated sloughing of natural tissue planes [(10)]. It is the end stage of PAD, clinically classified as Rutherford 5 or 6 depending on the extent.

Gangrene is of three types. Dry gangrene is dehydrated ischemic tissue caused by progressive ischemia distal to arterial occlusion. Wet gangrene is a complication of dry gangrene followed by secondary bacterial infection, presenting with foul smell, pus or discharge and erythema, Gas gangrene is a fulminant condition with widespread necrosis of tissues secondary to infection with Clostridium perfringens (but also could be secondary infection of tissues with Escherichia coli, Bacteroides, Staphylococcus epidermidis, and streptococcal infections) presenting with crepitus and gas shadows on X-rays [(10) (11)].

The staging of severity of CLTI is multifactorial. Previously used systems which were popular before the introduction of Rutherford Staging were the Fontaine staging [12], Wagner staging [13] among others.

The various classification systems are enumerated below, and most of them can be clinically correlated with each other.

**Table 2 : Fontaine Staging of Ischaemic Foot wounds**

| **Stage** | | **Symptoms** |
|---|---|---|
| I | | Asymptomatic, incomplete blood vessel obstruction |
| II | A | Mild claudication pain (distance >200m) |
| | B | Moderate to severe claudication pain (distance <200m) |
| III | | Rest pain |
| IV | | Tissue loss (necrosis, ulcer or gangrene) |

**Table 3 : Wagner Grading of infected foot wounds**

| **Grade** | **Description of the wound** |
|---|---|
| 0 | No open lesion or a pre-ulcerative lesion. May have deformity or cellulitis |
| 1 | Partial- or full-thickness ulcer (superficial) |
| 2 | Deep ulcer extending to ligament, tendon, joint capsule, bone, or deep fascia without abscess or osteomyelitis (OM) |
| 3 | Deep abscess, OM, or joint sepsis |
| 4 | Partial / forefoot gangrene |
| 5 | Whole foot gangrene |

The older concept of Critical Limb Ischaemia (CLI) was very precise and hence restricted in definition, being defined as rest pain associated with ankle systolic pressure (AP) less than 40mm Hg, Ankle Brachial Index (ABI) less than 0.4 or tissue loss associated with AP less than 60mm Hg [14]. This definition did not include Diabetes Mellitus as a cause of tissue loss or infection and / or ischaemia. It was then opined that diabetic patients had a combination of foot sepsis, neuropathy and ischaemia which would make a specific diagnostic cutoff

very difficult. They recommended that diabetics be included in a separate category of foot sepsis itself. Hence it is clear that even in the infancy of Vascular Surgery, Diabetes was identified as a primary aetiology for non-ischaemic gangrene and foot infection even though its significance could not be quantified.

Non-ischemic gangrene may also occur in limbs with intact peripheral pulses due to thrombosis in the microcirculation. Venous limb gangrene causes microthrombi as a part of acute deep vein thrombosis (DVT) coexisting with Superficial venous thrombosis (SVT) clinically known as *Phlegmasia cerulia dolens*. Symmetric peripheral gangrene is another condition where multiple limbs may develop symmetric gangrene despite adequate perfusion; for example, purpura fulminans in Neisseria meningitidis with systemic septicaemia [(15)].

A major cause of non-ischaemic foot and limb amputation is Diabetic Foot Infections (DFIs). In 2016, the World Health Organisation (WHO) declared Diabetes to be a world-wide epidemic [(16)] (at par with a pandemic) and predicted an immense financial as well as medical burden on the global scale in the future. The longer life expectancy of diabetic patients brought about an increase in the incidence of complications. Prime among the complications enumerated in the report was an increased risk of neuropathy, non-ischaemic DFUs and resultant lower limb amputations.

The University of Texas Wound Classification System (Table 4) was one of the first attempts to classify non-ischaemic (primarily hyperglycaemia and its complications induced) foot infections [(17)]. Another classification system is the PEDIS (Perfusion, Extent, Depth, Infection and Sensation) Score - it has excellent capability in prediction of the outcome of DFUs[(18)].

**Table 4 : The University of Texas Staging System for Diabetic Foot Ulcers**

| Stage | Grade 0 | Grade I | Grade II | Grade III |
|---|---|---|---|---|
| A | Pre- or post-ulcerative lesion completely epithelialized | Superficial ulcer, not involving tendon capsule or bone | Ulcer penetrating to tendon or capsule | Ulcer penetrating to bone or joint |

| | | | | |
|---|---|---|---|---|
| B | Infection | Infection | Infection | Infection |
| C | Ischaemia | Ischaemia | Ischaemia | Ischaemia |
| D | Infection and Ischaemia | Infection and Ischaemia | Infection and Ischaemia | Infection and Ischaemia |

Presently the WIfI (Wound, Ischaemia, Foot Infection) Staging is the most recent classification of foot sepsis. Established by the Society of Vascular Surgery (SVS) [19] it is an exhaustive system that uses a combination of wound characteristics (W), severity of limb ischemia (I), and the presence of infective parameters (FI) to stage the wound. It provides prognostic guidance regarding treatment recommendations and has more or less accurately shown to predict the response to revascularization. Patients can also be clinically staged by the risk of amputation based on the wound staging.

**Table 5 : WIfI Staging System of Foot Wounds**

| **Wound (W)** | | |
|---|---|---|
| Grade | Ulcer | Gangrene |
| 0 | No ulcer | No gangrene |
| 1 | Small, shallow ulcer on distal leg or foot; no exposed bone, unless limited to distal phalanx | No gangrene |
| 2 | Deeper ulcer with exposed bone, joint, or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement | Gangrenous changes limited to digits |
| 3 | Extensive, deep ulcer involving forefoot and/or midfoot; deep, full-thickness heel ulcer ± calcaneal involvement | Extensive gangrene involving the forefoot/midfoot; full-thickness heel necrosis ± calcaneal involvement |
| | | |

| **Ischaemia (I)** | | | |
|---|---|---|---|
| Grade | ABI | Ankle Systolic Pressure | Toe Pressure / TcPO2 |
| 0 | ≥ 0.80 | > 100 mm Hg | ≥ 60 mm Hg |
| 1 | 0.6–0.79 | 70–100 mm Hg | 40–59 mm Hg |
| 2 | 0.4–0.59 | 50–70 mm Hg | 30–39 mm Hg |
| 3 | ≤ 0.39 | < 50 mm Hg | < 30 mm Hg |
| | | | |
| **Foot Infection (FI)** | | | |
| Grade | Clinical Manifestations of Infection (at least 2 of the following) :<br>• Local swelling or induration<br>• Erythema 0.5–2 cm around the ulcer<br>• Local tenderness or pain<br>• Local warmth<br>• Purulent discharge (thick, opaque to white, or sanguineous secretion) | | |
| 0 | No symptoms or signs of infection - Exclude other causes of an inflammatory response of the skin (trauma, gout, acute Charcot, fracture, thrombosis, venous stasis) | | |
| 1 | Local infection involving only the skin and the subcutaneous tissue | | |
| 2 | Local infection with erythema >2 cm, or involving structures deeper than skin and subcutaneous tissues, and no systemic inflammatory response signs | | |
| 3 | Local infection with the signs of SIRS, as manifested by two or more of the following:<br>• Temperature > 38 or < 36°C<br>• Heart rate > 90 beats/min<br>• Respiratory rate > 20 breaths/min or PaCO2 < 32 mm Hg<br>• White blood cell count > 12,000 or < 4,000 cu/mm or 10% immature bands | | |

**Table 6 : Estimation of risk of amputation at 1 year - WIfI classification**

| | Ischemia – 0 | | | | Ischemia – 1 | | | | Ischemia – 2 | | | | Ischemia – 3 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| W-0 | VL | VL | L | M | VL | L | M | H | L | L | M | H | L | M | M | H |
| W-1 | VL | VL | L | M | VL | L | M | H | L | M | H | H | M | M | H | H |
| W-2 | L | L | M | H | M | M | H | H | M | H | H | H | H | H | H | H |
| W-3 | M | M | H | H | H | H | H | H | H | H | H | H | H | H | H | H |
| | fI-0 | fI-1 | fI-2 | fI-3 | fI-0 | fI-1 | fI-2 | fI-3 | fI-0 | fI-1 | fI-2 | fI-3 | fI-0 | fI-1 | fI-2 | fI-3 |

VL – Very Low Risk (Stage 1)

L – Low Risk (Stage 2)

M – Moderate Risk (Stage 3)

H – High (Stage 4)

**Table 7 : Estimation of benefit of revascularisation - WIFI Classification**

| | Ischemia – 0 | | | | Ischemia – 1 | | | | Ischemia – 2 | | | | Ischemia – 3 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| W-0 | VL | VL | VL | VL | VL | L | L | M | L | L | M | M | M | H | H | H |
| W-1 | VL | VL | VL | VL | L | M | M | M | M | H | H | H | H | H | H | H |
| W-2 | VL | VL | VL | VL | M | M | H | H | H | H | H | H | H | H | H | H |
| W-3 | VL | VL | VL | VL | M | M | M | H | H | H | H | H | H | H | H | H |
| | f-0 | fI-1 | fI-2 | fI-3 | fI-0 | fI-1 | fI-2 | fI-3 | fI-0 | fI-1 | fI-2 | fI-3 | fI-0 | fI-1 | fI-2 | fI-3 |

The major foot complications of DFUs are cellulitis, abscesses, dry gangrene, wet gangrene, and necrotizing fasciitis. Each of these endpoints have different pathophysiological concepts and there is a grey zone between each of them where symptoms can overlap [(20)]. The spectrum of defining gangrene saw a shift from a purely ischaemic cause to a multi-factorial aetiology.

The risk of a diabetic undergoing an amputation is almost 20 to 30 times that of a non-diabetic [(21)]. DFU is the single most common precursor lesion leading to a foot amputation in a non-ischaemic limb [(22)]. 85% of diabetic patients

presenting with a non-healing ulcer will end up with an amputation [23]. Diabetics who develop a foot ulcer have an annual mortality rate of almost 10%, which spikes to 20% if they undergo an amputation [24].

The pathophysiology of Diabetic foot ulcers is multifactorial. Peripheral neuropathy and PAD are the major risk factors, co-existing with soft tissue infection, tissue oedema, altered limb biomechanics, poor glycaemic control and advanced age along with prolonged diabetic course [25]. Diabetic Neuropathy is a mixed neuropathy, comprising somatic (motor and sensory) and autonomic. Somatic sensory neuropathy is a progressive loss of sensations in the foot also known as LOPS (Loss of Protective Sensation). Motor neuropathy involves wasting of the leg muscles (more affected are the anterior compartment) and flexor-extensor imbalance. This leads to hammer and claw toe deformity and equinus deformity of the foot with abnormal pressure points in the forefoot and toe tips [26]. Sympathetic autonomic nerve dysfunction results in reduced sweating. This causes higher risk of cracking and fissure formation due to dry and fragile skin. This neuropathy can also result in arterial–venous shunting and impaired microvascular regulation of the skin [27]. PAD in diabetics is primarily infrapopliteal (below the level of the knee joint – affecting the tibial vessels) in distribution, classically presenting with heavily calcified arteries which are non-compressible. Abnormalities in the macro and distal microvascular circulation are seen in diabetics, which can result in non-healing ulcers in the digits with ischaemic properties despite palpable pedal pulses.

The aim of Vascular Surgery is limb salvage, i.e. primarily to heal the wound / prevent limb loss and to re-establish adequate arterial blood flow into the foot. Revascularisation forms a prime management of ischaemic ulcers, and it also is an important method of preventing extension of gangrene. However, end stage tissue damage in the form of gangrene needs amputation of the affected extremity.

The management of wet and gas gangrene is amputation of the affected digit or extremity. This is done to prevent proximal extension of the tissue infection. In case of dry gangrene auto-amputation can be considered after complete demarcation of the ischaemic extremity, however surgical amputation is preferred

to avoid risk of development secondary infection which will lead to wet gangrene, which results in more extensive tissue loss due to oedematous tissue and attempt to achieve infection free margins [28].

Foot debridement and amputation form a major proportion of surgical procedures in Vascular Surgery. Control of infection and removal of the gangrenous tissue is the first step in preparing a threatened limb for revascularisation and healing. Surgical debridement of the infected (wet gangrene) tissue freshens the otherwise chronic and stunned wound and creates an acute fresh wound bed [29].

**Types of Lower limb Amputations**

Only the amputation levels considered in this study are described below.

1. Ray Amputation – It is performed for gangrene of a single toe without medial or lateral extension through the adjacent web-spaces. Deep extension of an ulcer with evidence of Osteomyelitis is also an indication for toe amputation. Ray amputation involves excision of the head of the Metatarsal along with the toe, thus exposing the shaft of the Metatarsal (the Ray). A tennis racquet skin incision with the 'head' of the racquet surrounding the base of the toe and the handle along the dorsum of the foot overlying the Metatarsal shaft till the mid shaft level. The first and 5$^{th}$ toes Ray amputation involves aligning the handle of the racquet along the medial or lateral border of the foot respectively. Any sesamoid bones encountered are resected and exposed tendons are sharply divided under traction and allowed to retract into the foot.

2. Trans Metatarsal Amputation (TMA) - First defined by McKittrick in 1949 [30] and modified by Wagner [31]. Amputation of 1 or even two digits does not alter foot biomechanics much. However the removal of three toes or more, especially if the 1$^{st}$ toe is included leads to major alteration in pressure dynamics in weight bearing and walking. Hence the Trans-Metatarsal Amputation (TMA) is advocated for extensive forefoot gangrene or infections. The incision extends from midshaft of 1$^{st}$ Metatarsal level to that of the 5$^{th}$ Metatarsal. The soft tissues are divided along

the level of the incision and the bones are osteotomized just proximal to the skin incision level with a bone saw (Gigli or mechanical).

3. Multiple Toe Amputation – Combination of 2 or more toes being amputated similar to Ray Amputation.

**Higher levels of foot amputation** [32]

These amputations result in extreme instability of the foot and ankle along with high risk of foot and ankle contracture deformities. This occurs due to unopposed action of the Tendoachilles. The patients usually require special prostheses or ankle-foot orthotic footwear to balance. These amputations were not included in the Study.

1. Lisfranc Amputation - Disarticulation of the first, third, fourth, and fifth tarsometatarsal joints, with osteotomy of the second metatarsal 1 to 2 cm distal to the medial cuneiform.
2. Chopart's Amputation – Disarticulation is done at the level of the talo-calcaneo-navicular joint and the calcaneo-cuboid joint.
3. Syme's Amputation - Disarticulation of the ankle joint with division of the medial and lateral malleoli at the level of the articular surface of the Tibia.

**Consequences of Amputation**

The feet act as uniquely adapted end organs of weight bearing. Following amputation, the residual limb must assume the tasks of load transfer, adapting to uneven terrain and propulsion. This involves re-learning the basics of locomotion and utilizing tissues that are not biologically engineered for the purpose of walking [33].

Normal walking involves a complex series of events, defined as the gait cycle [34]. It starts when the heel of one foot strikes the ground and ends when that

same heel touches the ground again and is divided into 2 phases – stance (when the foot is on the ground and bearing weight) and swing (while the foot is in the air and moving forward in the air)

**Stance phase** is subdivided into 5 sub-phases :

(a) Heel strike – initial contact of the heel with the ground and transfer of the body weight to that limb

(b) Foot flat – loading response, the body weight is transferred ahead, foot rolls forward till the entire plantar surface is in contact with the ground.

(c) Midstance – the body is driven pushed even further forward, causing the greater trochanter of the femur to be exactly above the middle of the foot. The entire weight is now on the index limb.

(d) Heel-off – the heel lifts off the ground, the forefoot rolls anteromedially and the body weight is now distributed between the base of 1$^{st}$ toe and the opposite foot heel.

(e) Toe-off – plantarflexion of the ankle occurs and the toes are also pushed off the ground, beginning the swing phase.

**Swing phase** is subdivided into three phases:

(a) Early swing – acceleration phase involving ankle dorsiflexion with simultaneous knee and flexion. It lasts till the mid-foot is brought directly below the level of the body's centre of gravity.

(b) Mid-swing – The foot continues to swing forward, lasting from the time the foot swings past the body's centre of gravity and crosses the contralateral leg. It coincides with the other limb's midstance phase.

(c) Late swing – deceleration phase where the foot slows down, descends with extension of the hip and knee; and brought into position for the heel strike.

**Gait**

Gait is a multi-joint and multi-organ / multi-system activity. Multiple muscle groups and joints concurrently are in synchronous activity along with the central

and peripheral nervous systems to ensure proper walking. The most common gait disturbances seen following a foot amputation are: [35]

(a) Antalgic / painful gait – shorter stance phase of the involved limb, coinciding with shorter swing phase of contralateral limb. Associated with decreased walking speed and decreased cadence (steps per minute). Also known as "limping gait."

(b) Arthrogenic gait – Due to abnormal joint mobility. Seen in case of stiff joints (following glycosylation of joint capsule proteins in uncontrolled Diabetes) and Charcots. The most common sign is the dragging of the toe tips on the ground during the swing phase.

(c) Trendelenberg gait – Seen due to weakness of the contralateral (stance) limb hip flexors (Gluteus medius and minimus). This causes the free (swing) side of the pelvis to drop downward. This results in hip swinging / wobbling.

(d) Steppage / foot drop gait – Most commonly seen in Neuropathy. Weak foot dorsiflexors prevent the ankle dorsiflexion in the early stance phase, resulting in the toes continuing to point toward the ground. The toes again may drag along the ground during walking, predisposing to toe tip injuries, ulcers and calluses. The person overcompensates with increased knee flexion resulting in a marching sort of walk.

(e) Equinus gait – Seen in high TMAs or complete resection of the 5th Metatarsal where the Peroneus muscles are detached from their insertions. There is unopposed action of the Tibialis muscles, club-foot deformity is seen and walking / weight bearing is done mainly by the dorsolateral / lateral border of the foot.

**Tests of Balance and Ambulation** :

The main objective of patient rehabilitation following amputation (major or minor) is to restore independent standing, balance and walking either with support or prosthesis. This ensures that the patient is confident to attempt return to his activities prior to the onset of foot sepsis / gangrene, considering optimal conditions of safety and comfort [36]. The very activity of independent walking also guarantees improvement in the patient's morbidity and mortality parameters [37]. Functional assessment is hence needed to quantify the patient's true ability in terms of walking autonomy and to detect those factors that limit his mobility. The tests

planned to be used had the following characteristics (the tests have been adopted from the evaluation of transfemoral / above knee and transtibial / below knee amputates):

(a) Relevant to the outcome measures and parameters being measured for the evaluation of ambulation status of the patient, as considered by experts in the fields of rehabilitation and balance.

(b) Should be compatible with use in everyday clinical practice – allowing for rapid evaluation and interpretation in an OPD setup without much loss of time.

(c) Should not need expensive equipment (especially for evaluation of biomechanics and gait)

(d) Applicable to any amputee, regardless of age, aetiology of amputation, level of amputation and type of prosthesis.

**Berg Balance Scale / Berg Balance Test** [38]**:**

It is the most widely used clinical test to evaluate balance disorders, evaluating the ability of the patient to maintain balance in different situations. The patient is made to perform a series of 14 different exercises and the ease of performance of each is measured on an ordinal scale from 0 to 4. The final total score compares to the balance capability of the patient. The test was designed for evaluation of stroke patients' recovery however; it has shown high reliability and validity even in amputees [39]. The components of the Berg Balance Test are enumerated in Annexure 2.

The test has excellent intra-examiner and inter-examiner reliability and test-retest reproducibility. It correlates well with instrumental tests of biomechanics [40]. The test does not examine gait, only the balance capability of the patient in one position; but ability and ease of change of posture is evaluated. It has been proven that balance has a high association with gait performance of amputees; that is higher capability of balance causes improved walking ability and thus better quality of life [41].

**Locomotor Capability Index (LCI-5)**

It is a 14-item questionnaire (Table 9) specifically designed to measure the walking capability of lower limb amputees [42]. It evaluates the basic (questions 1, 4, 5 and 8 to 11) as well as advanced (questions 2, 3, 6, 7 and 12 to 14) locomotor skills of the patient and thereby assesses the functional independence [43]. Each question is graded from 0 to 4 (thus 5 response categories). 0 (not able to), 1 (yes, with help from another person), 2 (yes, with supervision), 3 (yes, independently with ambulation aids) and 4 (yes, without ambulation aids). The 5$^{th}$ version (LCI-5) combines answers 3 and 4 into a single level 3 (yes, unassisted). Thus, the total LCI score is the sum of the item scores and can range from 0 (worst) to 42 (best).

The LCI-5 scores correlate excellently with the TUG results, and gives an indication of the relative independence of the patient in daily activities. As mentioned above, higher level of independence translates to better psychological outcomes. The test has high validity scores and excellent consistency as well as test-retest reliability. The LCI-5 is displayed in Annexure 3.

**Academic Medical Centre Linear Disability Score (AMC LDS)** :

The Academic Medical Centre (AMC) at Amsterdam devised a questionnaire to evaluate the spectrum of functional status in individuals. It is a generic question Bank consisting of 77 different questions spanning across various illnesses and disabilities [44].

The CLI AMC LDS [45] evaluates patients presenting with Category 4, 5 and 6 ischaemic limbs. It comprises 28 questions which is proven to be clinically valid and excellent responsiveness in pre / post op appraisal of patients' functional status [46]. The Test is well suited to assess the effect of treatment over time, and can also compare different treatment modalities. The CLI AMC LDS is shown in Annexure 4.

The AMC LDS was used in this Study (over the usually preferred in PAD studies VasQOL) since it is a more extensive questionnaire. It correlates

excellently with the Vascular Quality of Life index (VasQOL) questionnaire which evaluates the health-related status of the patient and his personal response to treatment. Furthermore, the VasQOL questionnaire concentrates more on the PAD component with direct queries regarding the patient's opinion on the decreased blood flow in his limbs, unlike the AMC LDS which focusses on the functional status – an important measure of amputees [47]. Each question is scored on a scale from 1 to 100 based on the ease of the patient to complete the activity (like a percentage of normal function). The answers marked are "yes" "yes but with difficulty" and "no" with a 4$^{th}$ option "not applicable" if he has never done the activity before. The "transformed" LDS is the median score of all 28 questions and indicates the Functional Score (FS) of the patient. An improvement in the FS over the follow up period indicates successful treatment and that the amputation has caused better functional quality of life (i.e. it has benefited) of the patient.

**2 Minute Walk Test (2MWT)** [48]

The 2MW Test measures the distance covered by the patient in two minutes at the self-selected walking speed. The patient is asked to cover the greatest possible distance in two minutes on a marked indoor track. He is allowed the use of his walker / crutches etc but not support from his attenders. The average walking speed is calculated which corresponds to the free walking speed or comfortable walking speed and thus reflects the greatest bioenergetic efficiency of walking [49]. Even though the Test was designed for transtibial amputation patients, the 2MWT has been subsequently extrapolated to foot amputees as well, [50] where it is shown to be consistently reproducible intra-examiner and inter-examiner.

The 6 Minute walk Test (6MWT) was initially planned to be used in this study however, it is well proven that 6MWT is more difficult to complete by amputees, especially those with comorbidities affecting systemic functional status. The 2MWT is shorter and more appropriate for such patients. Furthermore, another study by the same authors showed good inter-relation between the 2MWT, 6MWT and the original 12MWT [51] It can also be correlated with the

findings of the Berg Balance Test, Timed Up and Go (TUG) test, LCI-5 Score and Motor Function Measure-32 Test [52]. In amputees, it is feasible, sensitive to changes linked to rehabilitation and correlates with physical ability and the use of the prosthesis [53].

The mean normative 2-MWT distance for adults is 180.9 metres, with women and men able to walk a mean distance of 176 metres and 189.4 metres, respectively [54]. Distance covered by lower limb / foot amputees during the Test if more than 113 metres was extrapolated to be likely to walk more than 300 metres in the 6MWT, thus demonstrating adequate community ambulation / independence potential. Hence 113 metres was taken as cutoff in this study.

**Timed Up-and-Go Test (TUG)** [55]

It is a screening Test that is a very sensitive as well as specific measure of the probability of fall during walking. The patient starts in a seated position, wearing their regular footwear as applicable and can use a walking aid if needed. The patient stands up upon therapist's command; walks 3 meters, turns around, walks back to the chair and sits down. The time stops when the patient is seated. The patient's gait, stride and sway are evaluated along with any imbalance, use of wall etc to steady himself, improper use of the walking aid, etc. If a lower limb amputee needs more than 19 seconds to complete the test it is an indication for high risk of fall [56].

The test has high sensitivity and specificity for measuring balance capability while walking. It is a rapid test, and easily replicable. However it does have a higher rate of re-test variation.

**To summarise**

There are multiple methods and physical / clinical tests of evaluating the ambulatory and functional status of a patient following amputation. More important is how they correlate with each other and with the physical findings (sensitivity and specificity) and their predictive value in recovery (so that it can

be compared with actual evaluation during the follow-up visit) – which can guide further management of the patient by the health care persons.

# MATERIALS AND METHODS

# MATERIAL AND METHODS

**TYPE OF STUDY:**

- Hospital based (Single Centre) study
- Prospective, Observational study

**PERIOD OF THE STUDY:**

- One and half years – Initial recruitment period from 1st Jan 2021 to 31st Dec 2021 with consequent follow up for 6 months from the date of amputation.

**PLACE OF STUDY:**

- Multi-specialty Hospital in an Urban setup with Tertiary Vascular Surgery services.

**STUDY POPULATION:**

- Patients who presented with foot sepsis with etiology - ischaemic / CLTI and non ischaemic / DFU and undergoing toe(s) / forefoot (TMA) amputation (or revision of foot amputation level which was done at any other hospital) at this hospital (total **377**)

**INCLUSION CRITERIA:**

- Patients who underwent upto-forefoot level amputation procedure at this Hospital and consent for evaluation of their ambulant / rehabilitation status in the 6 months follow-up period.

**EXCLUSION CRITERIA:**

- Patients who did not consent to participate in the Study
- Patients whose general condition even prior to onset of foot symptoms were extremely poor (bedridden, non ambulant, cardiac failure or neurological deficit)

which would render them unable to perform the evaluation tests of functional status.

- Patients who undergo above forefoot (proximal to Trans-Metatarsal) level of Amputation.

- Patients who are bilateral amputees (patient has already undergone an amputation in the non-index limb at any level – Ray, TMA, foot, or Above / Below Knee either in the past or in the same hospital stay or during the follow up period).

- Any event in the form of systemic infection / sepsis, Major Adverse Cardiac Events (MACE) / Major Adverse Limb Events (MALE) during the follow up period causing a debilitating loss of overall functional status.

**SAMPLE SIZE**

- All patients undergoing foot amputation at the Centre in the Year 2021 and being followed up after initial inclusion / exclusion criteria are applied (**total 311**). This was adequate since the estimation at the beginning of the Study was to have a Sample size of 250 patients for a power of 0.8.

## METHODOLOGY IN BRIEF

All patients who presented with ischaemic gangrene or ulcer to this Institute, as also those presenting with a non-ischaemic DFU requiring amputation of one or multiple toes were considered to be the Study Population. Patients who already underwent amputation outside and then presented to the Centre were also included in the Study Population if they needed further revision of the amputation level.

All these patients were evaluated pre-op for their comorbidities, relevant complaints and past / personal history, comorbidities. The patients were examined and wounds / limbs were clinically staged according to the WIFI scoring system. Subdivision into Ischaemic and non-ischaemic (DFU) limbs were made according to the presence of pedal pulses which was then cross-referenced with the ABI

(ischaemic if <0.7) and Ischaemia score of the WIFI class (I2 and I3). Their pre-operative ambulatory status was examined and noted. They were then explained about the Study and provided with the Informed Consent form. If they consented to participate in the Study they were then evaluated for their ambulatory parameters and clinical tests of balance, walking capability. Simultaneously the status of the feet was evaluated clinically for Neuropathy (if Diabetic) and Foot X-Rays were also taken for evaluation of foot deformities and Osteomyelitis along with Pulse Volume Recording (PVR) and Trans-Cutaneous Partial pressure of Oxygen (TCPO2) was measured.

Following amputation (and revascularisation surgery if applicable), the wound status of the patient was re-evaluated and vascularity of the limb was assessed again with the post-operative PVR and TCPO2 Tests. Patients who were deemed to have non salvageable limbs following amputation / debridement / source control and thus undergoing below or above knee amputations were excluded from the Study.

Some textbooks advocate the primary closure of the wound with sutures however our institutional practice is to leave the surgical wound open to granulate and heal by secondary intention. This protocol allows for regular examination of the wound bed during the post operative visits, and early intervention in case it turns ischaemic or infected. Similarly all amputee wounds were managed with regular dressings as per Standard institutional protocol and all patients had to wear protective Diabetic footwear. Wounds that were healthy and granulating in subsequent visits were subjected to Split Skin Grafting (SSG) for early healing.

Patients were assessed in the immediate post operative period for the time taken to stand, bear weight on the amputated foot and walk. Re-evaluation of the patient was again done in the follow up period at 1 week, 1 month, 2 months, 3 months, and 6 months post op. The wound healing status and condition of the foot was also evaluated in the follow up period, with examination of the wound scar, ankle joint stability or deviation / deformity. The same was correlated to the ambulatory status, balance and walking capability of the patient. The Berg Balance

Test, Locomotor Capability Index (LCI) – 5 score and AMC LDS (specific for CLI patients) were used to compare the balance and ambulatory status of the patients' pre-op and during the follow up period. Any patients suffering a MALE or MACE causing death / debilitating loss of systemic function during the follow up period were also excluded.

The CLI AMC LDS questionnaire has been slightly modified in this Study to cater to Indian practices, the question 1 (can you vacuum a flight of stairs) is modified to "can you lift a basket / box of 5kg weight up a flight of stairs" and question 2 (vacuum a room and move light furniture) is changed to "can you clean up a room, involving moving light furniture". Also, patients were asked to round up their scores to the nearest multiple of 5 (5, 10, 15, 20 and so on) for ease of calculation and comparison.

Similarly, the Timed Up-and-Go Test was not done at 1 week post op since the cut-off for lower limb amputees in the early postop period is 19 seconds on average. This itself is an indication of high risk of fall. The test was first done at 1 month post op for the patient to get used to the assisting device and change of balance following the amputation.

At the end of the Study, 6 parameters were selected to define successful return to medical and societal functional Status. They were :

(a) Wound healed
(b) Able to stand without support.
(c) Bergs Balance Test risk of fall - Low or Medium (minimum score 38/56)
(d) TUG Test – Low risk of fall (completed the test in less than 19 seconds)
(e) Non antalgic gait (able to walk without pain)
(f) Able to complete 2MWT distance of 113 meters.

Those who fulfilled all parameters were deemed to have successfully completed the Study. Partial success was defined as achievement of at least 2 parameters in addition to Berg Balance Test score $\geq$38 and ability to stand without support.

## STATISTICAL ANALYSIS

The power of the Study was determined to be 80% (0.8) with a minimum sample Size of 250. This was achieved (Sample Size 311). At the end of the Study, the results were tabulated and statistically scrutinized to derive the conclusion. 236 patients completed the entire follow up. The data on categorical variables is shown as n (% of cases) and the data on continuous variables is presented as mean and standard deviation (SD). The inter-group statistical comparison of distribution of categorical variables was tested using Chi-Square test. The progression and relation between the average scores of various Tests were compared using the unpaired T-test. All results are shown in tabular (labelled as Table 1, 2, 3 and so on) as well as graphical format (labelled as Graph 1, 2, 3, 4 and so on) to visualize the statistically significant difference more clearly.

In the entire study, the p-values less than 0.05 were considered statistically significant. The entire data was statistically analysed using Statistical Package for Social Sciences (SPSS ver 24.0, IBM Corporation, USA) for MS Windows [57] [58] [59].

## SCIENTIFIC COMMITTEE APPROVAL

The Study design has been approved by the Scientific Committee of Bhagwan Mahaveer Jain Hospital, Bengaluru in their Committee Meeting held on 22nd July 2021. Certificate of the Committee is attached as per Annexure 5.

## ETHICS COMMITTEE APPROVAL

The Study design has been approved by the Ethics Committee of Bhagwan Mahaveer Jain Hospital, Bengaluru in their Committee Meeting held on 22nd July 2021. Certificate of the Committee is attached as per Annexure 6.

# PHOTOGRAPHS

**Figure 1: Great (1st) Toe Amputation**

**Figure 2 : Single (3rd) Toe Amputation**

**Figure 3: Single (5th) Toe Amputation**

**Figure 4: All Toes (Trans Metatarsal) Amputation**

**Figure 5: Debridement of the Dorsum of Foot**

**Figure 2: Multiple (2nd to 5th) Toes Amputation**

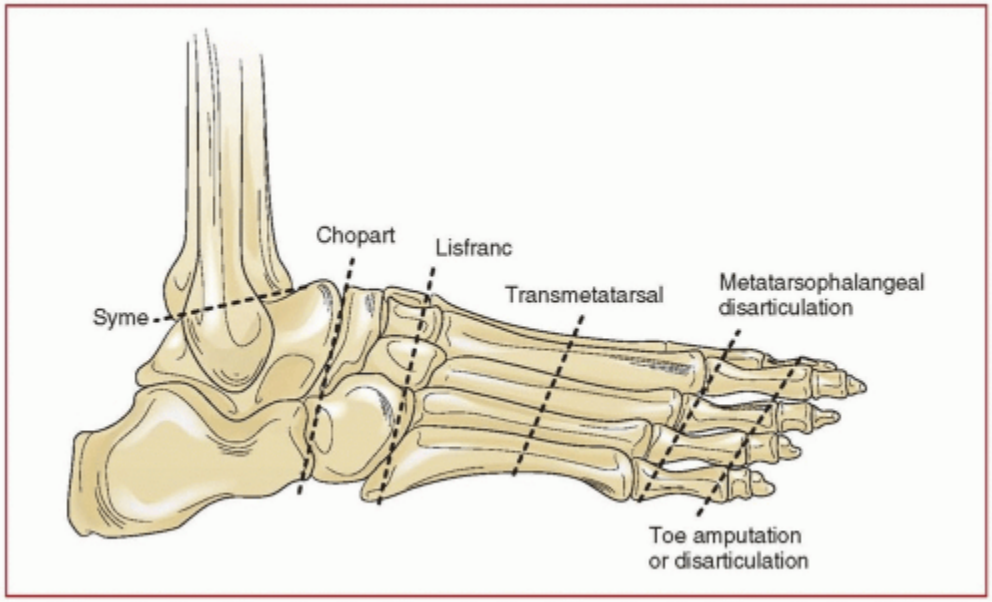



**Figure 7: Schematic of Levels of Foot Amputation**

# RESULTS

**Patient Demographics:**

A total of four hundred and forty three (443) patients underwent foot amputation (Ray, multiple toes or TMAs) at this Centre during the period from 1st January 2021 to 31st December 2021. Sixty six (66) patients did not give consent for participation in the Study, thus leaving three hundred and seventy seven who were enrolled for post op follow-up as the Study Population (n = 377).

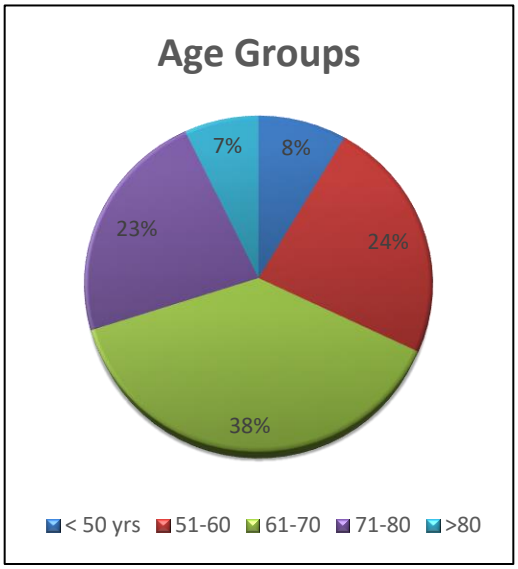
19 patients during their follow up underwent re-do foot amputation of additional toes. Out of these, 2 patients actually underwent three amputation surgeries, hence they have 3 entries under their name. However for the sake of evaluation they have been considered as a new entry since they have a new wound and new level of amputation after the revision surgery.

There were 317 men (84.08% males) and 60 women (15.92% females) in the Study. The mean age was 65.08 years (range 33-92 yrs, SD 10.69) with the distribution in age groups as per Table 8 and Graph 1.

**Table 8 : Age-wise Distribution of Study Population**

| Age group (years) | Number of patients | Percentage (%) |
|---|---|---|
| ≤ 50 | 32 | 8.49 |
| 51 - 60 | 89 | 23.61 |
| 61 - 70 | 143 | 37.93 |
| 71 - 80 | 86 | 22.81 |
| > 80 | 27 | 7.16 |
| Total | **377** | **100** |

**Graph 1 : Age-wise grouping of Study Population**




Details of the comorbidities are listed as per Table 9 below :

**Table 9 : Demographics and Comorbidities of Study Population**

| Co-morbidities | Number of patients (Total 377) | Percentage (%) |
|---|---|---|
| Diabetes Mellitus | 344 | 91.25 |
| Hypertension | 230 | 61.01 |
| Ischemic heart disease | 135 | 35.81 |
| | | |
| Chronic Kidney disease | 67 | 17.77 |
| Dyslipidaemia | 48 | 12.73 |
| Anaemia | 87 | 23.08 |
| CVA | 32 | 8.49 |
| Respiratory disease | 35 | 9.28 |

Diabetes Mellitus was the most common comorbid condition with 344 (91.25%) suffering from the illness. Out of these, 169 (49.13% of Diabetics) were Insulin dependent and 295 (85.76% of Diabetics) were taking Oral

Hypoglycaemics (OHAs) for their treatment. There were 230 (61.01%) patients who were hypertensive.

Ischaemic Heart Disease (IHD) and Chronic Kidney Disease (CKD) were also found to be significantly high in the positive history of the patients. 32 patients also had a prior history of Stroke. Thus the involvement of other CV beds in the Study Population was significantly high.

Smoking and Tobacco consumption also formed a significant part of the Study Population with 187 (49.60%) patients revealing a positive history of either.

**Presenting Complaints and Initial Examination :**

The patients were grouped into either Ischaemic (CLTI -281, 74.54%) or non-ischaemic (DFUs - 96, 25.46%) limbs based on their ABI or presence of rest pain. Among the CLTI patients, minor tissue loss (Rutherford Class 5) were 178 patients (63.35%) and major tissue loss (Rutherford Class 6) comprised 99 patients (35.23%). Further subdivision into the WIfI Class of wounds revealed the following distribution (as per Table 10) – Most of the wounds were severe (W2 or W3) :

**Table 10 : Distribution of patients as per WIFI Staging**

| Category | 0 | 1 | 2 | 3 | Total |
|---|---|---|---|---|---|
| **W** | 0 | 22 (5.84%) | 286 (75.86%) | 69 (18.3%) | 377 |
| **I** | 87 (23.08%) | 29 (7.69%) | 19 (5.04%) | 242 (64.19%) | 377 |
| **fI** | 39 (10.34%) | 138 (36.60%) | 150 (39.79%) | 50 (13.26%) | 377 |

114 patients were non ambulant preop – either wheelchair dependent or bedridden. 105 were ambulant without any support and 158 were dependent on either a walker or walking stick for support during walking. Berg's Balance Test (Table 11) and the other Tests of ambulation were performed at the time of

presentation. Most patients showed a low to moderate risk of fall. High risk corresponded significantly with the Wound status and extent of gangrene / infection ($p<0.001$).

**Table 11 : Pre-op Berg Balance Scores**

| Berg Balance | Frequency | % (Total 377) |
|---|---|---|
| **High** | 27 | 7.16 |
| **Medium** | 241 | 63.93 |
| **Low** | 59 | 15.65 |
| **Not assessed** | 50 | 13.26 |

The AMC LDS and LCI-5 Scores were also calculated and tabulated, which showed corresponding values with the Berg Balance Scores – which is in accordance with the literature available.

Comparison of the results of individual Tests and cross-evaluation was done at each stage. The various Tests used have been stated along with the respective result, and a p value of less than 0.05 was determined to be statistically significant for the sake of the Study.

**Post operatively (same hospital stay)**:

9 patients underwent revision foot amputation 8 TMAs and 1 second toe amputation following 3rd toe in the post op period itself, and were followed up according to their final postop status. Those patients who were determined to have non salvageable limbs subsequently underwent Below Knee Amputation (10) or Above Knee Amputation (13).

Results are as per the Table 12 :

**Table 12 : Details of Amputation Surgeries performed**

| | Frequency | |
|---|---|---|
| **Total Population = 377** | Initial Surgery | **Final number after revision = 311** |
| 1st Toe only | 68 | **60** |
| Single Toe Amputation (excluding 1st Toe) | 73 | **65** |
| Multiple Toe Amputation | 102 | **88** |
| All Toes (TMA) | 134 | **98** |
| Above Knee Amputation | - | **13** |
| Below Knee Amputations | - | **10** |
| Excluded for other reasons | | 43 (from 377) |

Since the CLTI patients underwent revascularisation post amputation, all the patients were determined to have adequate blood flow into the foot. Hence the 2 subgroups (CLTI and DFUs) were not followed up separately. 3 patients who were initially classified as CLTI due to rest pain (I3 as per WIfI score) despite having ABI more than 0.7 (which favours DFU rather than CLTI); Their pain relieved post amputation and furthermore they were unwilling for revascularisation. These patients were reclassified into the DFU group and followed up accordingly - all these 3 patients' wounds subsequently healed.

Patients were re-evaluated for their fitness to complete the Study and 6 were excluded due to severe functional deficit secondary to their comorbid conditions (4 cardiac, 1 Spinal deformity, 1 Hemiparesis). Those who underwent Below Knee Amputation (10) and Above Knee Amputation (13) were also removed. 3 patients withdrew consent for follow up and were excluded as were 2 more patients who were unwilling for AKA / BKA. Bilateral Amputees (28) were also excluded from the Study at this stage.

7 patients suffered an adverse Cardiac event (MACE) in the same hospital stay out of which 3 were fatal. 1 patient had a life threatening UGI bleed (massive

heamatemesis) on the 1st post op day and severe deterioration of general condition. His attenders requested for Discharge against Medical Advice (DAMA). Thus, remaining population at this Stage was 311 which is the Sample size for all further evaluation (Graph 2)

In Hospital, the time to stand with respect to the level of amputation as shown in Table 13 (Average 1.91 days, Median 2 days, SD 0.97)

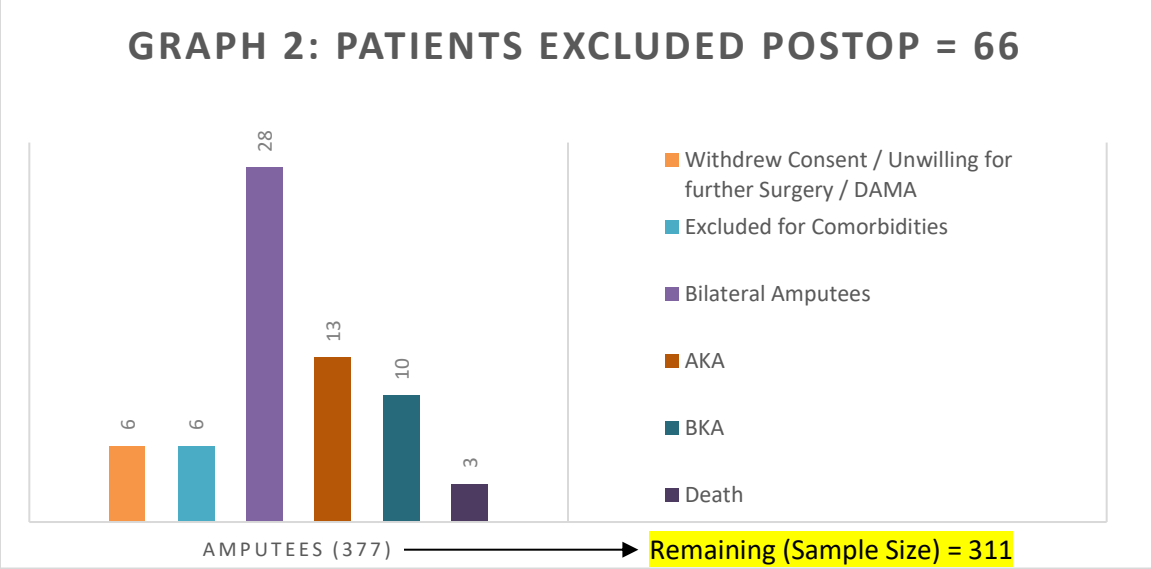



**Table 13 : Time to Stand post Amputation**

| | Frequency | | | | | |
|---|---|---|---|---|---|---|
| | 1 day | 2 days | 3 days | More than 3 days | Did not stand | P value |
| 1st Toe only (60) | 29 | 20 | 10 | 1 | 0 | **Not significant** |
| Single Toe (65) (excluding 1st Toe) | 43 | 16 | 2 | 2 | 2 | |
| Multiple Toes (88) | 20 | 38 | 22 | 5 | 3 | **<0.005** |
| All Toes - TMA (98) | 12 | 52 | 22 | 8 | 4 | **<0.001** |
| Total = 311 | | | | | | |

79 patients were able to stand without support in hospital itself. 9 patients were unable to ambulate or stand prior to discharge. The distribution of patients standing with /without support and ability to ambulate with / without support are enumerated as per Tables 14 and 15 respectively :

**Table 14 : Stand without Support - Postop**

| | Stand without support | P value |
|---|---|---|
| 1st Toe only (60) | 18 | Not significant |
| Single Toe (excluding 1st Toe) (65) | 33 | |
| Multiple Toes (88) | 17 | **<0.001** |
| All Toes – TMA (98) | 11 | **<0.001** |
| Total | 79 | |

**Table 15 : Walk with or Without Support - Postop**

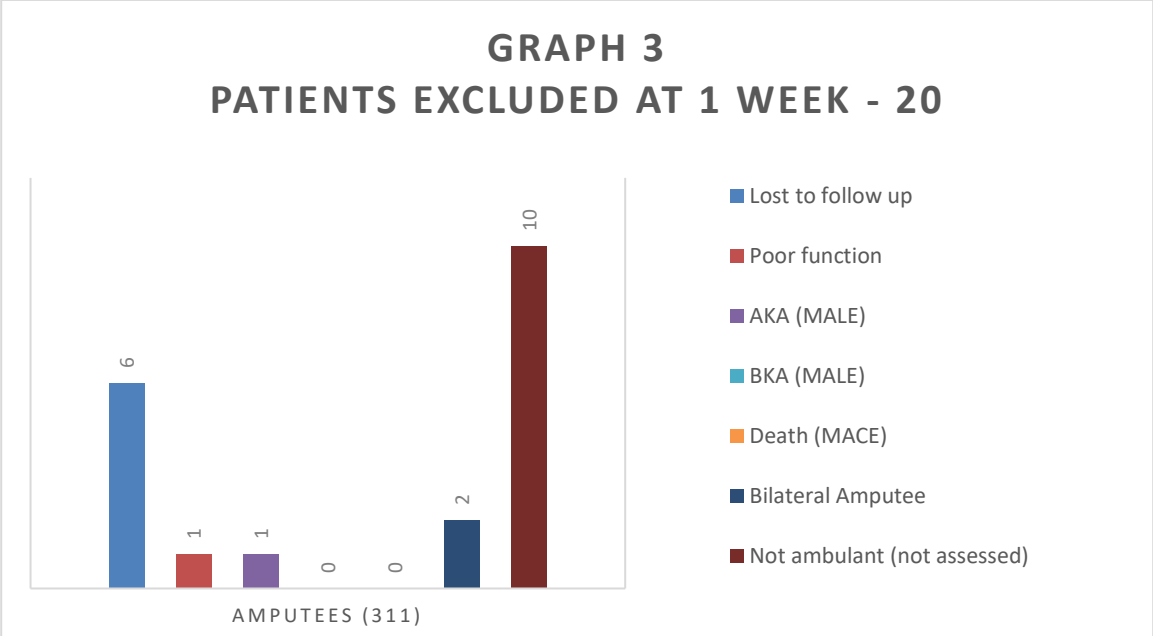
| | Walk without support | Walk with support | Did not Walk | P value |
|---|---|---|---|---|
| 1st Toe only (60) | 0 | 60 | 0 | |
| Single Toe (65) (excluding 1st Toe) | 2 | 61 | 2 | |
| Multiple Toes (88) | 1 | 84 | 3 | |
| All Toes – TMA (98) | 0 | 94 | 4 | **<0.001** |
| Total (Sample Size) = 311 | | | | |

The above tables (13, 14 and 15) show that 1st Toe amputation status was not statistically significant for causing delay in postop ambulation / walking. However, increase in the number of toes amputated resulted in longer period to stand and to walk - especially if the 1st toe was also amputated. TMAs were associated with the longest in hospital rehabilitation time (median 2 days to stand with SD 1 day) which was statistically significant ($p<0.001$). None of the TMA patients either stood or walked without support.

**At 1 week of follow up :**

At 1 week, 301 patients reported for follow up but only 291 patients were evaluated. 6 patients (including the UGI bleed and DAMA patients) did not report back and were removed (lost to follow up) from the Study.

4 patients who were not walking at the time of discharge were now ambulant. 10 patients continued to be non-ambulant after 1 week and could not be assessed (including 1 patient who was COVID positive). 1 patient was excluded from the Study due to persistent poor functional status (severe COPD) thus rendering him unable to perform the Tests. There were 4 re-do amputations (3 TMA, 1 single toe amputation) and these patients were accordingly re-entered into the Study under a fresh Serial number. There were 2 MALE events – 1 Above Knee Amputation (excluded from the Study) and 1 stent thrombosis (which was managed surgically and recovered with no further loss of amputation level or functional status hence continued in the Study). Another 2 patients underwent amputation on the contralateral limb and had to be excluded. The distribution is shown in Graph 3.



143 (49.1%) of the 291 patients were able to stand without support and 285 (99%) were ambulant – 3 (1%) without support, 22 (7.6%) with walking stick and 258 (88.7%) with walker. This is shown in Table 16.

**Table 16 : Stand with / without support at 1 week postop**

| Patients Evaluated = 301 | Stand without Support (1 week) | | P value |
|---|---|---|---|
| | Yes (%) | No (%) | |
| 1st Toe only (57) | 37 (64.91) | 20 (35.09) | |
| Single Toe (64) (excluding 1st Toe) | 44 (68.75) | 20 (31.25) | |
| Multiple Toes (83) | 32 (38.55 | 51 (61.45) | **0.002** |
| All Toes – TMA (87) | 30 (34.14) | 57 (65.52) | |
| Non Ambulant | 0 | 10 | |
| Total | 143 (47.51) | 158 (52.49) | 301 |

The results were compared by Chi Square test and found to be statistically significant in respect to number of Toes amputated. Multiple Toes Amputation and TMAs were independently significant factors for inability to stand without support at 1 week postop (p=0.002).

Bergs Balance Test was conducted on all the ambulant patients and the Scores are as in Table 17. TMA was significantly associated with high risk of fall. Single toe amputations involving the 2nd to 5th toes usually had a medium risk of fall, which corelated with the age of the patient. All calculations were done using the Chi Square Test with respect to type of foot amputation.

**Table 17 : Berg Balance at 1 Week (amputation level – wise distribution)**

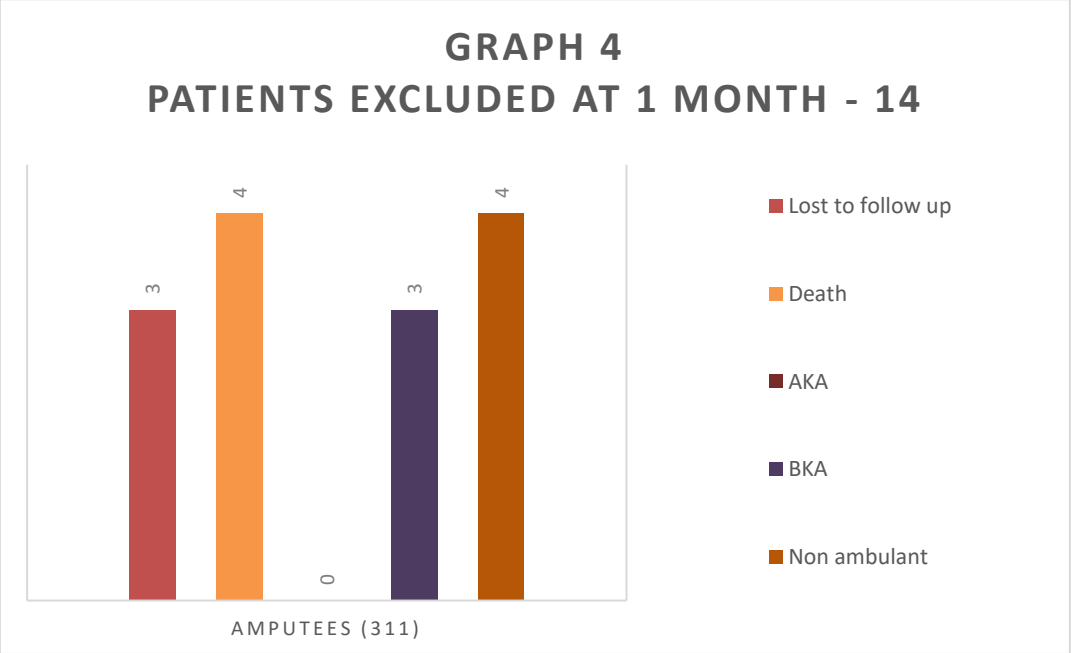
| | Berg Balance Score / Risk (1 week) | | | |
|---|---|---|---|---|
| | High (%) (Less than 20) | Medium (%) (21-40) | Low (%) (41 - 56) | P value |
| 1st Toe only (57) | 12 (21.05) | 45 (78.95) | 0 | |

| | | | | |
|---|---|---|---|---|
| Single Toe (64) (excluding 1st Toe) | 9 (14.06) | 55 (85.94) | 0 | Not Significant |
| Multiple Toes (83) | 46 (55.42) | 37 (44.58) | 0 | **<0.001** |
| All Toes – TMA (87) | 64 (73.56) | 23 (26.44) | 0 | **<0.001** |
| **Total = 291** | 131 (45.02) | 160 (54.98) | 0 | |
| Non Ambulant = 10 | | | | |

**At 1 month follow up** :

All ambulant patients underwent evaluation in the form of Berg's Balance Test, AMC LDS, LCI-5 Score, Timed-Up and Go Test and 2 Minute Walk Test. In addition, they were evaluated for their capability to stand and walk without support and the gait.

3 patients were lost to follow up. There were 3 MALEs (Below Knee Amputations - excluded from the Study) and 1 patient presenting with an ischaemic wound due to drop in PVR on evaluation (managed with conservative measures). 9 MACEs were recorded in between 1 week till the first month postop out of which 4 were fatal / terminal events. The distribution of cases excluded at 1 month follow up is as per Graph 4 below :



3 patients continued to be non-ambulant at 1 month of follow up (considered as high risk in Bergs Test and TUG). In contrast, 1 patient who was not evaluated at post op (due to COVID restrictions) reported back at this point and hence was allowed to continue in the Study. 12 patients who underwent revision foot surgery (8 TMAs and 4 additional toe amputation) were evaluated for their Scores (Berg, AMC LDS and LCI-5) and then assigned a fresh Serial number for follow-up – these same scores were used as the baseline pre-op in the fresh entry.

Thus 283 patients came for follow up at 1 month out of whom 277 patients were evaluated. The results are displayed as per Tables 18 to 20.

**Table 18 : Berg Balance Score – 1 month**

| | Berg Balance Score / Risk (1 month) | | | |
|---|---|---|---|---|
| | High (%) (Less than 20) | Medium (%) (21-40) | Low (%) (41 - 56) | P value |
| 1st Toe only (56) | 3 (5.36) | 50 (89.28) | 3 (5.36) | |
| Single Toe (61) (excluding 1st Toe) | 0 (0) | 35 (57.38) | 26 (42.62) | |
| Multiple Toes (75) | 1 (1.33) | 69 (92) | 5 (6.67) | **≤0.001** |
| All Toes – TMA (85) | 13 (15.29) | 72 (84.71) | 0 (0) | |
| Total | 17 (6.85) | 226 (77.66) | 34 (12.27) | 277 |
| Non Ambulant = 3 | | | | |

**Table 19 : Walk with / without Support (1 month)**

| | Walk with / without Support (1 month) | | | |
|---|---|---|---|---|
| | Walker (%) | Walking Stick (%) | Without support (%) | P value |
| 1st Toe only (56) | 48 (85.71) | 7 (12.50) | 1 (1.79) | |
| Single Toe (61) (excluding 1st Toe) | 22 (36.07) | 33 (54.10) | 6 (9.84) | |

| | | | | |
|---|---|---|---|---|
| Multiple Toes (75) | 67 (89.33) | 8 (10.67) | 0 (0) | **<0.001** |
| All Toes – TMA (85) | 85 (100) | 0 (0) | 0 (0) | |
| Total = 277 | 222 (78.45) | 48 (16.96) | 7 (2.47) | |

**Table 20 : 1 month evaluation of 2MWT and TUG Tests**

| | 1 month (Total 277) | |
|---|---|---|
| | Yes (%) | No (%) |
| Timed Up and Go - High Risk of Fall | 160 (57.76) | 117 (42.23) |
| 2MWT – Distance (113 m) covered | 54 (19.49) | 223 (80.51 |

**Follow up at 2 months, 3 months and 6 months** –

Similar to 1 month, all results were sequentially tabulated at 2, 3 and 6 months. The series of patients followed up are displayed in Table 21 :

**Table 21 : Exclusion Criteria during follow up**

**Patients at Discharge (Sample Size) = 311**

| **Post op visit** | **1 week** | **1 month** | **2 months** | **3 months** | **6 months** |
|---|---|---|---|---|---|
| Patients evaluated | 291 | 277 | 251 | 243 | 235 |
| Non Ambulant / poor function | 11 | 3 | 0 | 0 | 0 |
| Bilateral amputees | 2 | | | | |
| Lost to follow up | 6 | 3 | 3 | 6 | 6 |
| AKA | 1 | 1 | 4 | 0 | 0 |
| BKA | 0 | 3 | 3 | 2 | 1 |
| MACE fatal | | 4 | 6 | 0 | 1 |

All the above events resulted in the patient being removed from the Study. Revision foot surgery resulted in the patient re-entering the study from the beginning with a new Serial number allotted due to fresh foot amputation (after assessing functional status) – this is shown in table 22.

**Table 22 : Patients re-assigned following revision Amputation during follow up period**

| **Post op visit** | **1 week** | **1 month** | **2 months** | **3 months** | **6 months** |
|---|---|---|---|---|---|
| Evaluated at the visit, then re-assigned | | | | | |
| Revision toe Amputation | 3 | 4 | 3 | 1 | 0 |
| Revision TMA | 1 | 7 | 4 | 1 | 0 |
| Not Excluded from Evaluation, continued in further follow up | | | | | |
| MACE non fatal | 1 | 1 | 0 | 1 (severe anaemia) | 0 |

By 2 months, all patients were able to stand and maintain balance in stationary position, with or without support irrespective of the level of foot amputation. At the end of 6 months follow up (out of 235 patients) 194 patients (82.20%) were able to stand without support and 42 (17.80%) patients needed support / assistance to stand. The distribution of the patients as per amputation level is shown in Table 23 :

**Table 23 : Ability to Stand without Support at 6 months follow up**

| | Stand without Support at 6 months | | P value |
|---|---|---|---|
| | Yes (%) | No (%) | |
| 1st Toe only | 45 (80.36) | 11 (19.64) | 0.679 |
| Single Toe (61) (excluding 1st Toe) | 46 (75.41) | 15 (24.59) | 0.107 |
| Multiple Toes (75) | 51 (68) | 24 (32) | **<0.001** |
| All Toes – TMA (85) | 52 (61.18) | 33 (38.82) | **<0.001** |

| | | | |
|---|---|---|---|
| Total | 194 (82.20) | 41 (17.80) | 0.072 |

The results showed that ability to stand without support in the early postop period (1 week and 1 month) was significantly associated with multiple toe amputation level and TMAs, both of which showed a p value of less than 0.001. The status of Single Toe Amputation (including exclusively 1st Toe) were not significantly associated with ability to stand without support by the end of the Study. Chi Square Test was used for calculation.

Comparison of the Results of the Ambulatory Function Tests over all follow-up visits are entered in the Tables 24, 25 and 26 as below:

**Table 24 : Berg Balance Test – Comparison month wise**

| **Berg Balance Test - Sample Size = 311** | | | | |
|---|---|---|---|---|
| | 1 month | 2 months | 3 months | 6 months |
| Not evaluated (% of 311) | 34 (10.9) | 60 (19.3) | 73 (23.5) | 78 (20.68) |
| Numbers excluded since previous visit | | 16 | 7 | 7 |
| | | | | |
| **Number evaluated** | **277 (%)** | **251 (%)** | **243 (%)** | **235 (%)** |
| High risk | 15 (5.4) | 2 (0.8) | 0 (0) | 0 (0) |
| Med risk | 228 (82.3) | 159 (63.3) | 74 (30.5) | 35 (15.3) |
| Low risk | 34 (12.3) | 90 (35.9) | 169 (69.5) | 200 (84.7) |
| **P<0.001** | | | | |

**Table 25 : Timed-Up and Go Test – Comparison month wise**

| **Timed Up & Go Test - Sample Size = 311** | | | | |
|---|---|---|---|---|
| | 1 month | 2 months | 3 months | 6 months |
| Not evaluated (% of 311) | 34 (10.9) | 60 (19.3) | 73 (23.5) | 78 (20.68) |

| | | | | |
|---|---|---|---|---|
| Numbers lost to follow up since last time | | 16 | 8 | 6 |
| | | | | |
| **Number evaluated** | **277 (%)** | **251 (%)** | **243 (%)** | **235 (%)** |
| High risk | 160 (57.8) | 114 (45.4) | 81 (26.04) | 56 (18.32) |
| Low risk | 117 (42.2) | 137 (54.6) | 162 (52.09) | 179 (57.55) |
| | | **P<0.001** | | |

**Table 26 : 2 Minute Walk Test – Comparison month wise**

| **2MWT - Sample Size = 311** | | | | | |
|---|---|---|---|---|---|
| | | 1 month | 2 months | 3 months | 6 months |
| Not evaluated (from Sample Size) | | 34 (10.9) | 60 (19.3) | 73 (23.5) | 78 (20.68) |
| Numbers lost to follow up since last time | | | 16 | 8 | 6 |
| | | | | | |
| **Number evaluated** | | **277 (%)** | **251 (%)** | **243 (%)** | **235 (%)** |
| Walker | | 222 (71.38) | 168 (66.93) | 115 (47.32) | 93 (39.4) |
| Walking Stick | | 48 (15.43) | 67 (26.69) | 95 (39.10) | 96 (41.1) |
| Without Support | | 7 (2.25) | 16 (6.38) | 33 (13.58) | 46 (19.5) |
| | | | **P<0.001** | | |
| Distance (113m) covered | Yes | 55 (19.85) | 70 (27.84) | 119 (48.91) | 132 (55.93) |
| | No | 227 (80.15) | 181 (72.16) | 124 (51.19) | 103 (44.07) |
| | | | **P<0.001** | | |

## INTERPRETATION OF FOLLOW UP FINDINGS

The above tables show a progressive improvement in the ambulatory and walking capability of the patients as the follow up period progressed. Overall number of patients who graduated from walker to walking stick to walking without support as well as the percentage of the same (compared to that stage denominator population) increased significantly on all aspects. Evaluation of the results of Berg Balance Test, 2MWT and Timed Up and Go Tests were done using the Chi Square Test.

These progresses in the Berg Balance Test Score correspondingly were associated with an improvement in the AMC LDS and LCI-5 Score. This was significant for the results of each Test. when comparing the results of only 1st Toe Amputation (at 2 months and 6 months) and for TMAs (at all levels of follow up). Thiese scores were evaluated using the Unpaired t-test for AMC LDS results and LCI-5 Score and this is expressed in Tables 27 and 28. The results for the AMC LDS and LCI-5 over follow up for Single Toe amputation (excluding 1st Toe) and multiple Toe amputations was not statistically significant.

**Table 27 : AMC LDS and LCI-5 Score – Comparison monthwise**

**Only 1st Toe Amputated**

| 1st Toe Amputation | | N | Mean | SD | p-value |
|---|---|---|---|---|---|
| AMC LDS 1 month | Yes | 56 | 66.07 | 11.86 | 0.053 |
| | No | 221 | 62.35 | 15.52 | |
| AMC LDS 2 months | Yes | 46 | 76.96 | 8.06 | **0.011** |
| | No | 205 | 72.95 | 14.21 | |
| AMC LDS 3 months | Yes | 42 | 84.17 | 8.90 | 0.099 |
| | No | 198 | 81.52 | 11.13 | |
| AMC LDS 6 months | Yes | 39 | 88.59 | 5.96 | **0.021** |
| | No | 194 | 85.88 | 9.06 | |
| LCI 5 Score 1 month | Yes | 56 | 30.07 | 5.45 | 0.466 |
| | No | 221 | 29.46 | 6.05 | |

| | | | | | |
|---|---|---|---|---|---|
| LCI 5 Score 2 months | Yes | 46 | 34.07 | 4.82 | 0.355 |
| | No | 205 | 33.31 | 5.69 | |
| LCI 5 Score 3 months | Yes | 42 | 37.21 | 3.71 | 0.590 |
| | No | 198 | 36.87 | 3.96 | |
| LCI 5 Score 6 months | Yes | 39 | 38.82 | 2.14 | 0.191 |
| | No | 194 | 38.28 | 3.06 | |

**Table 28 : AMC LD Score and LCI-5 Score – Comparison monthwise - TMAs**

| Trans Metatarsal Amputation | | N | Mean | SD | p-value |
|---|---|---|---|---|---|
| AMC LDS 1 month | Yes | 85 | 51.71 | 12.74 | **< 0.001** |
| | No | 192 | 68.15 | 12.90 | |
| AMC LDS 2 months | Yes | 77 | 65.52 | 11.14 | **< 0.001** |
| | No | 174 | 77.30 | 12.70 | |
| AMC LDS 3 months | Yes | 76 | 74.54 | 10.20 | **< 0.001** |
| | No | 164 | 85.43 | 9.24 | |
| AMC LDS 6 months | Yes | 75 | 80.07 | 9.32 | **< 0.001** |
| | No | 158 | 89.30 | 6.52 | |
| LCI 5 Score 1 month | Yes | 85 | 25.96 | 5.10 | **< 0.001** |
| | No | 192 | 31.19 | 5.56 | |
| LCI 5 Score 2 months | Yes | 77 | 30.49 | 4.25 | **< 0.001** |
| | No | 174 | 34.75 | 5.55 | |
| LCI 5 Score 3 months | Yes | 76 | 34.66 | 3.56 | **< 0.001** |
| | No | 164 | 37.98 | 3.62 | |
| LCI 5 Score 6 months | Yes | 75 | 36.44 | 3.03 | **< 0.001** |
| | No | 158 | 39.29 | 2.40 | |

## WOUND HEALING

The rate of healing of wounds was also was a factor affecting the balance and ambulatory capability of the patients. Subjects experienced a significant

improvement in the Berg Balance Score in the immediate visit after complete wound healing (either on its own or by Skin Grafting). This was true for all the types of Amputated wounds, but especially significant in TMA wounds and in older age group patients. Results of wound healing status as displayed in Table 29 below :

**Table 29 : Wound healing Status (follow-up)**

| Wound Healed Total | Yes | | Complications | |
|---|---|---|---|---|
| | Primary healing | SSG | Callus | Contractures |
| 1 month | 8 | 5 | 0 | 0 |
| 2 months | 82 | 19 | 24 | 1 |
| 3 months | 88 | 19 | 82 | 1 (same) |
| 6 months | 28 | 6 | 30 | 1 (same) |
| **Study population (311)** | 206 | 49 | 136 | 1 |

Few (9) wounds did not heal even at the end of 6 months. 8 were healthy / granulating or almost healed with just wound edge trophic changes. However 1 patient presented with a bad foot and heel abscess for which he had to undergo a Below Knee Amputation.

The wound and foot condition plays a pre-emptive role in the stability and walking capability (including gait, speed and balance) of the patient. Patients who underwent TMA and multiple toe amputations were at risk of equinus and / or varus deformity at the ankle. Those who developed deformity resulted in instability of the foot during walking and standing. Development of foot deformity was significantly related to delay in Berg Balance scores and walking without support. On the other hand, correction of the deformity either by modifying footwear or by surgery caused the patient to regain lost function. This was calculated using the paired t-test and Chi square test.

Similarly wound healing was associated with Callus formation and trophic ulcers at the wound edge. These have been enumerated in Table 28. They signify abnormal pressure points in the foot. Management of these was by offloading the incriminating pressure point and trimming of the callus to re-distribute the pressure point.

**Gait Evaluation**

All patients from 1 month onward were assessed for their gait during the 2MWT. Majority of the patients had normal gait throughout their follow-up. Patients who developed gait disturbances were evaluated for their stance, walking effort and correlated with their Neuropathy status. The details are as per Table 30 below:

**Table 30 : Gait Assessment at 1 month**

| Total = 277 | Frequency | Percent |
|---|---|---|
| Normal | 237 | 83.39 |
| Antalgic | 11 | 3.97 |
| Arthrogenic | 9 | 3.25 |
| Equinus | 9 | 3.25 |
| Limping | 1 | 0.36 |
| Shuffling | 3 | 1.08 |
| Steppage | 5 | 1.81 |
| Trendelenberg | 1 | 0.36 |
| Non ambulant | 6 | 2.17 |
| Not assessed | 1 | 0.36 |
| Total | 277 | 100 |

The table shows the distribution of the 277 patients assessed at 1 month follow-up period. Antalgic gait, suggestive of pain in the amputation wound / foot was the most common abnormal gait seen. Equinus deformity of the ankle resulting in the Equinus gait had already begun to set in in 9 patients. High steppage gait was associated with Severe Diabetic Neuropathy.

**Subsequent Gait Assessment :**

Similarly gait assessment continued at every follow up period. The results are tabulated in Table 31.

**Table 31 : Gait Assessment – Follow up 1 month to 6 months**

| Type of Gait | Frequency (%) | | | |
|---|---|---|---|---|
| | 1 month | 2 months | 3 months | 6 months |
| **Total assessed** | **277** | **251** | **243** | **235** |
| Normal | 231 (83.39) | 208 (82.87) | 202 (83.13) | 196 (83.47) |
| Antalgic | 11 (3.97) | 7 (2.79) | 7 (2.88) | 6 (2.54) |
| Arthrogenic | 9 (3.25) | 9 (3.59) | 9 (3.70) | 8 (3.39) |
| Equinus | 9 (3.25) | 13 (5.18) | 14 (5.76) | 15 (6.36) |
| Limping | 1 (0.36) | 1 (0.40) | 1 (0.41) | 1 (0.42) |
| Shuffling | 3 (1.08) | 3 (1.20) | 3 (1.23) | 3 (1.27) |
| Steppage | 5 (1.81) | 5 (1.99) | 5 (2.06) | 6 (2.54) |
| Trendelenberg | 1 (0.36) | 1 (0.40) | 1 (0.41) | 0 (0) |
| Non ambulant | 6 | 2 | 1 | 0 |
| Not assessed | 1 | 2 | 0 | 0 |

Analysis of the Gait during follow up period revealed progressive improvement in terms of type of gait (tending towards normal). This was evaluated by the Unpaired t Test and found to be significant. Initial gait was determined by the type and extent of Amputation, as also the development of Equinus Gait (with increasing frequency along the Course of follow up) being significantly and associated with both TMA and Equinus deformity. These associations were evaluated using the Chi Square Test and p value was **<0.002**.

**SUBGROUP ANALYSIS**

The subgroup Analysis of those 235 patients who completed the Study was done. The improvement in their Berg Balance Scores, TUG risk and 2MWT findings was charted over their follow-up visits. The details are as per Table 32 below :

**Table 32 : Subgroup Analysis – Patients who completed the Study (235)**

| | **Frequency (%)** | | | |
|---|---|---|---|---|
| | 1 month | 2 months | 3 months | 6 months |
| Not assessed / Non Ambulant | 3 | 1 | 1 | 0 |
| | **Berg Balance Scores** | | | |
| Low | 37 | 84 | 163 | 200 |
| Medium | 187 | 150 | 71 | 35 |
| High | 12 | 0 | 0 | 0 |
| | | | | |
| | **Timed UP-and-Go Test Results** | | | |
| Low | 100 | 127 | 157 | 179 |
| High | 132 | 107 | 77 | 56 |
| | | | | |
| | Support for Walking | | | |
| Without Support | 6 | 16 | 32 | 46 |
| Walking Stick | 46 | 61 | 89 | 96 |
| Walker | 180 | 157 | 113 | 93 |
| | | | | |
| | Gait | | | |
| Normal | 195 | 196 | 195 | 196 |
| Abnormal | 37 | 38 | 39 | 37 |
| | | | | |
| | | | | |
| Distance >113m | 54 | 68 | 118 | 132 |
| Distance <113m | 178 | 165 | 117 | 103 |

This progress of the 235 subjects shows an overall improvement in all parameters of evaluation – Examination findings, Standard Ambulatory Tests and overall function.

**AT THE CONCLUSION OF THE STUDY**

116 (49.36%) of the 235 patients who completed entire follow up of 6 months fulfilled all the 6 parameters of success, and thus were determined to have recovered from their Amputation Surgery with adequate return to medical and societal functional status. 70 patients (29.78%) achieved partial success at the end of the Study. By the end of follow up period only 50.54% were deemed to have successfully completed their recovery. Thus, the Study was successful in evaluating the foot Amputee patients and following their rehabilitation.

Totally 142 patients out of the initial Study Population of 377 (35.54%) ended up being excluded from the Study or lost to follow up. The details of these subjects is enumerated in Graphs 2, 3 and 4 along with Table 22. The high dropout rate was mainly due to non-salvageable limbs (MALE ending up in a BKA or AKA), MACEs resulting in death or drastic decline in functional status and loss to follow up. This high attrition rate is in line with the natural history of foot sepsis in CLTI and non-ischaemic DFUs which has remained stable throughout the last 30-40 years in spite of advancements in treatment modalities and strategies [(6)].

# DISCUSSION

## OVERVIEW

### PATIENT DEMOGRAPHICS

443 patients underwent some degree of Toe / foot amputation at our Centre in the Year 2021. 66 refused to participate in the Study, thus 377 were enrolled as the Study Population.

Males comprised an overwhelming 85% of the Study population, keeping in terms with global studies. This was more evident in the ischaemic / CLTI group. Age wise distribution of the patients revealed majority being senior citizens (age 60 years and older).

The most common comorbidities were Diabetes Mellitus (91%) and Hypertension (61%); followed by Ischaemic Heart Disease (36%). There was involvement of multiple CV beds as well, which conforms to the global demographics of foot sepsis (especially CLTI). Smokers comprised just 50% of the Study population which is surprisingly lower than the global literature findings.

### PRESENTATION AND INITIAL PHYSICAL EXAMINATION

Ischaemic limbs (CLTI) were the majority of the Study Population, consisting almost 75% of patients. Distribution of the patients according to their WIFI status and cross-checking with the Risk of Amputation (Table 6) showed that almost 83% of the patients were at risk of major lower limb amputation.

The pre-op ambulant status of the patients correlated closely with the extent of the wound / gangrene (W stage) and the systemic condition (FI stage). Similarly this also correlated with the results of the Bergs Balance Test, AMC LDS and the LCI-5 Scores of the patients. More extensive wound and limited ambulant status (use of walker or wheelchair) corresponded with higher risk of fall as per the Berg Balance Score.

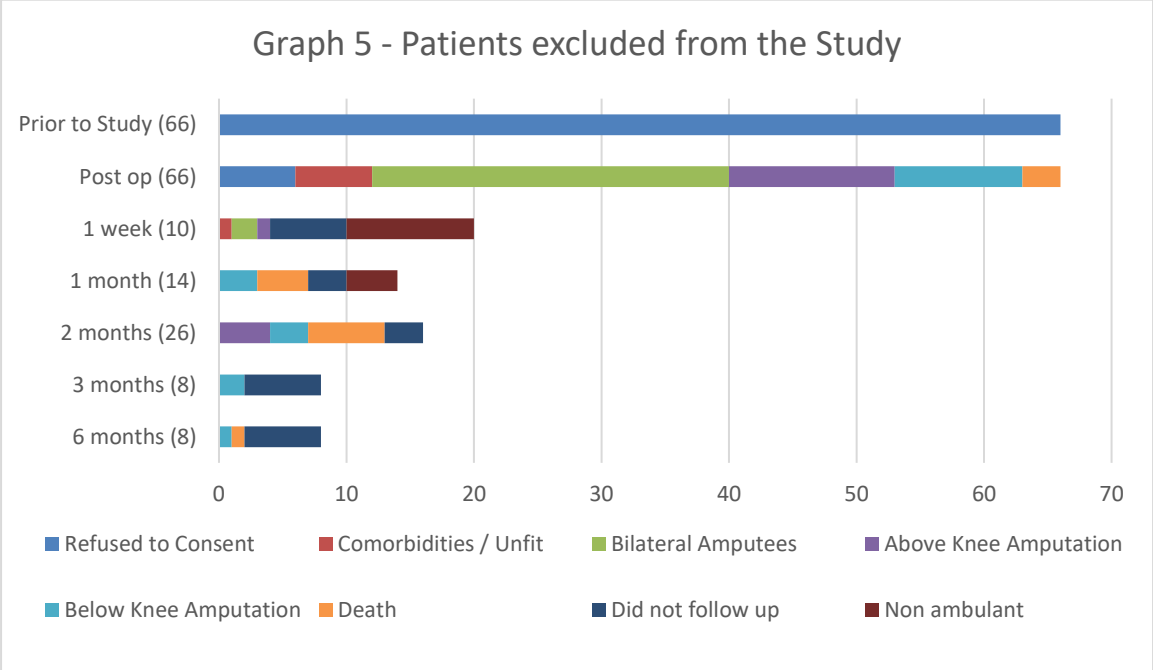
## IN HOSPITAL STAY AND OPERATIVE FINDINGS

278 out of the 281 CLTI patients underwent lower limb revascularisation in the same hospital stay. Those patients with past history of revascularisation with good flow into the foot were classified into the non ischaemic group. It is known that technical success of the revascularisation procedure guides the rates of wound healing and improvement in quality of life (relief from rest pain, better psychological impact due to seeing a healthy wound) and this was reflected in the Study. However these parameters have not been studied here.

Foot debridement (especially over the plantar aspect) was associated with longer time to heal (due to larger wound surface area, intra-op damage and discontinuity of the plantar arterial arch, wound cavity rather than smooth surface due to disruption of the foot arches). This correlated with longer time to stand and longer dependence on walker even if single toe amputation was done. 9 patients underwent revision amputation due to persistent unhealthy wound or development of gangrene of the adjoining toes. At the end of the hospital stay (time of discharge was usually 1-2 days following ambulation) the final tally of toe amputation status were 60 cases of 1$^{st}$ Toe amputation, 65 single toe (excluding 1$^{st}$ toe) amputation, 88 multiple toes amputated and 98 TMAs.

## IMMEDIATE POSTOP EVALUATION AND SUBSEQUENT FOLLOW UP

Patients were followed up at 1 week, 1 month, 2 months, 3 months and 6 months following surgery. At each stage they were examined for extent of wound healing, foot condition. Ambulatory Function Tests were also conducted. Patients who did not meet the Inclusion Criteria were removed from the Study at various stages of follow up. Reasons for exclusion included non salvageable limbs (MALEs), Cardiovascular events (MACEs) which either led to the patient's death or causing him to functionally deteriorate so that he could not meet the Inclusion criteria. The consolidated details are as per Table 22 and Graph 5.




Evaluation of the results and analysis revealed the following :

1. Average time to stand post op was 1.91 days (with SD 0.97 days), which was significantly delayed in case of Multiple Toe Amputations and TMAs (Table 14).

2. Ability to stand without support in the postop period itself was related directly with the extent of amputation. Multiple toe amputation and TMA cases had a significantly longer time to stand. (Table 15 on Page 45).

3. Multiple Toe amputations and TMA cases continued to have delayed return to functional status over 1 week, 1 month and 3 months. This can be also attributed to the larger wound which subsequently takes longer to heal, along with the obvious alteration in foot biomechanics.

4. The Berg Balance Test results (Tables 11, 17, 18, 23) show the progress of the patients from pre-op till the final follow-up. There was a significant improvement in the balance capabilities of the patients over the follow up period. Correspondingly the risk of fall of the patients continued to decrease. Exception to

this was in cases of extreme old age, frailty (poor functional status). The details of the fall risk as estimated by Berg Balance Test as shown in Table 23 on Page 49. To summarize, there was a serial progression from high risk of fall to low risk, which was statistically significant over the follow up period ($p<0.001$). The proportion of patients improving into the low risk category also increased if compared to the number of patients being evaluated at that point of the follow up (from 12.3% at 1 month to 84.7% at 6 months). This is especially profound in the case of multiple toe amputations and TMA patients as compared to single toe amputation patients, and this was also determined to be statistically significant when analysed by the Chi Square test.

5. The Bergs Balance Test score and calculated Risk of fall were independently comparable to the AMC LDS and LCI-5 Score of the patients. This was corroborated at initial presentation as well as during all follow up visits. This corresponds to the literature and descriptions of the Tests. Few patients who had poor motivation to walk at 1 week and 1 month (remaining non ambulant) had low AMC LDS; but their Berg Score and LCI-5 Score were not correspondingly low. This helped identify patients who needed extra motivation and inspiration to ambulate; subsequently these patients improved very well in their functional status.

6. The findings of the 2MWT (Distance covered, Gait and Use of Support) all were independently comparable to the Bergs Balance Test, AMC LDS and LCI-5 Score. The improvement in balance and overall functional status supported the recuperation and progress of the patient as the follow up period progressed.

7. The wound healing coincided with improvement in all factors – Berg Score, AMC LDS, LCI-5 Score. Healed wound resulted in significant improvement in the ambulatory scores.

8. Subgroup Analysis of the 235 patients who attended all follow up visits and completed the Study (Table 32, page 57) also showed serial improvement in all parameters of the Study suggestive of significant improvement in standing, balance and improvement in overall functional status over the follow-up period.

9. There was a high rate of attrition during the Study with many patients being lost to follow up or succumbing to their CV illnesses (MACE). There was also a

high rate of major amputations (Below and Above Knee) despite all efforts throughout the Study, which corresponds to the findings in literature regarding MALE and MACE in CLTI.

**RATIONALE FOR THE STUDY:**

At present, maximum number of amputation-related follow up studies are conducted in Physiotherapy and rehabilitation institutes. Most of the literature available on these studies are in Sports / Trauma / Orthopaedics / Podiatry and Rehabilitaion journals. On the contrary, there are very few studies evaluating the follow up of ischaemic (CLTI) / post DFU amputees.

Furthermore, even scarcer are the studies dealing with partial foot amputation (toes, TMAs, midfoot level, etc) which actually form the bulk of Vascular Surgery related amputations. The change in foot biomechanics following a partial foot amputation is even more profound than a BKA or AKA where the entire limb must be substituted and there are excellent Orthotic devices available for post-op.

This Study becomes especially relevant since it is vital for the patient to return as early as possible to optimum functional status and independence. The very ability to walk following a “disfiguring” amputation boosts psychological recovery; as well as medical point of view in the form of preventing complications of bed-bound status.

The management of post-amputation foot calluses (both primary and secondary prevention) and trophic ulcers due to altered biomechanics and change in foot pressure points, gait abnormalities also is essential so that the patient remains ambulant and functional. These can form nidus of re-infection and can cause a drastic setback to the patient’s health and psyche; especially if he lands up in re-do amputations following which the entire process of rehabilitation needs to start from scratch.

This Study also can also form the baseline for development of a Standard protocol for follow-up and monitoring of foot amputees in vascular Surgery. These are unique in the sense of compromised blood flow, poor wound bed due to

hyperglycaemia and Neuropathy; and persistent low-grade inflammation / infection. This will help train the patients as well as care-givers (attenders and Hospital staff) to be trained in the appropriate rehabilitation.

**DRAWBACKS / LIMITATIONS OF THE STUDY**

There was no scope for Randomisation or blinding in this Study. Moreover, being an observational Study there is a risk of Selection bias.

Being a Single Centre Study, the protocols regarding extent of amputation, determination of revascularisation, determination of non-salvageability of the limb, etc cannot be guaranteed the same result if the Study is replicated at another Institute. For this purpose and External validation, a Multi-Centre Study would be appropriate.

There is bound to be variations in the Scores due to interviewer (observer) bias as well as patient (subject) bias while answering the questions. Examination of gait and speed of walking also will vary with the time of the day, motivation and exhaustion level of the patient.

Non response bias – Lot of patients were lost to follow up. However this is a common observation in multiple prospective Studies conducted in India, that patients tend to become lax with follow up after their wound heals.

**TO SUMMARISE**

This Study shows the natural history and functional progression and improvement of foot and toe amputees over a period of 6 months post-op. The observations, results and the calculation of the same was done using valid and reliable Tests; and hence are reproducible (barring occasional bias). It has the potential a good formative platform for development of further protocols for Vascular foot amputees.

**CONFLICT OF INTEREST** : None

# SUMMARY AND CONCLUSIONS

The study concluded that:

Higher level of foot amputation (more number of toes amputated) is significantly associated with delayed ability to stand and walk in the early postop period (1 week and 1 month follow up).

Single Toe amputation status (not including the 1st Toe) has a significantly earlier recovery and return to walk without support as compared to 1st Toe, multiple Toes and TMA level amputations.

Complete wound healing status is significantly associated with early return to ambulatory function. However the risk of fall persists for longer duration well into the follow up period.

The progressive improvement in gait is significantly and directly related to the level of amputation (specifically for the 1st toe being amputated), rate of wound healing, and development of foot complications (calluses, trophic ulcers). The overall improvement in functional status is significant across all patients as observed and evaluated in the Subgroup Analysis.

The Berg Balance Test was the mainstay of assessment during the Study – it shows excellent sensitivity, specificity and predictive value in evaluating the patients' functional status at all points of follow up. The other Standard Tests of Ambulatory function are independent assessors but can be accurately correlated with the Bergs Balance Score.

Despite all advancements in revascularisation strategies and elite wound care being administered, the success rate of a foot amputation (defined by completely successful rehabilitation) is just 50% at 6 months. This contrasts with a Below or Above Knee Amputee who is assisted by excellent orthotics and rehabilitation protocols, and they can be functionally independent by 1 to 2 months post op.

This Study highlights the need of the hour in concentrating on protocols for improving the quality of life of foot level amputees, and not restricting the treatment of foot wounds to only amputation and / or revascularisation.

# REFERENCES AND BIBLIOGRAPHY

1. Maloney, T.R., Dilkes-Hall, I.E., Vlok, M. et al. Surgical amputation of a limb 31,000 years ago in Borneo. Nature 609, 547–551 (2022). https://doi.org/10.1038/s41586-022-05160-8

2. Celsus, A.C.: On Medicine in Eight Books. Page 380, Chapter XXXIII - Of the operation required in a gangrene.
https://www.gutenberg.org/cache/epub/64207/pg64207-images.html#Footnote_7_36

3. Hernigou P. Ambroise Paré II: Paré's contributions to amputation and ligature. Int Orthop. 2013 Apr;37(4):769-72. doi: 10.1007/s00264-013-1857-x. Epub 2013 Mar 10. PMID: 23474839; PMCID: PMC3609990.

4. Seerig, A.W.H.: Armamentarium chirurgicum oder mo¨glichst vollsta¨ndige Sammlung von Abbildungen und Beschreibung chirurgischer Instrumente a¨lterer und neuerer Zeit (Vols. I–II und Tafelband mit 145 lithographierten Tafeln). Breslau, A. Gosohorsky, 1838, p. 124
(Translation : Armamentarium Chirurgicum or - As complete a collection as possible of illustrations and descriptions of older and more recent surgical instruments (Vols. I–II and volume of plates with 145 lithographed plates). Breslau, A. Gosohorsky, 1838, p. 124)

5. Rutherford 10th Edition, Ch3, page 41

6. Conte MS, Bradbury AW, Kolh P, White JV, Dick F, Fitridge R, Mills JL, Ricco JB, Suresh KR, Murad MH; GVG Writing Group. Global vascular guidelines on the management of chronic limb-threatening ischemia. J Vasc Surg. 2019 Jun;69(6S):3S-125S.e40. doi: 10.1016/j.jvs.2019.02.016. Epub 2019 May 28

7. Erratum in: J Vasc Surg. 2019 Aug;70(2):662. PMID: 31159978; PMCID: PMC8365864

8. Farber A, Eberhardt RT. The Current State of Critical Limb Ischemia: A Systematic Review. JAMA Surg. 2016 Nov 01;151(11):1070-1077

9. Rutherford RB, Baker JD, Ernst C, et al. Recommended standards for reports dealing with lower extremity ischemia: Revised version. J Vasc Surg. 1997;26(3):517–538. doi: 10.1016/S0741-5214(97)70045-4

10. Buttolph A, Sapra A. Gangrene. [Updated 2022 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan. https://www.ncbi.nlm.nih.gov/books /NBK560552

11. Brucato MP, Patel K, Mgbako O. Diagnosis of gas gangrene: does a discrepancy exist between the published data and practice. J Foot Ankle Surg. 2014 Mar-Apr;53(2):137-40

12. Fontaine R, Kim M, Kieny R. Surgical treatment of peripheral circulation disorders. Helv Chir Acta. 1954;21(5-6):499–533

13. Wagner FW., Jr The dysvascular foot: a system for diagnosis and treatment. Foot Ankle. 1981;2(2):64–122. doi: 10.1177/107110078100200202

14. Bell PRF, Charlesworth D, DePalma RG, et al. The definition of critical ischaemia of a limb. Working party of the international vascular symposium. Br J Surg. 1982;69(S6):S2. doi: 10.1002/bjs.1800691303

15. Creager MA, Kaufman JA, Conte MS. Clinical practice. Acute limb ischemia. N Engl J Med. 2012 Jun 07;366(23):2198-206

16. Global report on diabetes. Genebra: WHO; 2016. pp. 6–33

17. Armstrong DG, Lavery LA, Harkless LB. Validation of a diabetic wound classification system: The contribution of depth, infection, and ischemia to risk of amputation. Diabetes Care. 1998;21(5):855–859. doi: 10.2337/diacare.21.5.855

18. Schaper NC. Diabetic foot ulcer classification system for research purposes: a progress report on criteria for including patients in research studies. Diabetes Metab Res Rev. 2004 May-Jun;20 Suppl 1:S90-5. doi: 10.1002/dmrr.464. PMID: 15150820.

19. Mills JL, Sr, Conte MS, Armstrong DG, et al. The society for vascular surgery lower extremity threatened limb classification system: risk stratification based on Wound, Ischemia, and foot Infection (WIfI) J Vasc Surg. 2014;59(1):220–34.e2. doi: 10.1016/j.jvs.2013.08.003

20. Ang CL, Lim YJ. Recurrent admissions for diabetic foot complications. Malays Orthop J. 2013;7(3):21–26

21. Moxey PW, Gogalniceanu P, Hinchliffe RJ, Loftus IM, Jones KJ, Thompson MM, et al. Lower extremity amputations – a review of global variability in incidence. Diabetic Medicine. 2011;28:(10)1144–1153

22. Armstrong DG, Lavery LA, Harkless LB. Validation of a diabetic wound classification system: The contribution of depth, infection, and ischemia to risk of amputation. Diabetes Care. 1998;21(5):855–859. doi: 10.2337/diacare.21.5.855

23. Rutherford 10th Ed, Ch 116, page 1548

24. Gok U, Selek O, Selek A, et al. Survival evaluation of the patients with diabetic major lower-extremity amputations. Musculoskelet Surg. 2016;100:145–148

25. Rutherford 10th Ed, Ch 116, page 1549

26. Lavery LA, Armstrong DG, Vela SA, et al. Practical criteria for screening patients at high risk for diabetic foot ulceration. Arch Intern Med.1998;158:157–162

27. Flynn MD, Tooke JE. Aetiology of diabetic foot ulceration: a role for the microcirculation? Diabet Med. 1992;9:320–329

28. Al Wahbi A. Autoamputation of diabetic toe with dry gangrene: a myth or a fact? Diabetes Metab Syndr Obes. 2018 Jun 1;11:255-264. doi: 10.2147/DMSO.S164199. PMID: 29910628; PMCID: PMC5987754

29. Brown BJ, Crone CG, Attinger CE. Amputation in the diabetic to maximize function. Semin Vasc Surg. 2012;25(2):115–121

30. McKittrick LS, McKittrick JB, Risley TS. Transmetatarsal amputation for infection or gangrene in patients with diabetes mellitus. Ann Surg 1949;130:826–831

31. Wagner FW. Amputations of the foot and ankle. Clin Ortho. 1977;122:62–69

32. Blanc CH, Borens O. Amputations of the lower limb–an overview on technical aspects. Acta Chir Belg. 2004;104:388–392

33. http://eknygos.lsmuni.lt/springer/614/363-389.pdf The Diabetic Foot 2nd Ed. Ch 18 - Amputation and Rehabilitation of the Diabetic Foot by Sage et al

34. Palastanga, N., Field, D., & Soames, R. (2012). Anatomy and human movement: Structure and function. (6th ed.). Edinburgh: Elsevier Churchill Livingstone

35. Ataullah AHM, De Jesus O. Gait Disturbances. [Updated 2023 Feb 12]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560610

36. Gremeaux V, Damak S, Troisgros O, Feki A, Laroche D, Perennou D, Benaim C, Casillas JM. Selecting a test for the clinical assessment of balance and walking capacity at the definitive fitting state after unilateral amputation: a comparative study. Prosthet Orthot Int. 2012 Dec;36(4):415-22. doi: 10.1177/0309364612437904. Epub 2012 Mar 2. PMID: 22389424

37. Dillingham TR and Pezzin LE. Rehabilitation setting and associated mortality and medical stability among persons with amputations. Arch Phys Med Rehabil 2008; 89: 1038–45

38. https://www.sralab.org/rehabilitation-measures/berg-balance-scale

39. Meseguer-Henarejos AB, Rubio-Aparicio M, López-Pina JA, Carles-Hernández R, Gómez-Conesa A. Characteristics that affect score reliability in the Berg Balance Scale: a meta-analytic reliability generalization study. Eur J Phys Rehabil Med. 2019 Oct;55(5):570-584

40. Major MJ, Fatone S, Roth EJ. Validity and reliability of the Berg Balance Scale for community dwelling persons with lower-limb amputation. Arch

Phys Med Rehabil. 2013 Nov;94(11):2194-202. doi: 10.1016/j.apmr.2013.07.002. Epub 2013 Jul 13. PMID: 23856150

41. Wong CK. Interrater reliability of the Berg Balance Scale when used by clinicians of various experience levels to assess people with lower limb amputations. Phys Ther. 2014 Mar;94(3):371-8

42. Grise MC, Gauthier-Gagnon C, Martineau GG. Prosthetic profile of people with lower extremity amputation: conception and design of a follow-up questionnaire. Arch Phys Med Rehabil. 1993;74:862–870. doi: 10.1016/0003-9993(93)90014-2

43. Gauthier-Gagnon C, Grise MC. Tools to measure outcome of people with lower limb amputation; Update on the PPA and LCI. J Prosthet Orthot. 2006;18:61–69. doi: 10.1097/00008526-200601001-00007

44. Holman R, Weisscher N, Glas CA, Dijkgraaf MG, Vermeulen M, de Haan RJ, et al. The Academic Medical Center Linear Disability Score (ALDS) item bank: item response theory analysis in a mixed patient population. Health Qual Life Outcomes 2005;3:83

45. Met R, Reekers JA, Koelemay MJ, Legemate DA, de Haan RJ. The AMC linear disability score (ALDS): a cross-sectional study with a new generic instrument to measure disability applied to patients with peripheral arterial disease. Health Qual Life Outcomes 2009;7:88

46. Franceline Alkine Frans, Rosemarie Met et al. Changes in functional status after treatment of Critical Limb Ischaemia. J Vasc Surg 2013;58(4):957-965

47. Met R, Reekers JA, Koelemay MJ, Legemate DA, de Haan RJ. The AMC linear disability score (ALDS): a cross-sectional study with a new generic

instrument to measure disability applied to patients with peripheral arterial disease. Health Qual Life Outcomes. 2009 Oct 12;7:88. doi: 10.1186/1477-7525-7-88. PMID: 19822016; PMCID: PMC2766362.

48. https://www.physiopedia.com/2_Minute_Walk_Test?utm_source=physiopedia&utm_medium=search&utm_campaign=ongoing_internal

49. Brooks D, Parsons J, Hunter JP, Devlin M, Walker J. The 2-minute walk test as a measure of functional improvement in persons with lower limb amputation. Arch Phys Med Rehab. 2001: 82(10):1478-83

50. Gaunaurd I, Kristal A, Horn A, Krueger C, Muro O, Rosenberg A, Gruben K, Kirk-Sanchez N, Pasquina P, Gailey R. The Utility of the 2-Minute Walk Test as a Measure of Mobility in People with Lower Limb Amputation. Arch Phys Med Rehabil. 2020 Jul;101(7):1183-1189. doi: 10.1016/j.apmr.2020.03.007. Epub 2020 Apr 6. PMID: 32272105

51. Brooks D, Hunter JP, Parsons J, Livsey E, Quirt J and Devlin. M. Reliability of the two-minute walk test in individuals with transtibial amputation. Arch Phys Med Rehabil 2002; 83: 1562–65

52. Reid, L., Thomson, P., Besemann, M., & Dudek, N. (2015). Going places: Does the two-minute walk test predict the six-minute walk test in lower extremity amputees?. Journal of Rehabilitation Medicine, 47(3), 256–261. https://doi.org/10.2340/16501977-1916

53. Gremeaux V, Damak S, Troisgros O, et al. Selecting a test for the clinical assessment of balance and walking capacity at the definitive fitting state after unilateral amputation: a comparative study. Prosthetics and Orthotics International. 2012;36(4):415-422. doi:10.1177/0309364612437904

54. Bohannon RW, Wang YC, Gershon RC. Two-minute walk test performance by adults 18 to 85 years: normative values, reliability, and responsiveness. Arch Phys Med Rehabil. 353 2015;96(3):472-477

55. https://www.physio-pedia.com/Timed_Up_and_Go_Test_(TUG)

56. https://www.sralab.org/rehabilitation-measures/timed-and-go

57. Bernard Rosner. Fundamentals of Biostatistics, 2000, 5th Edition, Duxbury, page 80-240.

58. Robert H Riffenburg. Statistics in Medicine 2005, 2nd Edition, Academic press. 85-125.

59. Sunder Rao P, Richard J, An Introduction to Biostatistics, A manual for students in health sciences, New Delhi: Prentice Hall of India. 2006; 4th Edition, 86-160.

# ANNEXURES

## Annexure 1 : INFORMED CONSENT FORM

## ASSESSMENT OF RESIDUAL FUNCTIONAL STATUS AND QUALITY OF LIFE IN FOOT AMPUTEES AT A TERTIARY VASCULAR SURGERY CENTRE – AN INSTITUTIONAL BASED PROSPECTIVE STUDY

**Name of Participant :** _____

**Introduction**

1. The purpose of this form is to provide you with information so you can decide whether to participate in this study. Any questions you may have will be answered by the researcher or by the other contact persons provided below.
2. Once you are familiar with the information on the form and have asked any questions you may have, you can decide whether to participate or no. Please note your participation is voluntary and you may decide to leave the study at any time.
3. If you agree, please either sign this form. If you do not wish your name to be registered on the form, a unique ID number will be allotted to you.
4. You may also refuse to answer specific questions you are uncomfortable with. You may withdraw permission for your data to be used, at any time up to in which case notes, transcriptions and recordings of all follow up will be destroyed.
5. Withdrawal or refusal to participate will not affect your relationship with your treating team or rehabilitation or recovery follow-up. You will continue to receive the standard and highest quality of medical care as per the guidelines.

**Purpose of the Study**

1. This study aims to follow up foot-only amputees and evaluate their recovery, return to ambulant status and quality of life parameters during their follow up period.
2. This will involve regular follow up of the participant (in this case you) immediately after surgery and on OPD basis from discharge till 6 months post operatively. You will be assessed for your gait, speed of walk, balance and need for support during this evaluation.
3. Prior to your discharge, if you consent to participate you will be handed a questionnaire in which you will be asked to share your expectations and targets for your own improvement for the next 6 months. This will be used to compare your actual progress during your follow up visits.
4. Whether you consent or not, you will be provided a rehabilitation and physiotherapy counseling which will advise you on the basic dos and don’ts during your recovery; what danger signs to look for and most common signs of potential complications which could hinder your recovery and rehabilitation progress. You will also not be discriminated during your follow up visits for if you do not agree to participate in this study.
5. The findings and interpretation of your progress will be entered and used in the dissertation, which may or may not be eventually published in a medical journal as well. The findings may be used to create a standardized protocol for

physiotherapy, training and rehabilitation of future foot amputees at this centre and others.

6. You will not be charged any extra amount for participating in this study as compared to other patients in the form of extra tests or investigations. Similarly, you will not receive any compensation (financial or otherwise) for participation either from the Principal Worker, Guide or the Department.

7. If you do not follow the instructions or advice of the Principal or Associate workers in a manner that either will hamper your progress or adversely affect the results of the Study, you will be withdrawn as a participant. Failure to regular follow up will also result in your removal from the Study.

## CONSENT BY THE PARTICIPANT

1. I _____ have read the above information in the participation form.

2. In addition to this I have also been verbally explained about the Study in brief, the Aims, objectives and methodology of conduct over the next 6 months. Any and all questions that I have asked, have been answered to my satisfaction.

3. I understand that I will have to follow the rehabilitation protocols explained to me. During my follow up visits I understand that I will be subjected to a few clinical tests and I will have to partake in them.

4. I understand that in any report on the results of this research my identity will remain anonymous and all information I provide for this study will be treated confidentially.

5. I understand that I am free to contact any of the people involved in the research to seek further clarification and information. I understand that I can at any time withdraw my consent for participation, and this withdrawal will not affect my follow up standard of care, management and treatment.

6. I hereby freely give my consent to be enrolled as a participant in the Study.

Name of the Participant : _____ Signature:

Name of the Witness : _____ Signature:

Name of the Principal Worker : Dr Vinay Nazareth _____ Signature :

Date _____

Place : JIVAS, BMJH Bangalore

## Annexure 2 : Berg's Balance Test

1. SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support.
( )4 able to stand without using hands and stabilize independently
( )3 able to stand independently using hands
( )2 able to stand using hands after several tries
( )1 needs minimal aid to stand or stabilize
( )0 needs moderate or maximal assist to stand

2. STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on.
( )4 able to stand safely for 2 minutes
( )3 able to stand 2 minutes with supervision
( )2 able to stand 30 seconds unsupported
( )1 needs several tries to stand 30 seconds unsupported
( )0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes.
( )4 able to sit safely and securely for 2 minutes
( )3 able to sit 2 minutes under supervision
( )2 able to able to sit 30 seconds
( )1 able to sit 10 seconds
( )0 unable to sit without support 10 seconds

4. STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( )4 sits safely with minimal use of hands
( )3 controls descent by using hands
( )2 uses back of legs against chair to control descent
( )1 sits independently but has uncontrolled descent
( )0 needs assist to sit

5. TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( )4 able to transfer safely with minor use of hands
( )3 able to transfer safely definite need of hands
( )2 able to transfer with verbal cuing and/or supervision
( )1 needs one person to assist
( )0 needs two people to assist or supervise to be safe

6. STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.
( )4 able to stand 10 seconds safely
( )3 able to stand 10 seconds with supervision
( )2 able to stand 3 seconds
( )1 unable to keep eyes closed 3 seconds but stays safely
( )0 needs help to keep from falling

7. STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( )4 able to place feet together independently and stand 1 minute safely
( )3 able to place feet together independently and stand 1 minute with supervision
( )2 able to place feet together independently but unable to hold for 30 seconds
( )1 needs help to attain position but able to stand 15 seconds feet together
( )0 needs help to attain position and unable to hold for 15 seconds

8. REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING

INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

9. PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION

INSTRUCTIONS: Pick up the shoe/slipper, which is place in front of your feet.

( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm(1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

10. TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING

INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.

( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

11. TURN 360 DEGREES

INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.

( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

12. PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED

INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touch the step/stool four times.

( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

13. STANDING UNSUPPORTED ONE FOOT IN FRONT

INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)

( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

14. STANDING ON ONE LEG

INSTRUCTIONS: Stand on one leg as long as you can without holding on.

( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
( ) 0 unable to try of needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

## Annexure 3 : Locomotor Capability Index - 5

| The common question is "Whether or not you wear your prosthesis at the present time, would you say that you are able to do the following activities with your prosthesis on?" | No (0) | Yes, If Someone Helps Me (1) | Yes, If Someone Is Near Me (2) | Yes, Alone, With Ambulation Aids (3) | Yes, Alone, Without Ambulation Aids (4) |
|---|---|---|---|---|---|
| 1. Get up from a chair | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. Pick up an object from the floor when you are standing up with your prosthesis | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3. Get up from the floor (eg, if you fell) | ☐ | ☐ | ☐ | ☐ | ☐ |
| 4. Walk in the house | ☐ | ☐ | ☐ | ☐ | ☐ |
| 5. Walk outside on even ground | ☐ | ☐ | ☐ | ☐ | ☐ |
| 6. Walk outside on uneven ground (eg, grass, gravel, slope) | ☐ | ☐ | ☐ | ☐ | ☐ |
| 7. Walk outside in inclement weather (eg, snow, rain, ice) | ☐ | ☐ | ☐ | ☐ | ☐ |
| 8. Go up the stairs with a hand-rail | ☐ | ☐ | ☐ | ☐ | ☐ |
| 9. Go down the stairs with a hand-rail | ☐ | ☐ | ☐ | ☐ | ☐ |
| 10. Step up a sidewalk curb | ☐ | ☐ | ☐ | ☐ | ☐ |
| 11. Step down a sidewalk curb | ☐ | ☐ | ☐ | ☐ | ☐ |
| 12. Go up a few steps (stairs) without a hand-rail | ☐ | ☐ | ☐ | ☐ | ☐ |
| 13. Go down a few steps (stairs) without a hand-rail | ☐ | ☐ | ☐ | ☐ | ☐ |
| 14. Walk while carrying an object | ☐ | ☐ | ☐ | ☐ | ☐ |

NOTE. In the standard LCI,[6,9] items are scored according to a 4-level ordinal scale: the LCI-5 levels 3 and 4 are merged in a unique level (3, yes, alone).

## Annexure 4 :

## Amsterdam Academic Medical Centre (AMC) Linear Disability Score (LDS)

| *Are you able to …* | *I can carry out the activity* | *I can carry out the activity with difficulty* | *I cannot carry out the activity* | *Not applicable* | *Linear transformed ALDS score* |
|---|---|---|---|---|---|
| 1. Vacuum a flight of stairs? | ☐ | ☐ | ☐ | ☐ | 87 |
| 2. Vacuum a room and move light furniture? | ☐ | ☐ | ☐ | ☐ | 84 |
| 3. Fetch groceries for 3-4 days? | ☐ | ☐ | ☐ | ☐ | 82 |
| 4. Travel by local bus or tram? | ☐ | ☐ | ☐ | ☐ | 78 |
| 5. Go shopping for clothes? | ☐ | ☐ | ☐ | ☐ | 73 |
| 6. Go to a party? | ☐ | ☐ | ☐ | ☐ | 70 |
| 7. Hang and take in a load of washing? | ☐ | ☐ | ☐ | ☐ | 69 |
| 8. Move a bed or table? | ☐ | ☐ | ☐ | ☐ | 66 |
| 9. Walk up a flight of stairs? | ☐ | ☐ | ☐ | ☐ | 65 |
| 10. Go to the bank or post office? | ☐ | ☐ | ☐ | ☐ | 64 |
| 11. Walk down a flight of stairs? | ☐ | ☐ | ☐ | ☐ | 62 |
| 12. Cross the road? | ☐ | ☐ | ☐ | ☐ | 58 |
| 13. Fetch a few things from the shop? | ☐ | ☐ | ☐ | ☐ | 56 |
| 14. Have a shower and wash your hair? | ☐ | ☐ | ☐ | ☐ | 50 |
| 15. Dust? | ☐ | ☐ | ☐ | ☐ | 50 |
| 16. Clean a toilet? | ☐ | ☐ | ☐ | ☐ | 48 |
| 17. Move between two low chairs? | ☐ | ☐ | ☐ | ☐ | 42 |
| 18. Clean a bathroom sink? | ☐ | ☐ | ☐ | ☐ | 42 |
| 19. Get in and out of a car? | ☐ | ☐ | ☐ | ☐ | 39 |
| 20. Clear the table after a meal? | ☐ | ☐ | ☐ | ☐ | 37 |
| 21. Prepare breakfast or lunch? | ☐ | ☐ | ☐ | ☐ | 36 |
| 22. Wash up? | ☐ | ☐ | ☐ | ☐ | 31 |
| 23. Make coffee or tea? | ☐ | ☐ | ☐ | ☐ | 25 |
| 24. Put long trousers on? | ☐ | ☐ | ☐ | ☐ | 24 |
| 25. Sit on the edge of a bed from lying down? | ☐ | ☐ | ☐ | ☐ | 21 |
| 26. Get out of bed into a chair? | ☐ | ☐ | ☐ | ☐ | 18 |
| 27. Go to the toilet? | ☐ | ☐ | ☐ | ☐ | 17 |

## Annexure 5 : Institutional Scientific Committee Approval

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caring with compassion

# SCIENTIFIC COMMITTEE

### APPROVAL CERTIFICATE OF DISSERTATION FOR NBE

Approval has been granted by Scientific Committee of Bhagwan Mahaveer Jain Hospital for the following Dissertation as per NBE requirement **ASSESSMENT OF FUNCTIONAL STATUS AND QUALITY OF LIFE IN FOOT AMPUTEES AT A TERTIARY VASCULAR SURGERY CENTRE : AN INSTITUTIONAL BASED PROSPECTIVE STUDY** Conducted by **DR.VINAY NAZARETH** Department of **VASCULAR SURGERY** under the guidance of **DR. VIVEKANAND** approximate period of study is from **JUNE 2021 to MAY 2022.**

Scientific Committee meeting held on **8/06/2021.**

**Date : 22/07/2021**

**Dr. (Wg Cdr) M.D.Marker**
**Medical Director**
**BMJH Scientific Committee**

Dr. (Wg Cdr) M.D. Marker
Medical Director
BHAGWAN MAHAVEER JAIN HOSPITAL
Bangalore-560 052

## Annexure 6 : Institutional Ethics Committee Approval

ETHICS COMMITTEE ON HUMAN RESEARCH
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A UNIT OF BHAGWAN MAHAVEER MEMORIAL JAIN TRUST
Millers Road, Vasanthnagar, Bangalore - 560 052.
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e-mail : bmjh.mdoffice@gmail.com

**APPROVAL CERTIFICATE OF DISSERTATION FOR NBE**

Approval has been granted by Ethics Committee of Bhagwan Mahaveer Jain Hospital for the following Dissertation as per NBE requirement **ASSESSMENT OF FUNCTIONAL STATUS AND QUALITY OF LIFE IN FOOT AMPUTEES AT A TERTIARY VASCULAR SURGERY CENTRE : AN INSTITUTIONAL BASED PROSPECTIVE STUDY** Conducted by **DR.VINAY NAZARETH** Department of **VASCULAR SURGERY** under the guidance of **DR. VIVEKANAND** approximate period of study is from **JUNE 2021 to MAY 2022.**

Ethics Committee meeting held on **8/06/2021.**

**Date : 22/07/2021**

**Dr. (Wg Cdr) M.D.Marker**
**Member Secretary**
**BMJH Ethics Committee**

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