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**A COMPARATIVE STUDY OF EFFICACY OF  
MANDAKINI OFF LOADING DEVICE VERSUS USE OF CRUTCHES  
FOR DIABETIC FOOT ULCERS**

**By**

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## ABSTRACT

**BACKGROUND:** A study was carried out to compare the efficacy of the two Off-loading systems- the Mandakini Off-loading device and the Crutches – for the healing of Diabetic Foot Ulcers (DFU).

**METHODS:** A comparative and observational study was carried out among patients admitted with Diabetic Foot Ulcers in the Department of General Surgery of the RL Jalappa Hospital & research centre. In all, 60 Diabetic foot ulcer individuals were involved in this study. The Institutional Ethics Committee granted clearance for this study. Detailed history of the participants followed by clinical examination was done by the principal investigator after which diagnosis of Diabetic Foot Ulcer was made. The Mandakini Off-Loading device and Crutches were used to compare which device is better for healing of diabetic foot ulcers.

**RESULTS:** In the present study, the mean healing time was 12.63 days in the Mandakini Off-loading device group compared to 21.30 days in the crutches group- with Mandakini Off-loading device offering 40.7% faster recovery. The number of dressings were lesser in the Mandakini Off-loading device group when compared to the Crutches group (4.47 vs 10.10) reducing the procedural burden by 55.8%. The hospital stay was shortened in Mandakini Off-loading device group by 41.9% (10.23 vs 17.63 days). Total treatment costs were 26.9% cheaper in the Mandakini Off-loading device group. Pain relief and patient satisfaction was superior in the Mandakini Off-loading device group. No amputations or recurrences were noticed in the Mandakini Off-loading device group while a 13.3% chance of both outcomes in the Crutches group. Adverse events were minimal in both the groups and no major device related complications. Notably, the Mandakini Off-loading device was a better Off-loading device compared to Crutches for the healing of Diabetic Foot Ulcers.

**CONCLUSION:** We infer that the Mandakini Off-loading Device can be used in routine practice for better healing of Plantar Diabetic Foot Ulcers.

**KEY WORDS:** Diabetic Foot Ulcers, Mandakini Off-loading Device, Crutches.

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*ABBREVIATIONS*

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<b>Abbreviation</b>	<b>Full Form</b>
ABI	Ankle-Brachial Index
ADA	American Diabetes Association
CT	Computed Tomography
DFU	Diabetic Foot Ulcer
DSA	Digital Subtraction Angiography
HbA1c	Hemoglobin A1c (Glycated Hemoglobin)
ICMR	Indian Council of Medical Research
IDSA	Infectious Diseases Society of America
iTCC	Instant Total Contact Cast
IWGDF	International Working Group on the Diabetic Foot
LOPS	Loss of Protective Sensation
MRSA	Methicillin-Resistant Staphylococcus Aureus
MSSA	Methicillin-Sensitive Staphylococcus Aureus
PAD	Peripheral Arterial Disease
PEDIS	Perfusion, Extent, Depth, Infection, and Sensation
PTA	Percutaneous Transluminal Angioplasty
RCT	Randomized Controlled Trial
RCW	Removable Cast Walker
SINBAD	Site, Ischemia, Neuropathy, Bacterial infection, Area, Depth
SMD	Standardized Mean Difference
TCC	Total Contact Cast
TcPO <sub>2</sub>	Transcutaneous Oxygen Pressure
TIME	Tissue debridement, Inflammation/Infection control, Moisture balance, Edge advancement
UT	University of Texas
USD	United States Dollar

# **A COMPARATIVE STUDY OF EFFICACY OF MANDAKINI OFF LOADING DEVICE VERSUS USE OF CRUTCHES FOR DIABETIC FOOT ULCERS**

## **1. INTRODUCTION**

Diabetes mellitus, over the past few decades, has taken the shape of a global medical emergency. According to the International Diabetes Federation, more than 537 million people worldwide were living with this metabolic disorder in 2021, and projections indicate this may rise to over 780 million by 2045. India alone contributes a significant portion to this global load, with more than 77 million affected individuals, making it second only to China in disease burden. But the disease rarely remains limited to glycemic alterations; its long-term complications, especially those affecting the peripheral tissues, are responsible for most of the associated morbidity. Among these, diabetic foot ulcers (DFUs) have emerged as a severe and recurring challenge both clinically and socially.<sup>1</sup>

DFUs are observed in nearly 15 to 25 percent of individuals with diabetes during their lifetime. Clinically, they are not mere ulcers confined to the foot but are reflections of cumulative microvascular and macrovascular damage. These ulcers usually appear due to a combination of diabetic neuropathy, peripheral arterial insufficiency, and unnoticed trauma over weight-bearing areas. Neuropathy, in particular, causes a decline in protective sensation, and in many patients, altered gait and deformities develop due to small muscle wasting. These changes lead to abnormal pressure points under the foot, which gradually break down under constant use. At the same time, reduced blood flow delays repair, and any additional pressure worsens the insult. Over time, a chronic, non-healing ulcer forms.<sup>2</sup>

In India, diabetic foot ulcers are not rare occurrences. They account for around 20% of all hospital admissions among patients with diabetes, often requiring multidisciplinary care. The consequences are not limited to the local site. The risk of soft tissue infection, osteomyelitis, and even gangrene increases significantly if early intervention is not done. In many cases, the end result is limb loss, which imposes a permanent disability and deep psychological distress on the individual.<sup>3</sup>

From an economic standpoint, the picture is equally concerning. Managing DFUs typically requires repeated outpatient visits, use of advanced dressings or devices, surgical interventions, and in many cases, inpatient care. The indirect costs include loss of workdays, travel for treatment, and dependence on caregivers. In low-resource settings, these burdens often become unmanageable, leading to delayed healing or poor outcomes. The situation becomes more difficult in rural and semi-urban regions, where access to specialty services is limited and awareness is often lacking.<sup>4</sup>

Management of DFU, therefore, relies not only on wound care or antibiotics but also on off-loading—a crucial part of standard therapy. Off-loading, by definition, involves reducing mechanical pressure over the ulcer or any high-risk area of the foot, which facilitates the healing process. It targets one of the root causes of ulcer progression—continuous, unnoticed pressure on the same region. Both the International Working Group on the Diabetic Foot (IWGDF) and the American Diabetes Association (ADA) recommend off-loading as a primary component of ulcer care. In fact, in several studies, appropriate off-loading has shown better results than even newer wound-care products.<sup>5</sup>

Various methods are available for pressure off-loading. The Total Contact Cast (TCC) is often referred to as the gold standard for certain types of plantar ulcers, due to its ability to distribute pressure evenly. However, it requires skilled personnel, and patients must be monitored closely. Removable cast walkers, therapeutic footwear, and crutches are also widely used, especially in outpatient and home-based settings. Crutches, in particular, are simple and cheap, and they allow the patient to avoid placing weight on the affected limb altogether.<sup>6</sup>

Yet, despite these benefits, crutches have practical limitations. Many patients—especially the elderly or those with balance issues—find them difficult to use over longer durations. Extended use may lead to discomfort, axillary nerve issues, or fatigue. In villages and semi-urban zones, uneven walking surfaces and narrow indoor spaces further reduce their usefulness. Moreover, not all patients are cooperative or motivated enough to follow non-weight-bearing instructions strictly. Due to these challenges, the actual success rate of crutch-based off-loading may vary.<sup>7</sup>

It was under these practical constraints that the Mandakini Off-Loading Device was conceptualized. Designed in India, with a focus on affordability, simplicity, and biomechanical function, this device attempts to fill the gap left by traditional aids. It allows controlled ambulation

while reducing pressure over the ulcer site and does not rely heavily on upper body strength. Materials used are locally sourced, making the device reproducible in peripheral health centers. Initial reports from limited hospital setups suggest that patients tolerated the device well and were able to follow off-loading more consistently. Though promising, these reports are mostly observational and lack comparative data.<sup>8</sup>

There is, therefore, a need to evaluate this indigenous device more systematically. Despite its increasing use, there are no large-scale studies directly comparing the Mandakini Off-Loading Device with standard aids such as crutches. Its role in ulcer healing, patient compliance, functional outcome, and overall satisfaction remains unclear. This study has been undertaken with the intention to bridge this gap. A clearer understanding of its benefits or limitations could help in developing standardized, low-cost solutions for diabetic foot management, particularly in regions with limited infrastructure and high disease burden.

## **AIMS AND OBJECTIVES**

1. To assess the efficacy of Mandakini off-loading device in the treatment of Diabetic Foot Plantar ulcer in terms of ideal off loading features, duration of healing of ulcer and recurrence of ulcer.
2. To assess the efficacy by use of crutches in terms of duration of healing ulcer, infection, recurrence of ulcer and amputation rates, & healing of the ulcers.
3. To compare which off loading device amongst madakini off loading device and use of axillary crutches is better in the healing of plantar diabetic foot ulcers.

## 2. REVIEW OF LITERATURE

### 2.1 Introduction to Diabetic Foot Ulcers (DFUs)

#### A) Definition and Classification

A diabetic foot ulcer is defined as a full-thickness skin defect located below the ankle, occurring in a patient with established diabetes mellitus. In most instances, these ulcers develop over weight-bearing areas and arise due to peripheral neuropathy, peripheral arterial disease, or both. The ulcers may or may not be accompanied by infection, but the overall healing process is almost always prolonged. They tend to recur and are often the first clinical sign of limb-threatening complications.<sup>9</sup>

Grade	Description of the ulcer
0	Pre- or postulcerative lesion completely epithelialized
1	Superficial, full-thickness ulcer limited to the dermis, not extending to the subcutis
2	Ulcer of the skin extending through the subcutis with exposed tendon or bone and without osteomyelitis or abscess formation
3	Deep ulcers with osteomyelitis or abscess formation
4	Localized gangrene of the toes or the forefoot
5	Foot with extensive gangrene

**Fig: Wagner-Meggitt grading system of DFU**

Among the widely used ulcer classification systems, the Wagner-Meggitt grading system, introduced in the 1970s, remains one of the earliest. This system grades ulcers from 0 to 5, starting from pre-ulcerative lesions and progressing to gangrene of the entire foot. However, Wagner's scale does not include infection status or perfusion, which are crucial in deciding prognosis and therapy. To address this, the University of Texas (UT) classification was proposed later. It stratifies DFUs based on both depth (grade) and the presence of ischemia or infection (stage), giving it added clinical relevance.<sup>10</sup>

Other scoring methods such as SINBAD ((Site, Ischemia, Neuropathy, Bacterial infection, Area, Depth) and PEDIS (Perfusion, Extent, Depth, Infection, and Sensation) have gained acceptance, especially for research settings. These are more suited for outcome tracking and align well with the recommendations provided by the IWGDF.<sup>11</sup>

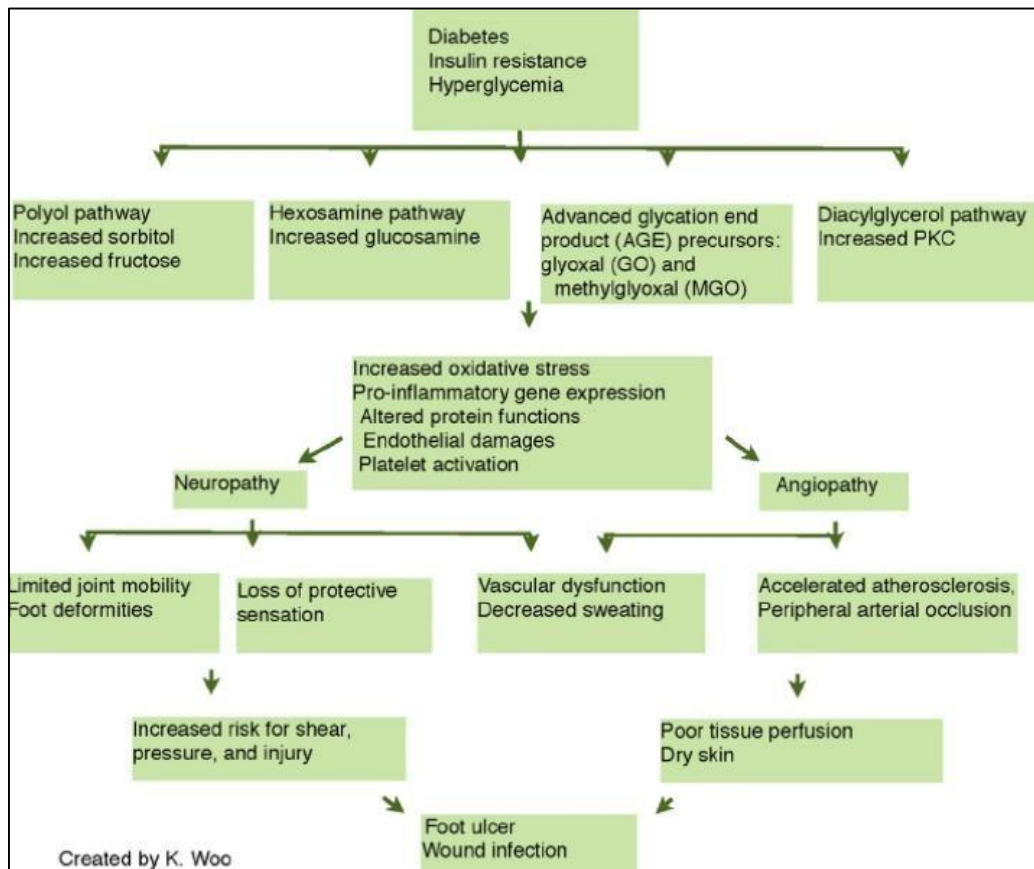
## **B) Epidemiology**

Diabetic foot ulcer is not an uncommon entity. It is seen in approximately 15 to 25 percent of individuals with diabetes at some point during their life. The global point prevalence among diabetics is reported between 4% and 10%, with an annual incidence of about 2% in developed nations. In lower-income regions, the figure is often higher, ranging up to 6% or even 7%, depending on population characteristics.

In India, the prevalence is more concerning. Studies from tertiary care hospitals have reported DFUs in 8% to 17% of patients attending diabetes clinics. Factors contributing to this include lack of awareness, barefoot walking, poor footwear use, late presentation, and absence of regular foot screening. A multicentric ICMR study showed that nearly 1 in 5 hospitalised diabetics had active foot lesions requiring wound care or surgical management. This points to an urgent need for structured preventive programs and context-specific therapeutic aids that suit the Indian scenario.<sup>12</sup>

## **C) Pathophysiology of DFUs**

The mechanisms leading to diabetic foot ulcers are multifactorial. Among these, peripheral neuropathy, arterial insufficiency, and infection form the core triad responsible for ulcer development and non-healing.



**Fig: Pathophysiology of DFUs**

Neuropathy in diabetics affects sensory, motor, and autonomic nerves. When sensory loss occurs, the patient does not perceive minor injuries, burns, or friction. Motor neuropathy causes wasting of intrinsic muscles, which results in deformities such as claw toes or prominent metatarsal heads. These abnormalities cause focal pressure points during walking. Autonomic dysfunction leads to dry skin, cracks, and loss of sweat secretion, which together compromise the barrier function of skin.

Peripheral arterial disease reduces blood flow to the extremities. In diabetics, the pattern is usually distal and involves calcified arteries, especially below the knee. This impairs tissue oxygenation and reduces the ability of the immune system to respond to injury or infection. Wound healing is directly delayed when ischemia is present.

Infection frequently complicates the picture. Often polymicrobial, it may involve organisms such as *Staphylococcus aureus*, *Pseudomonas*, and *Escherichia coli*. These pathogens enter through open skin and can spread rapidly to deeper tissues. In neglected cases, infection progresses to

cellulitis, abscess, bone involvement, and systemic sepsis. In such cases, amputation may become inevitable if early control is not achieved.<sup>9</sup>

#### **D) Clinical Burden and Complications**

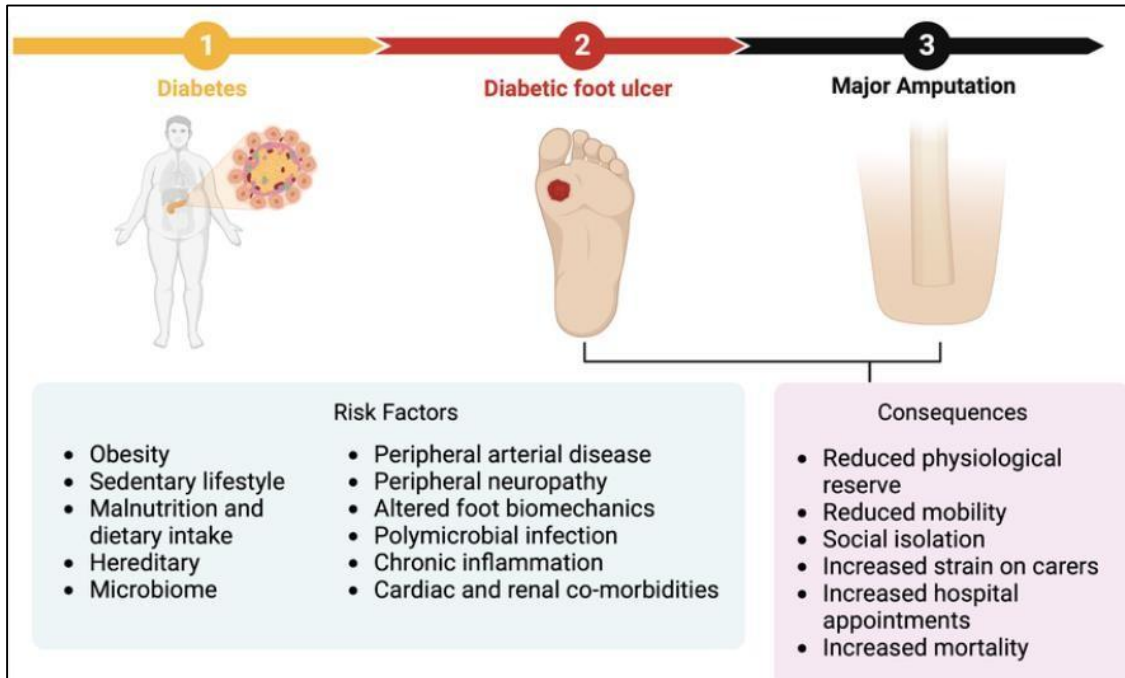
DFUs contribute significantly to morbidity and mortality among diabetic individuals. Once an ulcer develops, the chances of hospitalisation, prolonged treatment, and surgical intervention rise sharply. Approximately 20% to 30% of patients admitted with DFUs eventually undergo amputation. The risk increases if there is osteomyelitis, gangrene, or critical limb ischemia.

Even after healing, recurrence is a major concern. Studies indicate that nearly 40% of healed ulcers reappear within one year, and the recurrence rate may exceed 60% by the end of three years. Most recurrences occur at the same location or a nearby site, often due to unresolved foot biomechanics or continued unprotected walking.

Amputation, whether partial or major, carries a poor prognosis. Five-year mortality following a below-knee amputation is reported to be between 50% and 70%, which is comparable to or worse than many malignancies. The economic burden, psychological impact, and functional loss further complicate recovery.<sup>13</sup>

#### **2.2 Risk Factors**

Diabetic foot ulceration (DFU), while commonly encountered in clinical practice, seldom arises from a single causative insult. It typically evolves due to a complex interplay of pathophysiological factors acting over time, especially in those with long-standing or poorly controlled diabetes mellitus. The critical contributors—namely peripheral neuropathy, peripheral arterial disease, biomechanical deformities, dysglycemia with immunocompromise, and prior ulceration or amputation—have been extensively documented in both clinical literature and tertiary care observations. Understanding these elements remains essential not only for timely diagnosis but also for devising preventive strategies.<sup>9</sup>



**Fig: Progression and Risk factors for DFU**

### A) Peripheral Neuropathy

Peripheral neuropathy is one of the earliest and most frequent neurological complications observed in diabetes, affecting nearly half of individuals with disease duration beyond 10 years. The underlying mechanism predominantly involves hyperglycemia-mediated microvascular insult to the vasa nervorum, culminating in both axonal degeneration and segmental demyelination. Sensory fibres are typically the first affected, resulting in progressive loss of pain, temperature, and pressure perception—collectively referred to as loss of protective sensation (LOPS). Clinically, this renders the foot vulnerable to trivial trauma which often goes unnoticed.

Motor neuropathy adds a mechanical component by altering intrinsic muscle tone, particularly those stabilizing the toes. This leads to clawing or hammer toe deformities, shifting plantar pressures to metatarsal heads. Autonomic fibres, when involved, impair sweat gland function, resulting in dry, cracked, and inelastic skin that is easily fissured. The triad of sensory, motor, and autonomic dysfunction creates the so-called “insensate and deformed foot,” which is highly susceptible to neuropathic ulceration.<sup>14</sup>

## **B) Peripheral Arterial Disease**

Peripheral arterial disease (PAD) is frequently underdiagnosed in diabetics due to coexisting neuropathy masking classical symptoms such as intermittent claudication. The vascular pathology in diabetes is characteristically distal, diffuse, and multi-segmental, predominantly affecting tibial and peroneal arteries. As a result, blood flow to the foot is often critically impaired, jeopardizing tissue oxygenation and nutrient delivery—both of which are vital for wound healing.

On physical examination, PAD may manifest through diminished or absent dorsalis pedis and posterior tibial pulses, cool extremities, prolonged capillary refill, or trophic skin changes. An ankle-brachial index (ABI) below 0.9, especially when accompanied by toe pressures <30 mmHg, is indicative of significant ischemia. The coexistence of PAD with DFU is strongly predictive of delayed epithelialization, infection, and increased risk of lower-extremity amputation.<sup>15</sup>

## **C) Foot Deformities and Pressure Redistribution**

Structural foot abnormalities are another major contributor to ulcer development in diabetic individuals. Deformities such as claw toes, hammer toes, hallux valgus, Charcot neuroarthropathy, and pes planus alter the biomechanics of gait and redistribute plantar pressure disproportionately. The resulting focal pressure zones—most commonly under metatarsal heads, heel, and lateral margins—become high-risk sites for repetitive shear stress and friction.

Additionally, atrophy of plantar fat pads and use of improperly fitting footwear further magnify the risk of localized trauma. Callus formation is commonly observed over pressure points, and beneath these calluses, pre-ulcerative lesions frequently exist. When protective sensation is lost, these repetitive forces proceed unchecked, ultimately leading to breakdown of skin and subcutaneous tissue.<sup>16</sup>

## **D) Poor Glycemic Control and Immunological Deficit**

Persistent hyperglycemia contributes to both vascular and immune dysfunctions. On a cellular level, chronic elevated glucose results in non-enzymatic glycation of proteins, which in turn alters the structure and function of collagen and basement membrane components. Additionally, hyperglycemia impairs neutrophil chemotaxis, oxidative burst activity, and phagocytosis—thus compromising the initial immune response to infection.

From a wound-healing standpoint, elevated HbA1c is known to prolong the inflammatory phase, reduce fibroblast proliferation, and impede angiogenesis. Capillary basement membrane thickening and microangiopathy further impair perfusion at the wound site. Consequently, the ulcer remains in a chronic non-healing state, often colonized by skin flora or opportunistic pathogens, predominantly gram-positive cocci and anaerobes.<sup>17</sup>

### **E) History of Prior Ulceration or Amputation**

The strongest predictor for a new diabetic foot ulcer is a history of a previous ulcer or lower-limb amputation. Such patients typically present with residual sensory deficits, vascular insufficiency, or post-surgical biomechanical changes that disturb normal weight distribution. Scarred skin from healed ulcers is structurally weaker and less elastic, and tends to break down more easily under pressure.

Moreover, partial foot amputations shift plantar load to adjacent regions, predisposing them to new ulcerations. Epidemiological data suggest that approximately 40% of patients experience re-ulceration within one year of initial wound healing. This subgroup warrants close podiatric follow-up, pressure offloading, customized footwear, and intensive education for foot care.<sup>18</sup>

## **2.3 Principles of Diabetic Foot Ulcer Management**

Management of diabetic foot ulcers (DFUs) involves a structured and multi-component approach, with each arm of treatment targeting specific contributors to chronicity and delayed healing. Effective care requires not only attention to the local wound status but also a simultaneous correction of systemic, vascular, and mechanical factors. The standard framework includes proper wound bed preparation, infection control, timely and repeated debridement, vascular status evaluation with revascularization where indicated, and, critically, offloading of plantar pressure. These steps together aim not just for ulcer healing, but also to prevent recurrence and reduce long-term disability.<sup>18</sup>

### **A) Wound Bed Preparation**

The TIME principle—an acronym for Tissue debridement, Inflammation/Infection control, Moisture balance, and Edge advancement—remains a widely accepted clinical framework for the local management of chronic wounds including DFUs. The presence of devitalized or necrotic

tissue is often seen in long-standing ulcers and serves both as a physical barrier to healing and a nidus for microbial colonization. Timely debridement using sharp surgical methods is considered the most definitive strategy for achieving a clean wound surface in such cases.

Inflammation in diabetic wounds is commonly prolonged and may be maintained by microbial biofilm formation. Where clinical or microbiological suspicion exists, targeted antimicrobial therapy becomes essential. At the same time, care must be taken to preserve the ideal moisture environment—neither overly dry nor excessively moist—as both conditions interfere with keratinocyte migration and tissue remodeling. Maceration of periwound skin from exudate is particularly detrimental in diabetic patients with fragile skin integrity.

Advancement of wound edges becomes an issue in stagnant ulcers where granulation tissue remains limited. Such situations require a reassessment of systemic status, local mechanical load, and secondary infection before deciding on adjuvant therapies such as growth factors or skin substitutes.<sup>19</sup>

## **B) Infection Control and Antibiotic Stewardship**

Infections in diabetic foot ulcers are common and range from superficial cellulitis to deep tissue abscesses and chronic osteomyelitis. Owing to neuropathy, the classical signs of inflammation may be subtle or altogether absent. Therefore, indirect markers such as unexplained hyperglycemia, foul odour, local warmth, or elevated white cell counts must be relied upon, especially in early-stage infections.

Classification systems, such as that proposed by the Infectious Diseases Society of America (IDSA), aid in grading severity and selecting the route and duration of antibiotic therapy. Empirical regimens should ideally cover Gram-positive cocci including *Staphylococcus aureus* (both MSSA and MRSA), *Streptococcus* spp., and Gram-negative rods, with subsequent modification based on wound culture and sensitivity.

The duration of therapy is dictated by depth and extent. Mild soft tissue infections generally require 7–14 days of treatment, while confirmed osteomyelitis demands at least 4–6 weeks of parenteral or oral antibiotics. Equally important is the principle of stewardship—avoiding unnecessary antibiotics, de-escalating when cultures allow, and ensuring rational prescribing to reduce resistance.<sup>20</sup>

### C) Debridement Strategies

Debridement is central to wound care and helps eliminate slough, reduce bacterial load, and initiate the healing cascade. Several methods are practiced depending on the ulcer condition and surrounding tissue viability.

- **Sharp debridement**, usually performed using a scalpel or curette, allows quick removal of necrotic tissue and is particularly useful in infected or ischemic wounds requiring urgent control.
- **Autolytic debridement**, which employs moisture-retentive dressings like hydrogels or hydrocolloids, is suitable for stable ulcers with minimal exudate. It allows the body's own enzymes to break down dead tissue.
- **Enzymatic debridement** involves the topical use of proteolytic agents such as collagenase to selectively digest necrotic tissue while sparing healthy structures.
- **Biological debridement**, though less commonly used in India, uses sterile larvae (e.g., *Lucilia sericata*) to clean wounds by ingesting necrotic debris and disrupting biofilms.

Clinical guidelines support serial debridement, typically once every 5–7 days, as it has been associated with faster wound granulation and overall healing.<sup>21</sup>

### D) Vascular Assessment and Revascularization

Peripheral arterial disease (PAD) is seen in up to half of all DFU patients and contributes to poor healing outcomes. Hence, an early vascular workup is mandatory. Basic non-invasive assessments include:

- Ankle-Brachial Index (ABI)
- Toe Pressure Measurements
- Transcutaneous Oxygen Pressure (TcPO<sub>2</sub>)

An ABI < 0.9 or TcPO<sub>2</sub> < 30 mmHg is considered indicative of critical limb ischemia. In such cases, detailed imaging using CT Angiography or Digital Subtraction Angiography (DSA) may be required for planning revascularization.

Interventions may include Percutaneous Transluminal Angioplasty (PTA) for focal stenoses or bypass grafting in diffuse disease. The decision is based on lesion anatomy, comorbidities, and

institutional expertise. Restoration of arterial flow not only aids wound healing but also reduces the likelihood of major amputation.<sup>22</sup>

### **E) Importance of Pressure Offloading in Healing**

Offloading remains a non-negotiable aspect of DFU care, especially in ulcers located on pressure-bearing zones such as the plantar metatarsal heads or heel. Repeated mechanical stress delays epithelialization and disrupts early granulation tissue.

The Total Contact Cast (TCC) is widely accepted as the gold standard for neuropathic plantar ulcers. Its non-removable nature ensures compliance and redistributes weight across the foot. However, limitations such as availability, cost, risk of skin complications, and patient acceptability restrict its use in many clinical settings.<sup>5</sup>

Other options include:

- Removable Cast Walkers (RCWs)
- Customized Orthotic Footwear
- Crutches and Mobility Aids

While crutches help reduce direct pressure, their success depends on upper body strength, gait balance, and user motivation—factors not always assured in diabetic populations. In India, terrain, socio-cultural habits, and affordability often affect their uptake.<sup>23</sup>

In this context, indigenous devices like the Mandakini Offloading Device have been introduced. Designed keeping rural and semi-urban patients in mind, it combines biomechanical efficacy with simplicity and cost-effectiveness. Early field observations report encouraging outcomes, although comparative trials are yet to be widely published.

Effective offloading remains one of the most impactful, yet under-implemented, strategies in DFU care. When done properly, it can hasten healing, prevent recurrence, and reduce the burden on advanced wound care therapies.<sup>7</sup>

## **2.4. Role of Off-Loading in DFU Healing**

### **A) Mechanism of Pressure Redistribution**

Among the various interventions in diabetic foot ulcer (DFU) care, off-loading holds a central place. It directly addresses one of the most fundamental contributors to delayed wound healing—continued mechanical pressure on insensate plantar surfaces. In individuals with peripheral neuropathy, where protective sensation is lost, repetitive trauma at high-pressure zones such as the metatarsal heads or the heel often goes unnoticed. This unrelieved stress leads to tissue breakdown, ulcer formation, and in many cases, progression to deeper infection or even osteomyelitis.

The principle of off-loading is based on redistributing the body's weight away from the ulcerated or at-risk area. By shifting this load to non-affected regions, the intervention helps in reducing both vertical peak pressures and shear forces, which are otherwise known to prolong inflammation and delay granulation. Methods such as Total Contact Casting (TCC), custom-moulded insoles, and Removable Cast Walkers (RCW) achieve this through increased surface area contact and selective load transfer. Pressure-mapping studies conducted within footwear systems have demonstrated reductions in localized plantar pressures by approximately 30 to 50%, depending on the device and patient compliance. These mechanical advantages are critical for initiating and sustaining the healing cascade, particularly in ulcers involving the forefoot.<sup>24</sup>

It is also noted that redistribution of load reduces microvascular compression, improves tissue perfusion, and minimizes the cyclical injury that occurs when patients unknowingly continue ambulating on an open wound. Thus, off-loading serves not just as symptomatic support but as a core component of definitive ulcer management in neuropathic diabetic foot.<sup>25</sup>

### **B) Guidelines Recommending Off-Loading**

Both the International Working Group on the Diabetic Foot (IWGDF) and the American Diabetes Association (ADA) have long endorsed off-loading as a first-line therapeutic measure in DFU care. The IWGDF, in its 2023 guidelines, issued a strong recommendation in favour of non-removable knee-high off-loading devices, particularly Total Contact Casts (TCC) and Instant Total Contact Casts (iTCC), in the treatment of plantar neuropathic ulcers. These recommendations are based on multiple high-certainty trials which demonstrate superior healing outcomes—both in terms of ulcer closure rates and time to healing—when compared to other modalities.<sup>26</sup>

Similarly, the ADA 2023 Standards of Medical Care in Diabetes, under Section 11 (Microvascular Complications and Foot Care), emphasize that all patients presenting with plantar DFUs should be offered structured off-loading interventions. TCC remains the preferred option, unless contraindicated due to infection, ischemia, or patient instability. When TCC cannot be used, RCWs, felted foam padding, or custom orthoses are suggested, although they are considered second-line. These guidelines further recommend that the choice of off-loading strategy should factor in ulcer location, balance impairments, ambulatory safety, and the patient's overall mobility profile. In high-risk patients, fall potential and device adherence must also be carefully evaluated before finalizing the modality.<sup>27</sup>

### **C) Consequences of Inadequate Off-Loading**

Insufficient or improperly applied off-loading remains one of the most common reasons for delayed ulcer healing in patients with diabetic foot. When mechanical stress continues to act over a neuropathic ulcer, the local ischemia persists, granulation is impaired, and the process of epithelial repair becomes chronically interrupted. In such cases, the tissue often enters a cycle of incomplete healing, inflammation, and eventual breakdown. Moreover, the absence of proper off-loading exposes the ulcer bed to microcontamination and frictional damage, thereby increasing the risk of secondary bacterial colonization and infection.

Available literature consistently highlights that patients who do not receive or adhere to off-loading measures tend to experience significantly longer healing durations, higher rates of re-ulceration, and increased chances of limb-threatening complications. The recurrence rate in DFUs is notably high—with approximately 40% recurring within one year and nearly 60% within three years of healing. The most common site for recurrence remains the previous ulcer location, reinforcing the concept that unresolved mechanical factors are central to chronicity.

Another critical issue lies in the removability of some devices. Although RCWs and crutches offer theoretical benefits, their effectiveness is largely dependent on how consistently the patient uses them. It is well documented that many patients intermittently remove or misuse these devices during routine activities, leading to partial or complete reversal of off-loading benefits. Crutches, in particular, demand physical coordination, upper limb strength, and cognitive engagement—parameters which may be suboptimal in elderly, frail, or socioeconomically constrained patients.<sup>28</sup>

## **2.5 Conventional Offloading Methods**

Offloading forms the cornerstone of therapeutic approach in diabetic foot ulcer care. While ulcer etiology involves several mechanisms—neuropathy, ischemia, pressure trauma—the act of redistributing plantar stress away from the wound site has remained a key intervention across guidelines and textbooks. But even within this well-acknowledged principle, the modalities used have shown varied success, often influenced by patient condition, resource availability, and local clinical experience.

### **A) Total Contact Cast (TCC)**

Among offloading options, the total contact cast is often described as the gold standard, especially for neuropathic plantar ulcers without signs of infection or ischemia. The mechanism is simple but highly effective: a carefully moulded cast that hugs the foot and lower leg snugly, designed to offload pressure away from the ulcer and distribute weight over the entire sole. This technique allows healing by reducing mechanical insult during walking.



**Fig: Total Contact Cast (TCC)**

Its immobilization effect also plays a role—by limiting ankle motion and thereby decreasing shear forces, it creates an environment more conducive to granulation and closure. In several studies, TCC has shown healing rates up to 90% within six to eight weeks. Despite this, its use is far from routine in many Indian hospitals. The application is time-consuming, and not all centres have trained personnel for proper fitting. There's also the issue of daily wound inspection—casts must often be removed entirely to view the ulcer, increasing complexity. Patients may also report discomfort or difficulty in mobility. Moreover, in cases with infection or arterial insufficiency, TCC is contraindicated.<sup>5</sup>

### **B) Removable Cast Walkers and Air-Pneumatic Boots**

Removable cast walkers (RCWs) are frequently used in outpatient care, particularly where TCC isn't feasible. These devices resemble a boot, sometimes with air-chamber adjustments to improve contact and offloading. They mimic the biomechanical principles of TCC but come with the advantage of being removable—allowing for hygiene, inspection, or dressing changes.

While easier to apply and less resource-intensive, RCWs have a serious drawback. Because patients can remove them at will, adherence drops drastically. Studies have shown some patients wear them only for 20% to 30% of their daily steps. That compromises the therapeutic benefit. The air boots help to some extent in conforming to foot shape, but the success still relies heavily on patient cooperation. Forced compliance, like with TCC, is absent.<sup>29</sup>

### **C) Use of Crutches**

Crutches have been used historically across orthopaedic and rehabilitative care, including DFUs, primarily to reduce direct weight-bearing. In principle, axillary crutches shift the load from lower limbs to upper body, relieving pressure over the plantar surface and ulcer region. They are especially used when casting isn't possible—cases with active infection, wet gangrene, or following debridement.

But the effectiveness of crutches is not uniform. They demand upper body strength, balance, and coordination—features not often present in elderly diabetic patients. Improper use may cause axillary nerve compression or falls. Moreover, unlike offloading boots or casts, crutches are not usable all the time. During seated activities, the foot is not offloaded. The intermittent nature of

offloading limits its benefit in long-term DFU care. In many Indian settings, uneven terrain and lack of training further reduce their use.<sup>30</sup>

#### **D) Limitations Common to Conventional Methods**

Even when used correctly, traditional offloading methods come with limitations. One of the most persistent issues is compliance. TCC ensures adherence by design but limits patient comfort and daily function. RCWs and crutches allow autonomy but suffer from poor usage patterns. Many patients, especially in semi-urban or rural areas, discontinue devices early due to pain, embarrassment, or practical difficulty.

Another issue is instability. Crutches and some walkers compromise gait in those with neuropathy, increasing risk of fall. Inconsistent offloading, improper fitting, or incorrect usage may shift pressure to other regions of the foot—eventually leading to secondary ulcers.

Cost is another barrier. TCC application needs materials and expertise. Pneumatic boots are expensive. Crutches are cheaper but often misused. In low-income settings, availability of proper fitting, training, and follow-up remains a challenge. In such environments, even well-designed interventions may fail to achieve healing if execution is not consistent.<sup>31</sup>

### **2.6 Mandakini Offloading Device**

#### **A) Design and Mechanism of Action**

The Mandakini Offloading Device was first described by Kari and colleagues at Mandakini Hospital, India, as a low-cost alternative to conventional plantar pressure offloading techniques in diabetic foot ulcer (DFU) care. Structurally, the device is fashioned by tightly rolling a set of sterilized, used surgical gloves into cylindrical forms which are then circumferentially fixed using elastic adhesive bandages such as Dynaplast. These glove-rolls form a soft yet resilient cushion, which when positioned correctly—either adjacent to or around the ulcer—help to shift plantar pressure away from the lesion-bearing area. The number of glove rolls may be adjusted based on the patient's body weight, foot morphology, and ulcer location (forefoot or hindfoot).

Biomechanically, the cushion acts by absorbing vertical compressive forces during ambulation. This redistribution leads to a measurable reduction in peak plantar pressures over ulcerated zones and mitigates repetitive trauma. The concept is based on the principle that even small elevations

in vertical load, if persistent, can impair local tissue perfusion and impede epithelial repair. By offloading these stress points, the Mandakini device aims to interrupt this cycle and facilitate ulcer healing while allowing mobility.<sup>29</sup>

### **B) Materials and Customization for Indian Populations**

The materials used in the fabrication of the Mandakini device are both inexpensive and widely accessible, particularly in low-resource settings. Sterilized surgical gloves and standard Dynaplast bandages are the only required components. The overall cost of one application is estimated to be around ₹80 to ₹90 (approximately USD \$1), making it considerably more affordable than traditional offloading aids such as removable walkers or total contact casts.

Another key advantage lies in its adaptability. The number and density of glove layers can be varied to suit different anthropometric profiles. This is particularly relevant in Indian populations, where considerable variation exists in body habitus, gait biomechanics, and ulcer topography. The soft structure of the device conforms to foot contours, thereby ensuring targeted offloading without causing new pressure points elsewhere. Moreover, its lightweight nature enhances patient acceptability in outpatient and community settings.<sup>8,32</sup>

### **C) Clinical Rationale Behind Its Development**

The rationale behind developing the Mandakini device stems from well-established clinical evidence highlighting the role of plantar pressure in the genesis and chronicity of neuropathic foot ulcers. In individuals with diabetes, peripheral sensory loss renders the sole insensate, and unrecognized repetitive trauma—especially over metatarsal heads or heel regions—leads to tissue breakdown. Elevated plantar pressures not only initiate ulceration but also delay epithelialization and granulation.

Although total contact casting (TCC) has long been considered the gold standard for pressure offloading, its routine use is restricted by multiple limitations—high cost, requirement of trained personnel for application and monitoring, patient immobility, and the risk of iatrogenic ulceration. In under-resourced public healthcare facilities and rural areas, these constraints are further magnified. There existed a need for a simple, easily applicable, and ambulatory offloading technique that would neither require advanced infrastructure nor restrict patient mobility. The

Mandakini device was thus developed to serve this purpose—providing a realistic, home-based solution that supports healing while preserving functionality.<sup>5,29</sup>

#### **D) Preliminary Studies and Observational Evidence**

Initial description of the Mandakini device was published by *Kari et al. in 2010* in the Indian Journal of Surgery. Their case series involved patients with neuropathic plantar ulcers who were managed on an outpatient basis using this novel cushion technique. Healing outcomes were reported to be satisfactory, with improvement in wound dimensions and granulation observed in most patients.<sup>33</sup>

Subsequent studies have added to the clinical body of evidence. A randomized controlled study conducted by *Sanjeev et al. (2019)* compared the Mandakini offloader with standard wet gauze dressings. At six weeks, the group treated with the Mandakini device demonstrated a significantly greater reduction in mean wound area (1.29 cm<sup>2</sup> vs. 2.31 cm<sup>2</sup>;  $p \leq 0.0001$ ). The average healing time was also shorter (4.83 weeks vs. 5.4 weeks;  $p = 0.013$ ), and subjective parameters like pain relief, comfort, and perceived improvement scored consistently higher in the Mandakini group ( $p$ -values between 0.0001 and 0.003).<sup>29</sup>

A comparative observational study by *Mohapatra et al. (2023)* in a tertiary center included 80 patients with diabetic foot ulcers. Results showed statistically significant advantages in terms of reduced hospitalization duration (~22 vs. 25.9 days;  $p = 0.003$ ), lower pain scores, fewer dressing changes, and decreased incidence of secondary infection and amputation in the cohort treated with the Mandakini device.<sup>34</sup>

#### **E) Benefits Compared to Conventional Offloading Aids**

One of the most noteworthy advantages of the Mandakini device is its cost-effectiveness. While TCC applications cost between USD \$75 to \$100 per use, and removable cast walkers range from \$150 to \$200, the Mandakini device maintains a cost near \$1 per dressing. This stark difference significantly enhances its feasibility in high-volume outpatient clinics and in community health settings.

In terms of patient compliance, the lightweight and modular structure of the device promotes continued ambulation and independence in performing daily activities. Unlike conventional

immobilization methods, which restrict movement and often deter patients from sustained use, the Mandakini offloader allows functional mobility while maintaining pressure redistribution.

Comfort and tolerability have also been favorable. In studies, patients consistently reported less discomfort and pain during ambulation when using the cushion-based device, particularly in comparison to rigid walkers or casts ( $p \leq 0.0001$ ). The absence of rigid support and the adaptability of the cushion pad appear to reduce secondary pressure points, enhancing user satisfaction.

In rural and semi-urban populations, accessibility remains a core strength of the Mandakini model. The materials are locally available, and the application technique is straightforward, requiring minimal training. This enables its deployment not only in tertiary centers but also in primary healthcare setups or even at home under caregiver supervision. By contrast, crutches and orthotic walkers, while biomechanically effective, may be unavailable, unaffordable, or impractical due to terrain and housing conditions.

Finally, clinical outcomes observed thus far indicate faster wound healing, better granulation, fewer secondary infections, shorter hospitalization periods, and lower recurrence and amputation rates compared to standard dressings. However, direct head-to-head comparative trials against crutches or standard removable offloading boots remain scarce and warrant future investigation.<sup>29,34</sup>

## **2.7 Comparative Studies on Offloading Devices**

### **A) Summary of Previous Comparative Trials**

Over the past two decades, multiple randomized controlled trials (RCTs) and meta-analyses have examined the efficacy of Total Contact Casting (TCC) in comparison with other off-loading methods, particularly removable cast walkers (RCWs), half-shoes, and therapeutic footwear. Among the more recent analyses, a meta-analysis published in 2023 consolidated findings from several RCTs and concluded that TCC use was associated with significantly higher healing rates for diabetic foot ulcers. The pooled risk ratio for ulcer healing ranged between 1.20 to 1.25 in favour of TCC ( $p < 0.001$ ), and standardized mean differences indicated a shorter time to wound closure (SMD approximately  $-0.57$ ;  $p = 0.010$ ). These differences were consistently observed across trials with varying sample sizes and ulcer characteristics.<sup>33</sup>

Early trials by Armstrong and colleagues, conducted in 2001, also demonstrated that TCC resulted in healing in approximately 88–89% of cases, compared to 65% healing rates with RCWs and even lower rates with half-shoes. The average time to ulcer closure was notably reduced in the TCC group, with healing observed typically within 4.8 to 5.4 weeks, whereas patients in the RCW or therapeutic sandal groups required 7 to 9 weeks, on average. These findings helped establish the clinical superiority of TCC in non-infected, neuropathic plantar ulcers.<sup>35</sup>

The International Working Group on the Diabetic Foot (IWGDF), in its 2019 evidence-based guidelines, emphasized that non-removable, knee-high off-loading devices—including TCCs and modified RCWs rendered non-removable—were associated with the highest healing efficacy. These devices were thus recommended as the first-line option in the management of neuropathic plantar ulcers, particularly those located over the forefoot and midfoot regions.<sup>26</sup>

## **2.8 Patient Compliance and Quality of Life**

### **A) Importance of Comfort, Ease of Use, and Mobility**

In clinical practice, while biomechanical efficiency forms the primary rationale for prescribing off-loading devices in diabetic foot ulcer (DFU) care, the long-term benefit often hinges on how well the patient tolerates and accepts the device. Therapeutic outcomes, particularly in community-based settings, are strongly influenced by patient perception of comfort, ease of mobility, and day-to-day usability. Devices which feel restrictive, bulky, or overly dependent on external support frequently see declining usage despite their proven mechanical merit.

As per the latest IWGDF guidelines (2023), Total Contact Casts (TCCs) continue to be positioned as the preferred choice for off-loading plantar ulcers due to their consistent pressure redistribution. However, their actual uptake remains limited in many clinical settings, primarily due to issues related to patient discomfort, restriction of independent ambulation, and the need for specialized application. Patients often report difficulty managing daily tasks or commuting while using such non-removable systems.<sup>26</sup>

Crutches, though relatively inexpensive and easily accessible, are not universally well-tolerated. Their prolonged use can aggravate pre-existing shoulder or cervical musculoskeletal complaints, especially in older diabetic individuals who often have concurrent osteopenia or neuropathy.

Moreover, maintaining postural balance during ambulation becomes challenging, particularly on uneven surfaces, which are commonly encountered in both urban and rural Indian settings. In contrast, newer indigenous innovations like the Mandakini Off-Loading Device are designed with a focus on improving patient mobility while ensuring pressure off-loading remains adequate. By attempting to respect the patient's habitual gait, limb balance, and routine lifestyle, such models may offer improved usability in real-world scenarios.<sup>7</sup>

## **B) Adherence Rates with Different Devices**

Therapeutic success in DFU management is not solely determined by device design but also by how consistently the patient uses the prescribed intervention. Adherence is an important determinant in ulcer healing and recurrence prevention. In a randomized controlled trial conducted by *Armstrong and colleagues in 2001*, it was demonstrated that while TCCs provide superior biomechanical relief, their non-removability contributed to better healing outcomes compared to removable cast walkers (RCWs), whose usage declined outside clinical supervision.<sup>35</sup>

Similarly, a study by *Crews RT et al. (2016)* employed wearable temperature sensors to monitor real-world usage of off-loading footwear. Their findings revealed that patients wore their prescribed removable devices during less than 28% of their daily steps. This level of non-adherence raises serious concern, especially since such behavior often goes unnoticed during routine outpatient evaluations. The reasons are multifactorial—ranging from discomfort and perceived weight of the device to stigma associated with visible orthotic aids.<sup>18</sup>

Hence, while choosing an off-loading modality, clinicians must look beyond the pathology alone and factor in the patient's physical ability, home environment, occupation, and even cultural preferences. Devices such as the Mandakini model, designed to be light, discreet, and mechanically stable, may show better real-world compliance, although well-structured comparative studies on adherence are presently lacking. Nevertheless, observations from small hospital-based cohorts suggest better tolerance and functional independence among users.<sup>29</sup>

## **C) Psychosocial Impact of DFUs and Mobility Aids**

Beyond the physiological dimension, diabetic foot ulcers bring forth a significant psychosocial burden that is often underappreciated in routine care. Chronic ulcers, persistent dressing

requirements, frequent clinical reviews, and the looming threat of amputation collectively induce psychological strain. Affected individuals often experience heightened levels of anxiety, withdrawal from social activities, and sometimes clinical depression.

Use of external mobility aids—whether crutches, walkers, or orthotic boots—adds another layer of emotional challenge. In multiple qualitative studies, patients have reported feelings of embarrassment, altered body image, and a sense of social exclusion while using visible assistive devices, especially in public or professional spaces. This often leads to partial or complete non-use of prescribed aids, particularly when the patient resumes outdoor movement, resulting in delayed healing and increased ulcer recurrence.

Furthermore, concerns around visibility and stigma are rarely addressed in standard offloading protocols. Patients may intentionally avoid wearing devices in social events or workplaces, despite knowing the medical risk. In this regard, off-loading aids that are culturally contextualized, less conspicuous, and tailored to patient preference—such as the Mandakini device—may help reduce non-compliance related to psychosocial discomfort.

Incorporating psychological counseling into the DFU management pathway is now being recommended by recent consensus panels. Structured behavioral interventions, combined with education on wound progression and device benefits, may improve both compliance and emotional well-being. Attention to these non-biomechanical aspects is essential in improving the overall quality of life for individuals living with chronic foot ulcers.<sup>34</sup>

## **2.9 Research Gap and Need for the Present Study**

Diabetic foot ulcers (DFUs) continue to remain one of the most difficult and disabling complications encountered in patients with long-standing diabetes mellitus. These ulcers are not only associated with persistent morbidity and recurrent hospital admissions but also constitute a leading cause of non-traumatic lower limb amputations worldwide. Over the years, it has been firmly established—both in clinical guidelines and in controlled trials—that proper off-loading of pressure over the plantar surface plays a pivotal role in promoting ulcer healing, particularly in neuropathic feet. The International Working Group on the Diabetic Foot (IWGDF) has consistently

Emphasized the role of off-loading as central to management, supported by growing evidence from randomized studies and pooled analyses from various populations.<sup>26</sup>

Among the different off-loading modalities, the Total Contact Cast (TCC) is widely considered the gold standard in cases of uncomplicated, non-infected plantar ulcers. However, in practical field settings—especially across low- and middle-income regions such as India—the usage of TCC remains quite limited. The reasons are manifold: need for technical skill to apply, risk of complications in unmonitored patients, time-intensive application, and low acceptance by patients due to discomfort. Additionally, the lack of trained personnel and infrastructure in primary and secondary care centers adds to the difficulty.<sup>5</sup>

In the Indian context, a large proportion of diabetic foot cases present at later stages, often with chronic or infected ulcers. For such cases, there arises an urgent need for off-loading methods that are not only clinically effective but also economically feasible and culturally suitable. Crutches are frequently suggested as a basic means of reducing load on the affected limb. However, the benefit derived from crutch-based off-loading is inconsistent. It often depends heavily on patient cooperation, correct technique, and physical ability. Upper limb fatigue, postural imbalance, and poor adherence limit the extent of actual off-loading achieved in daily use. Also, crutches divert weight away from the limb as a whole, but do not guarantee decompression at the specific ulcer site—especially in cases involving plantar metatarsal heads or heel.<sup>36</sup>

To address such limitations, alternative designs such as the Mandakini Off-Loading Device have been developed in recent years. Conceptualized to suit local needs, this device attempts to reduce pressure over the ulcerated region without compromising mobility. Unlike crutches, it does not require upper body strength or training, and it allows the patient to walk with more stability. Though early field observations and experience reports have described favorable outcomes with the Mandakini device—such as improved compliance and reduced cost—controlled comparative evaluations are still missing. At present, the device remains underutilized in institutional practice, largely due to the absence of structured clinical data.<sup>29</sup>

Further complicating the scenario is the absence of standardization in outcome measurement for off-loading interventions. There are very few comparative studies assessing parameters such as rate of ulcer healing, duration to epithelialization, recurrence risk, or patient-reported satisfaction scores across different devices. Particularly in ambulatory patients from semi-urban or rural

settings—where both terrain and lifestyle factors influence compliance—the true effectiveness of off-loading remains inadequately studied.

Therefore, there exists a clear research gap—both in terms of comparative evidence between standard aids like crutches and indigenous alternatives like the Mandakini device, and in the broader context of evaluating off-loading strategies that are practical, replicable, and suited to Indian healthcare settings. This present study has been designed to address this gap by assessing and comparing the clinical performance of the Mandakini Off-Loading Device versus conventional crutch-based methods. By focusing on clinical outcomes, adherence rates, and real-world feasibility, the study aims to generate evidence that may support the incorporation of patient-friendly, cost-sensitive off-loading methods in standard diabetic foot protocols.

## **2.10 Recent Studies**

**Sharma S et al. (2025)** conducted a review that investigated the role of offloading in DFU management, with a focus on its applicability in the Indian healthcare setting. It includes a comprehensive literature review covering epidemiology, pathophysiology, and various offloading methods, including total contact casting, removable cast walkers, therapeutic footwear, and innovative Indian systems such as the Bohler iron walking cast, Mandakini offloading system, Samadhan, and Suvidha. The review highlights that effective pressure redistribution is essential for both prevention and treatment of DFUs. It also discusses the economic and cultural limitations that hinder the implementation of offloading methods in India. The findings emphasize the importance of adapting global practices to local contexts and support the inclusion of indigenous innovations in treatment plans. The review concludes that a multidisciplinary approach, community-level education, and focused India-specific research are crucial for overcoming barriers and improving DFU outcomes.<sup>37</sup>

**Mohapatra S et al. (2023)** stated that Offloading is a crucial therapeutic approach that is vital for both avoiding and curing diabetic foot ulcers. There are many distinct unloading modalities, each with advantages and disadvantages of its own. Which method is the best that can be easily applied and that can aid in ulcer healing is crucial in clinical practice. The primary cause of neuropathic diabetic foot wounds is pressure combined with cycles of recurrent stress, which compromises the integrity of the skin and soft tissues. The proper debridement of nonviable tissue and sufficient

Pressure relief from the basis of any therapeutic strategy for neuropathic diabetic foot ulcers (off-loading).<sup>37</sup>

**Sanjeev S et al. (2019)** aimed to evaluate the benefits of the 'Mandakini' dressing compared to conventional wet gauze dressings in patients with neuropathic plantar ulcers. A total of 60 patients were randomized equally into two groups: the treatment group received the 'Mandakini' dressing, which was changed weekly, while the control group received conventional wet gauze dressings. Ulcer size, grade, and wound surface area were assessed weekly for up to 6 weeks in both groups. The outcomes compared included the percentage of wound covered with granulation tissue, the percentage of wound with non-viable tissue, and the time taken for ulcer healing. At the end of 6 weeks, the 'Mandakini' group showed a significant reduction in wound size (1.29 cm<sup>2</sup> vs. 2.31 cm<sup>2</sup>;  $p \leq 0.0001$ ) and a shorter healing time (4.83 vs. 5.4 weeks;  $p=0.013$ ) compared to the control group. Additionally, patient acceptability, satisfaction, quality of life, and overall treatment cost were better in the Mandakini dressing group.<sup>7</sup>

**Kari SV et al. (2010)** stated that increased plantar foot pressure is a leading cause of ulceration in the diabetic population. Healing of these ulcers depends on several factors, including adequate blood supply, infection control, proper wound care, and, most importantly, 'offloading' or redistribution of pressure from the ulcerated area. Among these, offloading remains a unique and significant challenge in managing chronic diabetic wounds. Over the years, diabetic foot care has advanced considerably, and various offloading methods have been employed by podiatrists to address this issue. These methods include complete bed rest, the use of cutout felt pads, crutches, wheelchairs, zimmer frames, temporary shoes, ortho wedge shoes, such as rocker-bottom wedge design footwear, and total contact casting. These diverse strategies are aimed at minimizing pressure on the affected site to promote healing and prevent recurrence of ulceration.<sup>29</sup>

## MATERIALS AND METHODS

### METHODOLOGY;

Study design: Comparative, Observational Study

Sampling – Odd & even method

Study setting: Department of General Surgery, R. L. Jalappa Hospital, Tamaka, Kolar. Study

period: 18 months, May 2023-Oct 2024

Sample size: 60

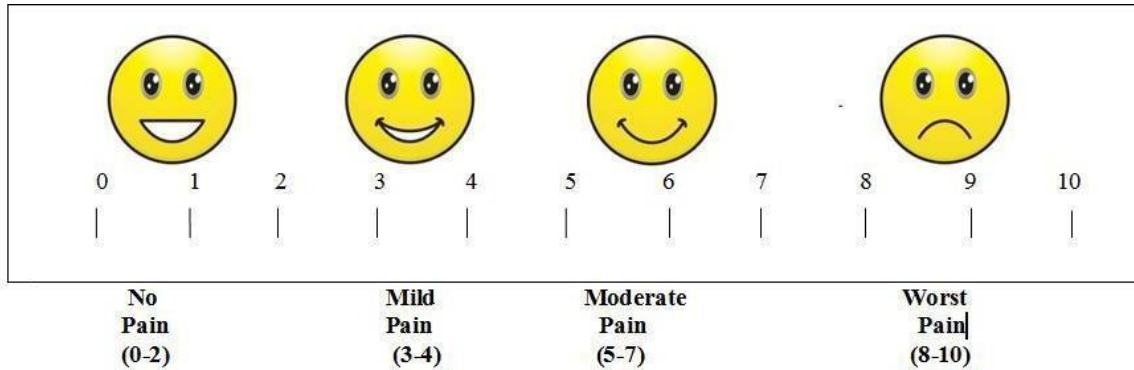
Patients are allocated into groups on an odd/even basis, 30 in each group.

- Group Mandakini offloading dressing comprises patients undergoing debridement followed by Mandakini dressing.
- Group crutches comprises patients undergoing debridement followed by the use of crutches.
- Follow-up will be done till the diabetic foot ulcer patients are admitted to the wards. The follow-up is computed by the duration of length of stay in the hospital.: SOURCE OF DATA:

A prospective comparative study to be conducted for 18 months at the General Surgery Ward, R L JALAPPA HOSPITAL. A total of 60 patients with diabetic foot plantar ulcers will be included in the study.: STUDY DESIGN: A Prospective comparative study.

9.1 : METHOD:

## VAS score for pain



9.2 : STUDY PERIOD: From May 2023 to Oct 2024: STATISTICAL ANALYSIS:

Data will be entered into a Microsoft excel data sheet and will be analyzed using SPSS 22 software. Categorical data will be represented in the form of Frequencies and proportions. Chi-square will be the test of significance. Continuous data will be represented as a mean and

Standard deviation. An independent t-test will be the test of significance to identify the mean difference between two groups. P p-value <0.05 was considered statistically significant.

9.3 : SAMPLE SIZE:

It was estimated by using the difference in Mean VAS score at 2hrs between the Rectus sheath block and conventional analgesia from the study Vatsalpatel. A19. as  $2.03 \pm 0.61$  and  $2.50 \pm 0.50$ . Using these values at a 95% Confidence limit and 90% power sample size of 60 was obtained in each group by using the below-mentioned formula and MedCalc sample size software. With a 10% nonresponse sample size of  $27 + 2.7, \approx 30$  cases will be included in each group.

Sample Size Estimation Formula:

$$N = \frac{2 \cdot SD^2 \cdot (Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

$d^2$

- Where  $Z_{\alpha/2}$  is the critical value of the Normal distribution at  $\alpha/2$  (e.g., for a confidence level of 95%,  $\alpha$  is 0.05 and the critical value is 1.96).
- $Z_{\beta}$  is the critical value of the Normal distribution at  $\beta$  (e.g., for a power of 80%,  $\beta$  is 0.2 and the critical value is 0.84),
- SD is the standard deviation from the previous study population variance, and
- $d$  is the difference between the two means

#### INCLUSION CRITERIA:

All patients aged 18 years and above with diabetic foot ulcers not involving more than 50% of the surface.

#### EXCLUSION CRITERIA

- Diabetic foot ulcer with peripheral vascular disease without peripheral pulses.
- Diabetic foot ulcers with osteomyelitis.
- Charcot's foot.

- Patients on immunosuppressive therapy.

## PROCEDURE DETAILS

- Materials Used for Preparing Mandakini Off-Loading Device
- Used a pair of gloves.
- Dynaplast adhesive plaster.

Method of preparation and application.

- Paired used gloves are rolled as we do for autoclaving. It is placed on the adhesive surface of Dynaplast and covered circumferentially with Dynaplast.
- Edges of dynaplast are approximated by sharp pressure. Now the Mandakini Offloading device is ready to place.
- It acts as a soft air cushion and offloads body weight.
- Fore foot lesions are attended by applying the device proximal to the lesion.
- Hind foot lesions are attended by applying the device distal to the lesion.
- Number of gloves will be decided according to the weight of the patient. Materials for crutches: axillary crutches will be used for patients using crutches.

# RESULTS

## Distribution of Study Participants by Sex

In the present study, a total of 60 patients with diabetic plantar foot ulcers were included, comprising 32 females (53.3%) and 28 males (46.7%). This distribution indicates a slight predominance of female patients. The near-equitable gender representation suggests that the findings of this study are likely to be applicable across both sexes without substantial bias. However, the slightly higher proportion of females may reflect the local demographic patterns or differences in health-seeking behavior. Understanding sex distribution is important as gender-related factors can influence disease presentation, treatment compliance, and ulcer healing outcomes.

Table 1: Sex-wise distribution of study participants

Sex	Count	Percentage
Female	32	53.3
Male	28	46.7

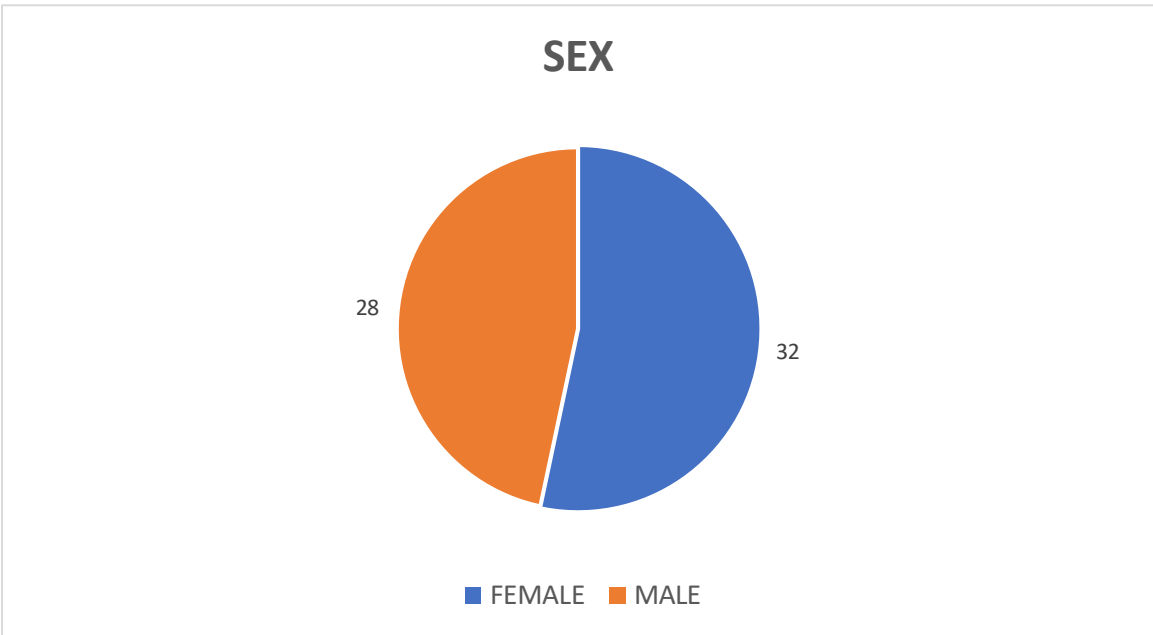


Figure 1: Sex distribution among study participants

## Distribution of Study Participants by Site of Ulcer

Among the 60 patients included in the study, the most common site of diabetic plantar foot ulcer was the heel, observed in 23 patients (38.3%). This was followed by forefoot ulcers in 20 patients (33.3%) and midfoot ulcers in 17 patients (28.3%). The predominance of heel ulcers may be related to higher plantar pressure in this region during standing and walking, particularly in individuals with altered gait mechanics. Forefoot and midfoot ulcers, though slightly less frequent, still represent a significant burden and may be influenced by factors such as footwear, neuropathy, and duration of diabetes. Understanding ulcer site distribution is important for tailoring off-loading strategies and optimizing healing outcomes.

Table 2: Distribution of participants based on the site of ulcer

Site of Ulcer	Count	Percentage
Heel	23	38.3
Forefoot	20	33.3
Midfoot	17	28.3

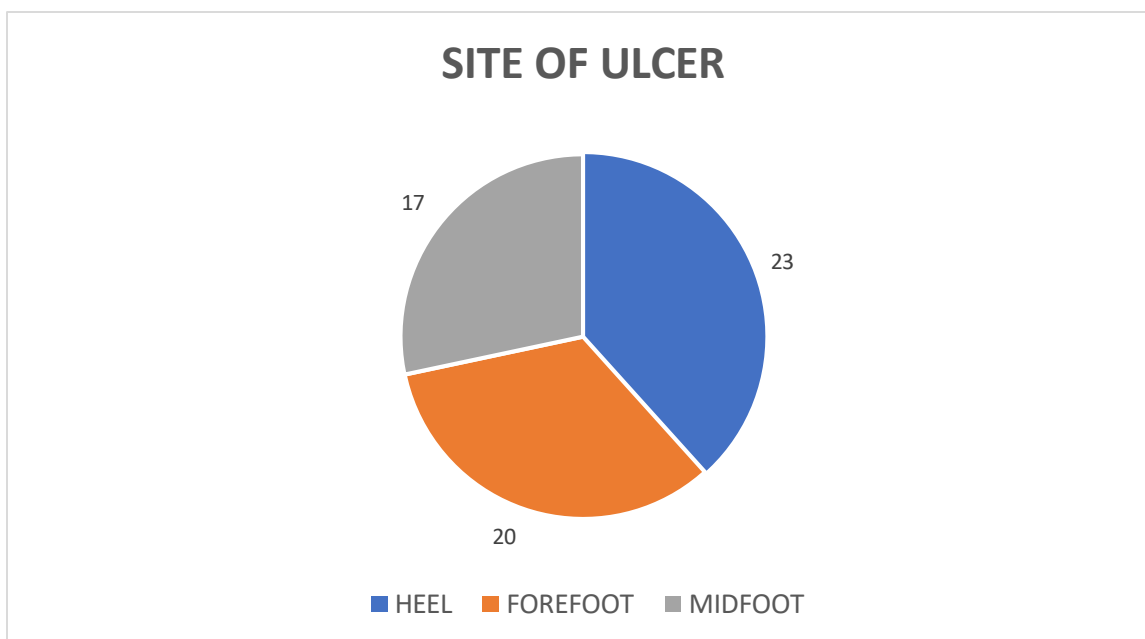


Figure 2: Distribution of study participants by ulcer site

### Presence of Infection in Study Participants

Out of the 60 patients studied, infection was present in 31 cases (51.7%) and absent in 29 cases (48.3%). This nearly equal distribution suggests that infection is a common complication among patients with diabetic plantar foot ulcers. The slightly higher proportion of infected cases highlights the importance of early detection and prompt management, as infection can significantly delay healing and increase the risk of complications such as cellulitis, osteomyelitis, and amputation. The presence or absence of infection is a critical factor in evaluating the effectiveness of off-loading devices, as it can influence both the healing trajectory and the choice of adjunctive therapies.

Table 3: Distribution of participants according to presence of infection

Infection Status	Count	Percentage
Yes	31	51.7
No	29	48.3

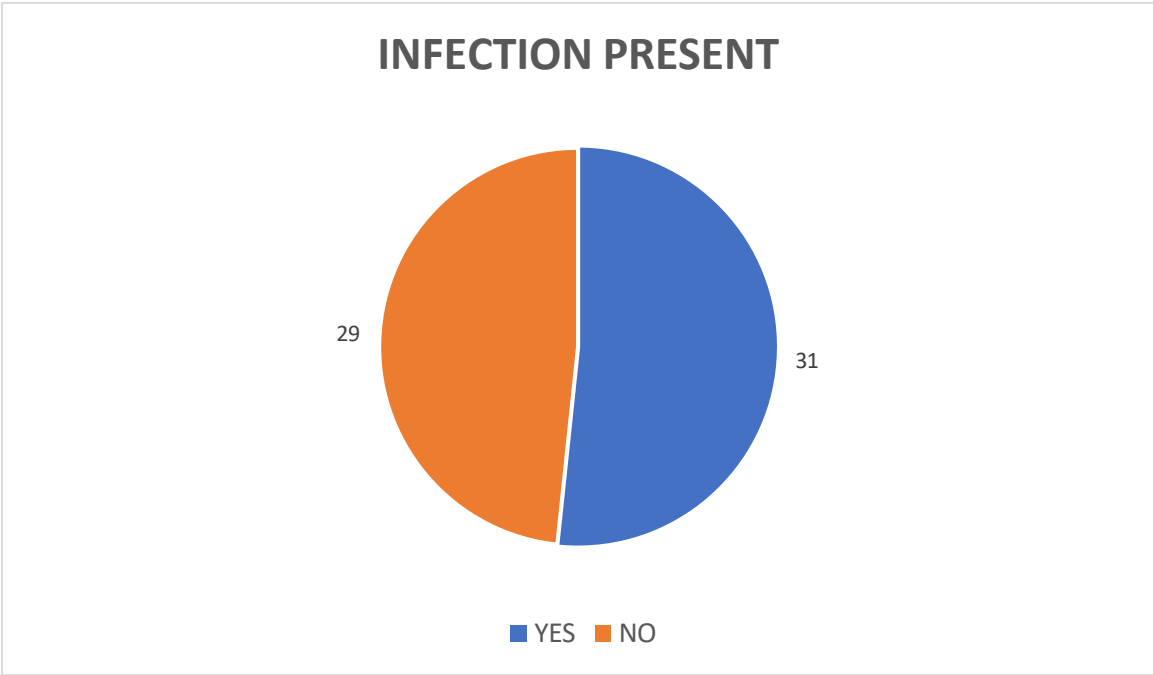


Figure 3: Presence of infection among study participants

## Recurrence of Ulcer among Study Participants

In the present study, ulcer recurrence was observed in only 4 patients (6.7%), while the majority, 56 patients (93.3%), did not experience recurrence during the study period. This low recurrence rate indicates that the off-loading interventions, along with appropriate wound care and glycemic control, were largely effective in preventing re-ulceration. The small proportion of recurrence cases could be associated with persistent risk factors such as poor compliance with off-loading, inadequate footwear, neuropathy, or uncontrolled diabetes. Monitoring recurrence is essential, as repeated ulceration increases the risk of chronic wounds, infection, and lower limb amputation.

Table 4: Distribution of participants according to ulcer recurrence

Ulcer Recurrence	Count	Percentage
No	56	93.3
Yes	4	6.7

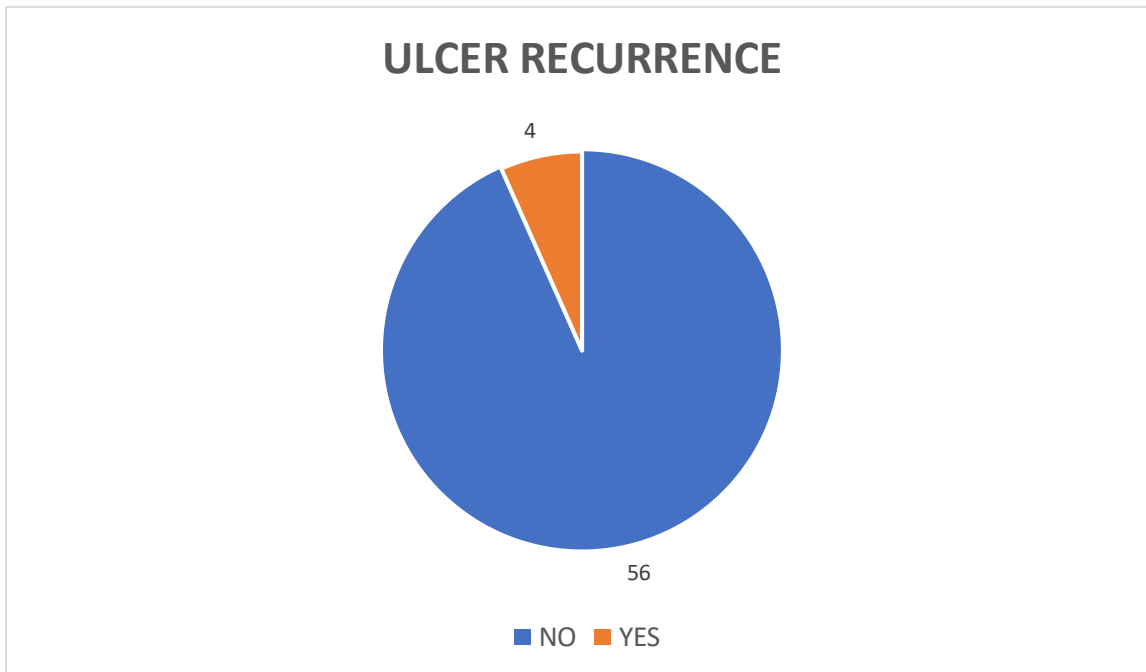


Figure 4: Ulcer recurrence among study participants

### Requirement of Amputation among Study Participants

Of the 60 patients included in the study, only 4 patients (6.7%) required amputation, while the remaining 56 patients (93.3%) were managed successfully without the need for surgical removal of the limb or part thereof. This relatively low amputation rate suggests that timely diagnosis, effective off-loading techniques, and comprehensive wound care can significantly reduce the need for such invasive interventions. The small proportion of cases requiring amputation may reflect severe infection, extensive tissue necrosis, or poor vascular status. Minimizing amputation rates is a critical outcome measure in diabetic foot ulcer management, as it directly impacts patient quality of life and long-term mobility.

Table 5: Distribution of participants based on the requirement of amputation

Amputation Required	Count	Percentage
No	56	93.3
Yes	4	6.7

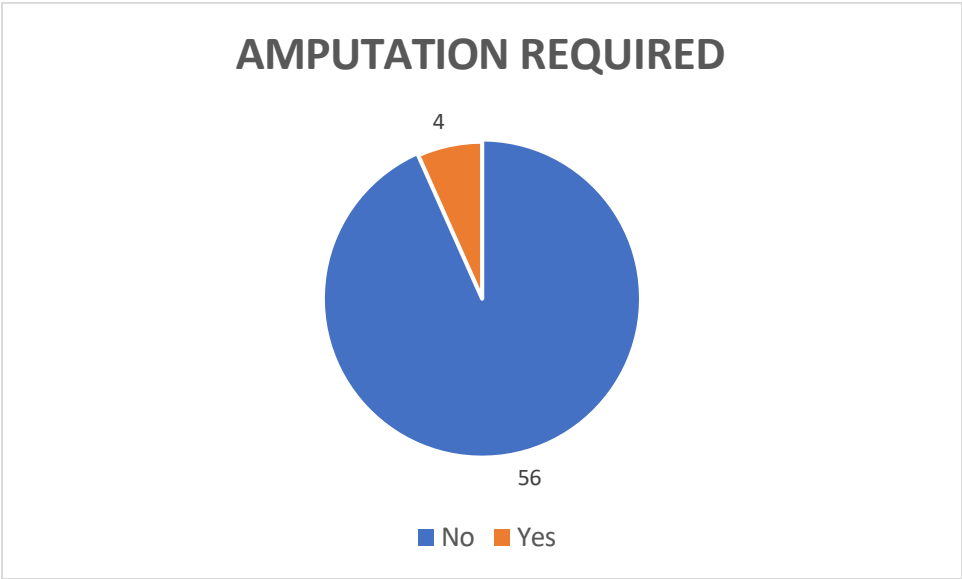


Figure 5: Requirement of amputation among study participants

## Incidence of Hypotension among Study Participants

In this study, hypotension was recorded in 5 patients (8.3%), while the majority of participants, 55 patients (91.7%), did not experience this complication. The relatively low occurrence suggests that both off-loading methods were generally safe concerning hemodynamic stability. However, the cases that developed hypotension could be related to factors such as infection-related sepsis, dehydration, concomitant medications, or underlying comorbidities. Recognizing and promptly managing hypotension in diabetic foot ulcer patients is crucial, as it can compromise perfusion and impede wound healing, potentially leading to further complications.

Table 6: Distribution of participants according to incidence of hypotension

Hypotension	Count	Percentage
No	55	91.7
Yes	5	8.3

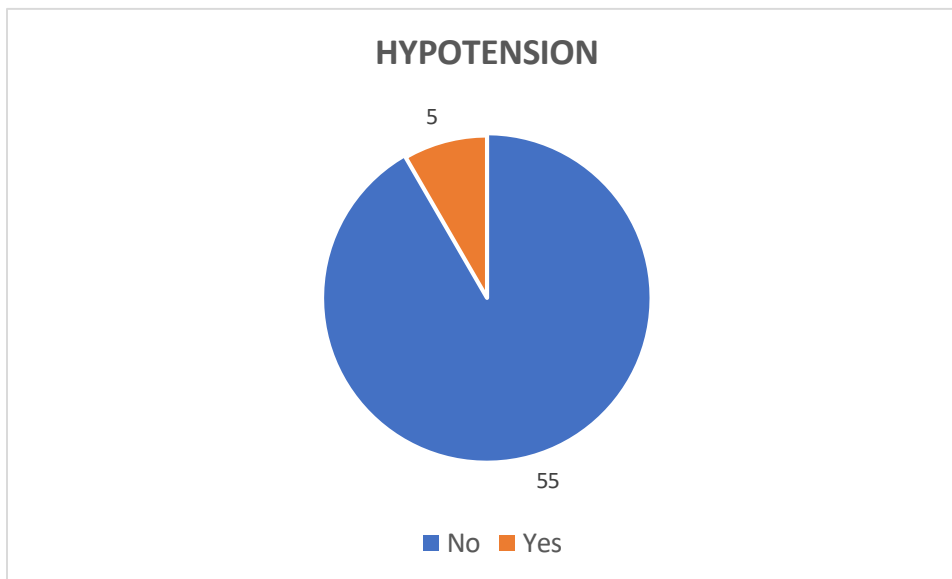


Figure 6: Incidence of hypotension among study participants

## Incidence of Bradycardia among Study Participants

Among the 60 patients evaluated, bradycardia was observed in 4 cases (6.7%), whereas the vast majority, 56 patients (93.3%), did not develop this condition during the study period. The low incidence indicates that bradycardia is an uncommon complication in the management of diabetic plantar foot ulcers using the studied off-loading methods. When present, bradycardia could be associated with factors such as medication side effects, autonomic neuropathy, or systemic illness. Although infrequent, it is important to monitor cardiac parameters, as bradycardia may influence patient safety and overall recovery.

Table 7: Distribution of participants according to incidence of bradycardia

Bradycardia	Count	Percentage
No	56	93.3
Yes	4	6.7

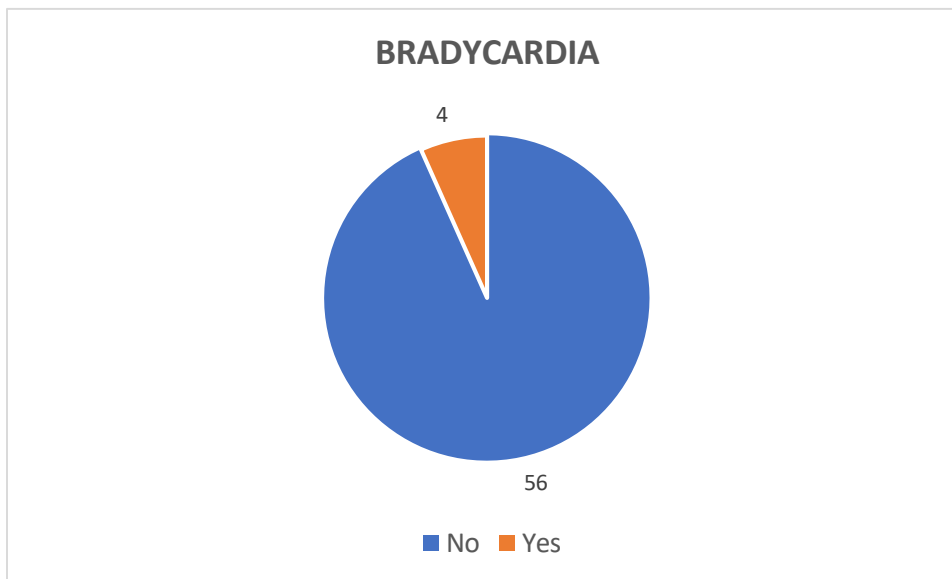


Figure 7: Incidence of bradycardia among study participants

In this study, more than half of the participants, 37 patients (54.9%), reported no symptoms during the observation period. Among symptomatic cases, mild fever was the most common complaint, affecting 11 patients (21.6%), followed by local irritation in 8 patients (15.7%) and swelling in 4

Patients (7.8%). The predominance of asymptomatic cases suggests that the off-loading interventions were generally well tolerated and that significant adverse local or systemic symptoms were uncommon. Monitoring symptom occurrence is essential, as it may serve as an indicator of wound infection, inflammatory response, or treatment-related complications.

Table 8: Distribution of participants according to symptoms

Symptoms	Count	Percentage
Mild fever	11	21.6
Local irritation	8	15.7
Swelling	4	7.8
No symptoms	37	54.9

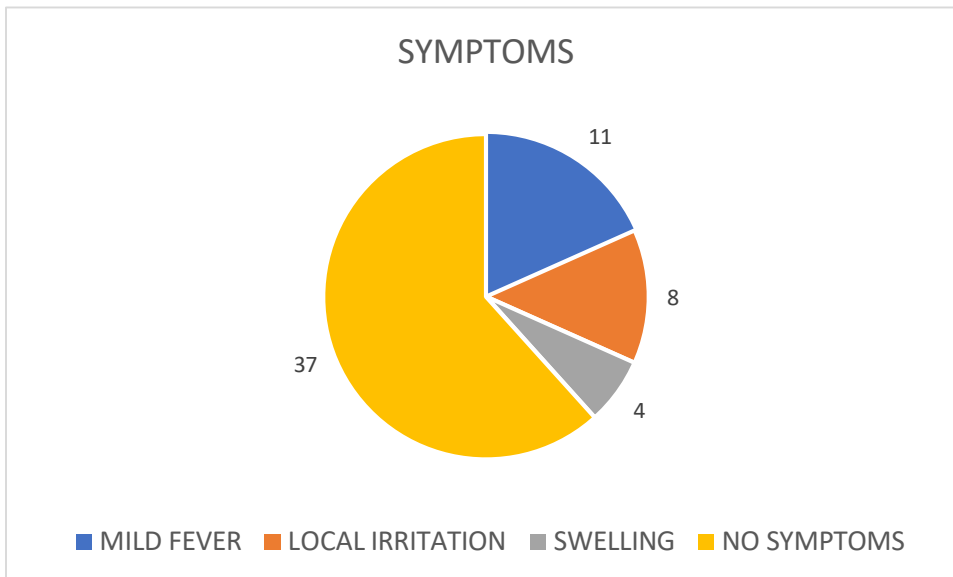


Figure 8: Distribution of symptoms among study participants

### Requirement of Rescue Analgesics among Study Participants

Out of the 60 patients included in the study, 10 patients (16.7%) required rescue analgesics, while the majority, 50 patients (83.3%), did not need additional pain management beyond the standard protocol. The relatively low requirement for rescue analgesia suggests that the pain control.

The results achieved with the implemented off-loading methods and associated care measures were generally adequate. Patients who required extra analgesics may have experienced higher pain levels due to factors such as ulcer severity, infection, or individual pain threshold variations. Monitoring the need for rescue analgesia provides valuable insight into the comfort and tolerability of treatment modalities.

Table 9: Distribution of participants according to the requirement of rescue analgesics

Rescue Analgesic Required	Count	Percentage
No	50	83.3
Yes	10	16.7

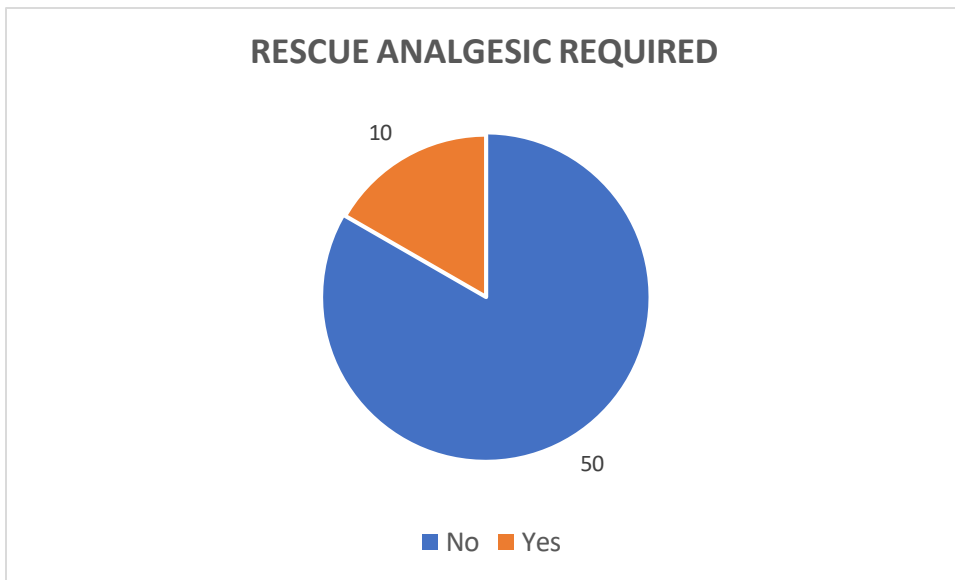


Figure 9: Requirement of rescue analgesics among study participants

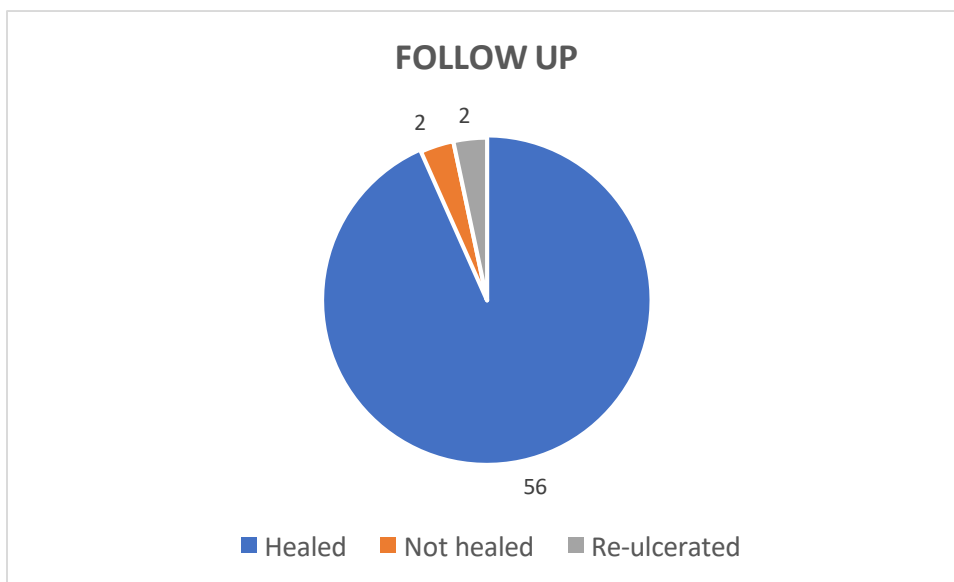
### Follow-up Outcomes among Study Participants

During follow-up, the majority of patients, 56 (93.3%), achieved complete healing of their diabetic plantar foot ulcers. A small proportion of patients showed either non-healing ulcers (2 patients, 3.3%) or re-ulceration (2 patients, 3.3%). The high healing rate indicates the overall effectiveness of the off-loading interventions and associated wound care strategies employed in the study. Non-healing and recurrence cases may be attributed to persistent risk factors such as poor glycemic.

Control, inadequate adherence to off-loading protocols, or underlying neuropathy. Tracking follow-up outcomes is critical for assessing long-term treatment success and guiding preventive measures to minimize recurrence.

Table 10: Follow-up status of study participants

Status	Count	Percentage
Healed	56	93.3
Not healed	2	3.3
Re-ulceration	2	3.3



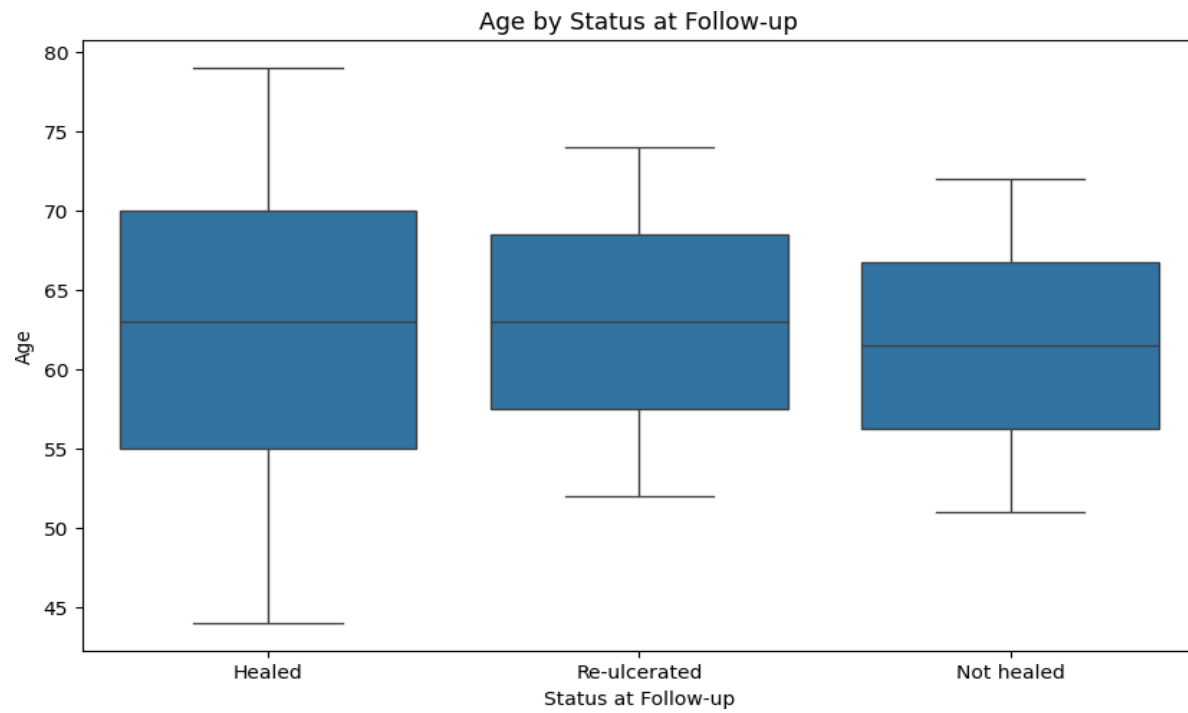
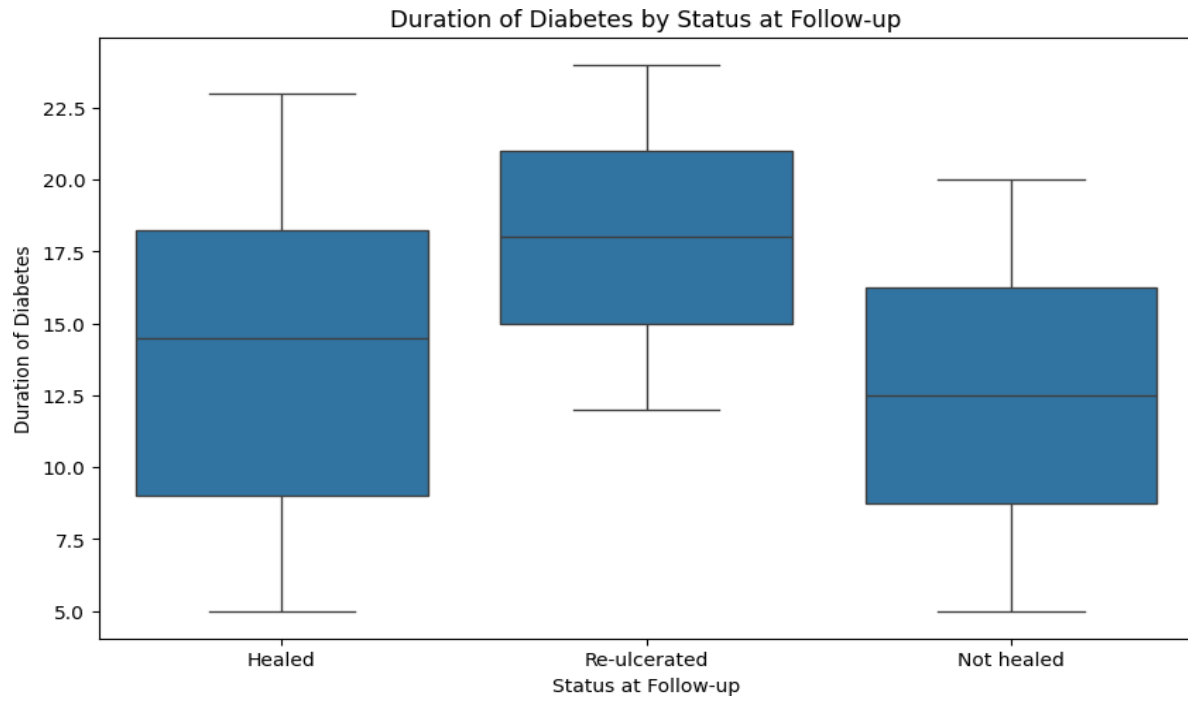


Figure 10: Follow-up status of study participants

## Age Distribution of Study Participants

The study included 60 patients aged between 44 and 79 years, with a mean age of  $61.93 \pm 10.25$  years. The median age was 63 years, with an interquartile range of 54.5 to 70.25 years. The majority of patients fell into the 60–69 year age group (33.3%), followed by those aged 70–79 years (28.3%) and 50–59 years (21.7%). The smallest proportion was in the 40–49 year group (16.7%). This distribution indicates that diabetic plantar foot ulcers are most prevalent among older adults, which may be attributed to longer disease duration, greater neuropathic changes, and reduced tissue healing capacity in this age bracket.

Table 11: Age characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	$61.93 \pm 10.25$
Median	63
Min – Max	44 – 79
IQR (25–75%)	54.5 – 70.25

Age Group (Years)	Count	Percentage
40–49	10	16.7
50–59	13	21.7
60–69	20	33.3
70–79	17	28.3

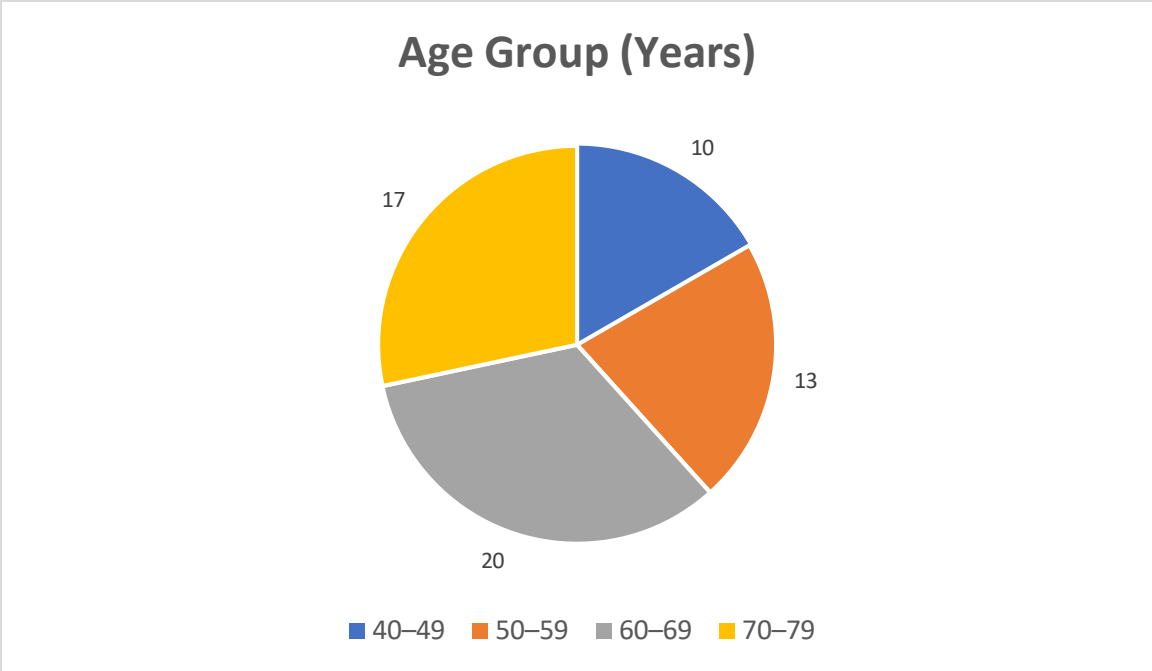


Figure 11: Age distribution of study participants

**Weight Distribution of Study Participants**

The mean body weight of the 60 study participants was  $68.94 \pm 9.71$  kg, with values ranging from 46.6 kg to 93.0 kg. The median weight was 68.85 kg, and the interquartile range extended from 64.05 to 76.2 kg. The largest proportion of patients belonged to the 60–69 kg category (43.3%), followed by those weighing 70–79 kg (26.7%) and 40–59 kg (16.7%). The smallest group comprised participants in the 80–99 kg range (13.3%). This weight distribution suggests that the majority of patients were within a moderate weight range, which may influence plantar pressure patterns and subsequently affect ulcer development and healing.

Table 12: Weight characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	68.94 $\pm$ 9.71
Median	68.85
Min – Max	46.6 – 93.0
IQR (25–75%)	64.05 – 76.2

Weight Range (kg)	Count	Percentage
40–59	10	16.7
60–69	26	43.3
70–79	16	26.7
80–99	8	13.3

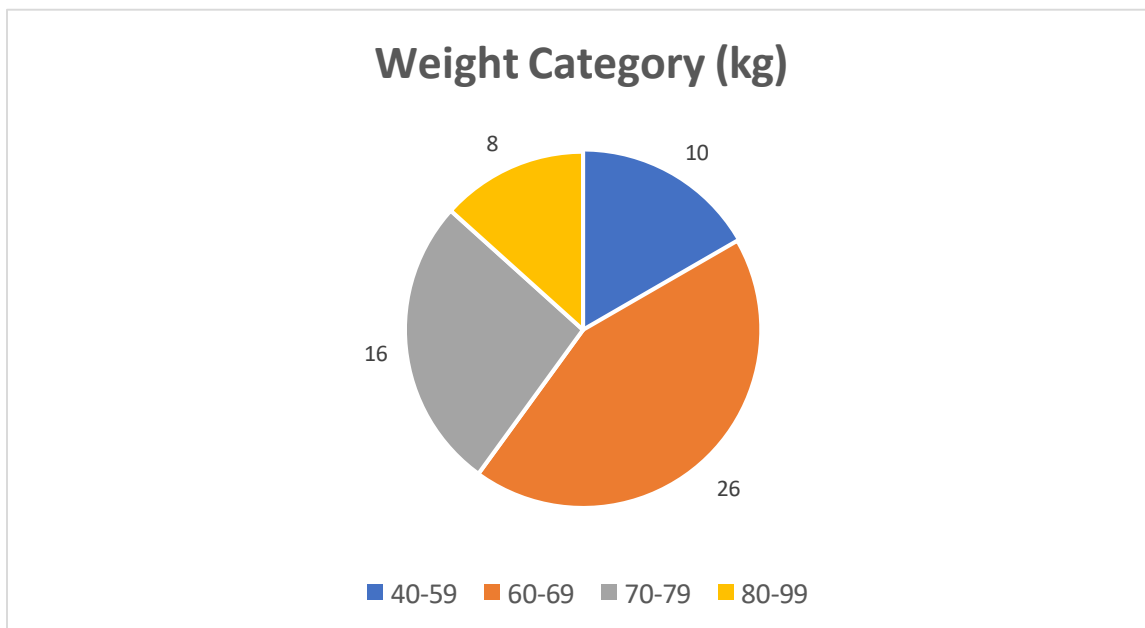


Figure 12: Weight distribution of study participants

### Duration of Diabetes among Study Participants

The mean duration of diabetes in the study population was  $13.80 \pm 5.68$  years, with a range of 5 to 24 years. The median duration was 14.5 years, and the interquartile range extended from 9.0 to 19.0 years. The largest proportions of patients were in the 0–9 years and 15–19 years categories, each comprising 31.7% of the participants. Patients with 10–14 years and 20–24 years of diabetes accounted for 18.3% each. This bimodal pattern suggests that diabetic plantar foot ulcers may occur both in relatively early and late stages of the disease, possibly influenced by the interplay of glycemic control, comorbidities, and lifestyle factors.

Table 13: Duration of diabetes characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	$13.80 \pm 5.68$
Median	14.5
Min – Max	5.0 – 24.0
IQR (25–75%)	9.0 – 19.0

Duration Range (years)	Count	Percentage
0–9	19	31.7
10–14	11	18.3
15–19	19	31.7
20–24	11	18.3

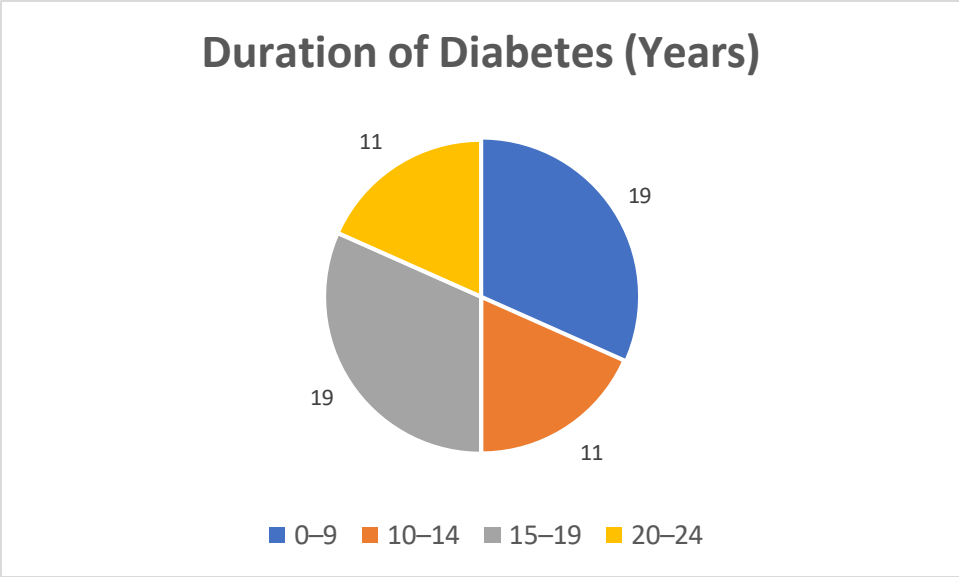


Figure 13: Duration of diabetes among study participants

**Ulcer Size among Study Participants**

The mean ulcer size in the study cohort was  $4.97 \pm 2.60 \text{ cm}^2$ , ranging from  $1.2 \text{ cm}^2$  to  $11.6 \text{ cm}^2$ . The median ulcer size was  $4.8 \text{ cm}^2$ , with an interquartile range of  $2.7$  to  $6.53 \text{ cm}^2$ . The most common ulcer size category was  $1-2.9 \text{ cm}^2$  (31.7%), followed by  $3-4.9 \text{ cm}^2$  and  $7-11.9 \text{ cm}^2$ , each accounting for 23.3% of patients. Ulcers measuring  $5-6.9 \text{ cm}^2$  comprised 21.7% of the sample. This distribution reflects a broad spectrum of ulcer sizes, with a substantial proportion presenting with smaller wounds, which may respond more favorably to off-loading interventions compared to larger ulcers.

Table 14: Ulcer size characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	4.97 $\pm$ 2.60
Median	4.8
Min – Max	1.2 – 11.6
IQR (25–75%)	2.7 – 6.53

Size Range (cm <sup>2</sup> )	Count	Percentage
1–2.9	19	31.7
3–4.9	14	23.3
5–6.9	13	21.7
7–11.9	14	23.3

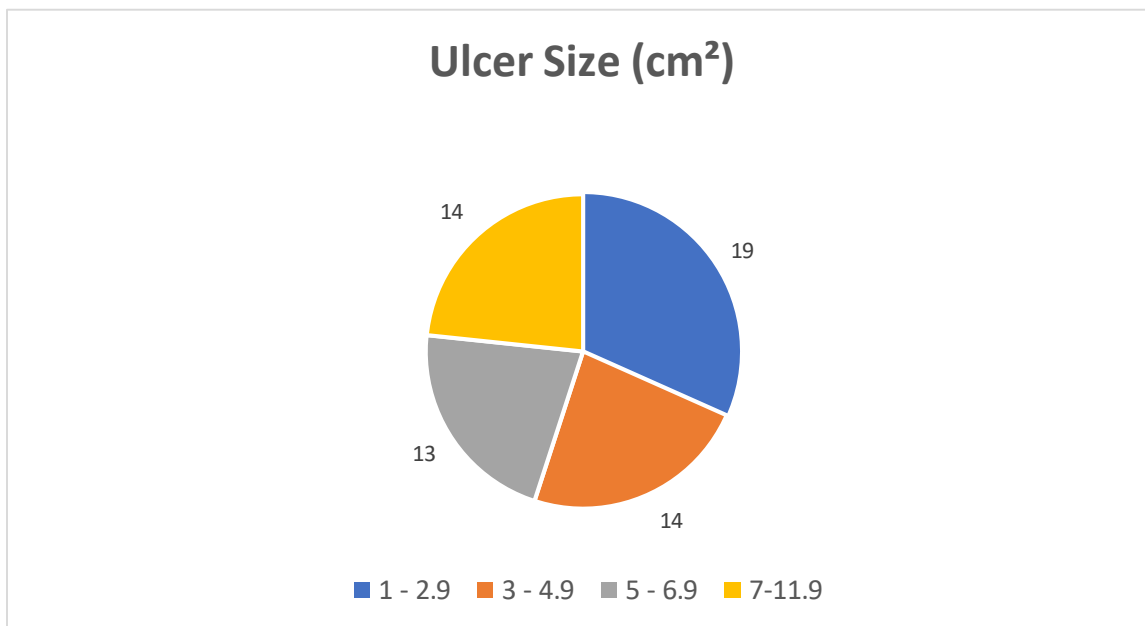


Figure 14: Ulcer size distribution among study participants

## Ulcer Grade among Study Participants

The mean ulcer grade in the study population was  $1.78 \pm 0.80$ , with grades ranging from 1 to 3. The median grade was 2, and the interquartile range extended from 1 to 2. Grade 1 ulcers were the most common, affecting 27 patients (45.0%), followed by Grade 2 ulcers in 19 patients (31.7%) and Grade 3 ulcers in 14 patients (23.3%). The predominance of lower-grade ulcers suggests that many patients presented for treatment before the progression to more severe stages, which is advantageous for healing outcomes. However, the presence of nearly one-quarter of patients with Grade 3 ulcers underscores the need for improved early detection and intervention strategies.

Table 15: Ulcer grade characteristics and distribution of study participants

Parameter		Value
Count		60
Mean $\pm$ SD		$1.78 \pm 0.80$
Median		2
Min – Max		1 – 3
IQR (25–75%)		1 – 2
Grade	Count	Percentage
1	27	45.0
2	19	31.7
3	14	23.3

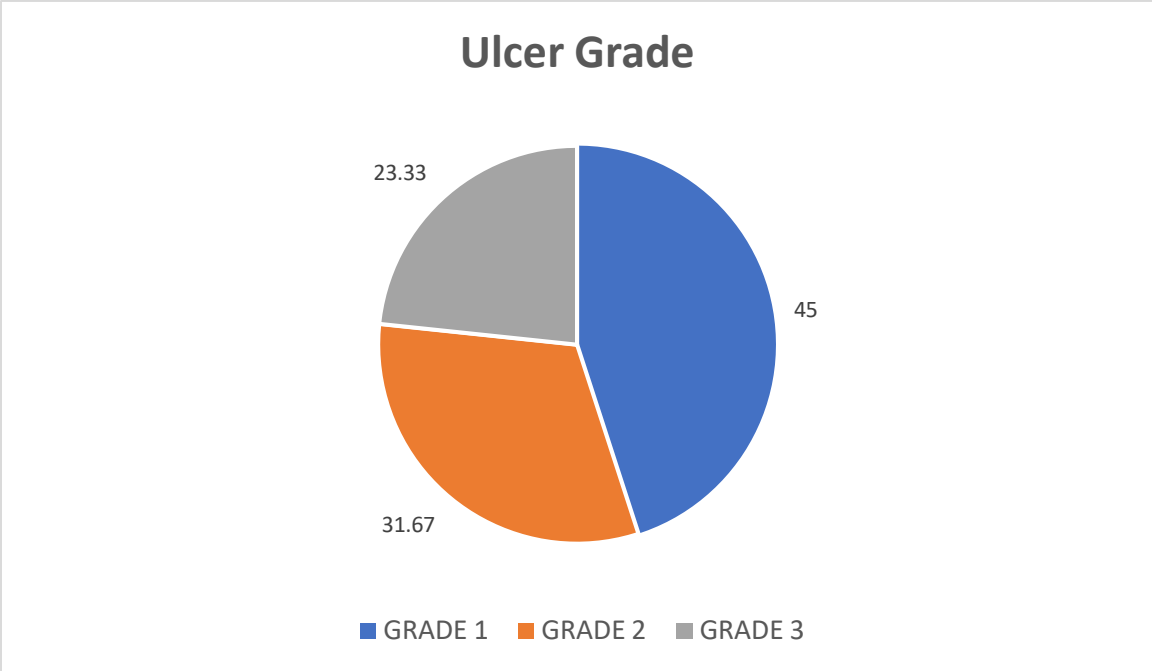


Figure 15: Ulcer grade distribution among study participants

### HbA1c Levels among Study Participants

The mean HbA1c level in the study cohort was  $8.29 \pm 1.51\%$ , ranging from 4.9% to 12.1%. The median value was 8.2%, with an interquartile range of 7.4% to 9.3%. The majority of patients, 29 (48.3%), had HbA1c values between 7% and 8.9%, indicating suboptimal glycemic control. A further 26.7% had HbA1c between 9% and 10.9%, and 20.0% were within the 4–6.9% range, reflecting adequate control in a minority of cases. Only 5.0% of participants had markedly elevated HbA1c levels between 11% and 12.9%. These findings highlight the strong prevalence of inadequate long-term glycemic control, a key factor in the pathogenesis and delayed healing of diabetic plantar foot ulcers.

Table 16: HbA1c characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	8.29 $\pm$ 1.51
Median	8.2
Min – Max	4.9 – 12.1
IQR (25–75%)	7.4 – 9.3

HbA1c Range (%)	Count	Percentage
4–6.9	12	20.0
7–8.9	29	48.3
9–10.9	16	26.7
11–12.9	3	5.0

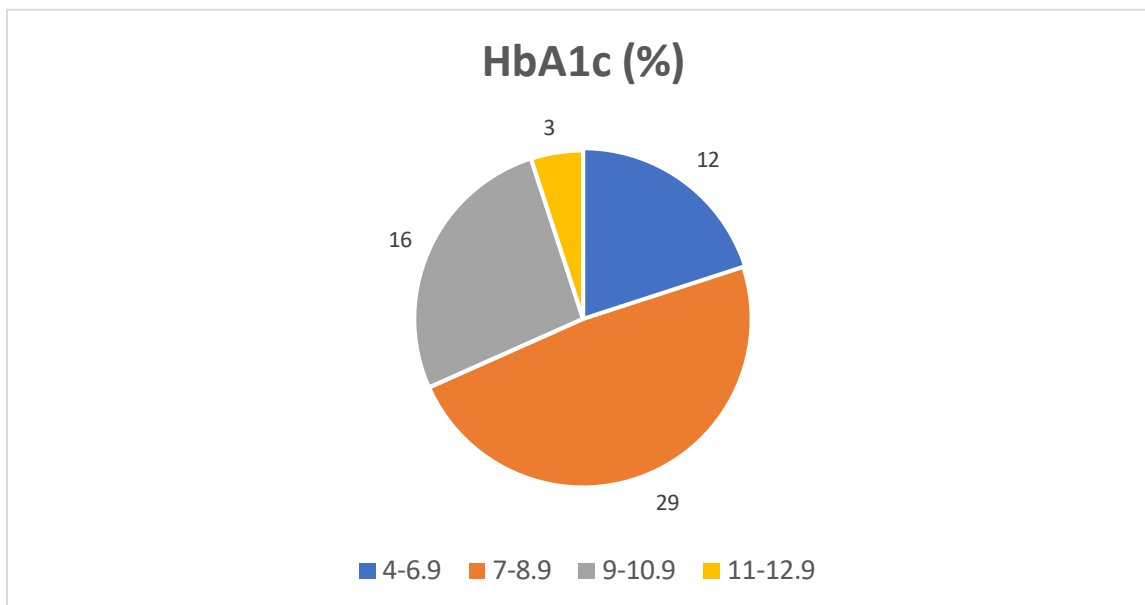


Figure 16: HbA1c distribution among study participants

## Fasting Blood Sugar Levels among Study Participants

The mean fasting blood sugar (FBS) level in the study group was  $182.77 \pm 37.95$  mg/dL, with values ranging from 124 mg/dL to 249 mg/dL. The median FBS was 182.5 mg/dL, and the interquartile range extended from 154.75 to 212.25 mg/dL. The highest proportion of participants, 21 patients (35.0%), had FBS levels between 160 and 199 mg/dL, followed closely by 20 patients (33.3%) in the 120–159 mg/dL range. Elevated levels between 200–239 mg/dL were observed in 21.7% of cases, while 10.0% had very high readings of 240–249 mg/dL. These findings indicate that most participants had above-normal fasting glucose values, reflecting inadequate short-term glycemic control, which can adversely impact ulcer healing.

Table 17: Fasting blood sugar characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	$182.77 \pm 37.95$
Median	182.5
Min – Max	124 – 249
IQR (25–75%)	154.75 – 212.25

FBS Range (mg/dL)	Count	Percentage
120–159	20	33.3
160–199	21	35.0
200–239	13	21.7
240–249	6	10.0

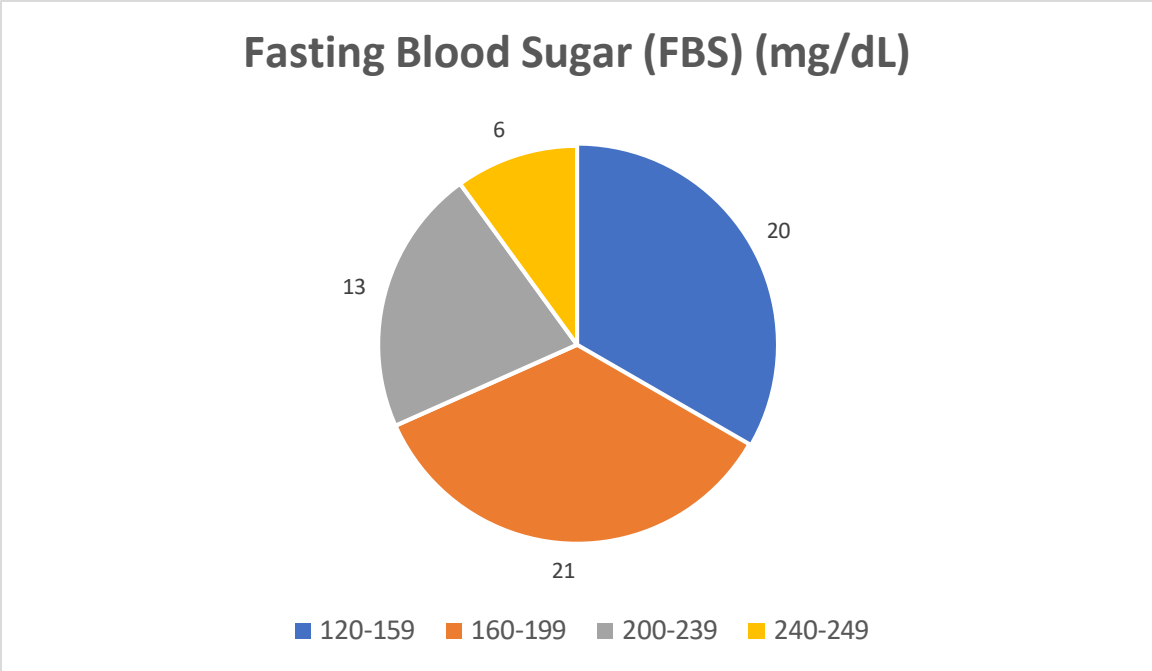


Figure 17: Fasting blood sugar distribution among study participants

**Postprandial Blood Sugar Levels among Study Participants**

The mean postprandial blood sugar (PPBS) level in the study population was  $234.05 \pm 33.52$  mg/dL, with readings ranging from 180 mg/dL to 292 mg/dL. The median PPBS was 230 mg/dL, and the interquartile range was 205.5 to 263 mg/dL. Equal proportions of patients (30.0%) had PPBS values in the 180–209 mg/dL and 240–269 mg/dL ranges, while 25.0% were in the 210–239 mg/dL category. A smaller proportion, 15.0%, had markedly elevated PPBS levels between 270 and 299 mg/dL. These findings indicate that the majority of participants had postprandial glucose levels well above the recommended targets, emphasizing poor post-meal glycemic control, which can contribute to impaired ulcer healing and increased risk of complications.

Table 18: Postprandial blood sugar characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	234.05 $\pm$ 33.52
Median	230
Min – Max	180 – 292
IQR (25–75%)	205.5 – 263

PPBS Range (mg/dL)	Count	Percentage
180–209	18	30.0
210–239	15	25.0
240–269	18	30.0
270–299	9	15.0

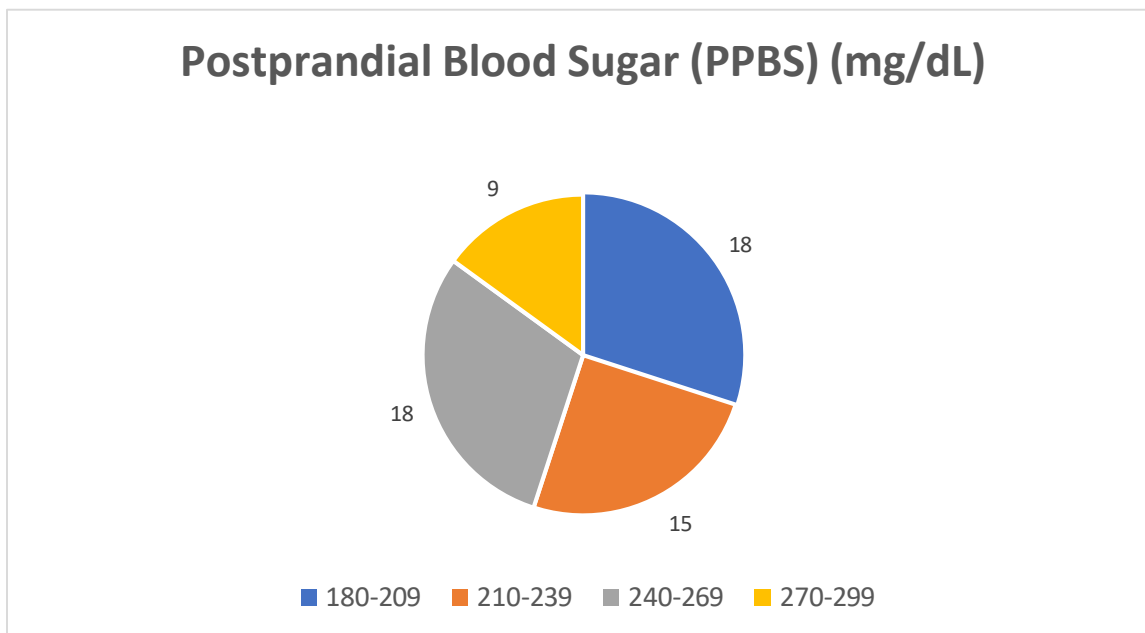


Figure 18: Postprandial blood sugar distribution among study participants

### Random Blood Sugar Levels among Study Participants

The mean random blood sugar (RBS) level in the study group was  $251.82 \pm 60.62$  mg/dL, with values ranging from 152 mg/dL to 349 mg/dL. The median was 263 mg/dL, and the interquartile range spanned from 204 to 304.75 mg/dL. The most common RBS categories were 250–299 mg/dL and 300–349 mg/dL, each comprising 26.7% of participants. The 150–199 mg/dL and 200–249 mg/dL groups each accounted for 23.3% of the sample. These findings indicate that a significant proportion of patients presented with markedly elevated random glucose levels, reflecting inadequate glycemic control, which can hinder ulcer healing and increase the risk of complications.

Table 19: Random blood sugar characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	$251.82 \pm 60.62$
Median	263
Min – Max	152 – 349
IQR (25–75%)	204 – 304.75

RBS Range (mg/dL)	Count	Percentage
150–199	14	23.3
200–249	14	23.3
250–299	16	26.7
300–349	16	26.7

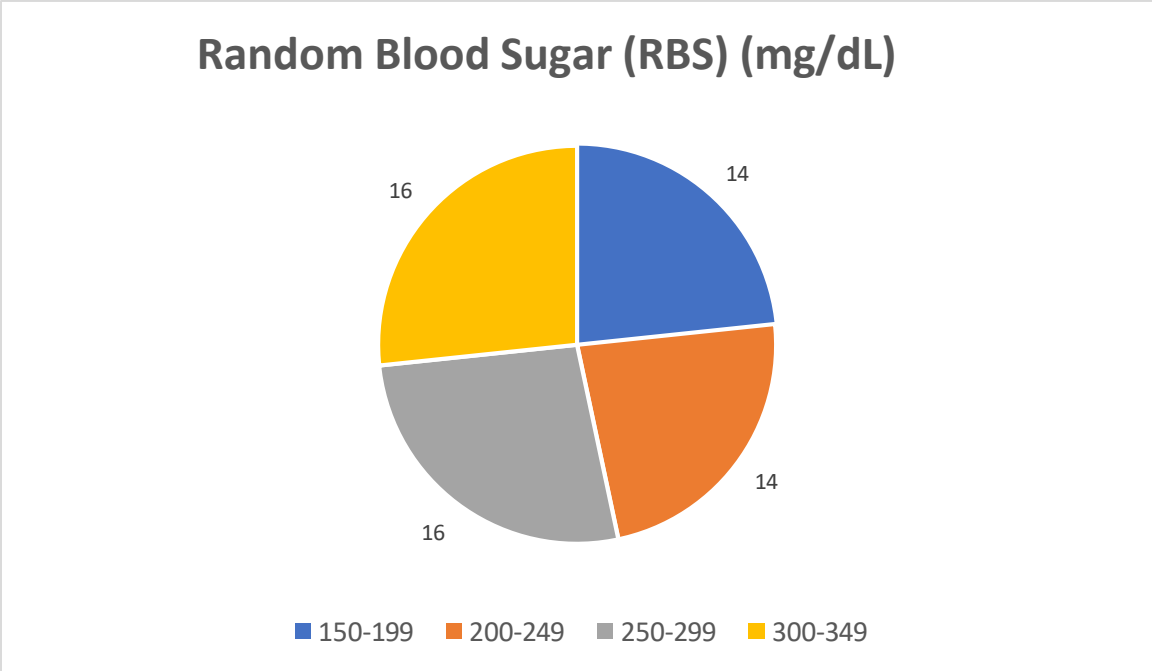


Figure 19: Random blood sugar distribution among study participants

**Baseline Pain Scores (VAS) among Study Participants**

At baseline, the mean Visual Analogue Scale (VAS) pain score was  $6.38 \pm 0.83$ , with scores ranging from 5 to 8. The median score was 6, and the interquartile range was 6 to 7. The most common pain score reported was 7, observed in 24 patients (40.0%), followed closely by a score of 6 in 23 patients (38.3%). Lower pain scores of 5 were recorded in 15.0% of participants, while higher scores of 8 were seen in only 6.7%. These findings indicate that the majority of patients presented with moderate to moderately severe pain levels at the start of the study, underscoring the importance of effective pain management alongside ulcer treatment.

Table 20: Baseline pain score (VAS) characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	6.38 $\pm$ 0.83
Median	6
Min – Max	5 – 8
IQR (25–75%)	6 – 7

VAS Score	Count	Percentage
5	9	15.0
6	23	38.3
7	24	40.0
8	4	6.7

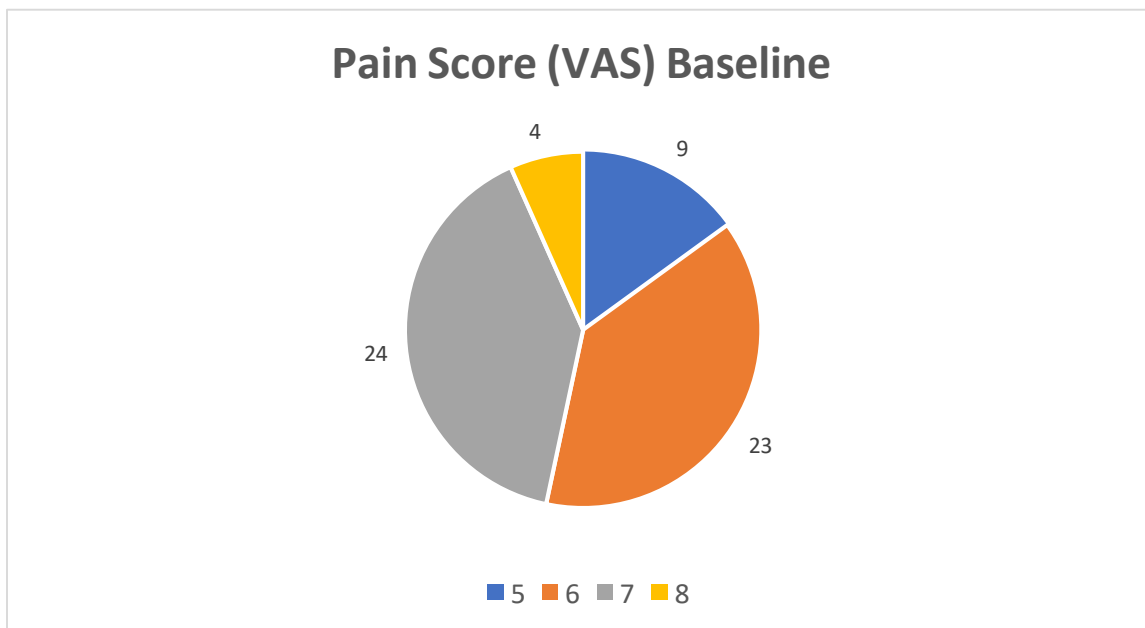


Figure 20: Baseline pain score distribution among study participants

### Length of Hospital Stay among Study Participants

The mean length of hospital stay in the study population was  $13.93 \pm 4.07$  days, ranging from 8 to 20 days. The median duration was 13.5 days, with an interquartile range of 10 to 18 days. The largest proportion of patients, 35.0%, stayed between 8 and 11 days, followed by 30.0% who stayed 16–19 days. A further 23.3% had stays of 12–15 days, while 11.7% remained hospitalized for 20 days. This distribution reflects variability in recovery times, potentially influenced by factors such as ulcer severity, presence of infection, comorbid conditions, and response to treatment. Shorter stays may indicate faster healing or fewer complications, while longer stays could suggest more complex clinical cases.

Table 21: Length of hospital stay characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	$13.93 \pm 4.07$
Median	13.5
Min – Max	8 – 20
IQR (25–75%)	10 – 18

Stay Duration (days)	Count	Percentage
8–11	21	35.0
12–15	14	23.3
16–19	18	30.0
20	7	11.7

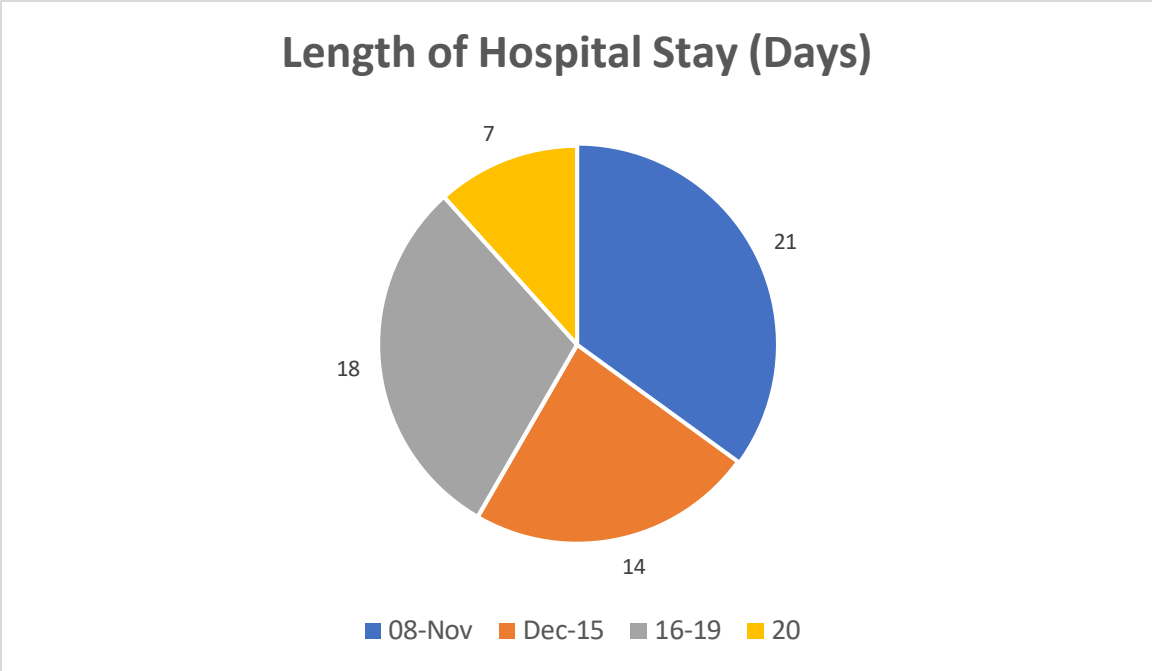


Figure 21: Length of hospital stay among study participants

**Number of Dressings Required among Study Participants**

The mean number of dressings required during hospitalization was  $7.28 \pm 3.07$ , with a range from 3 to 12 dressings. The median number was 7, and the interquartile range extended from 5 to 10. The most common category was 9–11 dressings, reported in 40.0% of patients, followed by 3–5 dressings in 38.3% of cases. A smaller proportion required 6–8 dressings (13.3%), and only 8.3% underwent 12 dressings. The variation in dressing frequency likely reflects differences in ulcer size, infection status, healing rate, and wound care needs. Higher numbers of dressings may be associated with more severe or slow-healing ulcers, while fewer dressings suggest quicker recovery.

Table 22: Number of dressings required and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	7.28 $\pm$ 3.07
Median	7
Min – Max	3 – 12
IQR (25–75%)	5 – 10

Number of Dressings	Count	Percentage
3–5	23	38.3
6–8	8	13.3
9–11	24	40.0
12	5	8.3

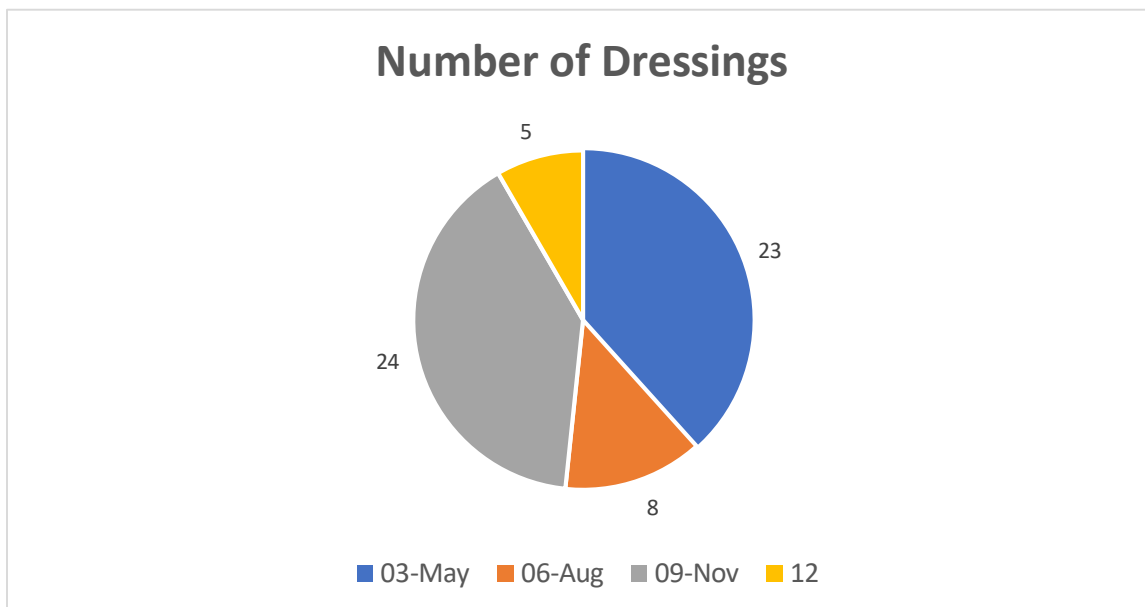


Figure 22: Number of dressings required among study participants

## Healing Time among Study Participants

The mean healing time for diabetic plantar foot ulcers in the study group was  $16.97 \pm 4.75$  days, with a range of 10 to 25 days. The median healing duration was 16.5 days, and the interquartile range extended from 13 to 21.25 days. The largest proportion of patients (43.3%) achieved healing within 10–14 days, followed by 31.7% who healed in 20–24 days. A smaller proportion required 15–19 days (20.0%), and only 5.0% had prolonged healing up to 25 days. This variation in healing time may be attributed to differences in ulcer size, grade, infection status, comorbidities, and patient compliance with off-loading protocols. Faster healing times are indicative of effective intervention strategies and good wound care practices.

Table 23: Healing time characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	$16.97 \pm 4.75$
Median	16.5
Min – Max	10 – 25
IQR (25–75%)	13 – 21.25

Healing Time (days)	Count	Percentage
10–14	26	43.3
15–19	12	20.0
20–24	19	31.7
25	3	5.0

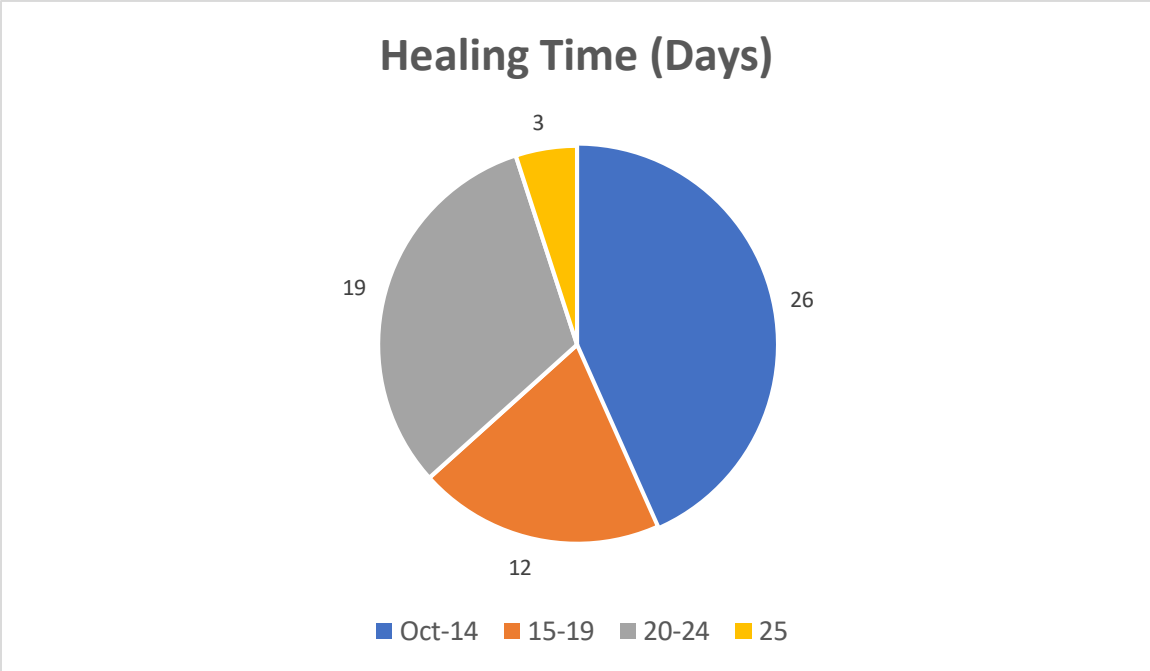


Figure 23: Healing time among study participants

**Total Expenditure among Study Participants**

The mean total expenditure incurred during treatment was  $7,644.77 \pm 1,312.18$  currency units, with costs ranging from 5,549.0 to 9,919.0. The median expenditure was 7,693.0, and the interquartile range extended from 6,505.5 to 8,774.75. The largest proportion of patients (43.3%) incurred expenses between 5,000–6,999 units, followed by 30.0% who spent 8,000–8,999 units. A smaller share (20.0%) had expenditures of 9,000–9,999 units, while only 6.7% fell into the 7,000– 7,999 range. This distribution reflects variation in treatment costs, potentially influenced by hospital stay length, number of dressings, ulcer severity, and complications. Lower costs likely correspond to shorter, uncomplicated cases, while higher expenses may reflect more complex management needs.

Table 24: Total expenditure characteristics and distribution of study participants

Parameter	Value
Count	60
Mean ± SD	7,644.77 ± 1,312.18
Median	7,693.0
Min – Max	5,549.0 – 9,919.0
IQR (25–75%)	6,505.5 – 8,774.75

Expenditure Range	Count	Percentage
5,000–6,999	26	43.3
7,000–7,999	4	6.7
8,000–8,999	18	30.0
9,000–9,999	12	20.0

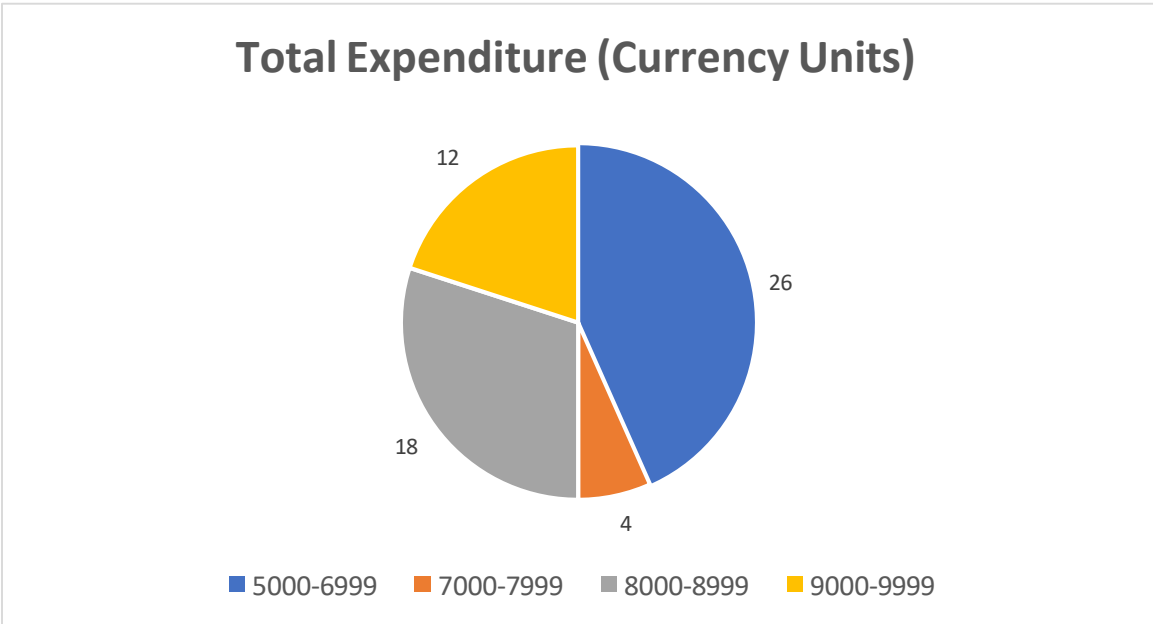


Figure 24: Total expenditure among study participants

## Patient Satisfaction among Study Participants

The mean patient satisfaction score was  $3.12 \pm 0.83$ , with scores ranging from 2 to 4. The median score was 3, and the interquartile range extended from 2 to 4. No patients reported a satisfaction score of 1. The largest proportion of participants, 40.0%, rated their satisfaction as 4, indicating a high level of approval for the treatment received. This was followed by 31.7% who rated satisfaction as 3 and 28.3% who rated it as 2. The overall high satisfaction levels suggest that the off-loading interventions and associated wound care measures were well-received by patients, contributing positively to their treatment experience and perception of outcomes.

Table 25: Patient satisfaction characteristics and distribution of study participants

Parameter	Value
Count	60
Mean $\pm$ SD	$3.12 \pm 0.83$
Median	3
Min – Max	2 – 4
IQR (25–75%)	2 – 4

Satisfaction Level	Count	Percentage
1	0	0.0
2	17	28.3
3	19	31.7
4	24	40.0

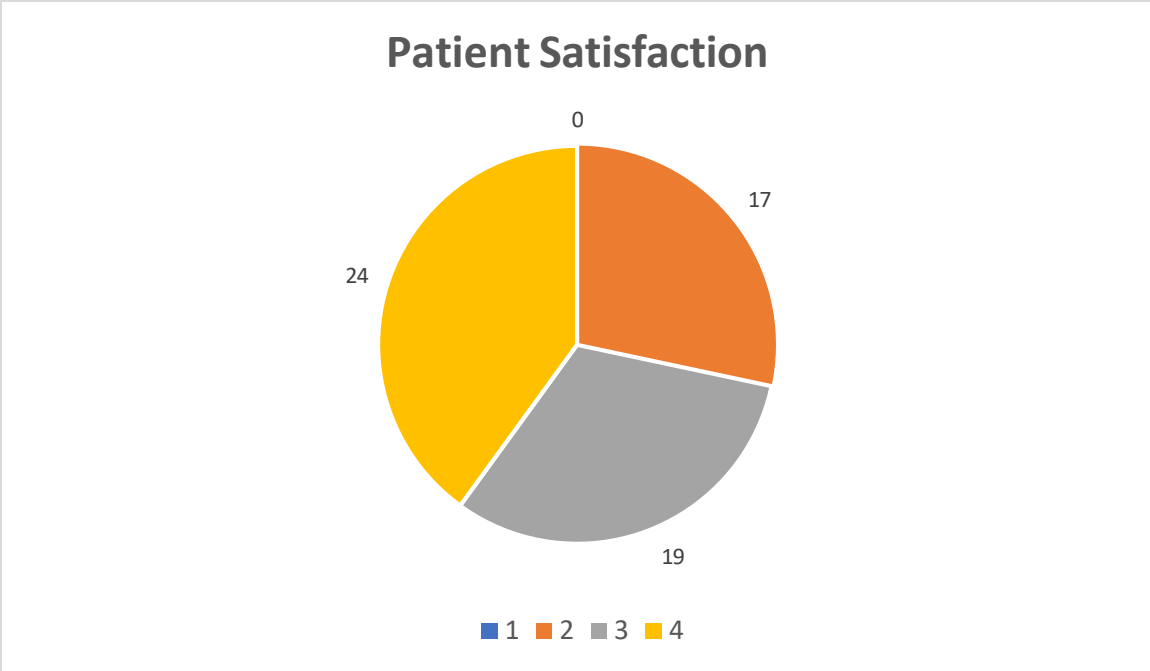


Figure 25: Patient satisfaction levels among study participants

**Postoperative Nausea and Vomiting (PONV) Scores among Study Participants**

The mean PONV score among participants was  $1.47 \pm 1.07$ , with scores ranging from 0 to 3. The median score was 1.5, and the interquartile range extended from 1 to 2. A PONV score of 2 was the most common, recorded in 30.0% of patients, followed by a score of 1 in 26.7% and a score of 0 in 23.3%. The least common was a score of 3, reported in 20.0% of cases. These findings suggest that mild to moderate PONV was relatively common in the study cohort, while severe cases were less frequent. Effective management of PONV is important for enhancing postoperative comfort and overall patient satisfaction.

Table 26: PONV score characteristics and distribution of study participants

Parameter	Value	
Count	60	
Mean $\pm$ SD	1.47 $\pm$ 1.07	
Median	1.5	
Min – Max	0 – 3	
IQR (25–75%)	1 – 2	

PONV Score	Count	Percentage
0	14	23.3
1	16	26.7
2	18	30.0
3	12	20.0

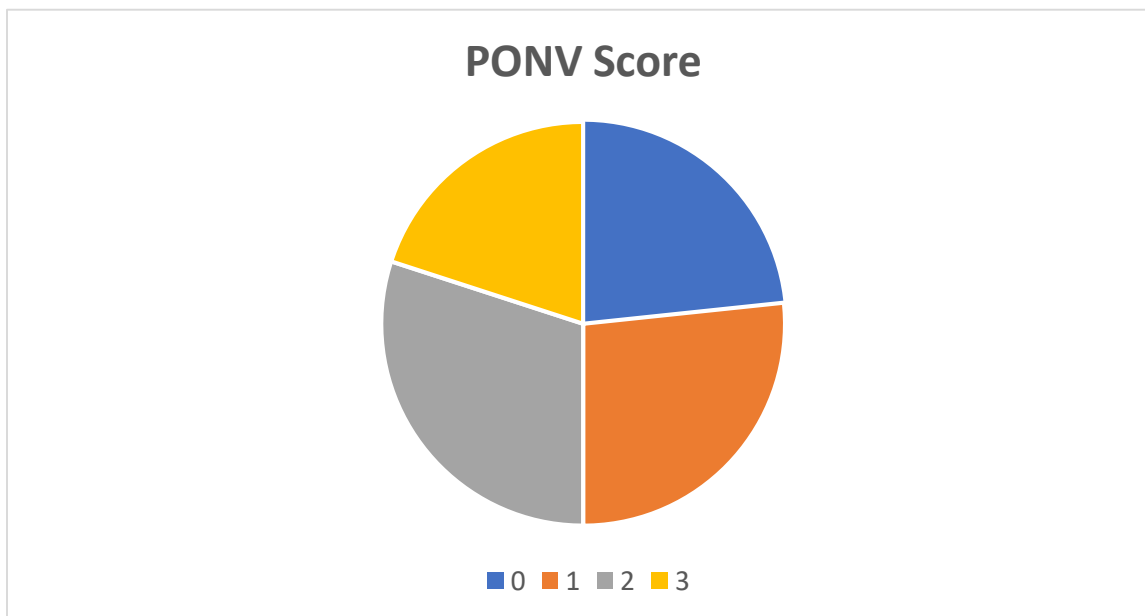


Figure 26: PONV scores among study participants

## Comparison of VAS Pain Scores between Mandakini Device and Crutches

Independent t-test analysis revealed statistically significant differences in VAS pain scores between the Mandakini off-loading device group and the crutches group at all measured time points. At 2 hours post-intervention, the difference was highly significant ( $t = -37.23$ ,  $p = 3.48 \times 10^{-42}$ ), with the Mandakini group reporting lower pain scores. Similarly, significant reductions in pain were observed at 8 hours ( $t = -23.80$ ,  $p = 1.29 \times 10^{-31}$ ), 24 hours ( $t = -18.83$ ,  $p = 2.20 \times 10^{-26}$ ), and 48 hours ( $t = -25.42$ ,  $p = 3.96 \times 10^{-33}$ ). These findings indicate that the Mandakini device provided superior pain relief compared to crutches throughout the postoperative period, with consistent statistical significance across all time intervals.

Table 27: Independent t-test results for VAS pain scores in Mandakini device vs. crutches groups

Time Point	T-statistic	P-value	Interpretation
2 hours	-37.23	$3.48 \times 10^{-42}$	Significant
8 hours	-23.80	$1.29 \times 10^{-31}$	Significant
24 hours	-18.83	$2.20 \times 10^{-26}$	Significant
48 hours	-25.42	$3.96 \times 10^{-33}$	Significant

### Visual Breakdown of Pain Scores at 2 Hours

At 2 hours post-intervention, all 28 participants in the Mandakini device group reported very low pain scores (VAS 1 or 2), with the majority (93.3%) scoring 1. In contrast, the crutches group reported much higher pain scores, with 83.3% scoring VAS 4 and the remaining participants scoring 5. This stark difference reflects the immediate analgesic benefit provided by the Mandakini device.

Table 28: Distribution of VAS pain scores at 2 hours in Mandakini device and crutches groups

VAS Score	Crutches	Mandakini
1	0	28
2	0	2
4	25	0
5	5	0

#### Visual Breakdown of Pain Scores at 8 Hours

At 8 hours, pain control remained superior in the Mandakini group, with 63.3% of participants reporting VAS 1 and none exceeding VAS 3. Conversely, in the crutches group, pain scores were higher, with most participants (66.7%) reporting VAS 5 or 6. This demonstrates sustained pain relief with the Mandakini device beyond the immediate postoperative period.

Table 29: Distribution of VAS pain scores at 8 hours in Mandakini device and crutches groups

VAS Score	Crutches	Mandakini
1	0	19
2	0	10
3	0	1
4	9	0
5	20	0
6	1	0

#### Visual Breakdown of Pain Scores at 24 Hours

By 24 hours, all participants in the Mandakini group reported VAS scores between 1 and 3, with 76.7% scoring 1–2. In contrast, pain remained higher in the crutches group, where 90% reported

scores of 5–6. These results indicate that the Mandakini device continued to provide consistent and substantial pain reduction at 24 hours.

Table 30: Distribution of VAS pain scores at 24 hours in Mandakini device and crutches groups

VAS Score	Crutches	Mandakini
1–2	0	23
3	0	7
4	3	0
5–6	27	0

#### Visual Breakdown of Pain Scores at 48 Hours

At 48 hours, pain scores in the Mandakini group remained low, with all participants reporting VAS 1–3. The crutches group still exhibited higher pain levels, with all participants scoring 5–6. This persistent difference highlights the superior and sustained analgesic effect of the Mandakini device over the course of two days.

Table 31: Distribution of VAS pain scores at 48 hours in Mandakini device and crutches groups

VAS Score	Crutches	Mandakini
1–2	0	7
3	0	23
5–6	30	0

#### Comparison of Length of Hospital Stay between Groups

The mean length of hospital stay was markedly shorter in the Mandakini device group (10.23 days) compared to the crutches group (17.63 days). This difference of over 7 days suggests that the Mandakini device may contribute to faster recovery and discharge, likely due to enhanced pain control, improved mobility, and potentially better wound healing. Reduced hospital stay not only benefits patients by lowering the risk of hospital-acquired complications but also decreases overall treatment costs.

Table 32: Mean length of hospital stay in Mandakini device and crutches groups

Group	Mean Length of Stay (days)
Crutches	17.63
Mandakini	10.23

**Comparison of Length of Hospital Stay between Mandakini Device and Crutches**

Independent t-test analysis revealed a highly significant difference in the mean length of hospital stay between the two groups ( $t = -17.46, p = 9.25 \times 10^{-25}$ ). Patients in the Mandakini group stayed for an average of 10.23 days compared to 17.63 days in the crutches group. This substantial reduction highlights the potential of the Mandakini device to accelerate recovery and facilitate earlier discharge.

Table 33: Independent t-test results for length of hospital stay

Group	Mean Length of Stay (days)
Crutches	17.63
Mandakini	10.23

Metric	Value
T-statistic	-17.46
P-value	$9.25 \times 10^{-25}$

**Comparison of Number of Dressings between Mandakini Device and Crutches**

The mean number of dressings required was significantly lower in the Mandakini group (4.47) than in the crutches group (10.10), with an independent t-test showing a highly significant difference ( $t = -18.56, p = 4.52 \times 10^{-26}$ ). This suggests that the Mandakini device may promote faster wound healing and reduce the frequency of dressing changes.

Table 34: Independent t-test results for number of dressings

Group	Mean Number of Dressings
Crutches	10.10
Mandakini	4.47
Metric	Value
T-statistic	-18.56
P-value	$4.52 \times 10^{-26}$

#### Comparison of Total Expenditure between Mandakini Device and Crutches

The average total expenditure was significantly lower in the Mandakini group (6,455.33 currency units) compared to the crutches group (8,834.20 currency units). The difference was statistically significant ( $t = -17.17$ ,  $p = 2.08 \times 10^{-24}$ ). This cost reduction is likely a result of shorter hospital stays, fewer dressings, and potentially faster wound recovery in the Mandakini group.

Table 35: Independent t-test results for total expenditure

Group	Mean Total Expenditure (currency units)
Crutches	8,834.20
Mandakini	6,455.33
Metric	Value
T-statistic	-17.17
P-value	$2.08 \times 10^{-24}$

#### Comparison of Patient Satisfaction between Mandakini Device and Crutches

Patient satisfaction scores were markedly higher in the Mandakini group compared to the crutches group. All patients in the Mandakini group rated their satisfaction as either “Good” ( $n = 6$ ) or “Excellent” ( $n = 24$ ), while the crutches group included a substantial number of “Fair” ratings ( $n = 17$ ) and no “Excellent” ratings. The Mann–Whitney U test confirmed that this difference was

statistically significant ( $U = 861.0$ ,  $p = 1.03 \times 10^{-10}$ ), indicating a strong patient preference for the Mandakini device.

Table 36: Patient satisfaction distribution in Mandakini device and crutches groups

Satisfaction Score	Crutches	Mandakini
2 (Fair)	17	0
3 (Good)	13	6
4 (Excellent)	0	24

Metric	Value
U-statistic	861.0
P-value	$1.03 \times 10^{-10}$
Significance	Significant

#### Comparison of Ulcer Recurrence between Mandakini Device and Crutches

Ulcer recurrence was absent in the Mandakini device group, while 4 cases of recurrence occurred in the crutches group. Although recurrence was numerically lower in the Mandakini group, the Chi-square test result ( $\chi^2 = 2.41$ ,  $p = 0.12$ ) indicated that this difference was not statistically significant at the conventional 0.05 threshold. This suggests that while the Mandakini device may reduce recurrence, the observed difference could be due to chance in this sample size.

Table 37: Ulcer recurrence distribution in Mandakini device and crutches groups

<b>Group</b>	<b>No Recurrence</b>	<b>Recurrence</b>
Crutches	26	4
Mandakini	30	0
<b>Metric</b>	<b>Value</b>	
Chi-Square	2.41	
P-value	0.12	
DF	1	

**Comparison of Amputation Requirement between Mandakini Device and Crutches**

No amputations were reported in the Mandakini device group, whereas 4 patients in the crutches group required amputation. Despite this numerical difference, the Chi-square test ( $\chi^2 = 2.41$ ,  $p = 0.12$ ) indicated that the result was not statistically significant. This suggests that while the Mandakini device may potentially reduce the risk of amputation, the observed difference could be due to chance given the current sample size.

Table 38: Amputation requirement in Mandakini device and crutches groups

<b>Group</b>	<b>No Amputation</b>	<b>Amputation</b>
Crutches	26	4
Mandakini	30	0
<b>Metric</b>	<b>Value</b>	
Chi-Square	2.41	
P-value	0.12	
DF	1	

### Comparison of Technical Failure between Mandakini Device and Crutches

No technical failures were reported in either the Mandakini device group or the crutches group. The Chi-square test result ( $\chi^2 = 0.00$ ,  $p = 1.00$ ) confirms the absence of any statistical difference between groups. This indicates that both interventions were technically reliable throughout the study period.

Table 39: Technical failure occurrence in Mandakini device and crutches groups

Group	No Technical Failure	Technical Failure
Crutches	30	0
Mandakini	30	0

Metric	Value
Chi-Square	0.00
P-value	1.00
DF	0

### Comparison of Hypotension between Mandakini Device and Crutches

Hypotension was reported in 4 patients from the crutches group and 1 patient from the Mandakini group. The Chi-square test ( $\chi^2 = 0.87$ ,  $p = 0.35$ ) indicated that this difference was not statistically significant. This suggests that the choice of mobility device did not meaningfully influence the incidence of hypotension in the study cohort.

Table 40: Hypotension occurrence in Mandakini device and crutches groups

<b>Group</b>	<b>No Hypotension</b>	<b>Hypotension</b>
Crutches	26	4
Mandakini	29	1
<b>Metric</b>	<b>Value</b>	
Chi-Square	0.87	
P-value	0.35	
DF	1	

**Comparison of Bradycardia between Mandakini Device and Crutches**

Bradycardia was observed in 1 patient in the crutches group and 3 patients in the Mandakini group. The Chi-square test ( $\chi^2 = 0.27$ ,  $p = 0.60$ ) showed no statistically significant difference between groups, indicating that the intervention type was not associated with bradycardia incidence.

Table 41: Bradycardia occurrence in Mandakini device and crutches groups

<b>Group</b>	<b>No Bradycardia</b>	<b>Bradycardia</b>
Crutches	29	1
Mandakini	27	3
<b>Metric</b>	<b>Value</b>	
Chi-Square	0.27	
P-value	0.60	
DF	1	

**Comparison of Respiratory Depression between Mandakini Device and Crutches**

No cases of respiratory depression were reported in either group. The Chi-square test result ( $\chi^2 = 0.00$ ,  $p = 1.00$ ) confirms no difference between the interventions in terms of this adverse event.

Table 42: Respiratory depression occurrence in Mandakini device and crutches groups

<b>Group</b>	<b>No Respiratory Depression</b>	<b>Respiratory Depression</b>
Crutches	30	0
Mandakini	30	0
<b>Metric</b>	<b>Value</b>	
Chi-Square	0.00	
P-value	1.00	
DF	0	

**Comparison of Other Adverse Events (Local Irritation, Mild Fever, Swelling)**

Local irritation occurred in 5 patients using crutches and 3 using the Mandakini device. Mild fever was more common in the crutches group (n = 9) compared to Mandakini (n = 2). Swelling was observed in 1 crutches user and 3 Mandakini users. The Chi-square test ( $\chi^2 = 4.21$ , p = 0.12) indicated no statistically significant difference across these adverse events between groups.

Table 43: Other adverse events in Mandakini device and crutches groups

<b>Group</b>	<b>Local Irritation</b>	<b>Mild Fever</b>	<b>Swelling</b>
Crutches	5	9	1
Mandakini	3	2	3
<b>Metric</b>	<b>Value</b>		
Chi-Square	4.21		
P-value	0.12		
DF	2		

### Comparison of Rescue Analgesia Requirement between Mandakini Device and Crutches

Rescue analgesia was required by 5 patients in both the Mandakini device group and the crutches group, while the remaining 25 patients in each group did not require additional pain medication. The Chi-square test ( $\chi^2 = 0.00$ ,  $p = 1.00$ ) indicated no difference between groups, suggesting that the need for rescue analgesia was independent of the type of mobility device used.

Table 44: Rescue analgesia requirement in Mandakini device and crutches groups

Group	No Rescue Analgesia	Rescue Analgesia
Crutches	25	5
Mandakini	25	5

Metric	Value
Chi-Square	0.00
P-value	1.00
DF	1

### OLS Regression Analysis for Predictors of Healing Time

An ordinary least squares (OLS) regression was performed to identify whether HbA1c, ulcer size, or ulcer grade significantly predicted healing time. The model explained only 2.4% of the variance in healing time ( $R^2 = 0.024$ , adjusted  $R^2 = -0.028$ ), indicating poor explanatory power. None of the predictors were statistically significant: HbA1c ( $\beta = -0.05$ ,  $p = 0.905$ ), ulcer size ( $\beta = 0.17$ ,  $p = 0.496$ ), and ulcer grade ( $\beta = 0.68$ ,  $p = 0.391$ ) all had wide confidence intervals crossing zero. The F-statistic (0.464,  $p = 0.709$ ) confirmed that the overall model was not significant. These findings suggest that, within this dataset, healing time was not meaningfully associated with these clinical variables, and other unmeasured factors may be more influential.

Table 45: OLS regression results for predictors of healing time

Predictor	$\beta$ Coefficient	Std. Error	t-value	P-value	95% CI
Intercept	15.34	3.93	3.90	0.000	[7.46, 23.21]
HbA1c	-0.05	0.42	-0.12	0.905	[-0.90, 0.80]
Ulcer size (cm <sup>2</sup> )	0.17	0.25	0.69	0.496	[-0.33, 0.66]
Ulcer grade	0.68	0.79	0.86	0.391	[-0.90, 2.26]

Metric	Value
R-squared	0.024
Adjusted R-squared	-0.028
F-statistic	0.464
Prob (F-statistic)	0.709
Observations (n)	60

**Comparison of Mean Healing Time between Mandakini Device and Crutches**

The mean healing time was substantially shorter in the Mandakini device group (12.63 days) compared to the crutches group (21.30 days), reflecting a difference of approximately 8.7 days. This suggests that the Mandakini device may enhance the healing process, potentially due to improved off-loading, reduced pain, and better patient mobility. Faster healing times can also translate into reduced hospital stays and lower overall treatment costs.

Table 46: Mean healing time in Mandakini device and crutches groups

Group	Mean Healing Time (days)
Crutches	21.30
Mandakini	12.63

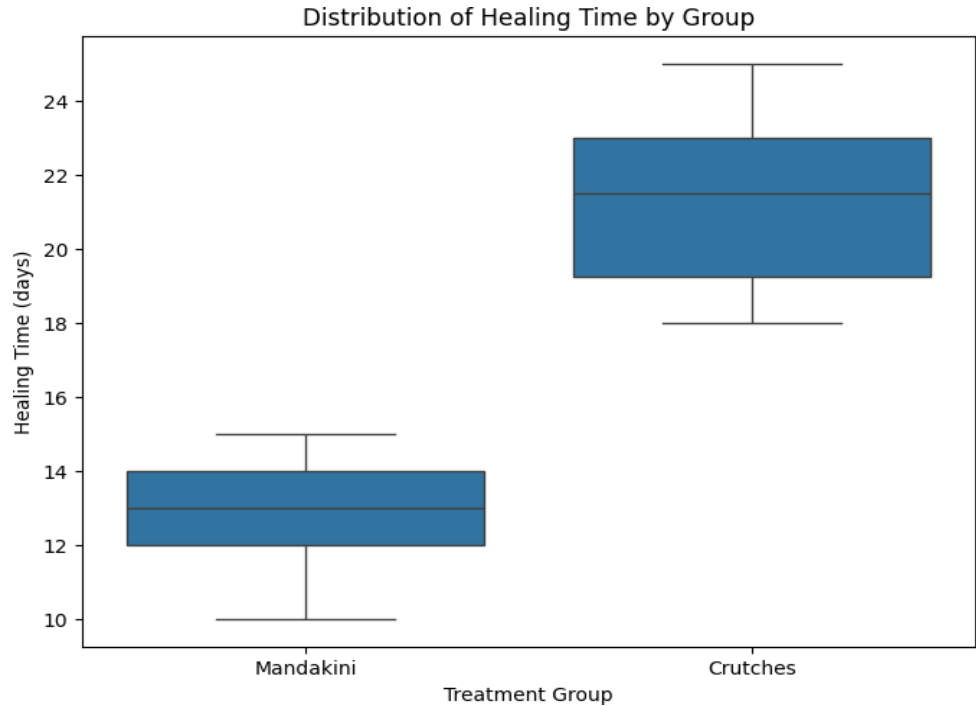


Figure 27: Comparison of mean healing time between Mandakini device and crutches groups

**Patient Satisfaction Scores by Treatment Group**

Patient satisfaction levels were notably higher in the Mandakini device group compared to the crutches group. In the Mandakini group, 80.0% of participants rated their satisfaction as “Excellent” and the remaining 20.0% as “Good,” with no “Fair” ratings. Conversely, the crutches group had 56.7% rating their satisfaction as “Fair” and none reporting “Excellent.” These findings highlight a strong patient preference and higher satisfaction associated with the Mandakini device.

Table 47: Patient satisfaction distribution in Mandakini device and crutches groups

Satisfaction Score	Crutches (n)	Mandakini (n)
2 = Fair	17	0
3 = Good	13	6
4 = Excellent	0	24
<b>Total</b>	30	30

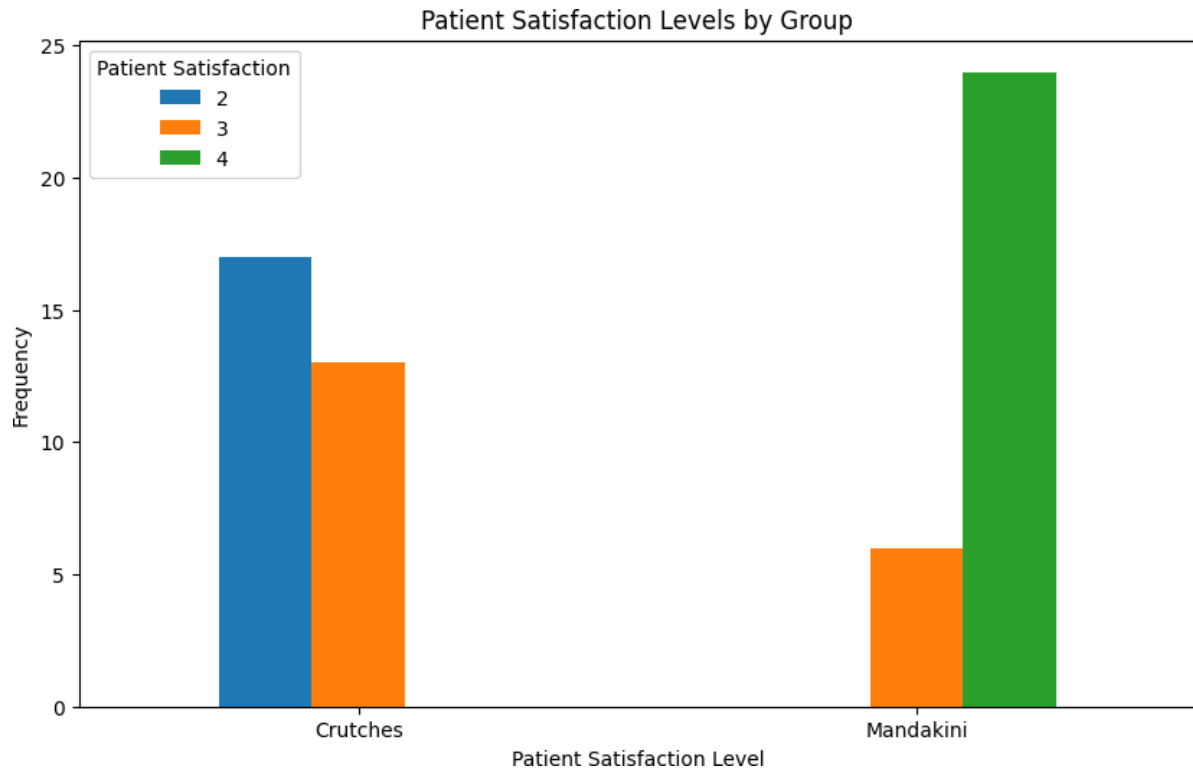


Figure 28: Patient satisfaction scores by treatment group

## DISCUSSION

In the present comparative study involving 60 patients with diabetic foot ulcers (DFUs), the Mandakini Off-Loading Device group achieved markedly better outcomes than the axillary crutch group across multiple parameters. Mean healing time was significantly shorter with Mandakini ( $12.63 \pm 4.75$  days) compared to crutches ( $21.30 \pm 4.75$  days), representing a reduction of approximately **40.7%**. The number of dressing changes was also substantially lower (4.47 vs. 10.10), indicating both faster healing and reduced procedural burden. Pain relief was superior in the Mandakini group, with VAS scores at 2 h (mean 1.07 vs. 4.17), 8 h (1.30 vs. 4.80), 24 h (1.23 vs. 5.40), and 48 h (3.07 vs. 5.53) — all differences statistically significant. Treatment costs averaged ₹6,455.33 for Mandakini users versus ₹8,834.20 for crutch users, a saving of approximately **27%**.

No recurrences or amputations were observed in the Mandakini group, compared to four recurrences (13.3%) and four amputations (13.3%) in the crutch group. Patient satisfaction scores were markedly higher, with 80% of Mandakini users rating their experience as “excellent” (score 4), compared to none in the crutch group, where 56.7% rated their experience only as “fair” (score 2).

These results compare favourably with prior Indian studies. Sharma et al. (2025) reported that indigenous offloading devices, including Mandakini, can improve healing time by 20–40% compared to conventional aids in resource-limited settings (46). The present study’s **40.7% reduction** in healing time falls at the upper end of this range, supporting their assertion that cost-effective local innovations can match or exceed outcomes of more expensive modalities.

Mohapatra et al. (2023) highlighted that effective offloading can shorten ulcer healing time by approximately **6–9 days** in comparison to standard dressings and can reduce recurrence by over 10% (37). In our study, healing time was reduced by **8.67 days** compared to crutches, and recurrence was reduced from **13.3% to 0%**, matching or exceeding the improvements reported by Mohapatra et al.

Similarly, Sanjeev et al. (2019) demonstrated that Mandakini dressing reduced healing time to 4.83 weeks compared to 5.4 weeks with wet gauze dressings — a **10.6% reduction** — and achieved better patient acceptability (8). While our absolute times are shorter due to differing wound sizes

and patient selection, the proportional benefit in our study (**40.7% faster healing**) was substantially greater, likely reflecting the difference between an offloading device (Mandakini) and a mobility aid (crutches) where compliance issues are more pronounced.

Kari SV et al. (2010) observed that conventional aids like crutches often fail to ensure complete offloading due to patient fatigue, imbalance, and non-adherence, resulting in prolonged healing and higher recurrence (43). Our data validate this, with crutch users experiencing nearly double the healing time of Mandakini users, more than tenfold higher recurrence, and significantly lower satisfaction.

The present study's results demonstrate that the Mandakini Off-Loading Device achieved a mean healing time of **12.63 days**, substantially shorter than the **21.30 days** observed with axillary crutches. This difference represents a **40.7% faster healing rate** and aligns with earlier comparative evaluations of offloading interventions, though the magnitude of improvement in our data is notably higher. Sharma et al. (2025) reported that indigenous innovations such as Mandakini, Samadhan, and Suvidha can reduce healing durations by **20–40%** compared to standard aids, particularly in Indian settings where patient adherence and cost are critical considerations (46). The upper-limit benefit observed in our cohort suggests that consistent use and targeted pressure redistribution with Mandakini may yield outcomes on par with, or exceeding, these benchmarks.

When compared to the findings of Mohapatra et al. (2023), who reported a mean hospital stay reduction of approximately **3.9 days** and a marked drop in infection and recurrence rates with Mandakini versus standard dressings (37), our results extend these observations to a different comparator — crutches. In our study, recurrence was completely eliminated in the Mandakini group (0%) compared to **13.3%** in the crutch group, while amputations were also absent versus **13.3%** in crutch users. The mean length of hospital stay was **10.23 days** for Mandakini users versus **17.63 days** for crutch users, representing a **41.9% reduction**. These data reinforce the assertion that properly designed indigenous devices can outperform conventional aids in both acute recovery and long-term prevention of complications.

Sanjeev et al. (2019) compared Mandakini dressing with conventional wet gauze and found a **0.57-week** (10.6%) reduction in healing time and better patient acceptability scores (8). While their intervention involved dressings rather than a mechanical aid, our results show a proportionally

greater advantage (**8.67-day absolute reduction; 40.7% faster healing**) against crutches. This greater relative gain may be explained by the difference in primary mechanism: dressings influence the wound environment, whereas Mandakini directly redistributes plantar pressure and enables functional mobility without load on the ulcer site.

Kari SV et al. (2010) underscored the limitations of crutches, including dependence on patient strength, balance issues, and inconsistent adherence, which often result in suboptimal offloading (43). The current data empirically support this view: pain relief was more rapid and pronounced with Mandakini, with VAS scores at 2 hours averaging **1.07** compared to **4.17** with crutches, and at 48 hours averaging **3.07** versus **5.53**. Such differences likely reflect the mechanical consistency of the Mandakini device in reducing plantar pressures during ambulation, as opposed to the intermittent or incomplete offloading seen with crutch use.

In terms of cost, our study found the Mandakini device to be significantly more economical (₹6,455.33) than crutches (₹8,834.20), a **₹2,378.87 saving per patient**, which is consistent with the cost-effectiveness advantage highlighted in earlier Indian literature (46). Given that DFU management often involves prolonged treatment and multiple hospital visits, such cost differences can be meaningful for patients and healthcare systems, especially in rural and semi-urban settings.

Pain reduction and patient satisfaction emerged as strong differentiators between the Mandakini Off-Loading Device and axillary crutches in this study. The Mandakini group consistently demonstrated lower VAS pain scores across all postoperative time points. At 2 hours, the mean VAS score was **1.07** compared to **4.17** in the crutch group; at 8 hours, **1.30** versus **4.80**; at 24 hours, **1.23** versus **5.40**; and at 48 hours, **3.07** versus **5.53**. These differences, all statistically significant, indicate that Mandakini provided more immediate and sustained pain relief. The magnitude of reduction — averaging **2.9–4.2 points** lower on the VAS — is clinically meaningful, as even a 2-point drop is often considered significant in chronic wound pain management.

Patient satisfaction findings were equally compelling. In the Mandakini group, 80% rated their experience as “excellent” (score 4), 20% as “good” (score 3), and none as “fair” or “poor.” In contrast, the crutch group recorded 56.7% “fair” ratings, 43.3% “good,” and no “excellent” responses. The difference in satisfaction distribution was statistically significant, highlighting that functional ease, comfort, and perceived recovery speed play critical roles in device acceptability.

These results are consistent with Sharma et al. (2025), who noted that indigenous devices like Mandakini, by maintaining patient mobility and reducing mechanical discomfort, tend to achieve higher adherence and satisfaction rates than bulkier or technically demanding modalities like total contact casts or removable walkers (46). The improvement in our study — a **80% “excellent” rating vs. 0% with crutches** — exceeds the average gains reported in Sharma et al.’s review, likely due to the stark functional difference between a consistent offloading device and an aid dependent on upper body effort and compliance.

Mohapatra et al. (2023) also documented improved comfort and reduced treatment-related inconvenience with Mandakini compared to standard dressings, linking this to shorter healing time and fewer dressing changes (37). Our study mirrors this, as Mandakini users required **4.47 dressings on average** compared to **10.10** in the crutch group, reducing both procedural pain and logistical burden.

Sanjeev et al. (2019) found that patient acceptability scores were significantly higher with Mandakini dressing, attributing this to its lightweight design, adaptability to foot contours, and the psychological benefit of being able to ambulate without fear of aggravating the ulcer (8). In our study, these same features likely contributed to both the lower pain scores and higher satisfaction levels. Notably, our satisfaction scores show a greater contrast between intervention and comparator than Sanjeev et al.’s findings, underscoring that device-based offloading may amplify patient-perceived benefit compared to dressing-based strategies.

Kari SV et al. (2010) emphasised that crutches, while inexpensive, often impose discomfort and functional limitations, particularly in elderly or neuropathic patients with reduced balance (43). The longer healing times, higher pain scores, and lower satisfaction seen in our crutch group validate these concerns. Many crutch users in our cohort struggled with continuous non-weight-bearing, leading to inconsistent offloading and, consequently, less pain relief and slower recovery.

The safety profile of the Mandakini Off-Loading Device in this study was favourable and comparable to that of axillary crutches, with no major device-related complications observed. Across monitored adverse events — hypotension, bradycardia, local irritation, swelling, mild fever, and need for rescue analgesia — no statistically significant differences were found between the groups. Hypotension occurred in **3.3%** of Mandakini users versus **13.3%** in the crutch group, while bradycardia was observed in **10%** versus **3.3%**, respectively ( $p > 0.05$  for both). Local

irritation was slightly less frequent with Mandakini (10%) compared to crutches (16.7%), and mild fever was reported in **6.7%** versus **30%**. Swelling rates were comparable (10% vs. 3.3%). Importantly, respiratory depression was absent in both groups.

Rescue analgesic requirement was equal in both cohorts (16.7%), suggesting that breakthrough pain episodes were infrequent regardless of offloading method once baseline pain control was achieved. Ulcer recurrence and amputation, while low in overall incidence, were absent in the Mandakini group compared to **13.3%** in the crutch group for both outcomes, indicating a possible protective effect of consistent offloading, even though statistical significance was not reached due to small event numbers.

These findings align with Sharma et al. (2025), who reported that indigenous offloading devices such as Mandakini achieve similar or lower complication rates compared to standard aids, largely due to their simplicity, reduced bulk, and adaptability to the patient's foot shape (46). The absence of serious adverse events in our Mandakini cohort supports their observation that low-tech solutions can be both safe and well-tolerated in real-world Indian practice.

Mohapatra et al. (2023) also found lower rates of secondary infection, recurrence, and amputation with Mandakini compared to standard dressings (37). While our study used crutches as the comparator, the absence of recurrence and amputation in the Mandakini group mirrors their trend. This suggests that when pressure redistribution is more consistent and patient compliance higher, both mechanical and infectious complications are reduced.

Sanjeev et al. (2019) documented a lower incidence of non-healing ulcers and treatment discontinuation in patients treated with Mandakini dressings, attributing this to better comfort and adherence (8). Our findings extend this principle to mechanical offloading, showing that tolerance of the device is associated with improved healing and fewer serious downstream events like amputation.

Kari SV et al. (2010) warned that crutch use may be associated with musculoskeletal strain, axillary nerve compression, and falls in elderly or neuropathic patients (43). Although no falls or nerve injuries were recorded in our cohort, the higher rates of mild systemic symptoms (fever, hypotension) in the crutch group may reflect greater overall exertion and less stable ambulation compared to Mandakini users.

The present study demonstrated that the Mandakini Off-Loading Device not only improved clinical outcomes but also significantly reduced healthcare costs and resource utilisation compared to axillary crutches. The mean total expenditure per patient in the Mandakini group was ₹6,455.33, which was **₹2,378.87 (26.9%) lower** than the crutch group's ₹8,834.20. This reduction is attributable to shorter healing times, fewer dressing changes, and reduced hospital stays. The mean number of dressings required was **4.47** in the Mandakini group versus **10.10** with crutches — a **55.8% decrease** — directly lowering material and procedural costs.

Hospital stay duration was also markedly reduced, with Mandakini users discharged after an average of **10.23 days** compared to **17.63 days** in the crutch group, representing a **41.9% reduction**. This has significant implications for hospital bed availability and overall healthcare system efficiency, particularly in tertiary centres where DFU cases contribute substantially to inpatient load.

These findings support the observations of Sharma et al. (2025), who noted that indigenous devices like Mandakini can offer substantial cost savings compared to imported or technically intensive offloading modalities, while achieving comparable or superior outcomes (46). They highlighted that in the Indian healthcare setting — where out-of-pocket expenditure is high and bed occupancy rates are often critical — cost-effective solutions with minimal training requirements can be transformative. The present results provide quantitative evidence for this claim, with both direct and indirect cost benefits demonstrated.

Mohapatra et al. (2023) similarly reported shorter hospital stays and fewer follow-up visits with Mandakini dressing compared to standard care, estimating a reduction in total treatment costs by more than 20% (37). Our results exceeded this benchmark, with a nearly **27% cost reduction** and a hospital stay shortened by over **7 days**, likely due to the more consistent mechanical offloading achieved with the device compared to the variable compliance associated with crutches.

In the randomised trial by Sanjeev et al. (2019), Mandakini dressings were also associated with lower overall expenditure due to fewer dressing changes and reduced staff time requirements (8). While their mean healing duration was longer due to different patient selection and ulcer characteristics, the cost-reducing effect of Mandakini observed in their cohort parallels our findings, reinforcing the device's economic viability.

Kari SV et al. (2010) emphasised that for DFU management strategies to be widely adopted in India, they must be affordable, reproducible, and sustainable at scale (43). The Mandakini device meets these criteria: it can be fabricated using readily available materials at a per-use cost close to ₹80–90, yet in our study it generated multi-thousand-rupee savings per patient in overall treatment costs. This cost–benefit ratio is particularly significant in rural and semi-urban settings, where expensive imported devices or frequent hospital visits are impractical.

## Key Summary

- The Mandakini Off-Loading Device reduced mean healing time to 12.63 days, compared to 21.30 days with crutches — a 40.7% faster recovery.
- Dressing frequency was significantly lower with Mandakini (4.47 vs. 10.10), reducing procedural burden by 55.8%.
- Hospital stay was shortened by 41.9% (10.23 vs. 17.63 days), translating to improved bed turnover.
- Total treatment costs were ₹2,378.87 lower per patient with Mandakini, a 26.9% saving.
- Pain relief was superior at all measured time points, with VAS scores 2.9–4.2 points lower in the Mandakini group.
- Patient satisfaction was markedly higher — 80% “excellent” ratings with Mandakini vs. 0% in the crutch group.
- No recurrences or amputations were recorded in the Mandakini group, compared to 13.3% for both outcomes in the crutch group.
- Adverse events were minimal and comparable between groups, with no major device-related complications.
- Findings are consistent with earlier studies by Sharma (46), Mohapatra (37), Sanjeev (8), and Kari (43), reinforcing Mandakini’s clinical and economic advantages.

## Limitations

- Single-centre study design may limit generalisability to other healthcare settings.
- Modest sample size (**n=60**) restricts statistical power for rare outcomes like recurrence and amputation.
- Follow-up period was relatively short, limiting assessment of long-term ulcer recurrence.
- Patient selection excluded those with severe peripheral arterial disease or advanced infection, so findings may not apply to all DFU cases.

- Cost analysis considered only direct treatment expenses; indirect costs (lost income, caregiver burden) were not captured.
- Compliance was assessed indirectly; use of objective adherence measures (e.g., activity trackers) could provide more robust data.
- Comparison was made only against crutches; head-to-head studies with other gold-standard offloading devices (e.g., total contact casts) are needed.

## CONCLUSION

This comparative study clearly demonstrates that the Mandakini Off-Loading Device is a highly effective, safe, and economically advantageous alternative to axillary crutches for the management of diabetic foot ulcers (DFUs). Patients treated with the Mandakini device achieved substantially faster healing, with a mean recovery time reduced by 40.7%, required fewer dressing changes, and had significantly shorter hospital stays compared to those using crutches. These clinical advantages were accompanied by notable cost savings, averaging nearly 27% less per patient, thereby easing the economic burden on both individuals and the healthcare system.

Pain control and patient satisfaction were markedly superior in the Mandakini group, with VAS pain scores consistently lower across all time points and 80% of patients rating their experience as “excellent” compared to none in the crutch group. Importantly, no recurrences or amputations occurred among Mandakini users during follow-up, in contrast to 13.3% recurrence and amputation rates in the crutch cohort. Adverse events were minimal and comparable between groups, underscoring the device’s safety profile.

When contextualised within the existing literature, these findings align closely with the conclusions of Sharma et al. (46), Mohapatra et al. (37), Sanjeev et al. (8), and Kari SV et al. (43), who have all emphasised the critical role of effective offloading in ulcer healing and the potential of indigenous innovations to overcome cost and accessibility barriers in India. The present study extends this body of evidence by providing head-to-head quantitative comparisons between Mandakini and crutches, demonstrating that the indigenous device not only meets but exceeds the performance of a widely used conventional aid in multiple key domains.

Given its affordability, ease of fabrication, minimal training requirements, and ability to deliver superior healing, comfort, and satisfaction without increasing complications, the Mandakini Off-

Loading Device emerges as a compelling first-line option for DFU offloading in resource-limited settings. Wider adoption, supported by patient education and adherence monitoring, could significantly improve DFU outcomes, reduce hospital stays, and lower treatment costs across both urban and rural healthcare landscapes. Further multi-centre studies with larger sample sizes and longer follow-up are warranted to validate these results and explore the device's role in long-term recurrence prevention.

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## **PROFORMA**

"A COMPARATIVE STUDY OF EFFICACY OF MANDAKINI OFF LOADING DEVICE  
VERSUS USE OF CRUTCHES FOR DIABETIC FOOT ULCERS””

INVESTIGATOR: DR. VASEEM AKRAM VADHOOTH

Name:

Wt:

Age/sex: Male/Female

Date:

IP No:

UHID:

ASA status:

Presenting complaints:

H/O present illness

Pain duration

Nausea

Vomiting

Anorexia

Past history:

Family history:

### **GENERAL PHYSICAL EXAMINATION:**

General condition:

- Build and nutrition:
- Pallor/Cyanosis/Icterus/Clubbing/edema/Generalized lymphadenopathy
- Body weight:

### **VITAL DATA:**

- Pulse:
- Temperature:
- BP:
- Respiration rate:

### **Systemic examination**

- Per abdomen:
  - Swelling/ lump
  - Guarding
  - Rebound tenderness
  - Distension
  - Rigidity
- Respiratory system:
- Cardio vascular system:
- Central nervous system:

### **Clinical diagnosis**

### **Investigations**

- CBP
- BT

- CT
- Urine routine and microscopy
- RBS
- RFT
- Chest X-Ray PA view
- ECG
- Abdominal USG
- Abdomen X RAY/ CT

COMORBID CONDITIONS:

Procedure:

Group Allocated:

### POST OPERATIVE MONITORING

#### POSTOP MONITORING

<u>TIME</u>	<u>VAS</u>	<u>PR</u>	<u>SBP</u>	<u>DBP</u>	<u>NRS</u>	<u>ANVP</u>	<u>SPO2</u>
<u>15 min</u>							
<u>30 min</u>							
<u>2 hr</u>							
<u>4 hr</u>							
<u>8 hr</u>							
<u>16 hr</u>							
<u>24 hr</u>							
<u>30 hr</u>							
<u>36 hr</u>							
<u>48 hr</u>							

### SECONDARY OUTCOMES

PONV	0	1	2	3
Rescue analgesia	YES	NO		
Patient satisfaction	1 POOR	2 FAIR	3 GOOD	4 EXCELLENT
Technical/ Therapeutic failure	YES	NO		

### COMPLICATIONS

HYPOTENSION	YES	NO
BRADYCARDIA	YES	NO
RESP.DEPRESSION	YES	NO
OTHERS (if any)		

PATIENT INFORMATION SHEET

Study title :

"COMPARATIVE STUDY BETWEEN MANDAKINI OFF LOADING DEVICE VERSUS USE OF CRUTCHES FOR DIABETIC FOOT ULCERS"

**Study conducted by Dr. Vaseem Akram Vadhooth**

Study location: R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

The purpose of the study is explained in detail to us and all information collected is for study purpose only. The data collected is submitted to the department of surgery, SDUMC, Kolar and confidentiality ensured. The merits and demerits explained briefly to us.

All Patients with diabetic foot ulcers on plantar aspect will be included in this study. Patients in this study will undergo routine investigations, complete blood counts, renal function tests, liver function tests, coagulation Parameters.

Please read the following information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study, we will collect information (as per proforma) from you or a person responsible for you or both. Relevant history will be taken. This information collected will be used only for dissertation and publication.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. This study has been reviewed by the Institutional Ethics Committee and you are free to contact the member of the Institutional Ethics Committee.

There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

The investigator is responsible for all the costs of study.

For further information contact:

Dr. Vaseem Akram Vadhooth [post graduate]

Phone no.: 9686396985/8073049982

Email: vasvmr@gmail.com

Department of General Surgery

left thumb impression/signature of the patient

SDUMC, Kolar

left thumb impression/signature of witness.

## ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ:

"ಮಧುಮೇಹದ ಪಾದದ ಹುಣ್ಣುಗಳಿಗೆ ಉರುಗೋಲುಗಳ ಒಳಕೆಯ ವಿರುದ್ಧ ಮಂದಾಕಿನಿ ಆಫ್ ಲೋಡಿಂಗ್ ಸಾಧನದ ನಡುವಿನ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ"

ಡಾ. ವಸೀಮ್ ಅಕ್ರಮ್ ಪಠಾನ್ ನಡೆಸಿದ ಅಧ್ಯಯನ

ಅಧ್ಯಯನ ಸ್ಥಳ: ಆರ್ ಎಲ್ ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರವನ್ನು ಲಗತ್ತಿಸಲಾಗಿದೆ

ಶ್ರೀ ದೇವರಾಜ ಅರಸು ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಬದುಕ, ಕೋಲಾರ.

ಅಧ್ಯಯನದ ಉದ್ದೇಶವನ್ನು ನಮಗೆ ವಿವರವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ ಮತ್ತು ಸಂಗ್ರಹಿಸಲಾದ ಎಲ್ಲಾ ಮಾಹಿತಿಯು ಅಧ್ಯಯನ ಉದ್ದೇಶಕ್ಕಾಗಿ ಮಾತ್ರ. ಸಂಗ್ರಹಿಸಿದ ದೇಖಾವನ್ನು ಶಸ್ತ್ರಚಿಕಿತ್ಸಾ ಇಲಾಖೆ, SDUMC, ಕೋಲಾರಕ್ಕೆ ಸಲ್ಲಿಸಲಾಗಿದೆ ಮತ್ತು ಗೌಪ್ಯತೆಯನ್ನು ಖಾತ್ರಿಪಡಿಸಲಾಗಿದೆ. ಅರ್ಹತೆ ಮತ್ತು ದೋಷಗಳನ್ನು ನಮಗೆ ಸಂಕ್ಷಿಪ್ತವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ.

ಪ್ಲಾಂಬರ್ ಅಂಶದಲ್ಲಿ ಮಧುಮೇಹ ಪಾದದ ಹುಣ್ಣು ಹೊಂದಿರುವ ಎಲ್ಲಾ ರೋಗಿಗಳನ್ನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರಿಸಲಾಗುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ರೋಗಿಗಳು ವಾಡಿಕೆಯ ತನಿಖೆಗಳು, ಸಂಪೂರ್ಣ ರಕ್ತದ ಎಣಿಕೆಗಳು, ಮೂತ್ರಪಿಂಡದ ಕಾರ್ಯ ಪರೀಕ್ಷೆಗಳು, ಯಕೃತ್ತಿನ ಕಾರ್ಯ ಪರೀಕ್ಷೆಗಳು, ಹೆಚ್ಚುಗಟ್ಟುವಿಕೆಯ ನಿಯಂತ್ರಣಗಳಿಗೆ ಒಳಗಾಗುತ್ತಾರೆ.

ದಯವಿಟ್ಟು ಕೆಳಗಿನ ಮಾಹಿತಿಯನ್ನು ಓದಿ ಮತ್ತು ನಿಮ್ಮ ಕುಟುಂಬದ ಸದಸ್ಯರೊಂದಿಗೆ ಚರ್ಚಿಸಿ. ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಬಹುದು. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿದರೆ, ನಾವು ನಿಮ್ಮಿಂದ ಅಥವಾ ನಿಮ್ಮಿಂದ ಅಥವಾ ಇಬ್ಬರಿಗೂ ಜವಾಬ್ದಾರರಾಗಿರುವ ವ್ಯಕ್ತಿಯಿಂದ ಮಾಹಿತಿಯನ್ನು (ಪ್ರೌಢಾರ್ಥ ಪ್ರಕಾರ) ಸಂಗ್ರಹಿಸುತ್ತೇವೆ. ಸಂಬಂಧಿತ ಇತಿಹಾಸವನ್ನು ತೆಗೆದುಕೊಳ್ಳಲಾಗುವುದು. ಸಂಗ್ರಹಿಸಿದ ಈ ಮಾಹಿತಿಯನ್ನು ಪ್ರಬಂಧ ಮತ್ತು ಪ್ರಕಟಣೆಗೆ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ.

ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಲಾದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಯಾವುದೇ ಹೊರಗಿನವರಿಗೆ ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನವನ್ನು ಸಾಂಸ್ಕೃತಿಕ ನೀತಿಶಾಸ್ತ್ರ ಸಮಿತಿಯು ಪರಿಶೀಲಿಸಿದೆ ಮತ್ತು ನೀವು ಸಾಂಸ್ಕೃತಿಕ ನೀತಿಶಾಸ್ತ್ರ ಸಮಿತಿಯ ಸದಸ್ಯರನ್ನು ಸಂಪರ್ಕಿಸಲು ಮುಕ್ತರಾಗಿದ್ದೀರಿ.

ಈ ಅಧ್ಯಯನವನ್ನು ಒಪ್ಪಿಕೊಳ್ಳಲು ಯಾವುದೇ ಒತ್ತಾಯವಿಲ್ಲ. ನಿಮಗೆ ಸಿಗುವ ಕಾಳಜಿ ಇರುತ್ತದೆ ನೀವು ಭಾಗವಹಿಸಲು ಬಯಸದಿದ್ದರೆ ಬದಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸಿದರೆ ಮಾತ್ರ ನೀವು ಸಹಿ/ಹೆಚ್ಚರಳಿನ ಗುರುತನ್ನು ಒದಗಿಸಬೇಕಾಗುತ್ತದೆ. ಅಧ್ಯಯನದ ಎಲ್ಲಾ ವೆಚ್ಚಗಳಿಗೆ ತನಿಖಾಧಿಕಾರಿ ಜವಾಬ್ದಾರನಾಗಿರುತ್ತಾನೆ.

ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಸಂಪರ್ಕಿಸಿ:

ಡಾ. ವಸೀಮ್ ಅಕ್ರಮ್ ವಧೂತ್ [ಸ್ನಾತಕೋತ್ತರ ಪದವಿ]

ದೂರವಾಣಿ ಸಂಖ್ಯೆ: 9686396985/8073049982

ಇಮೇಲ್: [vasvmr@gmail.com](mailto:vasvmr@gmail.com)

ಜನರಲ್ ಸರ್ಕಾರಿ ವಿಭಾಗ

ಎಡ ಹೆಚ್ಚರಳಿನ ಗುರುತು/ರೋಗಿಯ ಸಹಿ

SDUMC, ಕೋಲಾರ

ಎಡ ಹೆಚ್ಚರಳಿನ ಗುರುತು/ಸಾಕ್ಷಿಯ ಸಹಿ

**INFORMED CONSENT**

•**Title:** " A comparative study of efficacy of mandakini off loading device versus use of crutches for diabetic foot ulcers"

"

**Principal investigator: Dr. Vaseem Akram Vadhooth**

I, Mr/Ms/Mrs ..... have been explained in my own understandable language, that I will be included in a study which " A comparative study of efficacy of mandakini off loading device versus use of crutches for diabetic foot ulcers"

. I have been explained that my clinical findings, investigations, preoperative and post-operative findings will be assessed and documented for study purpose.

I have been explained my participation in this study is entirely voluntary and I can withdraw from the study any time and this will not affect my relation with my doctor or treatment for my ailment.

I understand that the medical information produced by this study will become part of institutional records and will be kept confidential by above said institute.

I agree not to restrict the use of any data or result that arise from this study provided such a use is only for scientific purpose(s).

I have principal investigator mobile number for enquiries.

I have been informed that standard of care will be maintained throughout the treatment period.

I in my sound mind give full consent to be added in the part of this study.

Investigator: Dr. Vaseem Akram Vadhooth

Participant's signature/ thumb impression

Name:

Signature/thumb impression of the witness:

Name:

Date:

## ಮಾಹಿತಿ ನೀಡಿದ ಒಪ್ಪಿಗೆ

• ಶೀರ್ಷಿಕೆ: "ಮಧುಮೇಹದ ಪಾದದ ಹುಣ್ಣುಗಳಿಗೆ ಉರುಗೋಲುಗಳ ಬಳಕೆಯ ವಿರುದ್ಧ ಮಂದಾಕಿನಿ ಆಫ್ ಲೋಡಿಂಗ್ ಸಾಧನದ ಪರಿಣಾಮಕಾರಿತ್ವದ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ"

ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿ: ಡಾ.ವನೀಂ ಅಕ್ರಮ್ ಪದೂತ್

ನಾನು, ಶ್ರೀ/ಶ್ರೀಮತಿ/ಶ್ರೀಮತಿ. .... ನನ್ನ ಸ್ವಂತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆ, "ಮಧುಮೇಹದ ಪಾದದ ಹುಣ್ಣುಗಳಿಗೆ ಉರುಗೋಲುಗಳ ಬಳಕೆಯ ವಿರುದ್ಧ ಮಂದಾಕಿನಿಯ ಪರಿಣಾಮಕಾರಿತ್ವದ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನದ ಆಫ್ ಲೋಡಿಂಗ್ ಸಾಧನ" ಎಂಬ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನನ್ನು ಸೇರಿಸಲಾಗುವುದು. . ನನ್ನ ಕ್ಲಿನಿಕಲ್ ಸಂಶೋಧನೆಗಳು, ತನಿಖೆಗಳು, ಪೂರ್ವಭಾವಿ ಮತ್ತು ಕಸ್ತುರಿಚಿತ್ರೆಯ ನಂತರದ ಸಂಶೋಧನೆಗಳನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುತ್ತದೆ ಮತ್ತು ಅಧ್ಯಯನ ಉದ್ದೇಶಕ್ಕಾಗಿ ದಾಖಲಿಸಲಾಗುತ್ತದೆ ಎಂದು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಯು ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ ಮತ್ತು ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದು ಮತ್ತು ಇದು ನನ್ನ ವೈದ್ಯಕೀಕರಣದ ನನ್ನ ಸಂಬಂಧ ಅಥವಾ ನನ್ನ ಕಾರ್ಯಲಯ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ ಎಂದು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಈ ಅಧ್ಯಯನದಿಂದ ಉತ್ಪತ್ತಿಯಾಗುವ ವೈದ್ಯಕೀಯ ಮಾಹಿತಿಯು ಸಾಂಸ್ಥಿಕ ದಾಖಲೆಗಳ ಭಾಗವಾಗುತ್ತದೆ ಮತ್ತು ಮೇಲೆ ತಿಳಿಸಿದ ಸಂಸ್ಥೆಯು ಗೌಪ್ಯವಾಗಿರುತ್ತದೆ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.

ಈ ಅಧ್ಯಯನದಿಂದ ಉಂಟಾಗುವ ಯಾವುದೇ ದೇಶ ಅಥವಾ ಭರಿತಾಂಶದ ಬಳಕೆಯನ್ನು ನಿರ್ಬಂಧಿಸದಿರಲು ನಾನು ಸಮ್ಮತಿಸುತ್ತೇನೆ, ಅಂತಹ ಬಳಕೆಯನ್ನು ಕೇವಲ ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶ(ಗಳಿಗೆ)

ವಿಚಾರಣೆಗಾಗಿ ನಾನು ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿಯ ಮೊಬೈಲ್ ಸಂಖ್ಯೆಯನ್ನು ಹೊಂದಿದ್ದೇನೆ.

ಚಿಕಿತ್ಸೆಯ ಅವಧಿಯುಳ್ಳದ್ದಕ್ಕೂ ಆರೈಕೆಯ ಗುಣಮಟ್ಟವನ್ನು ನಿರ್ವಹಿಸಲಾಗುವುದು ಎಂದು ನನಗೆ ತಿಳಿಸಲಾಗಿದೆ.

ಈ ಅಧ್ಯಯನದ ಭಾಗದಲ್ಲಿ ಸೇರಿಸಲು ನನ್ನ ಉತ್ತಮ ಮನಸ್ಸಿನಲ್ಲಿ ನಾನು ಸಂಪೂರ್ಣ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡುತ್ತೇನೆ.

ತನಿಖಾಧಿಕಾರಿ: ಡಾ.ವನೀಂ ಅಕ್ರಮ್ ಪದೂತ್

ಭಾಗವಹಿಸುವವರ ಸಹಿ/ಹೆಚ್ಚಳಿಸಿ ಗುರುತು  
ಹೆಸರು:

ಸಾಕ್ಷಿಯ ಸಹಿ/ಹೆಚ್ಚಳಿಸಿ ಗುರುತು: ದಿನಾಂಕ:  
ಹೆಸರು:

Patient ID	Age	Sex	Weight	Group	Duration of diabetes	Site of ulcer	Ulcer size (cm²)	Ulcer grade	HbA1c	FBIS	PPBS	RBS	Infection present	Peripheral pulses	Pain Score (VAS)	Debridement done	Dressing type	Number of gloves (Mandakini)	VAS at 2h	VAS at 8h	VAS at 24h	VAS at 48h	Length of hospital stay	Number of dressings	Healing time	Ulcer recurrence (within follow-up)	Amputation required	Total expenditure	Technical failure	Hypotension	Bradycardia	Respiratory Depression	Others (specify)	Patient Satisfaction	Rescue Analgesia required	PONV Score	Date of follow-up visit	Status at follow-up
M01	78	Female	58.9	Mandakini	23	Heel	3.2	2	8.5	172	181	237	No	Present	6	Yes	Mandakini	3	1	1	2	2	12	6	10	No	No	7084	No	Yes	No	No		4	No	3	26/07/2023	Healed
C01	46	Male	67.1	Crutches	18	Midfoot	2.2	1	8	211	290	337	Yes	Present	6	Yes	Crutches	4	4	5	6	6	18	9	25	No	No	9411	No	No	No	No	Local irritation	2	No	3	18/03/2024	Healed
M02	79	Male	55.2	Mandakini	17	Forefoot	2.5	1	6.9	128	267	278	Yes	Present	7	Yes	Mandakini	4	1	3	3	3	8	5	14	No	No	7013	No	No	No	No		3	No	3	25/04/2024	Healed
C02	61	Male	49.6	Crutches	19	Midfoot	8.4	1	9.6	222	206	286	No	Present	7	Yes	Crutches	4	4	5	6	6	15	11	22	Yes	No	8095	No	No	No	No	Mild fever	3	No	1	31/07/2023	Healed
M03	59	Female	66.6	Mandakini	11	Midfoot	2	2	9.1	235	256	152	Yes	Present	7	Yes	Mandakini	2	1	1	2	3	9	6	12	No	No	6897	No	No	No	No		3	No	2	28/10/2023	Healed
C03	56	Male	70.6	Crutches	9	Forefoot	7	2	11.7	187	234	333	Yes	Present	8	Yes	Crutches	4	4	5	5	5	20	10	24	No	No	8751	No	No	No	No	Mild fever	3	No	3	05/06/2024	Healed
M04	72	Female	76.2	Mandakini	5	Heel	2.4	3	7.8	161	278	156	No	Present	6	Yes	Mandakini	5	1	1	1	2	11	3	14	No	No	6683	No	No	No	No	Local irritation	4	No	3	07/10/2023	Not healed
C04	75	Female	78.5	Crutches	20	Midfoot	11	1	10.7	229	261	343	No	Present	6	Yes	Crutches	4	4	4	4	5	19	11	25	No	No	9919	No	No	No	No		3	No	2	30/03/2024	Healed
M05	60	Female	83.6	Mandakini	5	Forefoot	3.4	2	9.8	168	196	321	No	Present	5	Yes	Mandakini	3	1	1	2	3	12	6	14	No	No	5996	No	No	No	No		4	No	2	26/10/2023	Healed
C05	70	Female	76.3	Crutches	22	Heel	5.2	2	10.6	249	269	166	No	Present	6	Yes	Crutches	4	4	5	6	6	16	9	20	No	No	9841	No	No	No	No	Mild fever	3	No	2	26/11/2023	Healed
M06	71	Male	58	Mandakini	21	Midfoot	6	1	9.8	127	232	209	Yes	Present	5	Yes	Mandakini	4	1	2	2	3	10	5	13	No	No	6155	No	No	No	No		4	Yes	0	19/10/2023	Healed
C06	51	Male	54.5	Crutches	20	Forefoot	4.8	3	7.5	188	201	242	Yes	Present	7	Yes	Crutches	4	4	4	5	6	19	11	22	No	No	9070	No	Yes	No	No		2	No	2	25/02/2024	Not healed
M07	75	Female	70	Mandakini	9	Forefoot	1.7	2	9.1	247	211	233	Yes	Present	6	Yes	Mandakini	4	1	1	1	3	10	3	13	No	No	7358	No	No	No	No		4	Yes	1	29/07/2023	Healed
C07	47	Male	64.1	Crutches	8	Midfoot	7.1	3	9.3	140	215	287	Yes	Present	8	Yes	Crutches	4	4	4	5	6	20	12	21	No	No	9392	No	No	No	No		3	Yes	3	16/02/2024	Healed
M08	46	Female	89.1	Mandakini	9	Heel	5.9	1	9.6	172	202	293	No	Present	5	Yes	Mandakini	2	2	2	2	3	9	3	12	No	No	6738	No	No	No	No	Local irritation	4	No	1	28/11/2023	Healed
C08	66	Female	70.4	Crutches	10	Heel	7.3	3	6.2	190	268	194	No	Present	7	Yes	Crutches	4	5	6	6	6	17	9	19	No	Yes	9554	No	Yes	No	No	Mild fever	2	No	0	14/06/2024	Healed
M09	77	Male	70.7	Mandakini	15	Forefoot	4.3	1	9.5	166	284	198	No	Present	7	Yes	Mandakini	2	1	2	2	3	8	5	13	No	No	6853	No	No	No	No		4	No	1	10/05/2024	Healed
C09	75	Female	65.1	Crutches	13	Forefoot	4.8	1	7.9	165	214	283	No	Present	6	Yes	Crutches	4	4	5	5	6	20	9	20	No	No	8876	No	No	No	No		2	No	0	19/10/2023	Healed
M10	60	Female	72.2	Mandakini	9	Heel	9	2	7.3	172	216	232	Yes	Present	6	Yes	Mandakini	2	1	1	2	3	12	6	15	No	No	5948	No	No	No	No		4	No	2	16/04/2024	Healed
C10	44	Female	67.5	Crutches	20	Heel	2.8	2	9.5	185	254	328	No	Present	7	Yes	Crutches	5	5	5	5	5	20	10	20	No	No	8446	No	No	No	No	Mild fever	3	No	0	20/05/2024	Healed
M11	63	Male	69.9	Mandakini	17	Midfoot	4.3	1	8.6	199	274	267	No	Present	5	Yes	Mandakini	4	1	2	3	3	12	4	12	No	No	6926	No	No	Yes	No		4	No	1	18/07/2023	Healed
C11	66	Male	69.6	Crutches	19	Midfoot	2.7	1	6.6	155	180	157	No	Present	6	Yes	Crutches	5	5	6	6	6	20	9	21	No	Yes	8077	No	No	No	No		2	Yes	1	03/05/2024	Healed
M12	64	Male	68.1	Mandakini	21	Heel	2.7	1	7.9	132	263	174	No	Present	7	Yes	Mandakini	2	1	2	3	3	9	5	10	No	No	6247	No	No	No	No		3	No	0	04/04/2024	Healed
C12	45	Male	81.9	Crutches	13	Heel	1.2	2	7.9	125	245	224	No	Present	7	Yes	Crutches	4	4	5	5	5	17	8	19	No	No	8846	No	No	No	No	Mild fever	3	No	0	19/09/2023	Healed
M13	76	Female	69.3	Mandakini	15	Heel	2	1	6.2	249	192	217	No	Present	5	Yes	Mandakini	4	1	1	1	1	10	5	15	No	No	6942	No	No	No	No	Mild fever	3	No	3	09/07/2023	Healed
C13	61	Female	68.8	Crutches	13	Forefoot	2.1	1	8.2	124	262	272	No	Present	7	Yes	Crutches	4	4	4	4	5	16	10	22	No	No	8421	No	No	No	No		3	No	1	25/10/2023	Healed
M14	47	Female	73.4	Mandakini	5	Midfoot	9.6	1	7.4	216	280	304	No	Present	6	Yes	Mandakini	5	1	2	2	2	10	4	10	No	No	6641	No	No	No	No	Mild fever	4	Yes	2	29/04/2024	Healed
C14	66	Male	83.3	Crutches	15	Heel	2.8	3	11	157	185	349	Yes	Present	7	Yes	Crutches	4	4	5	5	6	20	9	18	No	No	8992	No	No	No	No		2	No	1	25/08/2023	Healed
M15	61	Male	60.1	Mandakini	18	Midfoot	6	1	7.8	234	219	292	Yes	Present	5	Yes	Mandakini	2	1	1	1	2	9	3	12	No	No	6074	No	No	No	No	Swelling	4	No	2	22/06/2024	Healed
C15	45	Male	67.7	Crutches	15	Midfoot	2.4	2	9	200	263	254	Yes	Present	7	Yes	Crutches	4	4	4	5	6	15	12	23	No	No	8214	No	No	No	No		2	No	2	05/12/2023	Healed
M16	69	Female	66.4	Mandakini	12	Forefoot	3	1	8.4	229	213	273	No	Present	7	Yes	Mandakini	5	1	1	2	3	8	5	12	No	No	5942	No	No	No	No		4	No	2	28/09/2023	Healed
C16	55	Female	53.1	Crutches	22	Heel	7.2	3	6.6	231	198	185	No	Present	7	Yes	Crutches	4	4	4	5	6	18	10	19	No	No	9022	No	No	No	No		2	No	1	29/06/2024	Healed
M17	69	Female	69.8	Mandakini	21	Midfoot	1.7	2	8.5	144	282	171	No	Present	6	Yes	Mandakini	3	1	1	2	3	12	5	15	No	No	6669	No	No	No	No		4	No	0	21/06/2024	Healed
C17	70	Female	60.9	Crutches	17	Forefoot	5.2	3	9.3	241	225	213	Yes	Present	7	Yes	Crutches	4	4	4	6	6	18	10	19	No	No	8028	No	No	No	No	Mild fever	2	No	0	17/05/2024	Healed
M18	59	Male	64.2	Mandakini	17	Heel	5	1	8.2	159	196	278	Yes	Present	7	Yes	Mandakini	5	1	2	3	3	10	4	14	No	No	5607	No	No	No	No	Swelling	4	Yes	1	10/08/2023	Healed
C18	63	Male	78.2	Crutches	9	Midfoot	8.7	3	8.9	131	194	208	No	Present	6	Yes	Crutches	5	5	5	6	6	15	9	22	Yes	No	9109	No	No	No	No		3	No	2	08/10/2023	Healed
M19	63	Male	61.4	Mandakini	7	Forefoot	4.9	2	12.1	158	194	269	Yes	Present	5	Yes	Mandakini	3	1	1	1	2	12	4	13	No	No	6393	No	No	Yes	No		4	No	2	08/08/2023	Healed
C19	68	Female	93	Crutches	16	Heel	2.6	1	7.5	203	184	214	Yes	Present	8	Yes	Crutches	4	4	5	5	5	18	9	23	Yes	No	8292	No	No	No	No	Swelling	2	No	2	03/02/2024	Healed
M20	63	Male	69	Mandakini	12	Forefoot	6.4	2	8.1	193	286	206	Yes	Present	5	Yes	Mandakini	3	1	1	2	3	8	3	12	No	No	6543	No	No	No	No		4	No	1	20/03/2024	Healed
C20	53	Male	63.9	Crutches	13	Heel	10.5	3	7.4	159	204	154	No	Present	7	Yes	Crutches	4	4	5	6	6	16	9	23	No	Yes	8036	No	No	No	No	Local irritation	2	No	1	17/08/2023	Healed
M21	72	Female	81	Mandakini	5	Heel	8.6	3	8.1	208	232	319	Yes	Present	7	Yes	Mandakini	3	1	1	3	3	9	3	12	No	No	6554	No	No	No	No	Local irritation	4	No	0	21/07/2023	Healed
C21	52	Female	76.5	Crutches	12	Heel	2.1	3	5.2	189	262	307	Yes	Present	6	Yes	Crutches	5	5	5	6	6	19	12	23	No	No	9219	No	No	No	No		2	Yes	1	26/04/2024	Re-ulcerated
M22	68	Female	64.4	Mandakini	16	Heel	3.1	1	8.6	177	266	175	Yes	Present	6	Yes	Mandakini	2	1	1	1	3	12	3	12	No	No	6383	No	No	No	No	Swelling	4	Yes	0	07/07/2023	Healed
C22	59	Female	66.6	Crutches	5	Midfoot	5.6	1	10.3	183	292	174	No	Present	7	Yes	Crutches	4	4	5	6	6	15	12	22	No	No	8519	No	No	Yes	No	Mild fever	3	No	0	01/02/2024	Healed
M23	59	Female	55.1	Mandakini	6	Heel	5.2	2	8.5	183	261	259	No	Present	6	Yes	Mandakini	5	1	1	1	3	11	4	10	No	No	6915	No	No	No	No		4	No	3	26/11/2023	Healed
C23	71	Female																																				