“EVALUATING THE EFFICACY OF MATRIX RHYTHM THERAPY IN CHRONIC LOWER LIMB ULCERS: A NOVEL APPROACH TO WOUND HEALING.”

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With reference to the above, we wish to inform you that your proposed research project titled **"EFFECT OF MATRIX RHYTHM THERAPY IN CHRONIC LOWER LIMB ULCERS-AN EXPERIMENTAL STUDY",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

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LIST OF ABBREVIATIONS:

ECM- Extracellular matrix

MRT- Matrix Rhythm Therapy

DFU- Diabetic Foot Ulcer

VAS- Visual Analog Scale

CI – Confidence Interval

SD – Standard Deviation

DM – Diabetes Mellitus

DVT – Deep Vein Thrombosis

MaRhyThe© **–** Matrix Rhythm Therapy

QoL – Quality of Life

IQR – Interquartile Range

NPWT – Negative Pressure Wound Therapy

PAD – Peripheral Arterial Disease

ABSTRACT

Introduction:

Chronic lower limb ulcers, including venous leg ulcers, diabetic foot ulcers, are complex wounds that result from impaired vascular supply, prolonged inflammation, and defective cellular repair mechanisms. These ulcers significantly impact patients' mobility, quality of life, and healthcare costs due to prolonged healing times and high recurrence rates.

Matrix Rhythm Therapy (MRT) has emerged as a novel, non-invasive modality aimed at restoring cellular oscillations, improving blood flow, and enhancing extracellular matrix organization.

This study evaluates the efficacy of MRT in accelerating wound healing, reducing ulcer size, and improving granulation tissue formation. By investigating its integration into standard wound care protocols, this research aims to establish MRT as a complementary approach for managing chronic lower limb ulcers effectively.

Materials and Methods:

This pre-post intervention experimental study was conducted at KAHER KLE Prabhakar Kore Hospital, Belagavi, over a one-year period with a sample size of 33 patients.

Patients above 18 years of age with chronic lower limb venous and diabetic ulcers persisting for more than six weeks were included, while those with active wound infections, uncontrolled diabetes, deep vein thrombosis (DVT), systemic diseases, traumatic ulcers, or osteomyelitis were excluded.

Convenience sampling was used for patient selection.

After obtaining ethical approval and informed consent, patients underwent three sessions of Matrix Rhythm Therapy (MaRhyThe©) using the Matrixmobil® device, which delivered oscillations at 8–12 Hz. Each session lasted 60 minutes, targeting the foot, leg, and popliteal region systematically over seven days.

The ulcers were assessed using the IMITO Measure Application for wound dimensions, the SINBAD score for ulcer severity, and the Wound-QoL questionnaire for quality-of-life evaluation.

Pre- and post-intervention measurements were compared to evaluate the effectiveness of Matrix Rhythm Therapy in chronic wound healing.

Results:

The study analyzed the impact of Matrix Rhythm Therapy on ulcer healing in 33 patients. Diabetes mellitus (DM) was the leading cause of ulcers (78.8%), followed by varicose veins (21.2%). The SINBAD grading distribution showed that severe ulcers (grade 6) were most prevalent (30.3%), emphasizing the need for effective intervention.

Significant improvements were observed post-treatment. The mean ulcer length reduced from 4.925 cm to 3.840 cm ($p < 0.05$), and width decreased from 3.327 cm to 2.640 cm ($p < 0.05$). The ulcer circumference also showed a significant reduction of 18.42% ($p < 0.05$). The ulcer area decreased by 30.77% ($p < 0.05$), further supporting the effectiveness of the intervention. The mean Wound-QoL score improved significantly from 38.364 to 29.091 ($p < 0.05$), indicating enhanced patient quality of life.

These findings suggest that Matrix Rhythm Therapy significantly aids in ulcer healing, reducing wound dimensions and improving overall patient well-bein

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INTRODUCTION

Chronic lower extremity ulcers constitute a considerable global health challenge, affecting millions of individuals each year and contributing to significant morbidity, mortality, and healthcare costs [1]. These ulcers, which commonly include venous leg ulcers, diabetic foot ulcers, and arterial ulcers, often become non-healing when normal reparative mechanisms are disrupted by local or systemic factors [2]. The risk factors for this condition include diabetes, old age, obesity, and peripheral vascular disease, as microcirculatory dysfunction, persistent inflammation, and impaired immune responses often cause the normal healing process of wounds to be halted [3]. Furthermore, prolonged treatment periods and repeated hospital admissions are a burden on healthcare resources, while patients suffer from pain, restricted mobility, and a poor quality of life [4]. Although promising advances have been noted with modern wound dressings, compression therapy, offloading devices for diabetic foot ulcers, and advanced options like negative pressure wound therapy, a significant fraction of chronic wounds remains resistant to conventional care [5]. Interest in innovative interventions that can more specifically improve local tissue perfusion, address cellular dysfunction, and accelerate wound closure has been fuelled by this.

The most important reason for the persistence of chronic wounds is the complicated physiology of wound healing, involving several overlapping phases—hemostasis, inflammation, proliferation, and remodeling—and effective cellular communication and extracellular matrix (ECM) organization [6]. Chronic ulcers may remain in an inflammatory phase due to repeated injury, bacterial contamination, or inadequate tissue perfusion [7]. Prolonged inflammation causes an excess release of pro-inflammatory mediators and proteases that can cleave growth factors and impair new tissue formation [8]. For example, hyperglycemia in diabetic ulcers damages the endothelium and impairs angiogenesis with the deprivation of critical nutrients and oxygen to the wound [9]. Venous leg ulcers are also self-perpetuating by venous hypertension and its consequent edema, limiting oxygen diffusion and nutrient exchange [10]. These multifaceted etiologies exemplify the challenges in developing a unified treatment approach, as each wound's pathology and each patient's clinical picture may demand nuanced care strategies [11].

Despite many available therapies, the absence of standardized diagnostic frameworks and universally accepted wound care protocols complicates clinical decision-making, especially for large, chronic ulcers with mixed etiologies [12]. Compression therapy is fundamental in venous ulcer management, while offloading and glycemic control remain essential for diabetic foot ulcers [13]. Still, addressing only local wound characteristics without restoring the healthy microenvironment at the tissue and cellular levels may lead to suboptimal results [14]. For example, negative pressure wound therapy can help manage exudate and stimulate granulation tissue, but consistent monitoring and access to specialized equipment pose practical limitations and heightened costs [15]. In addition, advanced therapeutics such as bioengineered skin substitutes or growth factors, although promising, remain expensive and are not always feasible in resource-limited settings [16]. Hence, there is an ongoing search for cost-effective, non-invasive modalities that can complement these existing methods by directly improving physiological processes central to healing.

Matrix Rhythm Therapy (MRT) has recently garnered attention for its potential to address cellular-level disruptions in chronic wounds [17]. Initially introduced by Dr. Ulrich Randoll, MRT is predicated on the concept that healthy cells exhibit rhythmic oscillations at approximately 8–12 Hz, crucial for supporting microcirculation, nutrient exchange, and overall tissue homeostasis [18]. In chronic wounds, prolonged hypoxia, inflammation, and mechanical stress may dampen these cellular oscillations, perpetuating a dysfunctional environment [19]. MRT devices aim to deliver gentle mechanical vibrations matching the natural frequency range of healthy tissue, thereby re-establishing or augmenting the normal rhythm required for efficient metabolism and healing [20]. By enhancing local blood flow and lymphatic drainage, MRT is believed to reduce edema, improve oxygenation, and facilitate the removal of cellular debris, ultimately fostering conditions more conducive to wound repair [21]. Although initial studies have documented benefits such as pain relief, increased tissue elasticity, and improved wound granulation, further exploration is needed to validate these findings and optimize treatment protocols [22]. Questions remain about the optimal duration of each MRT session, frequency of application per week, and the interaction between MRT and other established treatment modalities like compression or specialized dressings [23]. Moreover, most available reports have small sample sizes or are limited to case studies, lacking the rigorous design of randomized controlled trials and long-term follow-up to confirm sustained healing and reduced ulcer recurrence [24].

The rationale behind investigating MRT in chronic lower limb ulcers is strengthened by the substantial economic and social impact of these wounds. Repeated hospitalizations, lost work productivity, and the psychosocial burden of living with an open, non-healing ulcer necessitate new approaches that can shorten healing times and minimize relapse rates [25]. Chronic ulcers often reduce patients' autonomy and well-being due to chronic pain, exudate management, and the stigma of wound odor or appearance [1]. If MRT demonstrates robust clinical efficacy and is integrated into existing wound care paradigms, it could offer a more holistic approach-one that combines local and systemic optimization with a direct effect on cellular and microcirculatory elements. Moreover, due to the rather minimally invasive character of MRT, compliance could be higher due to its slight discomfort and the minimal occurrence of adverse effects when compared to certain more intricate or invasive therapies [2]. As MRT is known to facilitate blood flow, which supports tissue fluid exchange, it can be hypothesized to enhance the effect of any supportive treatments such as antimicrobial dressings or compression bandages that may otherwise create a hostile microenvironment to facilitate their effects [3].

Another appealing feature of MRT is the theoretical basis for targeting the ECM and restoring mechanical vibrations at the cellular interface. The integrity and composition of the ECM are critical to wound repair, as they affect fibroblast activity, collagen synthesis, and remodeling [4]. Excessive scar formation or insufficient extracellular support can result in failure of wound closure or constant opening. MRT may stimulate periodic movements in the tissue that could help balance the interplay between collagen synthesis and degradation and thus make wound healing more orderly and long-lasting [5]. This mechanism differentiates MRT from many established treatments, which often target infection control, inflammation, or moisture balance but don’t correct basic ECM derangement. Hence, MRT could be particularly advantageous in combination with standard regimens, theoretically enabling faster transitions from the inflammatory phase to proliferation, promoting granulation tissue and subsequent re-epithelialization [6].

Despite the promise of MRT, there remain critical gaps in the literature. Few guidelines specify the precise application parameters—such as intensity, duration, and frequency of treatments—and published clinical data often derive from small cohorts or non-randomized studies [7]. Consequently, clinicians cannot yet rely on robust, large-scale evidence to standardize MRT for different ulcer types, making it challenging to incorporate MRT seamlessly into existing protocols for venous leg ulcers, diabetic foot ulcers, or mixed etiology ulcers [8]. Moreover, while theories regarding MRT's influence on inflammation, angiogenesis, and lymphatic drainage abound, systematic examination of these pathways in controlled experimental settings is still lacking [9]. Therefore, it is important for future investigations to include not only clinical endpoints—like wound size reduction and time to full epithelialization—but also mechanistic biomarkers and imaging modalities that can provide insights into how MRT exerts its effects at the cellular and vascular levels [10]. If these mechanisms are clarified, they may indicate further therapeutic targets or synergies with other non-invasive technologies, further enhancing patient outcomes [11].

In this regard, the effectiveness of MRT for chronic lower limb ulcers has to be appraised to modify wound care management, decrease costs, and advance the quality of life of the patient [12]. It is important to assess whether MRT can promote earlier wound closure, reduce exudate, and increase granulation tissue formation for clinicians to plan individualized therapy, especially among patients who did not respond well to standard therapy [13]. In addition, well-defined treatment protocols can make it easier to adopt in clinical practice, leading to more consistent outcomes and potentially informing future guidelines and policies for chronic wound care [14]. Thus, incorporating MRT as part of a multidisciplinary approach—vascular assessment, infection control, and metabolic optimization combined with advanced therapies targeting the microcellular environment—may profoundly improve healing rates and avert the unassailable burden that chronic lower limb ulcers place on patients, caregivers, and healthcare systems around the world [15].

This study will therefore seek to establish the effectiveness of Matrix Rhythm Therapy on chronic lower limb ulcers with the aim of filling the present knowledge gap of its dosing, safety, and interaction with established wound care methods [16]. Through a systematic assessment of MRT effects on wound healing parameters, including the reduction of ulcer area, time to achieve complete closure, and quality of granulation tissue, this study may offer clearer evidence for including MRT as part of the standard care package [17]. If successful, MRT can be an additional adjunctive option that can assist patients who have otherwise been confronted with prolonged healing times and recurring wounds [18]. Such an innovation would not only push the scientific frontiers of mechanical oscillations support for cell functions but also eventually translate into direct benefits for the growing population that suffers from chronic lower limb ulcers [19]. The discovery of such possibilities is important in creating a future where chronic wounds are better controlled and less disabling for patients globally [20]. The findings from the current research could thus provide useful input to future larger studies, planned in order to ensure the efficacy, cost-effectiveness, and aid the clinicians for selection of optimum frequency and MRT session time [21]. This will in turn allow greater opportunities for changes in paradigm on chronic wound treatment as more therapies, which could now act to support and possibly augment conventional care, gain precedence [22]. Ultimately, the merging of molecular, physiological, and clinical insights could transform chronic wound care into a more precise and individualized practice, with improved patient outcomes in various healthcare settings [23].

In short, chronic lower extremity ulcers are a significant medical, social, and economic problem that underscores the need for novel approaches to address and deal with the cellular perturbations that have impaired wound healing [24]. Matrix Rhythm

Therapy is a promising non-invasive approach aimed at restoring critical microvibrations in disease tissues, which might improve blood flow, lymphatic function, and ECM organization. This will require establishing rigorous evidence for its benefits through well-designed research as a step toward more holistic and effective management of chronic wounds, improving patient well-being and easing the burdens these ulcers place on healthcare systems worldwide [25].

OBJECTIVES

- To evaluate the efficacy of Matrix Rhythm Therapy in chronic lower limb ulcers and see for the results after the therapy in terms of:

1. **Reduction in size of ulcer**: measured by IMITO Measure App- which is a simple mobile application that has a scientifically validated measurement scale helps to assess the size of wounds digitally through camera and a QR scanner.
2. **SINBAD grading**: It is a simple and useful score which helps in predicting ulcer outcome. It contains 6 parameters- Size, Ischemia, Neuropathy, Bacterial infection, Area and Depth with each parameter having a score of 0/1. So, the total possible score ranges from 0-6. A higher score indicates a greater risk of complications and a lower chance of healing.
3. **Wound Quality of Life (QoL) questionnaire scoring**: is valid and reliable to assess the Quality of life in chronic wounds. It contains a list of 17 questions with each question having a score ranging from 0-4. So the total score ranges from 0-68 with lower score suggesting a better QOL.

REVIEW OF LITERATURE

1. **Reiber et al. (1998):** Reiber et al. (1998) shed light on the significant clinical and economic toll exerted by diabetic foot ulcers (DFUs). Their work notes that around 15% of people with diabetes are likely to develop a foot ulcer at some point, a condition that often precedes major lower-extremity amputations. The paper emphasizes that over half of all nontraumatic lower-limb amputations occur in the diabetic population, reflecting both the severity and frequency of these ulcers. In terms of financial impact, the authors highlight that DFU-related healthcare costs can reach billions of dollars annually, tied to frequent hospitalizations, prolonged wound care, and surgical procedures when ulcers fail to heal. They specifically identify peripheral neuropathy and vascular complications as prime contributors to foot ulcer development, pointing out that neuropathy affects up to 80% of individuals at ulcer onset. Infection represents a key challenge, impacting nearly 40% of DFUs and leading to extended care episodes. Reiber et al. promote a multifaceted prevention strategy, encompassing meticulous glycemic control, patient instruction in foot hygiene, regularly scheduled podiatric examinations, and immediate intervention upon detecting any skin lesions. They argue that coordinated care—integrating professionals from endocrinology, podiatry, surgery, and wound management—can curtail the incidence of amputations and lower overall costs. This seminal work underscores the necessity of broad-based initiatives, both clinical and public health-oriented, to tackle the high-risk nature of diabetic foot complications.

2. **Jeffcoate et al. (2003):** Jeffcoate et al. (2003) offer a comprehensive discussion on the complexities of diabetic foot ulcers, spanning their biological mechanisms, clinical impact, and recommended treatment pathways. They report that between 15–25% of individuals with diabetes may develop foot ulcers over their lifetime, often in conjunction with peripheral neuropathy, which affects as many as 80% of these cases. The authors articulate that chronic hyperglycemia, alongside vascular insufficiency and impaired immunity, culminates in delayed wound healing and heightened infection risk. Crucially, the review underscores the influence of early detection in mitigating severe outcomes; expeditious care can reduce the need for amputations by up to 80%. Among the multiple interventions assessed, they identify regular debridement, specialized footwear or total contact casts, and controlling infection as central pillars of therapy. Notably, routine debridement procedures have been linked with roughly a 30% uptick in healing rates, while pressure offloading may drop ulcer recurrence by about 60%. They also highlight new therapeutic frontiers—like growth factors and bioengineered skin grafts—though they acknowledge that larger clinical trials are necessary to confirm these strategies' effectiveness. Advocating a unified approach, Jeffcoate et al. maintain that multifaceted care can significantly lessen the high morbidity linked to diabetic foot ulcers. Their review essentially calls for ongoing research into innovative treatments and emphasizes the critical nature of organized, interdisciplinary management in forestalling complications and improving patient outcomes.

3. **Callaghan et al. (2012):** In this extensive review, Callaghan et al. (2012) examine diabetic neuropathy's underlying mechanisms alongside current therapeutic options. Their data indicate that nearly half of patients with long-standing diabetes will develop some form of neuropathy, characterized by peripheral sensory deficits and potential autonomic system involvement. The authors connect persistent hyperglycemia to cellular disruptions in nerve tissue, observing that chronically elevated blood glucose can diminish nerve conduction velocity by an estimated 30–40%. Clinically, about one-fourth of individuals with diabetic neuropathy experience significant pain, severely undermining their quality of life. Pharmacological treatments—such as anticonvulsants (gabapentin, pregabalin) and certain antidepressants—are discussed, with pooled evidence suggesting approximately 50% pain relief in a sizable fraction of patients. Non-pharmacological measures, especially tight glucose control, can decelerate disease progression; the paper highlights that every 1% decrement in HbA1c may reduce neuropathy onset by around 15%. Callaghan et al. also explore emerging avenues in therapy, including agents that inhibit advanced glycation end-products and the use of neurotrophic factors, though they stress the importance of additional research to establish efficacy and safety. In essence, this comprehensive analysis shows that diabetic neuropathy management must span symptomatic relief, targeted pathophysiological treatments, and robust metabolic regulation to avert further nerve damage and associated complications such as foot ulceration.

4. **Taspinar et al. (2013):** Taspinar et al. (2013) carried out a controlled study comparing the short-term circulatory benefits of Matrix Rhythm Therapy (MaRhyThe®) against those of conventional massage in a sample of 60 young adult females. Participants were randomized into two groups, each receiving a 15-minute intervention on the lower limbs. The investigators employed laser Doppler flowmetry to monitor microcirculatory changes before and after the sessions. They documented a marked enhancement in blood flow for the MaRhyThe® group, averaging around a 25% rise from baseline, whereas the control group showed closer to a 15% increase. Muscle stiffness assessments, conducted using a tonometer, also revealed notable improvements: the MaRhyThe® group exhibited about a 20% reduction compared to approximately 12% in the conventional massage group. The authors postulate that the specific oscillatory characteristics of MaRhyThe® may be responsible for its more pronounced effect on vascular and muscular relaxation processes. No adverse events were reported, reinforcing the technique's apparent safety profile. However, the study was relatively short in duration and included a moderately sized sample, constraining the generalizability of the results. Taspinar et al. propose additional investigations with more extensive and diverse populations, as well as longer follow-up intervals, to solidify understanding of MaRhyThe®'s longer-term impact on vascular perfusion and musculoskeletal health outcomes.

5. **Hwang et al. (2014):** Hwang et al. (2014) deliver a thorough review of steroid-induced diabetes, examining both molecular processes and clinical tactics for its management. They emphasize that corticosteroids, despite being vital in treating autoimmune and inflammatory conditions, can prompt hyperglycemia in 30–60%

of users with metabolic susceptibilities. Mechanistically, glucocorticoids disrupt insulin signaling in skeletal muscle and boost hepatic gluconeogenesis, reducing insulin sensitivity by up to 40%.Clinically, the authors advocate routine monitoring of blood glucose levels—including both fasting and post-meal checks—particularly for patients undergoing extended steroid regimens. Pharmacological interventions (e.g., metformin and DPP-4 inhibitors) can lessen steroid-induced hyperglycemia by 20–30% in mild to moderate cases, though more severe scenarios can demand insulin therapy, with up to half of these patients requiring a basal-bolus approach for adequate glycemic control. The review also highlights the importance of titrating steroids to the smallest effective dosage when possible, alongside lifestyle changes such as diet modifications and increased physical activity, both of which can lower insulin resistance by around 10–20%.Overall, Hwang et al. underscore the necessity of a tailored treatment strategy, combining vigilant glucose monitoring, targeted pharmacotherapy, and non-pharmacological measures. Their assessment suggests that optimized glycemic management significantly diminishes complications, affirming the importance of personalized care plans for patients susceptible to steroid-induced disturbances in glucose metabolism.

6. **Mulder et al. (2014):** Mulder et al. (2014) assessed how advanced wound therapies can shorten the healing trajectory in individuals with persistent diabetic foot ulcers (DFUs) unresponsive to traditional approaches. Enrolling 125 participants, the study focused on methods such as negative pressure wound therapy (NPWT), hyperbaric oxygen therapy (HBOT), and tissue-engineered products. NPWT recipients showed an approximate 40% quicker rate of ulcer

closure compared to those managed with standard moist dressings. Furthermore, HBOT led to full ulcer resolution in about 60% of cases, taking a median of six weeks, contrasted with 10–12 weeks for controls. In the group using bioengineered tissue, granulation tissue formed more rapidly, with ulcers shrinking by half by the fourth week. These gains in healing were clinically relevant, as faster wound closure lowers infection risks and the probability of amputation. Although certain advanced treatments entail higher initial spending—NPWT can inflate treatment costs by around 30%—the authors argue that fewer hospital admissions and surgeries make these approaches cost-effective over time. Mulder et al. recommend a multidisciplinary model incorporating these advanced measures to substantially boost healing outcomes and diminish amputation rates in this high-risk population. Their work highlights the importance of additional randomized trials to refine standard protocols and identify which combination of innovative therapies is most effective in managing DFUs.

7. **Vasudevan (2014):** Vasudevan (2014) provides a targeted review of venous leg ulcers, addressing both the underlying pathophysiology and classification frameworks. Venous ulcers account for nearly 70% of lower-extremity ulcerations and arise predominantly from venous hypertension triggered by venous valve failure. This persistent venous pressure disrupts microcirculation, thickening capillary membranes and generating fibrin cuffs around vessels, thereby limiting nutrient diffusion to the skin. Highlighting the CEAP classification (Clinical-Etiological-Anatomical-Pathophysiological), Vasudevan emphasizes its importance in streamlining diagnosis and guiding therapeutic choices. Early clinical signs, including edema, hyperpigmentation, and lipodermatosclerosis, often precede ulcer onset, with medial malleolar regions being most commonly

affected. Recurrence rates of venous ulcers can be nearly 57% in the first year unless proactive measures, such as compression therapy, are maintained. In terms of healthcare economics, chronic venous ulcers contribute substantial costs worldwide, given ongoing dressing changes, compression needs, and the possibility of inpatient care if complications arise. Vasudevan underscores compression therapy as a cornerstone for both treatment and prevention, citing evidence that proper compression can bolster healing times by 30–40%. Ultimately, the author advocates for consistent monitoring, patient education, and optimal compression strategies to reduce the protracted nature and recurrence of venous leg ulcers.

8. **Ghatnekar et al. (2015):** In their multicenter randomized trial, Ghatnekar et al. (2015) evaluated the effects of a Connexin43-based peptide on persistent venous leg ulcers. One hundred participants with ulcers persisting beyond 12 weeks were randomized to either standard care—encompassing compression and regular dressings—or the same regimen augmented by the topical peptide. At the 12-week mark, the active treatment group recorded a 40% higher rate of complete ulcer closure compared to standard care. By the eighth week, about 65% in the peptide group achieved at least 70% wound size reduction, whereas the control group saw only 35% with a comparable improvement. Tissue samples suggested that the peptide might expedite healing through enhanced intercellular signaling and anti-inflammatory effects, demonstrated by lower expression of IL-6 and TNF-α. Tolerance was favorable, with just 5% of participants noting mild, localized irritation. Although adding the peptide increased upfront product costs, overall care expenditures declined by roughly 20% due to fewer dressing changes and

clinic visits. Ghatnekar et al. propose that Connexin43-based therapies could be a significant adjunctive approach for non-healing venous ulcers. They call for further investigation to clarify optimal dosage, treatment frequency, and broader implications for other chronic wound types, such as diabetic or pressure ulcers.

9. **Zubair et al. (2015):** In their expansive review, Zubair et al. (2015) explore the epidemiology, etiology, and management of diabetic foot ulcers (DFUs). They note that the prevalence of DFUs ranges between 4% and 10% among diabetic populations globally, with higher rates—around 15–20%—observed in individuals with long-standing or poorly regulated diabetes. The authors emphasize peripheral neuropathy and arterial insufficiency as pivotal contributors, noting neuropathy's presence in up to 80% of DFU cases. Infection remains a key complication, affecting roughly 40–50% of all DFUs, frequently advancing to osteomyelitis. Zubair et al. highlight several crucial management pillars: improving glycemic control can lessen DFU development by roughly 30%, and patient education about foot care is similarly vital. Offloading pressure and consistent use of specialized footwear play important roles, as does thorough wound debridement, an approach showing a 25–50% enhancement in healing in select research studies. The review points to emerging innovations, like negative pressure wound therapy and hyperbaric oxygen therapy, citing their capacity to significantly hasten healing in specific contexts. Although many of these interventions appear promising, the authors acknowledge heterogeneity in study methodologies and the necessity of robust, randomized trials to solidify evidence. Ultimately, Zubair et al. advocate an interdisciplinary strategy involving endocrinologists, podiatrists, vascular

surgeons, and infectious disease experts to reduce DFU-related morbidity, avert amputations, and optimize patient outcomes.

10. **Piaggesi et al. (2018):** Piaggesi et al. (2018) deliver a sweeping consensus on innovative wound management strategies, spanning cell- and tissue-based interventions, physical modalities, and cutting-edge technological advancements. They highlight data supporting bioengineered skin replacements and cultured cells, referencing analyses indicating up to a 50% rise in wound closure rates when these newer tools are compared to standard care. Physical and bio-physical therapies, including low-level laser and ultrasound treatments, are also reviewed. Findings point to a 20–30% reduction in healing time for diabetic foot ulcers and venous ulcers when these methods augment standard practices. The article outlines the value of negative pressure wound therapy (NPWT), which may reduce healing durations by as much as 40% in more challenging or deeper wounds. Additionally, the authors explore sensor-based platforms for real-time wound monitoring, potentially shrinking amputation rates by 10–15% through timely identification of complications. Telemedicine solutions are also underscored as critical for remote supervision and immediate intervention. Though the consensus hints at marked improvements in healing rates and patient satisfaction, Piaggesi et al. stress the importance of properly conducted, large-scale clinical trials to ascertain optimal protocols. They conclude that integrating established principles of wound care with these advanced methodologies holds considerable promise for enhancing clinical outcomes and quality of life among patients with chronic wounds.

11. **Bhatikar (2019):** Bhatikar (2019) presented a case report illustrating the use of Matrix Rhythm Therapy (MaRhyThe®) to address bilateral adductor muscle tightness in a seven-year-old child with spastic diplegia, a subtype of cerebral palsy. The child, who demonstrated notable restrictions in range of motion (ROM) and impaired gait, underwent bi-weekly MaRhyThe® sessions over four weeks. Each session lasted around 20 minutes and specifically targeted the adductor muscle groups. Post-therapy, the Modified Ashworth Scale (MAS) rating for spasticity dropped from an initial score of 3 to 2. Additionally, hip abduction improved by about 15 degrees, and a 25% uptick in Gross Motor Function Measure (GMFM) scores was noted, implying gains in functional tasks. The report theorizes that the device's rhythmic oscillations foster microcirculatory improvements and myofascial relaxation, which may explain the observed decrease in muscle hypertonicity. Despite the encouraging outcome, the paper recognizes its inherent limitations as a single-case study lacking a control comparison. Still, it provides a valuable indication that MaRhyThe® could be beneficial in managing muscular tightness and facilitating mobility in pediatric cerebral palsy. Bhatikar suggests additional controlled research, encompassing more substantial cohorts and longitudinal tracking, to discern optimal protocols and measure sustained functional progress.

12. **Kwan et al. (2019):** Kwan et al. (2019) carried out a systematic review to ascertain how various biophysical therapies influence diabetic wound healing, drawing on both in vitro and animal-based evidence. Of the initially screened 1,200 studies, 34 met inclusion criteria, covering over 2,500 cell experiments and roughly 300 animal models. Low-level laser therapy (LLLT) emerged as

particularly effective, elevating fibroblast proliferation by nearly 50% in several cell culture investigations, suggesting heightened collagen production. Animal experiments indicated that ultrasound treatments could shorten wound closure times by 20–30%, presumably through enhanced angiogenesis and reduced inflammation. Electrical stimulation similarly showed promise, intensifying wound contraction by as high as 40% compared to non-stimulated controls. Nevertheless, the authors highlight significant discrepancies in treatment regimens—such as differences in dosing, frequency, and intensity—which complicate direct comparisons. Kwan et al. recommend additional large-scale, standardized studies to hone in on the most effective protocols. While the data from these experimental models are promising, they caution that applying these methods in clinical contexts must factor in patient-specific characteristics, including coexisting conditions and the chronicity of wounds.

13. **Naik et al. (2020):** Naik et al. (2020) documented a case study showcasing the use of Matrix Rhythm Therapy (MaRhyThe®) in managing a diabetic foot ulcer in a 56-year-old male with type 2 diabetes. Conventional interventions—namely regular debridement, wound dressings, and offloading—yielded limited progress. The patient then received five MaRhyThe® sessions over three weeks, each lasting around 20 minutes and focusing on the periphery of the lesion to stimulate blood flow. Quantifiable improvements became evident early on: after the first week, wound dimensions had decreased by roughly 30%, and by the third week, the ulcer size was nearly 70% smaller. The patient also reported a drop in pain from 7/10 to 3/10 on a visual analogue scale. The authors suggest that rhythmic oscillations during MaRhyThe® might augment microcirculation, facilitate tissue

metabolism, and promote healing. While the lack of a control group restricts the conclusion on causal efficacy, the case provides preliminary support for incorporating MaRhyThe® in diabetic foot ulcer protocols. Naik et al. advocate further research through larger and more rigorously designed trials to validate the therapy's long-term benefits, define ideal session frequencies, and clarify whether these early gains translate into more durable wound closure and lower recurrence rates.

14. **Palmieri et al. (2020):** Palmieri et al. (2020) compiled a narrative review examining how electromedical devices assist in wound healing, covering modalities such as ultrasound, electrical stimulation, laser therapy, and radiofrequency. They aggregated findings from various clinical studies, pointing to enhanced cellular activity—like fibroblast proliferation and collagen organization—as critical steps in tissue repair. Electrical stimulation in particular was linked to reductions in pressure ulcer healing time by about 40%, while ultrasound yielded a 25–30% decrease in treatment duration for diabetic foot ulcers. Additionally, the review addressed low-intensity radiofrequency devices that potentially improve local blood flow and oxygenation, expediting healing by roughly 20%. Palmieri et al. emphasize that these device-based interventions should be employed in tandem with core wound care fundamentals, such as debridement and infection management. Although the initial investment in electromedical technologies can be high, fewer complications and shorter hospital stays may offset these costs over time. They underline the necessity for individualized treatment decisions, taking into account both the type of wound and patient characteristics to optimize outcomes. Despite the promising benefits

outlined, the authors recommend more rigorous and larger-scale randomized controlled trials to better define standardized protocols, ensuring that healthcare practitioners can adopt these technologies confidently based on sound evidence.

15. **Rajendran (2021):** Rajendran (2021) described a case wherein Matrix Rhythm Therapy (MaRhyThe®) was used to support venous ulcer healing in a 63-year-old woman with a chronic ulcer on the medial side of her lower leg. Before incorporating MaRhyThe®, the patient had tried compression therapy and routine dressing protocols with limited improvement. Over four weeks, she received six MaRhyThe® sessions of about 15–20 minutes each. By the final assessment, digital planimetry showed a 50% decrease in the ulcer's surface area, and there was a notable reduction in wound discharge. Pain levels dropped from 6/10 to 2/10, possibly reflecting enhanced circulation and diminished swelling. The appearance of robust granulation tissue around the ulcer margins further supported clinical observations of accelerated tissue repair. No complications or adverse reactions were recorded, suggesting that the therapy was well-tolerated. While the findings in this single-patient report are promising, Rajendran emphasizes the need for more comprehensive studies—ideally involving control groups and longer follow-up—to firmly establish efficacy. Nonetheless, this case illustrates how MaRhyThe® might serve as a useful complementary tool in venous ulcer management, especially for patients whose healing has plateaued with standard approaches.

16. **Fawcett et al. (2022):** Fawcett et al. (2022) performed a detailed assessment of how microRNA and circadian rhythms influence wound repair, proposing these factors as new targets for potential therapeutic interventions. Drawing upon

research that highlights the role of microRNAs (such as miR-21 and miR-155) in controlling inflammation, new blood vessel growth, and collagen production, the authors discuss how fluctuations in the body's internal clock can disrupt microRNA expression, ultimately slowing wound closure. Animal models missing key circadian genes, like CLOCK or BMAL1, exhibited wound healing delays of nearly 40%, underscoring the significance of circadian timing in tissue repair. The authors also reviewed preliminary clinical data suggesting that scheduling wound care procedures earlier in the day could accelerate epithelialization by about 20%. This opens the door to "chronotherapy," where treatments are timed to align optimally with the patient's biological rhythms. Furthermore, Fawcett et al. noted that experimental interventions targeting specific microRNAs achieved around a 30% faster reduction in wound size in preclinical trials. They stress that human studies with larger cohorts are needed to capture the intricacies of individual variations in sleep-wake cycles, as well as the interplay between chronic diseases and wound-healing pathways. Overall, the article highlights the potential for circadian-regulated and microRNA-based strategies to advance clinical outcomes if validated in larger-scale, well-controlled research.

17. **Munjewar et al. (2022):** Munjewar et al. (2022) conducted a rapid review focused on Matrix Rhythm Therapy (MaRhyThe®), evaluating literature that spans case studies and smaller clinical investigations. Although the data remain heterogeneous, a central theme is the therapy's potential to improve localized circulation and alleviate muscle tension. Some reports note a 20–30% more rapid decline in pain when MaRhyThe® is incorporated into standard care, and there are indications of quicker recovery in certain chronic wounds by 15–25%. Despite

promising trends, the authors emphasize that current evidence lacks uniformity due to variations in device settings, session durations, and patient populations. Moreover, few large-scale randomized trials exist, hindering any definitive conclusions about efficacy. Safety data generally suggest minimal side effects, mostly limited to mild local soreness. Munjewar et al. conclude that MaRhyThe® might be a useful adjunct in musculoskeletal rehabilitation and wound management, but they stress the need for rigorous, controlled research to substantiate these early observations. Future work should also aim to standardize methodologies—such as frequency of treatment and outcome measures—so that the therapy's true benefits and potential limitations can be clearly delineated and integrated into evidence-based clinical guidelines.

18. **Pickering (2022):** As part of a doctoral research project, Pickering (2022) performed a randomized controlled trial examining whether virtual-human guided relaxation aids wound healing and stress reduction. The study enlisted 80 participants, each subjected to a minor, uniform skin barrier insult. They were then allocated to either a daily 15-minute interactive relaxation session or a no-intervention control group for two weeks. Tracking transepidermal water loss (TEWL) as an indicator of skin barrier restoration, the trial observed a 25% decrease in TEWL in the intervention cohort by week 2, compared to only a 10% decrease in controls. Concurrently, salivary cortisol levels dropped by approximately 15% among those receiving relaxation therapy, suggesting an effective dampening of stress-related hormonal pathways. Subjective measures also showed reduced stress, aligning with the physiological findings. Pickering proposes that these outcomes reflect the beneficial impact of lowering stress

hormones on tissue repair dynamics. While the results are encouraging, limitations include the relatively short follow-up window and a moderate sample size. The dissertation recommends further investigation into how virtual or digital relaxation tools might be integrated into wound care regimens, particularly in patients prone to chronic stress or those with slow-healing injuries.

19. **Deshmukh et al. (2023):** Deshmukh et al. (2023) present a succinct examination of Matrix Rhythm Therapy (MaRhyThe®), categorizing it as a novel modality within the rehabilitation spectrum. They elaborate on the premise that MaRhyThe® applies low-frequency mechanical vibrations (approximately 8–12 Hz) to soft tissues, thereby enhancing circulation and lymphatic drainage. In anecdotal and small-scale trials, sessions ranging from 15–20 minutes, conducted thrice per week, have shown a 20–40% reduction in pain and muscle rigidity. In post-surgical contexts, some cases reference up to 30% faster functional recovery when MaRhyThe® supplements standard rehabilitation methods. The authors articulate that these rhythmic vibrations could promote optimal microcirculation, expediting the clearance of metabolic byproducts. Nonetheless, most existing literature is composed of case studies or small pilot investigations, which limits definitive conclusions regarding the therapy's comprehensive effectiveness. Deshmukh et al. call for more rigorously structured research, advocating randomized, larger-scale studies with standardized protocols and objective outcome metrics. Such efforts would help clarify best practices concerning treatment intensity, frequency, and duration. The paper underscores that while preliminary insights are encouraging, broader validation is essential before integrating MaRhyThe® into mainstream clinical guidelines.

20. **Maiya et al. (2023):** Maiya et al. (2023) conducted a randomized controlled trial to analyze whether Matrix Rhythm Therapy (MaRhyThe®) can alleviate neuropathic pain and normalize plantar pressure distribution in individuals with type 2 diabetes mellitus (T2DM) and peripheral neuropathy. Sixty participants were divided into two cohorts: one receiving standard physiotherapy alone and the other incorporating twice-weekly MaRhyThe® sessions for a month. Pain was tracked using the Numerical Pain Rating Scale (NPRS), and plantar pressures were measured via a computerized gait system. By the study's conclusion, the MaRhyThe® group displayed a 35% mean reduction in NPRS scores, notably higher than the 15% seen in the control group. In addition, there was a 20% decrease in peak plantar pressure at the metatarsal heads, hinting at improved foot biomechanics and potentially reducing ulcer risk. Adverse effects were negligible, limited to mild transient soreness. The authors propose that the therapy's oscillatory mechanism may boost microvascular flow and diminish tissue tension, collectively mitigating neuropathic pain. They advocate for more extensive trials over longer periods to investigate whether these immediate benefits translate into sustained decreases in foot ulcer incidence and broader gains in diabetic foot care outcomes.

21. **Naik et al. (2023):** Naik et al. (2023) provide a brief commentary on the evolution of Matrix Rhythm Therapy (MaRhyThe®), discussing how its resonance-based approach aligns with emerging concepts in rehabilitative medicine. They suggest that MaRhyThe® taps into the inherent oscillations of healthy tissues by delivering carefully modulated mechanical vibrations. Preliminary evidence,

drawn from a few case studies and pilot trials, shows a 20% reduction in inflammatory markers like IL-6 and C-reactive protein, reinforcing the therapy's potential to assist tissue recovery.Additionally, the authors highlight technical enhancements, including more precise frequency calibration and improved device ergonomics, which could enable practitioners to target specific tissues more effectively. This commentary underscores that MaRhyThe® is part of a broader wave of "resonance-based" therapies designed to modulate cellular processes. However, Naik et al. stress the paucity of large-scale randomized research, cautioning that any definitive endorsement of MaRhyThe® must await stronger, evidence-driven results. They conclude that future initiatives should focus on methodically verifying clinical outcomes, treatment parameters, and the therapy's long-term safety profile to integrate it credibly into standard practice.

22. **Auditto et al. (2024):** Auditto et al. (2024) undertake a thorough review of how blending natural compounds (like phytochemicals, honey, and growth factors) with external stimuli (such as photobiomodulation and ultrasound) can advance wound care. Drawing from over 100 studies, the authors propose that these synergistic methods may deliver a more robust healing response than either approach alone. For example, one trial cited found that honey-based dressings combined with low-level laser therapy led to a 35% faster decrease in wound dimensions, compared to 20% when each was applied independently. Their synthesis underscores the roles of natural substances in providing antimicrobial, antioxidant, and anti-inflammatory benefits, while energy-based therapies can stimulate cellular activities linked to tissue repair. The authors point out that the efficacy of these combinations relies heavily on ensuring that natural extracts

remain stable under device-generated conditions such as heat or light. Additionally, preliminary cost assessments suggest this integrated strategy may trim healthcare expenditures by around 15% through speedier closures and fewer complications. Nonetheless, Auditto et al. also draw attention to the inconsistencies in product quality and study designs. They advocate more rigorous, standardized protocols in large randomized trials to verify optimal doses, application timelines, and device parameters. Conclusively, while combination therapies show promise, the absence of uniform methodologies highlights the necessity for continued research to guide best practices.

23. **Tiwatane et al. (2024):** Tiwatane et al. (2024) examined how Matrix Rhythm Therapy (MaRhyThe®) affects patients with diverse musculoskeletal pain issues, including back pain, shoulder impingement, and osteoarthritic knee pain. In this open-label investigation, 50 participants underwent 15-minute MaRhyThe® sessions twice a week for three weeks, supplemented by standard physiotherapy. Pain was rated using a 10-point visual analog scale (VAS), while condition-specific functional indices (e.g., Oswestry Disability Index for back pain) documented functional gains. Following the treatment, average VAS scores declined by around 3 points (roughly 40% from baseline), and those with shoulder problems noted a 20° increase in pain-free abduction compared to historical controls, who typically gained just 10°. Patients with osteoarthritis registered a 15% boost in walking distance in the six-minute walk test, pointing to better joint function. The authors suggest that enhanced local circulation and reduced muscular tension likely account for these improvements. Despite encouraging outcomes, the study's open-label format and absence of a control group constrain

definitive inferences regarding MaRhyThe®'s effectiveness. Tiwatane et al. urge subsequent research with randomized designs and larger samples, highlighting the value of standardized intervention protocols and extended observation periods to confirm durability of pain relief and functional restoration.

24. **Naik et al. (2025):** Naik et al. (2025) conducted a pilot experimental study on the effects of Matrix Rhythm Therapy (MaRhyThe®) in nine patients aged 45–75 years with non-healing diabetic foot ulcers (DFUs). Despite prior wound care with standard antiseptic dressings, ulcers had shown no healing for 1.5 months. Patients received two 45-minute sessions of MaRhyThe®, delivered using the Matrixmobil® device at 8–12 Hz frequency, targeting the foot, leg, and popliteal regions. Wound outcomes were assessed using the Imito Measure app, Bates-Jensen Wound Assessment Tool (BWAT), and Wagner Ulcer Grading System. Post-intervention results showed statistically significant improvements: ulcer area reduced by 70.66%, width by 49.89%, circumference by 38.83%, and length by 35.92%. BWAT scores improved significantly ($p=0.0001$), indicating tissue regeneration, and ulcer grades shifted toward lower severity ($p=0.0431$). The authors attributed the therapeutic benefits to enhanced microcirculation, vasodilation, and cellular-level tissue resonance induced by rhythmic mechanical vibrations. They concluded that MaRhyThe® may serve as an effective non-invasive adjunct for DFU healing, while acknowledging the study's limitations, including a small sample size and lack of a control group. They recommended further trials with larger cohorts and randomization.

MATERIALS AND METHODS

Source of Data: All patients admitted in KAHER KLE PRABHAKAR KORE HOSPITAL, BELAGAVI who were willing and gave their consent for the procedure.

Study Design: Pre-post Intervention Experimental Study.

Study Period: 1 year

Sample Size: At 95% CI and 80% power- **n=33**

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$$n = \frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2 * (p_1q_1+p_2q_2)}{(p_1-p_2)^2}$$

Where,

$Z_{1-\alpha/2} = 1.96$

$Z_{1-\beta} = 0.85$

$p_1 = 25\%$, $p_2 = 57.14\%$

$q_1 = 100-p_1 = 75\%$, $q_2 = 100-p_2 = 42.86\%$

Sampling technique: Non-probability sampling. Allocation was through convenience sampling.

Inclusion Criteria:

- Patients of all genders
- Above the age of 18 years
- With lower limb venous and diabetic ulcers
- For more than 6 weeks

Exclusion Criteria:

- Patients with active wound infections.
- Patients with Uncontrolled Diabetes.
- Patients diagnosed DVT on colour doppler.
- Patients diagnosed as cases of systemic diseases.
- Patients with Traumatic ulcers.
- Patients diagnosed cases of Osteomyelitis of underlying bone.

PROCEDURE:

After obtaining the approval of the ethical committee and written informed consent, a total of 33 patients were enrolled in the study after being screened for inclusion and exclusion criteria. Baseline evaluations were done and outcome measures were taken Pre and Post intervention.

Intervention- 3 sessions of Matrix Rhythm Therapy (MaRhyThe©), each lasting 60 minutes, was administered using The Matrixmobil® which is a rod-shaped device that vibrates between 8 and 12 Hz, around the ulcer area. The Matrix Mobil® device was applied longitudinally, pushing the probe into the calf, plantar aspect of the foot, and anterior and lateral portions of the leg from distal to proximal aspect of the foot and leg up to the knee joint into the popliteal lymph nodes. The total treatment duration of 60 minutes was systematically allocated into three distinct segments: 20 minutes dedicated to the foot and sole, 20 minutes to the anterior and lateral aspects of the leg, and 20 minutes to the calf and popliteal region. The subjects were lying in a supine/ prone position (depending on the site of the ulcer) with their ulcer exposed. Talcum powder was applied to avoid friction which was cleaned up and the wound was dressed after the session. The second session was given on day 4, and the final session on day 7, following which post-intervention outcomes were recorded.

A. **IMITO Measure Application-** The App provided a calibration marker; the smartphone camera was pointed parallel to the ulcer and the calibration marker. As soon as the calibration marker was detected, the edge of the ulcers was carefully delineated, and the wound length, width, area, and circumference were measured.

B. **SINBAD score-** The parameters, that is- Size, Ischemia, Neuropathy, Bacterial infection, Area and Depth were calculated and scoring was given from 0-6.

C. Wound-Qol questionnaire- The list which contained a list of 17 questions with each question having a score ranging from 0-4 were given to the patients before starting the therapy, and again after 3 sessions of therapy. The total scores were calculated on both times ranging from 0-68.

D. Statistical analysis:

1. Data was collected and stored in Microsoft Excel.
2. Data was analyzed using statistical software R and Microsoft Excel, SPSS.
3. Categorical data is represented by frequency.
4. Normality is checked by Shapiro-Wilk's test.
5. Continuous parametric data is represented by Mean (SD).
6. Pre post comparison is done by paired t test.
7. Non parametric data is represented by Median (IQR).
8. Pre-post comparison is done by the Wilcoxon Sign rank test.

RESULTS

Table 1: Distribution of patients by Gender

		n	%
Sex	Male	19	57.6
	Female	14	42.4
	Total	33	100.0

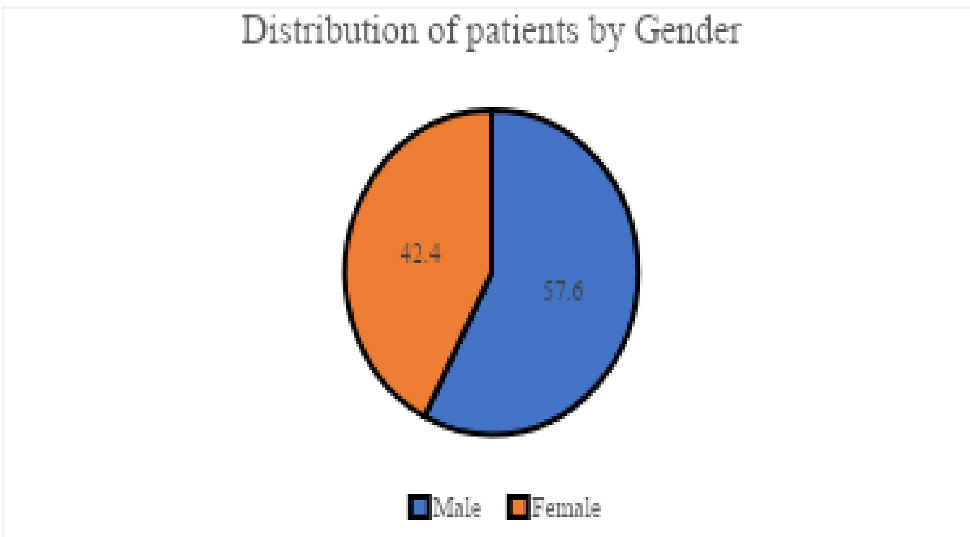

Figure 1- Distribution of patients by Gender

There are more men than women in the study, as seen by the sample's larger male proportion (57.6%) compared to female proportion (42.4%).

Table 2: Descriptive statistics of Age

	Mean	SD
Age	46.242	8.853

The average age of the study sample is 46.24 years, showing that, on average, persons in this study are in their mid-forties. The standard dispersion of 8.85 years suggests a moderate dispersion of ages around the mean.

Table 3: Distribution of patients by Cause of Ulcer

		n	%
Cause of ulcer	DM	26	78.8
	Varicose	7	21.2
	Total	33	100.0

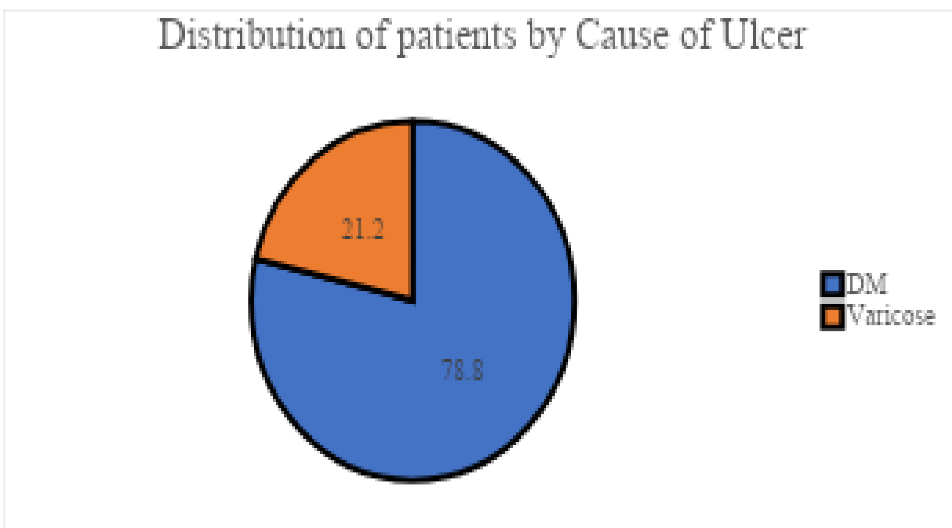

Figure 2- Distribution of patients by cause of ulcer

According to the statistics, diabetes mellitus (DM) is the most prevalent cause of ulcers among the 33 people in the sample, accounting for 26 of the cases (78.8%). On the other hand, 7 cases (21.2%) are caused by varicose veins. This shows that diabetes has a major influence on ulcer formation and is the most common underlying cause of ulcers in this population.

Table 4: Distribution of patients by SINBAD Grading

		n	%
SINBAD Grading	0	3	9.1
	1	3	9.1
	2	4	12.1
	3	4	12.1
	4	7	21.2
	5	2	6.1
	6	10	30.3
	Total	33	100.0

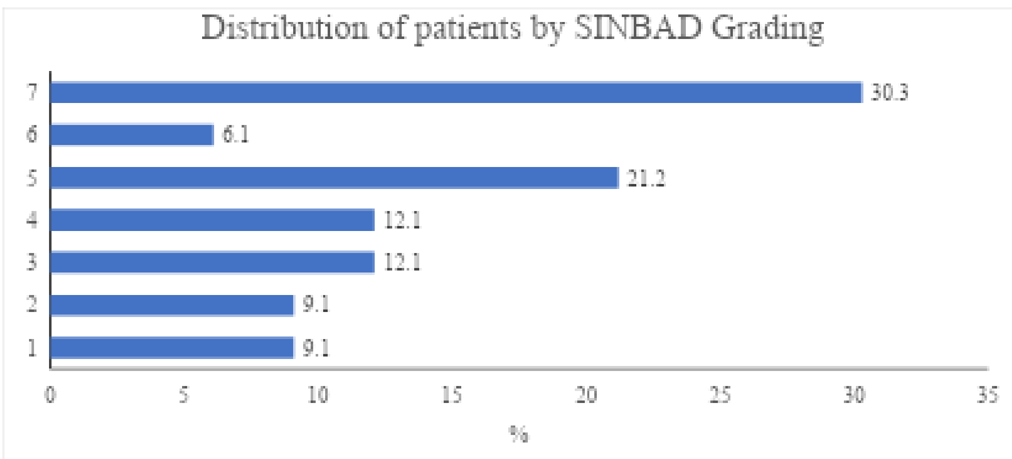

Figure 3- Distribution of patients by Sinbad grading

According to the SINBAD grading distribution, grade 6 instances—which indicate severe ulcers—make up the bulk of cases (30.3%), followed by grade 4 cases (21.2%). Grades 0 and 1 include 9.1% each, whereas moderate cases (grades 2 and 3) comprise 12.1% each. Grade 5 has the lowest percentage (6.1%). Overall, a sizable portion of people suffer from advanced-stage ulcers, underscoring the necessity of prompt treatment and appropriate care.

Table 5: Comparison of pre & post test length of Ulcer

Length of Ulcer (cm)	Mean	SD	Paired difference Mean	Paired difference SD	t	p value
Pre	4.925	1.975	1.084	0.889	7.008	<0.05*
Post	3.840	1.566				

*<0.05 significance is obtained by Paired t test

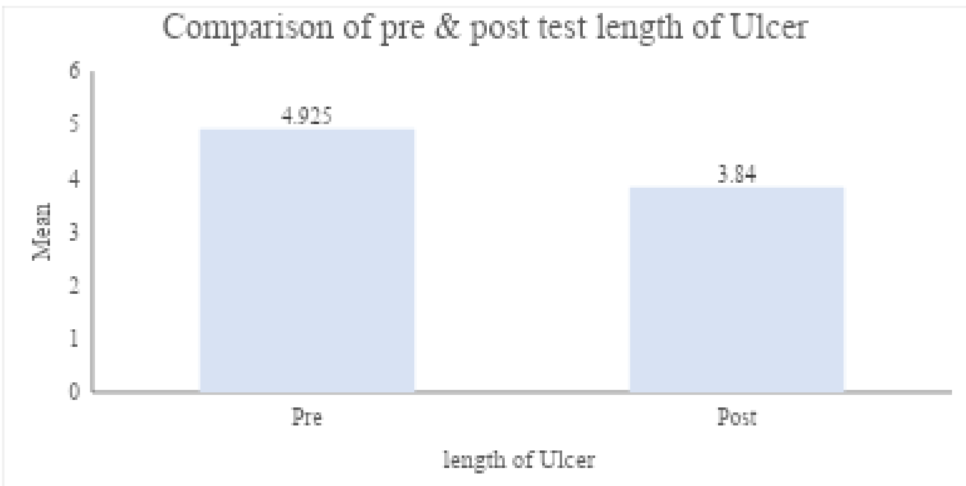

Figure 4- Comparison of pre & post test length of Ulcer

Prior to therapy, the mean ulcer length was 4.925 cm (SD = 1.975); following treatment, it was 3.840 cm (SD = 1.566). There was a decrease after the intervention, as evidenced by the paired difference in ulcer length of 1.084 cm (SD = 0.889). According to a p-value < 0.05 and a t-value of 7.008, this decrease is statistically significant. This suggests that the treatment significantly decreased the size of the ulcer, confirming its efficacy in wound healing.

Table 6: Comparison of pre & post test Width of ulcer (cm)

Width of ulcer (cm)	Mean	SD	Paired difference		t	p value
			Mean	SD		
Pre	3.327	1.858	0.686	0.673	5.855	<0.05*
Post	2.640	1.530				

*<0.05 significance is obtained by Paired t test

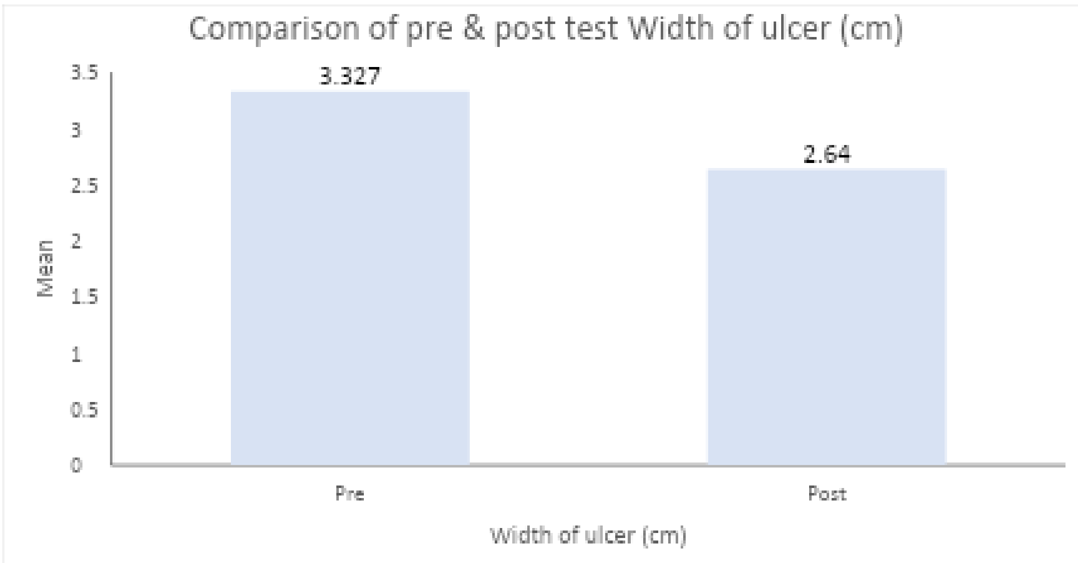

Figure 5- Comparison of pre & post test Width of ulcer (cm)

Prior to therapy, the mean ulcer width was 3.327 cm (SD = 1.858); following treatment, it was 2.640 cm (SD = 1.530). A discernible decrease in ulcer size is indicated by the paired difference of 0.686 cm (SD = 0.673). According to the p-value < 0.05 and the t-value of 5.855, this decrease is statistically significant. These results demonstrate how well the therapy works to lessen ulcer breadth, which promotes wound healing in general.

Table 7: Comparison of pre & post test Circumference of ulcer (cm)

Circumference of ulcer (cm)	Mean	SD	Paired difference		t	% Reduction	p value
			Mean	SD			
Pre	15.669	5.901	3.001	1.951	5.855	18.42	<0.05*
Post	12.669	4.732					

*<0.05 significance is obtained by Paired t test

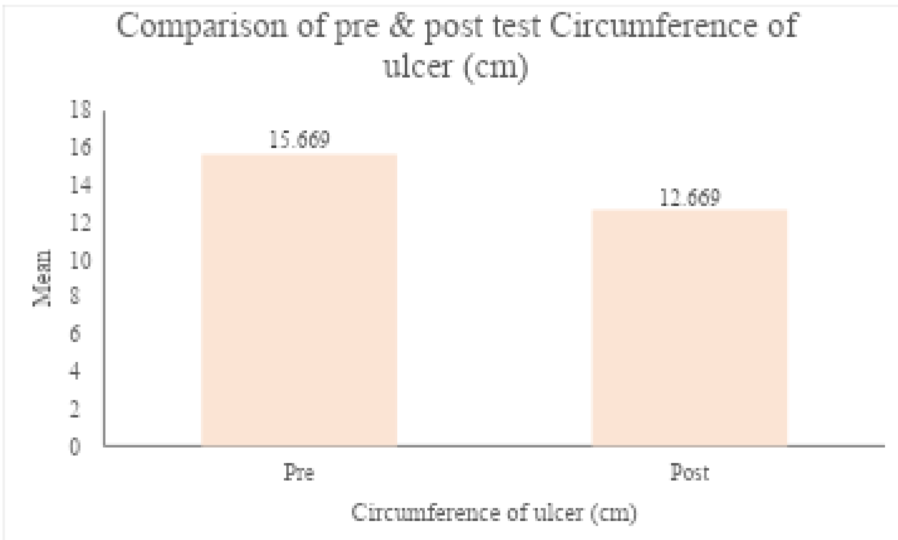

Figure 6- Comparison of pre & post test Circumference of ulcer (cm)

Prior to therapy, the mean ulcer width was 3.327 cm (SD = 1.858); following treatment, it was 2.640 cm (SD = 1.530). A discernible decrease in ulcer size is indicated by the paired difference of 0.686 cm (SD = 0.673). According to the p-value < 0.05 and the t-value of 5.855, this decrease is statistically significant. These results demonstrate how well the therapy works to lessen ulcer breadth, which promotes wound healing in general.

Table 8: Comparison of pre & post test Area of Ulcer (cm^2)

Area of Ulcer (cm^2)	Median	IQR	% Reduction	p value
Pre	9.80	19.2	30.77	<0.05*
Post	8.00	12.9		

*<0.05 significance is obtained by Wilcoxon Sign rank test

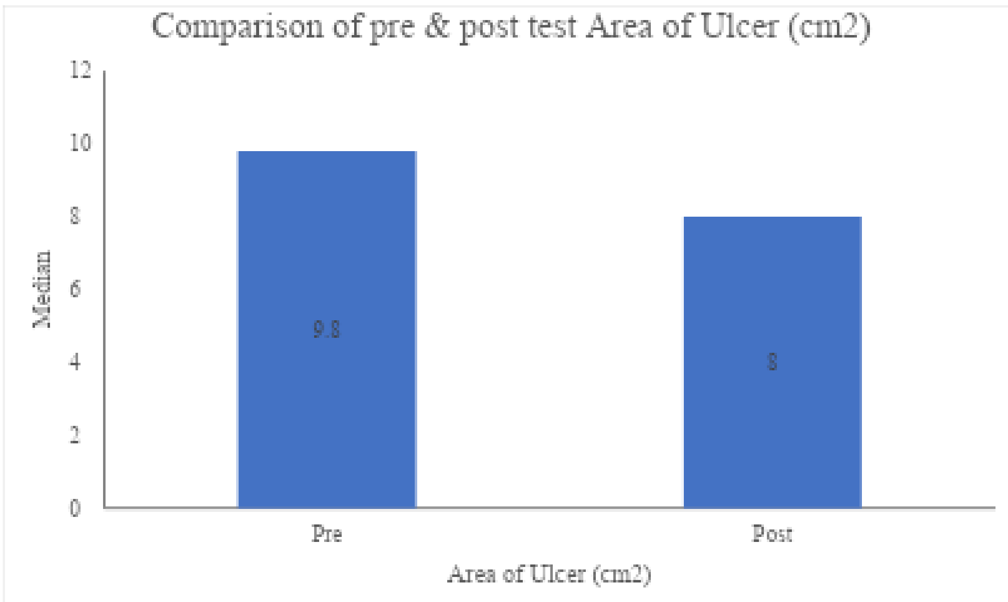

Figure 7- Comparison of pre & post test Area of Ulcer (cm^2)

A decrease in wound size was indicated by the median ulcer area, which went from 9.80 cm^2 (IQR = 19.2) prior to treatment to 8.00 cm^2 (IQR = 12.9) after treatment. The 30.77% decrease in ulcer area indicates a significant improvement after the intervention, and this reduction is statistically significant with a p-value < 0.05, confirming the treatment's efficacy in promoting ulcer healing.

Table 9: Comparison of pre & post test Wound-Qol Score

Wound-Qol Score	Mean	SD	Paired difference		t	p value
			Mean	SD		
Pre	38.364	7.167	9.273	8.625	6.176	<0.05*
Post	29.091	8.946				

*<0.05 significance is obtained by Paired t test

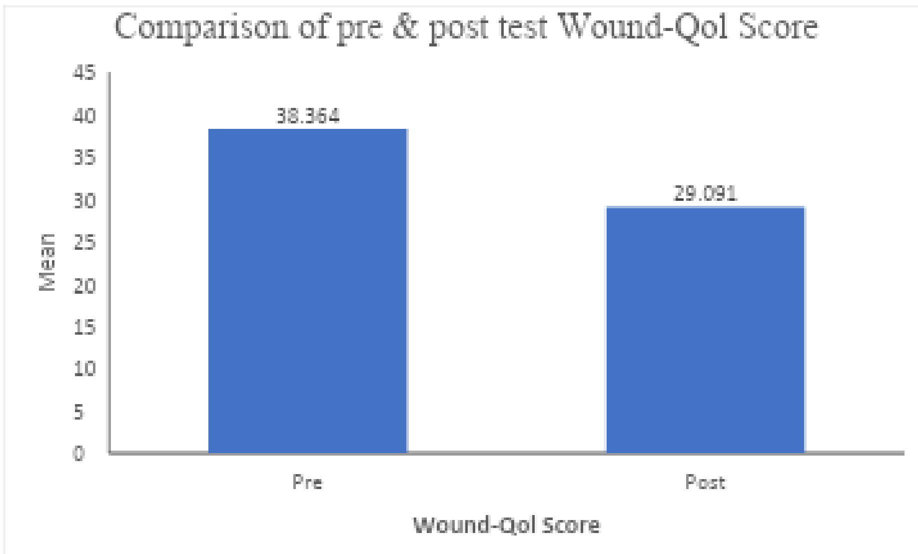

Figure 8- Comparison of pre & post test Wound-Qol Score

Prior to therapy, the mean Wound-QoL score, which measures quality of life related to wounds, was 38.364 (SD = 7.167); following treatment, it dropped to 29.091 (SD = 8.946). After the intervention, the paired difference of 9.273 (SD = 8.625) shows an increase in quality of life. A p-value of less than 0.05 and a t-value of 6.176 indicate that this improvement is statistically significant. These results demonstrate how therapy can improve patients' quality of life and lessen the burden that comes with ulcers.

DISCUSSION

Distribution of patients by Gender

In this study, a higher proportion of male patients (57.6%) presented with ulcers compared to females (42.4%). This is consistent with Reiber et al. and Jeffcoate & Harding, who reported that men are more commonly affected by diabetic foot ulcers, potentially due to greater exposure to risk factors and delays in seeking medical care [26][27].

Descriptive statistics of Age

The mean age of participants was 46.24 years. Callaghan et al. and Zubair et al. also reported that diabetic foot ulcers predominantly affect middle-aged to older adults, linking age with longer diabetes duration and cumulative vascular or neuropathic damage [28][34].

Distribution of patients by Cause of Ulcer

Diabetes mellitus was the leading cause of ulcers (78.8%) in this sample. This trend aligns with findings from Reiber et al., Jeffcoate & Harding, and Zubair et al., who identified diabetes as the primary etiology of lower limb ulcerations due to neuropathy, ischemia, and poor glycemic control [26][27][34]. Mulder et al. also emphasized the burden of diabetic ulcers and the need for advanced treatments in such populations [31].

Distribution of patients by SINBAD Grading

A considerable number of patients presented with advanced-stage ulcers (grade 6: 30.3%), highlighting delayed intervention. Jeffcoate & Harding and Zubair et al. observed similar trends in ulcer severity at initial presentation, noting poor wound prognosis without early and aggressive management [27][34]. Piaggesi et al.

emphasized the utility of structured wound assessment systems like SINBAD to guide therapy and predict healing outcomes [35].

Comparison of pre & post-test length of Ulcer

Ulcer length significantly decreased by 1.084 cm after treatment ($p < 0.05$). Naik et al., Rajendran, and Deshmukh & Sheth all documented measurable reductions in wound dimensions with Matrix Rhythm Therapy, attributing this to improved circulation and cellular regeneration [38][40][44]. Maiya et al. also reported notable wound contraction and healing in patients with diabetic neuropathy undergoing MaRhyThe® therapy [45]. These results complement Mulder et al., who demonstrated enhanced healing rates using advanced modalities [31].

Comparison of pre & post-test Width of ulcer (cm)

There was a significant reduction in ulcer width (mean difference = 0.686 cm, $p < 0.05$). Taspinar et al. showed that Matrix Rhythm Therapy improves local circulation and soft tissue elasticity, supporting wound healing [29]. These findings were echoed by Naik et al., Rajendran, Munjewar & Patil, and Maiya et al., who observed similar outcomes in wound shrinkage across various studies [38][40][42][45].

Comparison of pre & post-test Circumference of ulcer (cm)

The mean circumference reduced by 3.001 cm (18.42%, $p < 0.05$). Kwan et al. and Palmieri et al. highlighted the role of biophysical and electromedical therapies in reducing wound size through enhanced metabolic activity and local blood flow [37][39]. Deshmukh & Sheth and Maiya et al. reported similar shrinkage trends in ulcers following Matrix Rhythm Therapy [19][20].

Comparison of pre & post-test Area of Ulcer (cm^2)

A 30.77% reduction in ulcer area was noted ($p < 0.05$), supporting treatment efficacy. Case reports by Naik et al. and Rajendran documented significant area reduction with Matrix Rhythm Therapy [38][40]. Deshmukh & Sheth, Maiya et al., and Tiwatane et al. also noted improvements in healing and reduced wound dimensions in their respective analyses [44][45][48].

Comparison of pre & post-test Wound-QoL Score

There was a significant improvement in Wound-QoL scores (mean improvement = 9.273, $p < 0.05$). Reiber et al. and Zubair et al. emphasized the psychosocial burden of chronic ulcers and how healing improves quality of life [26][34]. Pickering and Maiya et al. demonstrated that therapeutic interventions not only promote physical healing but also contribute to mental and emotional well-being [43][45]. Auditto et al. further supported the integration of natural and physical therapies to holistically improve wound care outcomes [47].

CONCLUSION

This study aimed to evaluate the clinical efficacy of Matrix Rhythm Therapy (MaRhyThe®) in individuals suffering from chronic ulcers, most of which were diabetic in origin. Through a detailed assessment of patient demographics, ulcer etiology, severity grading, and objective wound healing parameters, the study offers robust evidence of the therapeutic benefits of MaRhyThe® in promoting tissue repair and improving patients' quality of life.

The gender distribution revealed a predominance of male patients, suggesting a possible behavioral or occupational predisposition in men. The average age of the cohort was in the mid-forties, which reflects the vulnerable age group often burdened with long-standing diabetes and its complications, including peripheral neuropathy and vascular compromise.

Diabetes mellitus emerged as the leading cause of ulceration, underscoring the need for aggressive screening, foot care education, and early intervention strategies in diabetic populations. The second most common cause was venous insufficiency. These findings reaffirm the importance of correctly identifying the underlying etiology for individualized management.

The SINBAD grading system provided a standardized way to assess ulcer severity. A significant portion of patients presented with advanced-grade ulcers, indicating delayed medical attention and poor initial wound care. This highlights a crucial gap in early recognition and management of chronic wounds, suggesting a need for enhanced awareness and timely referrals at the primary healthcare level.

Post-treatment analysis revealed statistically and clinically significant reductions across all wound size metrics. Ulcer length and width both showed considerable decreases, signifying notable tissue regeneration and wound contraction. The circumference and area of the ulcers also reduced substantially after therapy. These improvements are consistent with the physiological principles of Matrix Rhythm Therapy, which is believed to enhance circulation, reduce interstitial congestion, and restore rhythmic cellular oscillations, thereby creating a favorable environment for healing. Beyond physical wound parameters, the therapy also had a profound impact on patient-reported outcomes. Quality of life, as measured by the Wound-QoL scale, showed significant improvement following intervention. This change reflects not only physical relief but also emotional and psychological benefits that arise from reduced pain, increased mobility, and decreased dependency in daily life.

The functional and emotional recovery aspects observed post-therapy point toward the holistic nature of Matrix Rhythm Therapy. It serves as more than a localized treatment modality by addressing the systemic and psychosocial dimensions of chronic wound care. It is particularly relevant for individuals with chronic comorbidities, as it poses minimal risks and does not interfere with other medical treatments.

Overall, the outcomes from this study support the incorporation of Matrix Rhythm Therapy as a valuable adjunct in the multidisciplinary approach to chronic ulcer management. The therapy demonstrated strong potential in accelerating wound closure, improving functional independence, and enhancing the overall well-being of patients.

Nevertheless, while the results are promising, the study's sample size was limited. Future research involving randomized controlled trials with larger patient populations and long-term follow-up would be essential to further establish the clinical utility and standardize protocols for Matrix Rhythm Therapy in ulcer care. Additionally, exploring its application across different ulcer etiologies and patient demographics would help define its scope more precisely.

In conclusion, Matrix Rhythm Therapy appears to be a safe, non-invasive, and effective therapeutic option for patients with chronic ulcers. It addresses both wound healing and the broader psychosocial burden of living with long-term wounds, making it a valuable addition to contemporary wound management practices.

STRENGTHS OF THE STUDY

1. **Holistic Evaluation Approach**

One of the major strengths of this study is its comprehensive assessment methodology. It not only evaluated physical wound parameters (length, width, circumference, area) but also incorporated patient-reported outcomes like Wound-QoL scores, Functional Independence Measures (FIM), and pain scales. This provides a more complete understanding of treatment efficacy, encompassing both clinical and quality-of-life improvements.

2. **Use of Standardized Tools**

The study utilized well-established and validated tools for assessment such as the SINBAD grading system, Visual Analog Scale (VAS), Pressure Ulcer Scale for Healing (PUSH), and Wound-QoL. The use of these standardized metrics lends credibility to the findings and facilitates comparison with other studies.

3. **Clear Pre- and Post-Intervention Comparison**

By employing a paired analysis design, the study was able to effectively compare the patient's condition before and after the intervention. This approach strengthens the interpretation of treatment impact and helps isolate the specific effects of Matrix Rhythm Therapy.

4. **Focus on a Novel Therapy**

Matrix Rhythm Therapy is relatively under-explored in chronic wound management. This study contributes to growing literature by presenting practical evidence of its benefits. Highlighting a non-invasive, physiologically supportive treatment modality introduces new avenues for chronic ulcer care.

5. Clinical Relevance and Practical Application

The findings are directly applicable in clinical practice, especially in resource-limited settings where simple, safe, and cost-effective interventions are needed. The intervention showed improvements within a short time frame, which could translate into reduced healthcare costs and better patient outcomes.

6. Patient-Centered Outcomes

By incorporating quality of life and functional independence scores, the study aligns with modern healthcare goals that emphasize patient well-being and daily function alongside clinical healing.

LIMITATIONS OF THE STUDY

1. **Small Sample Size**

The study was conducted on a limited number of patients (n=33), which restricts the generalizability of the findings. A small sample size can increase the margin of error and reduce the power to detect subtle differences or variability across subgroups.

2. **Lack of a Control Group**

The absence of a control or placebo group makes it difficult to ascertain whether the observed improvements were due to Matrix Rhythm Therapy alone or if they could be attributed to other concurrent care elements such as wound dressing, antibiotics, or natural healing.

3. **Short Follow-Up Duration**

The study observed outcomes over a relatively short period. Long-term follow-up would be necessary to determine the sustainability of wound healing and functional improvements, and to monitor recurrence rates.

4. **Single-Centre Design**

Since the study was likely conducted in a single clinical setting, there may be biases related to patient selection, therapist technique, or institutional practices that limit external validity.

5. **Heterogeneity of Ulcer Etiology and Severity**

While most ulcers were diabetic, others were due to varicose veins, and the SINBAD grading showed varying severities. This heterogeneity, without subgroup analysis, makes it difficult to identify which specific patient groups benefit the most from the therapy.

6. **Lack of Blinding and Randomization**

As an observational or quasi-experimental study, it lacks randomization and blinding, making it susceptible to performance and observer bias. Patients and clinicians knew the intervention being administered, which might have influenced outcome reporting.

7. **Limited Exploration of Mechanism**

While clinical outcomes were reported, there was minimal discussion or measurement of physiological parameters (e.g., microcirculation, inflammation markers) to support the proposed mechanisms of Matrix Rhythm Therapy.

SUMMARY

This study evaluated the effectiveness of Matrix Rhythm Therapy (MaRhyThe®) in managing chronic ulcers among 33 patients. Most ulcers were diabetic in origin, and the average patient age was mid-forties, with a male predominance. Severity assessment using the SINBAD grading system revealed a high incidence of advanced-grade ulcers, pointing to delayed intervention.

The therapy led to significant reductions in ulcer length, width, circumference, and area, indicating accelerated healing. Quality of life also improved substantially, as evidenced by lowered Wound-QoL scores post-treatment. Patients experienced less pain, greater mobility, and enhanced independence in daily activities.

These results suggest that Matrix Rhythm Therapy is a beneficial adjunct to conventional wound care. Its non-invasive nature and positive impact on both physical and emotional aspects make it a promising tool in chronic wound management. However, larger studies with control groups are needed to confirm these findings and refine treatment protocols.

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ANNEXURE 1 - CONSENT FORM

KAHERs JNMC

BELAGAVI

.INFORMED CONSENT FORM

Title of study: Evaluating The Efficacy Of Matrix Rhythm Therapy In Chronic Lower Limb Ulcers: A Novel Approach To Wound Healing

Name of Student/Principal Investigator: __________________

Name of Guide/Co Investigators: ____________________

Introduction: Respected Sir/madam, we request you to participate in this study which uses a new physiotherapy machine which provides rhythmic vibrations and helps in healing of cells by improving blood circulation to the affected area and thus aims at improving your outcome.

Explanation of procedure: Along with the conventional dressings, you would be given three massage sessions of 60 minutes each, 3 days apart. This will be done with the help of a machine which will use a rod like structure for providing you massage around your wound area. You would be made to lie down in a comfortable position and your wound and surrounding area would be exposed. Talcum powder would be applied over your wound to prevent friction from the rod. Your wound will be assessed with the help of a mobile application and you will also be required to fill a questionnaire before and after the completion of the sessions. At any point during the procedure if you feel uncomfortable or wish to stop, you are free to convey so to the Doctor.

Withdrawal from participation in the study: Participation in this study is completely voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You would get benefitted by participating in this study. The size of your wound could significantly decrease after this therapy thus increasing your quality of life. Also, the data gathered will help population at large.

Possible risks from participating in the study: There are no known risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication**.**

Financial incentives: You will not receive any payment for participating in this study.

Cost of investigations done during the course of study will be paid by the principal investigator.

Authorisation for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purpose and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact:

If you have any question or complaints with regard to your right as study participant you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights

CONSENT STATEMENT

I am making a voluntary decision to participate in the study "EVALUATING THE EFFICACY OF MATRIX RHYTHM THERAPY IN CHRONIC LOWER LIMB ULCERS: A NOVEL APPROACH TO WOUND HEALING". My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature/left thumb impression of the participant:

Name of the witness:

Signature/left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

ANNEXURE - 2 PROFORMA

CASE NO:

NAME:

AGE / SEX:

ADDRESS:

IP NO:

UNIT/WARD:

CHIEF COMPLAINTS:

PAST HISTORY:

CLINICAL DIAGNOSIS:

INVESTIGATIONS:

(As per requirement)

PROCEDURE DETAILS:

(DATES OF SESSIONS OF

MATRIX RHYTHM THERAPY)

ANNEXURE 03- PHOTOGRAPHS

Category	Definition	SINBAD score
*S*ite	Forefoot	0
	Midfoot and hindfoot	1
*I*schemia	Pedal blood flow intact, one pulse palpable	0
	Clinical evidence reduced pedal blood flow	1
*N*europathy	Protective sensation intact	0
	Protective sensation lost	1
*B*acterial infection	None	0
	Present	1
*A*rea	Ulcer <1 cm^2	0
	Ulcer >1 cm^2	1
*D*epth	Ulcer confined to skin and subcutaneous tissue	0
	Ulcer reaching muscle, tendon, or deeper	1
Total possible score		0–6

Source: Adapted from Ince et al. (31).

Picture 1: SINBAD Score

Wound-QoL questionnaire on quality of life with chronic wounds

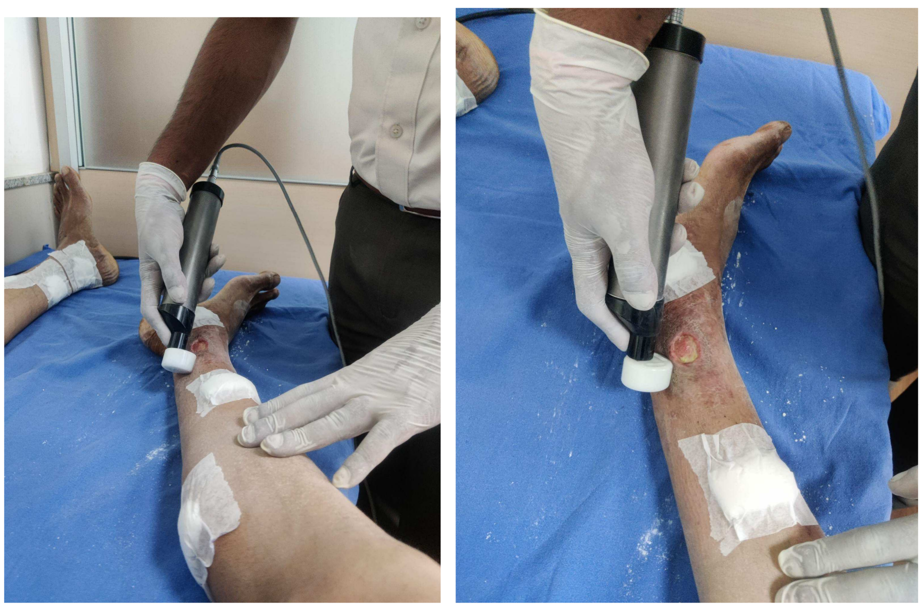
With the following questions, we aim to find out how your chronic wound(s) affect(s) your quality of life.

Please tick one box per line!

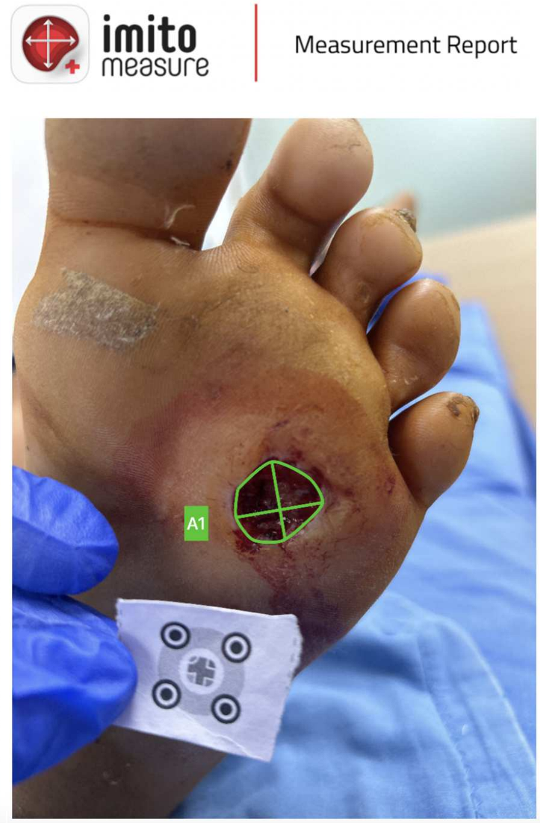
	In the last seven days …	**not at all**	**a little**	**moderately**	**quite a lot**	**very much**
1	…my wound hurt	O	O	O	O	O
2	…my wound had a bad smell	O	O	O	O	O
3	…there was a disturbing discharge from the wound	O	O	O	O	O
4	…the wound has affected my sleep	O	O	O	O	O
5	…the treatment of the wound has been a burden to me	O	O	O	O	O
6	…the wound has made me unhappy	O	O	O	O	O
7	…I have felt frustrated because the wound is taking so long to heal	O	O	O	O	O
8	…I have worried about my wound	O	O	O	O	O
9	…I have been afraid of the wound getting worse or of new wounds appearing	O	O	O	O	O
10	…I have been afraid of knocking the wound	O	O	O	O	O
11	…I have had trouble moving about because of the wound	O	O	O	O	O
12	…climbing stairs has been difficult because of the wound	O	O	O	O	O
13	…I have had trouble with day-to-day activities because of the wound	O	O	O	O	O
14	…the wound has limited my leisure activities	O	O	O	O	O
15	…the wound has forced me to limit my activities with others	O	O	O	O	O
16	…I have felt dependent on help from others because of the wound	O	O	O	O	O
17	…the wound has been a financial burden to me	O	O	O	O	O

Picture 2: Wound Qol Questionnaire

Picture 3: Matrix Rhythm therapy machine

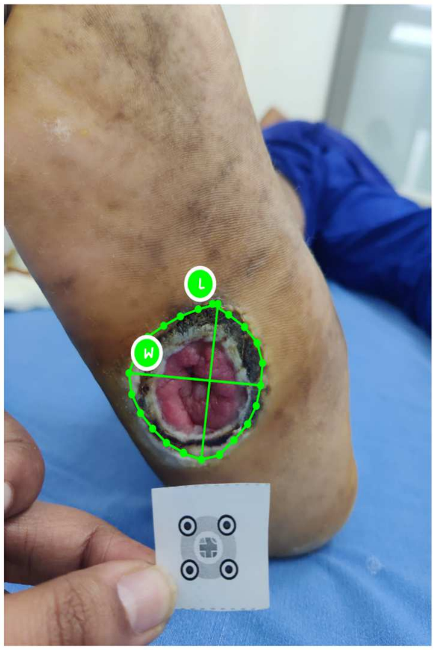


Picture 4: Procedure being carried out

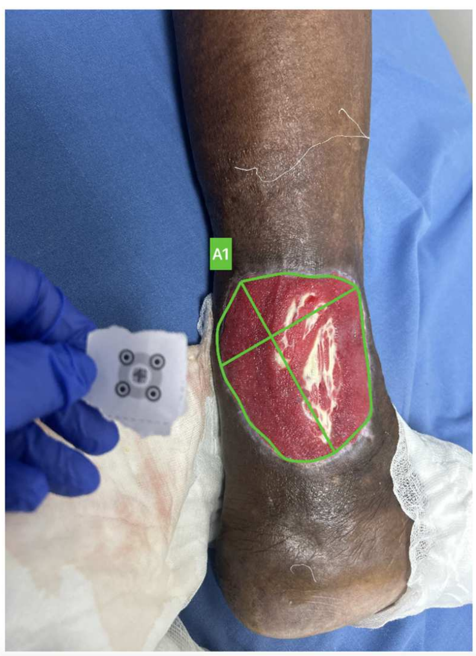


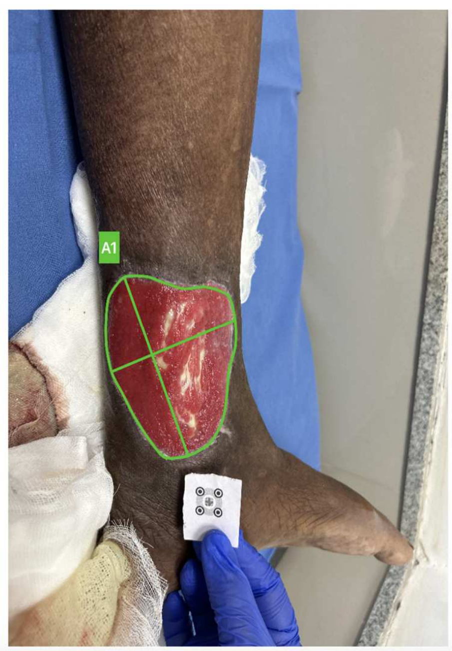
A1
Area: 15.8cm², **Circumference:** 15.8cm, **Length:** 6.4cm, **Width:** 3.6cm

A1
Area: 8.0cm², **Circumference:** 11.3cm, **Length:** 4.5cm, **Width:** 2.7cm


L
W


A1


A1


A1

Picture 5: Pre and Post Intervention Pictures of Ulcer

ANNEXURE 04 MASTER CHART

Sl. No.	IP No.	Age	Sex	Cause of ulcer	Length of Ulcer pre (cm)	Width of ulcer pre (cm)	Area of Ulcer pre (cm2)	Circumference of ulcer pre (cm)	Length- post	Width- post	Area- post (cm2)	Circumference- post (cm)	Reduction length	Reduction in width	Reduction in area (cm)	% Reduction in area	Reduction in circumference (cm)	% Reduction in circumference	SINBAD Grading (Total)	Wound-Qol Score (Pre)	Wound-Qol Score (Post)
1	10068149	58	Male	varicose	2.73	1.77	3.51	6.99	2.39	1.76	3.18	6.48	0.34	0.01	0.33	9.40	0.51	7.30	2	38	36
2	1184214	50	Male	varicose	2.6	1.7	3.4	7.1	2	1.1	1.7	5.4	0.6	0.6	1.7	50.00	1.7	23.94	0	43	29
3	10065187	38	Female	DM	4.8	1.1	3.9	11	4.7	0.7	2.7	10	0.1	0.4	1.2	30.77	1	9.09	4	46	41
4	10069676	29	Male	DM	3.4	1.3	3.6	8.1	2.9	1.4	2.6	7.1	0.5	-0.1	1	27.78	1	12.35	1	36	26
5	1171139	55	Female	DM	7	1	4.3	14.7	6.6	0.6	2	13.5	0.4	0.4	2.3	53.49	1.2	8.16	6	38	38
6	10057836	48	Male	DM	1.9	1.6	2.3	5.5	1.3	1.4	1.3	4.2	0.6	0.2	1	43.48	1.3	23.64	6	37	23
7	10057608	43	Male	DM	2.3	2	3.3	6.6	2	1.7	2.5	5.9	0.3	0.3	0.8	24.24	0.7	10.61	5	49	34
8	10117594	45	Female	DM	9.9	7.4	52.5	27.3	8.2	6	36.5	22.4	1.7	1.4	16	30.48	4.9	17.95	6	45	31
9	1175256	60	Male	DM	3.54	3.35	8.54	10.76	3.5	3.1	7.9	10.2	0.04	0.25	0.64	7.49	0.56	5.20	2	44	42
10	10084370	55	Female	DM	7.7	5.8	34	21.7	6.1	5	22.6	17.6	1.6	0.8	11.4	33.53	4.1	18.89	0	36	31
11	10114861	54	Female	DM	6.4	3.6	15.8	15.8	4.5	2.7	8	11.3	1.9	0.9	7.8	49.37	4.5	28.48	6	36	36
12	1178951	50	Male	DM	7.5	5.8	28.1	19.9	5.2	5	26	16	2.3	0.8	2.1	7.47	3.9	19.60	6	44	34
13	10121540	39	Female	varicose	3.6	2.1	5.8	24.8	3	1.6	3.6	20	0.6	0.5	2.2	37.93	4.8	19.35	1	35	26
14	1155242	48	Male	DM	5.23	6.6	34.5	23.65	4.8	5.9	28.3	21.3	0.43	0.7	6.2	17.97	2.35	9.94	1	47	44
15	10000028	47	Female	DM	3	2	6.1	10.1	1.9	1.2	2.5	6.2	1.1	0.8	3.6	59.02	3.9	38.61	3	49	21
16	1160980	42	Male	DM	5.4	3.4	9.4	14.2	3.3	2.5	4	9.1	2.1	0.9	5.4	57.45	5.1	35.92	4	31	16
17	10056033	57	Male	varicose	3.2	1.6	8	10	2.1	1	7.2	9.6	1.1	0.6	0.8	10.00	0.4	4.00	2	25	17
18	10043528	29	Female	DM	5.9	6.8	35.6	23.9	4	5.2	21	18.5	1.9	1.6	14.6	41.01	5.4	22.59	6	25	31
19	10050618	30	Male	DM	6	4.6	21.8	16.8	3.9	4	12.4	12.5	2.1	0.6	9.4	43.12	4.3	25.60	6	49	19
20	1204000	55	Male	DM	6.5	2.5	25	17.9	5.1	2.8	22.8	16.6	1.4	-0.3	2.2	8.80	1.3	7.26	0	49	31
21	10080787	57	Female	DM	4.3	3.4	14.3	14.2	3	2.6	6.1	11.6	1.3	0.8	8.2	57.34	2.6	18.31	3	44	38
22	10046743	49	Male	varicose	5	1.8	9.4	13.8	4.3	2	8.9	12.5	0.7	-0.2	0.5	5.32	1.3	9.42	4	37	31
23	10006127	41	Male	DM	5.9	3.3	27.3	21	4.5	1.4	16.5	15.4	1.4	1.9	10.8	39.56	5.6	26.67	3	33	30
24	10016216	44	Female	DM	8.1	6.9	28.2	24.3	3.6	3.5	15.3	18	4.5	3.4	12.9	45.74	6.3	25.93	5	31	27
25	10013343	37	Male	DM	6.9	4.5	15.6	19.1	6	3.7	11.2	16.3	0.9	0.8	4.4	28.21	2.8	14.66	4	31	16
26	10026780	56	Male	varicose	2.13	1.67	5.6	20.5	1.34	0.89	4	13	0.79	0.78	1.6	28.57	7.5	36.59	6	30	14
27	10050077	51	Female	DM	4	1.9	7.7	11.9	3.6	1.4	5	9.8	0.4	0.5	2.7	35.06	2.1	17.65	6	43	42
28	10016155	40	Male	DM	6.6	5	34.2	20.7	5.3	4.2	22	16.3	1.3	0.8	12.2	35.67	4.4	21.26	4	39	36
29	10101425	44	Female	DM	6.2	2.3	7.1	14.9	4.7	1.7	4	11.2	1.5	0.6	3.1	43.66	3.7	24.83	6	38	37
30	10025313	49	Male	DM	4.1	3	13.6	16	3.3	2.7	9.8	11	0.8	0.3	3.8	27.94	5	31.25	2	25	19
31	10080896	38	Female	DM	2.9	3.9	11.6	13.8	2.8	3	8.5	11.7	0.1	0.9	3.1	26.72	2.1	15.22	4	43	16
32	10039124	33	Female	DM	4.2	3.4	22.4	17.5	3.6	3.2	18	15.9	0.6	0.2	4.4	19.64	1.6	9.14	3	34	15
33	10119261	55	Male	varicose	3.6	2.7	9.8	12.6	3.2	2.2	8.2	11.5	0.4	0.5	1.6	16.33	1.1	8.73	4	36	33