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Effect Of Extracorporeal Shockwave Therpay On Diabetic Foot Ulcers- A Pilot Study

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Abstract: Introduction:
DFUs, or diabetic foot ulcers, are a prevalent problem in people with diabetes, contributing significantly to hospital admissions. The occurrence rate is around 25%, and if left untreated, these ulcers may lead to severe complications such as limb amputation and vascular disorders. ESWT or extracorporeal shockwave therapy has emerged as promising, non-intrusive approach promoting wound healing and minimizes pain in affected areas.

Objective:
The study aims to determine whether ESWT is beneficial for improving wound healing and reducing ulcer severity among diabetic individuals aged 40–74. The assessment tools utilized include the Wagner Ulcer Classification System, the ImitoMeasure Wound App, and the Bates-Jensen Wound Evaluation Instrument.

Methodology:
The preliminary investigation was carried out on ten individuals identified as having type 2 diabetes and DFUs persisting for more than three weeks. Before initiating the treatment, wound size—comprising length, width, area, and circumference—was measured using the ImitoMeasure Wound App. Ulcer grading was determined with the Wagner Ulcer Classification System, while healing progress, the Bates-Jensen Wound Assessment Tool was used to evaluate. Data were collected before and after each ESWT session.

Results:
A statistical analysis indicated a substantial improvement in wound characteristics, including size reduction and tissue regeneration, with a highly significant p-value of 0.001. The Bates-Jensen scores demonstrated enhanced healing outcomes.

Conclusion
The study's conclusions imply that ESWT is a useful therapeutic strategy for hastening the healing of diabetic foot ulcers.

Keywords: Foot ulcers caused by diabetes, extracorporeal shockwave therapy, wound healing, Bates-Jensen Wound Evaluation Instrument, Wagner Ulcer Grading system.

I. INTRODUCTION

Introduction:

Prolonged hyperglycaemia is the primary cause of diabetic foot ulcers (DFUs), which are a major cause of hospitalisations among diabetics. The condition poses a high risk of complications, including infections and lower limb amputations. Studies suggest that approximately 25% of diabetic individuals develop DFUs at some stage in their lifetime. The increasing global prevalence of diabetes further escalates the incidence of such complications.

DFUs arise due to prolonged exposure to elevated blood sugar levels, leading to skin breakdown and impaired wound healing. Some ulcers remain superficial, whereas others penetrate deeper layers of the skin. Factors such as neuropathy, vascular impairment, and infections exacerbate these ulcers, impacting mobility, daily activities, and overall quality of life.

In India, the prevalence of DFUs is rising in both urban and rural settings, with approximately 85% of diabetes-related amputations resulting from untreated foot ulcers. Conventional wound care methods enable only about 30% of DFUs to heal within a 20-week period. Alternative therapies such as ESWT, hyperbaric oxygen therapy, and tissue-engineered skin substitutes have been explored to enhance healing outcomes.

Acoustic waves are used in ESWT, a non-invasive therapeutic technique, to promote tissue repair. ESWT was first used to treat kidney stones and musculoskeletal disorders, but its ability to heal wounds has recently drawn attention. By altering biochemical pathways and hastening tissue regeneration, the technique has demonstrated promise in reducing pain. ESWT may offer a feasible treatment option for chronic wounds, including DFUs, according to clinical research.

Study Design and Participants:

KLES Dr. Prabhakar Kore Medical Research Centre and Hospital in Belagavi was site of this investigation. Participants were individuals aged 40–75 diagnosed with DFUs and controlled diabetes (HbA1C <7.5%). Patients with severe infections, deep vein thrombosis, or contraindications to ESWT were excluded.

Evaluation and Outcome Measures:

Twenty patients were initially screened, out of which 10 met the eligibility criteria. The ImitoMeasure Wound App was used to determine ulcer size and dimensions. Tissue healing was evaluated using the Bates-Jensen Wound Assessment tool, and ulcer severity was categorised using the Wagner Ulcer Classification System.

Procedure:

Participants received ESWT in either a supine or prone position, based on ulcer location. Before delivering shockwaves with an energy density of 0.25 mJ/mm2, an ultrasound gel was applied. There were at least five hundred shocks around the wound margin and 1,000 directed distally, with number of impulses varying based on the size of the wound. For a week, there were three weekly treatment sessions, each lasting two to five minutes.

Following ESWT, wounds were reassessed, and standard wound care practices—such as the application of silver sulfadiazine cream, saline cleansing, and pressure offloading—were maintained.

ANALYSIS OF STATISTICS:

SPSS 23 was utilised for data analysis. The distribution's normality was assessed using the Shapiro-Wilk test. Pre- and post-treatment outcomes were contrasted utilising a paired t-test, where $p < 0.05$ is the threshold for statistical significance because the dataset had a normal distribution.

ETHICAL APPROVAL:

Human use-related research has been granted by the Research and Ethical Committee of Karnataka, India's KLEU Institute of Physiotherapy Belagavi and has complied with all applicable national regulations and institutional policies. It has also followed the Declaration of Helsinki's tenets.

Consent that is informed: The study's participants provided their informed consent.

RESULTS: A normal distribution of the data was confirmed by the Shapiro-Wilk test. Significant gains in wound area, length, width, circumference, and overall healing progress were found by a paired t-test analysis.

PARAMETERS	Z- Value	p-Value
AREA(Cm2)	0.869	0.096
LENGTH	0.901	0.222
WIDTH	0.946	0.621
CIRCUMFERENCE	0.973	0.920
BWAT SCORE	0.874	0.112

The purpose of the paired sample t test is to determine the effect within the group because the collected data is not normally distributed. In the study, $P < 0.05$ was deemed statistically significant (CI 95%)

Fig 1 comparison of Area(cm2) before and after

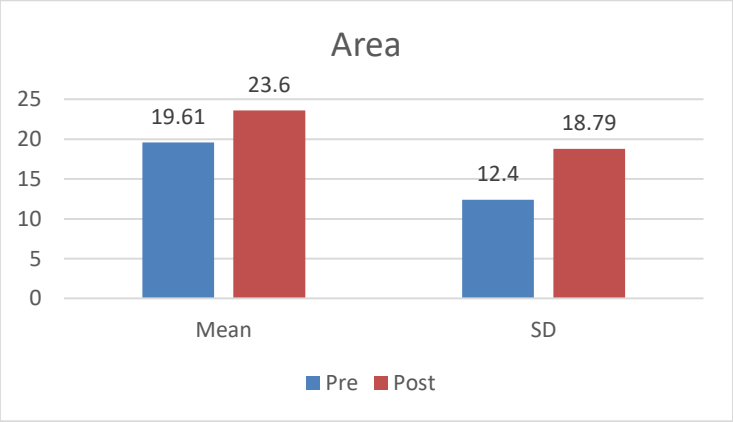


Fig 2: Width using the paired sample t test before and after

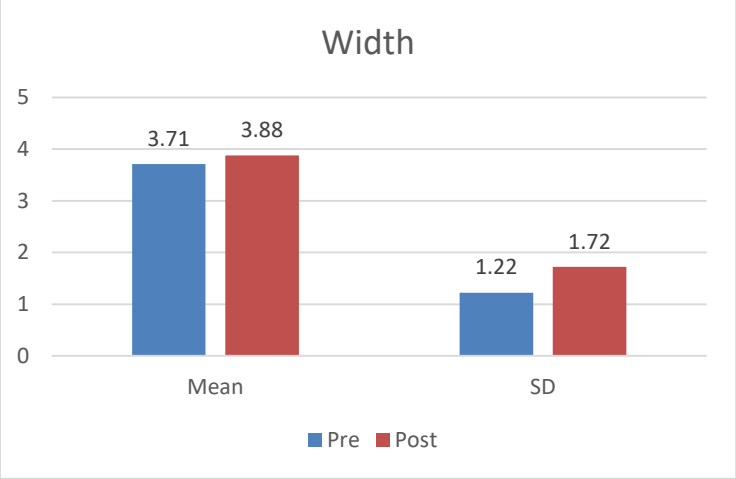


Fig 3: The paired sample t test is used to compare the length pre-test and post-test results.

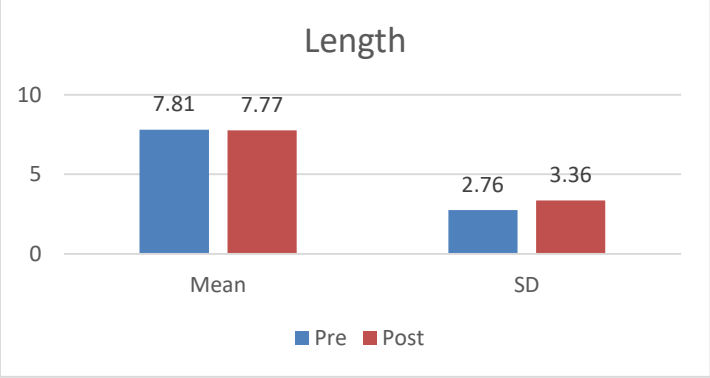


Fig 4: Using the paired sample t test, compare the results of the circumference pre-test and post-test.

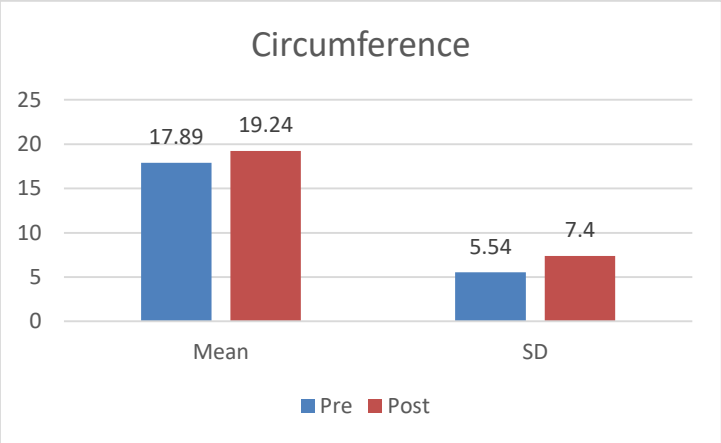
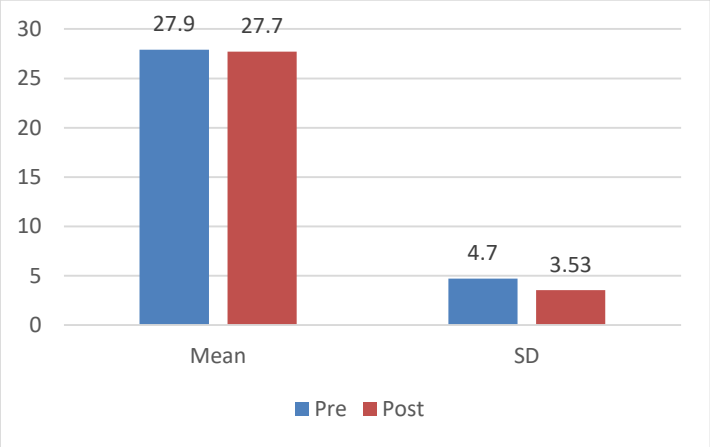


Fig 5: Utilising the paired sample t test to compare the Bates Jensen Wound Assessment Tool before and after



DISCUSION:

The purpose of the study was to assess how Extracorporeal Shockwave Therapy (ESWT) affected diabetic foot ulcers in people aged 40 to 74. Extracorporeal shockwave therapy may help patients with diabetic foot ulcers (DFU) in terms of wound characteristics, ulcer grade, and ulcer tissue recovery.

A high blood glucose level impairs the inflammatory system's capacity to fight off infection and diabetic conditions are more likely to develop into ischaemic conditions due to a decrease in blood perfusion. Among these is the dysfunction of diabetic wound microcirculation. [6,37] Many DFU patients experience endothelial cell dysfunction due to a decrease in vasodilators like nitric oxide, which ultimately leads to decreased microcirculation. DFU is a wound that is difficult to treat medically because it is chronic or non-healing.

Over time, extracorporeal shock wave therapy (ESWT) has gained recognition as a state-of-the-art wound-healing procedure. ESWT generates shearing forces in tissues by means of mechano-transduction. Blood flow and tissue regeneration will be enhanced by cellular production of growth and proliferation factors associated with angiogenesis, including nitric oxide synthesis (eNO.S), proliferative cell nuclear antigen (PCNA) and vessel endothelial growth factors (VEGF) Yang et al. found that ESWT application enhances the proliferation of human dermal fibroblasts in vitro and that following the application of ESWT, more fibroblasts were migrating to the diabetic wound site.

Based on prior research and hypotheses, shockwave therapy can improve blood supply by speeding microcirculation and revascularisation, which is the most likely explanation for the faster healing rate of diabetic foot ulcers after shockwave therapy. Extracorporeal shockwave therapy has been shown to stimulate cell proliferation, increase blood flow, and induce neovascularisation by activating vascular endothelial growth factor, proliferating cell nuclear antigen, and endothelial nitric oxide synthase. A pig model of chronic

myocardial ischaemia shows improved cardiac function and myocardial perfusion when ESWT is administered. Additionally, it may lessen the flaps' ischaemic zone by boosting tissue perfusion and reducing inflammation.

Additionally, shock waves trigger the release of multiple mediators, such as insulin-like growth factor-1 and transforming growth factor beta-1. These mediators increase the recruitment of skin fibroblasts and trigger a well-controlled inflammatory response, which aids in wound healing, especially chronic wounds. According to Moretti et al., the release of neurotrophic cytokines, enhanced peripheral circulation, inhibition of oxygen radicals, and anti-inflammatory effect have all been proposed a possible mechanism. Schaden et al. reported in 2005 that 102 patients, 104 of whom had chronic foot ulcers, received treatment for skin lesions using ESWT. No adverse side effects were observed, and 74% of patients fully recovered.

Studies show that ESWT is superior to traditional wound care. ESWT was associated with 190 better full healing and a shorter recovery period, according to the combined 189 effect size from Omar (2014) and Moretti (2009). ESWT causes shearing forces in tissues by acting as a mechano-transduction. By generating angiogenesis-related growth and proliferation factors at the cellular level, such as proliferative cell nuclear antigen (PCNA), vessel endothelial growth factors (VEGF), and nitric oxide synthesis (eNOS), this will enhance blood flow and tissue regeneration.

According to a study by Kue et al., the right amount of ESWT may influence fibroblast recruitment and encourage tissue remodelling. Additionally, the ESWT application promoted cell proliferation, reduced cell apoptosis, and markedly increased the topical blood flow perfusion rate. These results clearly indicated that ESWT enhances tissue regeneration.

According to Wang et al., Arno et al., and Kuo et al., one of the additional anticipated elements that promotes quicker healing of wound due to the anti-inflammatory effect of shock waves. This is because several investigations have shown that shock waves produce sufficient energy to induce controlled inflammation of the targeted tissue. It has been shown that this inflammation stimulates a variety of mediators, such as insulin-like growth factor 1 (CGF-I) and transforming growth factor beta 1 (TGF-B1). Additionally, it promotes the recruitment of skin fibroblasts, decreases tissue apoptosis and leukocyte infiltration, and starts the healing process. This is because the expression of oxygen radical synthesis is down-regulated.

Ulcer epithelialisation is markedly accelerated by ESWT (17, 19). Shockwave therapy has not been shown to have a detrimental effect on healing, and no studies have documented technical issues or complications.

LIMITATIONS:

The fact that the current study recruited more participants based on their gender was one of its limitations.

CONCLUSION:

According to the study's findings, participants with diabetic foot ulcers between the ages of 45 and 75 benefit from three ESWT sessions. The ulcer grading score, ulcer tissue healing score, and wound characteristics have all significantly decreased. ESWT can therefore be regarded as the preferred course of treatment for diabetic foot ulcers that do not heal.

STATEMENT OF DISCLOSURE:

No author has a financial stake in this study or has benefited financially from it.

FINANCES:
No funding was obtained for current study.

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