

**Effect of Mechanical Vibration Therapy on Healing of Foot Ulcer in Diabetic Polyneuropathy Patients.**Hesham G. Mahran<sup>1</sup>, Omar Farouk Helal<sup>2</sup>, Amir Abdel-Raouf El Fiky<sup>3</sup><sup>1</sup>. Department of Physical Therapy for Surgery, Faculty of Physical Therapy, Cairo University, Egypt.<sup>2</sup>. Physical Therapy Department, Faculty of Applied Medical Sciences, Umm Al Qura University. KSA.<sup>3</sup>. Department of Physical Therapy for Neurological Disorders and its Surgery, Cairo University. Egypt.[dr.mon5@hotmail.com](mailto:dr.mon5@hotmail.com).

**Abstract:** Diabetic foot complications are the most common cause of non-traumatic lower extremity amputations in the industrialized world. The risk of lower extremity amputation is higher in diabetics than in persons who do not have diabetes mellitus. Furthermore, foot complications are the most frequent reason for hospitalization in patients with diabetes. Diabetic neuropathy is the impact of diabetes on the nervous system, most commonly causing numbness, tingling and pain in the feet and also increasing the risk of skin damage due to altered sensation. Together with vascular disease in the legs, neuropathy contributes to the risk of diabetes-related foot problems (such as diabetic foot ulcers) that can be difficult to treat and occasionally require amputation. Early detection and appropriate treatment of these ulcers may prevent up to 85 percent of amputations. **Purpose:** To detect the effect of low mechanical vibration on healing of diabetic foot ulcer. **Methods:** Twenty nine diabetic patients with type 2 diabetes (21 males and 8 females) suffer from diabetic ischemic foot ulcer (grade A1) will be divided into 2 groups; 1st study group received low mechanical vibration for 15 minutes for session, 3session/day, 5day/week for 4 weeks and control group received no treatment. Assessment of wound size (length, width and area) by Visitrak device for both groups was done 3 times as follow; 1st assessment done before assessment, the 2nd assessment was done 2 weeks after the beginning of treatment and the 3rd assessment was done 4 weeks after beginning of treatment. **Results:** In study group; there was significant difference between pre- treatment mean value of ulcer area and two weeks post- treatment mean value of ulcer area as *p* value .019, there was significant difference between two weeks mean value of ulcer area and four weeks post- treatment mean value of ulcer area as *p* value 0.014, and there was significant differences between pre- treatment mean value of ulcer area and four weeks post- treatment mean value of ulcer area as *p* value .032. Between groups; there was significant difference between the study and control groups in mean value of ulcer areas after two weeks of treatment as *p* value 0.014, and there was highly significant difference between the study and control groups in mean value of ulcer area after four weeks of treatment *p* value 0.008. **Conclusion:** It can be concluded that low mechanical vibration may improve healing of diabetic foot ulcer. [Mahran HG, Helal OF, El-Fiky AA. **Effect of Mechanical Vibration Therapy on Healing of Foot Ulcer in Diabetic Polyneuropathy Patients.** *J Am Sci* 2013;9(7):76-87]. (ISSN: 1545-1003). <http://www.jofamericanscience.org>. 8

**Key words:** (diabetic polyneuropathy, foot ulcer, mechanical vibration).**1-Introduction:**

Diabetes mellitus, or simply diabetes, is a group of metabolic diseases in which a person has high blood sugar, either because the body does not produce enough insulin, or because cells do not respond to the insulin that is produced. This high blood sugar produces the classical symptoms of polyuria (frequent urination), polydipsia (increased thirst) and polyphagia (increased hunger). All forms of diabetes increase the risk of long-term complications (David G. and Gardner, 2011).

The major long-term complications relate to damage to blood vessels. Diabetes doubles the risk of cardiovascular disease. The main "macrovascular" diseases (related to atherosclerosis of larger arteries) are ischemic heart disease (angina and myocardial infarction), stroke and peripheral vascular disease. Diabetes also damages the capillaries (causes micro angiopathy). Diabetic neuropathy is the impact of

diabetes on the nervous system, most commonly causing numbness, tingling and pain in the feet and also increasing the risk of skin damage due to altered sensation. Together with vascular disease in the legs, neuropathy contributes to the risk of diabetes-related foot problems (such as diabetic foot ulcers) that can be difficult to treat and occasionally require amputation (Boussageon, 2011).

The vast majority of diabetic foot complications resulting in amputation begin with the formation of skin ulcers. Early detection and appropriate treatment of these ulcers may prevent up to 85 percent of amputations. Careful inspection of the diabetic foot on a regular basis is one of the easiest, least expensive and most effective measures for preventing foot complications (Bethesda, 1987).

Diabetic foot ulcers result from the simultaneous action of multiple contributing causes. The major underlying causes are noted to be

peripheral neuropathy and ischemia from peripheral vascular disease (Kelkar, 2006).

More than 60% of diabetic foot ulcers are the result of underlying neuropathy. The development of neuropathy in affected patients as a result of hyperglycemia-induced metabolic abnormalities. The accumulation of sugar products results in a decrease in the synthesis of nerve cell myoinositol, required for normal neuron conduction. Additionally, the chemical conversion of glucose results in increasing oxidative stress on the nerve cell and an increase in vasoconstriction leading to ischemia, which will promote nerve cell injury and death (Zochodone, 2008).

Neuropathy in diabetic patients is manifested in the motor, autonomic, and sensory components of the nervous system. Damage to the innervations of the intrinsic foot muscles leads to an imbalance between flexion and extension of the affected foot. This produces anatomic foot deformities that create abnormal bony prominences and pressure points, which gradually cause skin breakdown and ulceration. Autonomic neuropathy leads to a diminution in sweat and oil gland functionality. As a result, the foot loses its natural ability to moisturize the overlying skin and becomes dry and increasingly susceptible to tears and the subsequent development of infection (Bowering, 2001).

The loss of sensation as a part of peripheral neuropathy exacerbates the development of ulcerations. As trauma occurs at the affected site, patients are often unable to detect the insult to their lower extremities. As a result, many wounds go unnoticed and progressively worsen as the affected area is continuously subjected to repetitive pressure and shear forces from ambulation and weight bearing (Dyck et al., 1999).

Peripheral arterial disease (PAD) is a contributing factor to the development of foot ulcers in up to 50% of cases. It commonly affects the tibial and peroneal arteries of the calf. Endothelial cell dysfunction and smooth cell abnormalities develop in peripheral arteries as a consequence of the persistent hyperglycemic state. This is leading to constriction. Furthermore, the hyperglycemia in diabetes leads to an increased risk for plasma hypercoagulability. There is also the potential for alterations in the vascular extracellular matrix leading to stenosis of the arterial lumen. Moreover, smoking, hypertension, and hyperlipidemia are other factors that are common in diabetic patients and contribute to the development of PAD, this leads to occlusive arterial disease that results in ischemia in the lower extremity and an increased risk of ulceration in diabetic patients (Paraskevas et al., 2008).

The description foot ulcer should include characteristics of the ulcer, including size, depth, appearance, and location. There are many classification systems used to depict ulcers that can aid in developing a standardized method of description. These classification systems are based on a variety of physical findings. One of the most popular systems of classification is the Wagner Ulcer Classification System, which is based on wound depth and the extent of tissue necrosis. Several authors have noted a disadvantage of this system in that it only accounts for wound depth and appearance and do not consider the presence of ischemia or infection (Frykberg, 2002).

The University of Texas system is another classification system that addresses ulcer depth and includes the presence of infection and ischemia. Wounds of increasing grade and stage are less likely to heal without vascular repair or amputation (Oyibo et al., 2001).

The health effects of occupational vibration are heavily dependent on the characteristics of the vibration exposure (e.g. vibration frequency, direction and amplitude). Indeed, brief exposure to low magnitude mechanical vibration may have a number of benefits particularly with respect to enhancing local muscle blood flow (Kittusamy et al., 2004).

Researchers have been intrigued by the physiological response of humans to vibration for some time, and recently great attentions directed to the use of vibration in relation to its potential as a non-pharmacological means to improve peripheral blood flow (Bethesda, 1987).

In a study, done by **Mathiesen et al. (1984)** a vibration frequency of 45 Hz for 5–7 min was sufficient to cause significant increases in calf blood flow of up to 46% as measured by strain gauge plethysmography. They concluded that plantar vibration enhances venous drainage as well as peripheral blood flow and lymphatic flow (Mathiesen et al., 1985).

## 2- Methods:

The study was a randomized, controlled trial. Experimental group and control group were treated from October 2012 to march 2013.

**Subjects:** Twenty nine patients with diabetic ischemic foot ulcers (Eight females and twenty one males) recruited from Kasr El Aini Hospital, Cairo University were included in the study. Their ages ranged from 50-70 years.

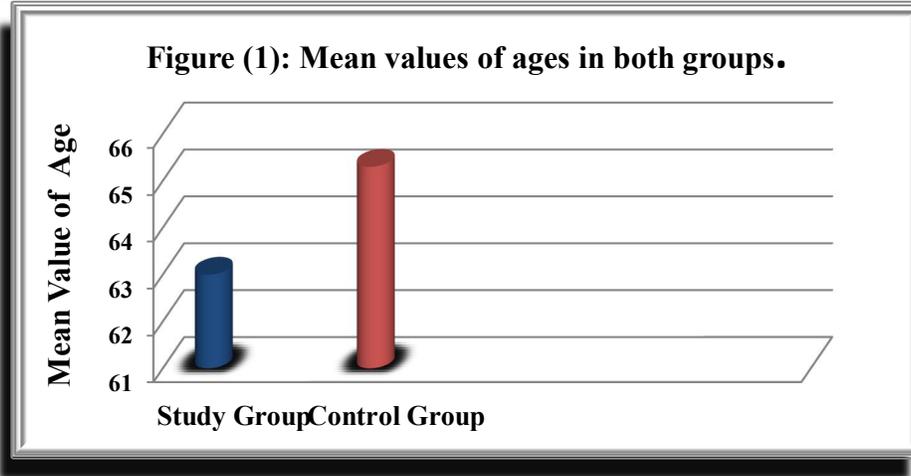
Patients were randomly assigned to experimental (Study) group, consisted of 15 patients and control group consisted of 14 patients.

The age mean was 63.00 + 7.28 years in the study group and 65.33 + 8.21 years in the control group and there were no significance difference

between both group in mean of age as ( $P > 0.05$ ) as shown in table and figure (1).

**Table (1):** Mean age difference between study and control group ( $p > 0.05$ ).

Group	NO. of patients	Mean of age	SD	Std. Error Mean.	P (value).
Study	15	63.00 (years).	7.28	3.25	0.967
Control	14	65.33 (years).	8.21	3.35	$P > 0.05$



**Inclusion criteria:** The duration of ulcer development was up to 12 months. Ulcers included were grade 1A, based on the University of Texas Diabetic Foot Ulcer Classification System (Armstrong et al, 1998) (Table 2).

**Table (2):** The University of Texas Diabetic Foot Ulcer Classification. As you move across the X axis (depth) and down the Y axis (stage), the risk of amputation increases.

The University of Texas Diabetic Foot Ulcer Classification				
	0	1	2	3
	Pre or Post Ulcerative Lesion	Superficial Wound into Dermis	Through Dermis to Subcutaneous Tissue, Muscle, Tendon, or Capsule	Penetrates to Bone
<b>A</b>	Not Infected or Ischemic 0%	Not Infected or Ischemic 0%	Not Infected or Ischemic 0%	Not Infected or Ischemic N/A
<b>B</b>	Infected 12.5%	Infected 8.5%	Infected 28.6%	Infected 92%
<b>C</b>	Ischemic 25%	Ischemic 20%	Ischemic 25%	Ischemic 100%
<b>D</b>	Infected and Ischemic 50%	Infected and Ischemic 50%	Infected and Ischemic 100%	Infected and Ischemic 100%

The sites of ulcers in patient's feet varied being in the lateral plantar 5<sup>th</sup> ray, big toe, heel, medial and lateral malleolus, and dorsum of the foot or the hallux. All patients were non weight bearing.

The level of sugar in blood was ranged from 120 to 130 mg /dl fasting and 170 to 180 mg /dl after meals, according to diet protocol of hospital and the all patients had the same calories intake and all the patients were well controlled regarding diabetes mellitus type II (insulin injection).

In the entire study sample, the levels of total serum protein in blood plasma were within normal range as it ranged from 60-80g/dl.

The Mean BMI (SD) was **25.3 (1.5)** Kg/m<sup>2</sup> in the study group and **26.2 (1.9)** Kg/m<sup>2</sup> in the control group and there was no significant difference between both group in mean of BMI as ( $P > 0.05$ ) as shown in Table (3).

**Table (3) show:** Mean values of (BMI) difference between study and control group ( $p > 0.05$ ).

BMI (kg/m <sup>2</sup> )	Mean (SD).	P (value)
Study group	25.3 (1.5)	0.273
Control group	26.2 (1.9)	>0.05

The purpose of the study and the testing protocol to be used were explained to the subjects. All patients were given their written voluntary informed consent before participation.

**Exclusive criteria:** Subjects were excluded if they had history of deep venous thrombosis, and hemorrhage in ulcer or did not complete their treatment. Medications that affect healing such as corticosteroid or vascular disorders not related to DM that can affect wound healing.

#### Instruments:

1- **The Mechanical vibrator** (Rela Wave; Matsuda Micronics Corp, Chiba, Japan) was developed in collaboration with Matsuda Micronics Corporation. The size of the vibrator was 616 x 182 x 114 mm (length x width x height), and the intensity, amplitude modulation cycle, and vibration time could be adjusted using the attached controller (Figure 2).



**Figure 2:** Vibrator device

The operation of its controls was quite easy. Each patient was issued a vibrator for his/her exclusive use during the study period.

The frequency and horizontal vibration acceleration of the present vibrator was 47 Hz and 1.78 m/s, respectively, based on the authors' previous studies.

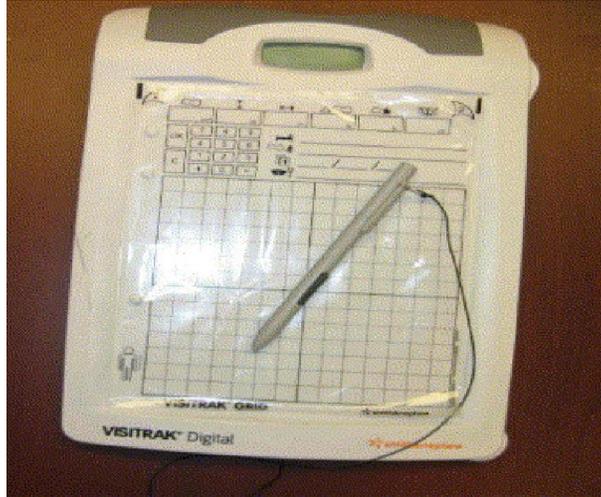
According to the Recommendations of Occupational Exposure Limits, at a frequency of 50 Hz and a vibration time of 16 minutes, the vertical and horizontal vibration acceleration should be 13.2 or less and 37.5 m/s, respectively. Hence, the specifications of the present vibrator are within the allowable range, and therefore, its safety is ascertained.

#### 2- Visitrak:

Digital planimetry is a measurement tool that provides a visible record of the dimensions of a wound. It enables the measurement of surface area, length, width, and amount of viable and non-viable tissue. It can also be used to calculate the % surface area change, from the last wound area measurement.

#### Visitrak features:

Shipping Weight: 5 pounds, ASIN: B009UMYREE, Smith & Nephew Medical Instruments and Equipment, United Kingdom (Figure3).



**Figure 3: Visitrak digital device**

### **Intervention:**

A brief questionnaire was introduced to obtain each subject's medical history. Subjects were questioned regarding the history of their disease, type of diabetes, duration of diabetes, and site of ulcer. Both groups received similar nurse wound care and medical treatment and to maintain moist environment without any granulation stimulation produce such as collagen or hormone.

In the experimental group, vibration was applied for 15 minutes three times a day, five days/week for one month. The vibrator was located underneath the ulcerated foot, as feet rested on cushion placed over vibrator.

On the first day of the intervention, one of the researchers checked by hand to ensure that vibration reached the patient's skin. The therapy was not given within two hours after meals, and the interval between therapies was set at two hours or longer.

Assessment of wounds by using Visitrak device was done 3 times in following manner; 1st assessment was done at the beginning of treatment, 2<sup>nd</sup> assessment was done two weeks after beginning of treatment and the 3<sup>rd</sup> assessment was done Four weeks after the beginning of treatment.

### **Procedures of measurement**

1. Insert the batteries.
2. Switch on.
3. Remove white backing paper from Visitrak Grid
4. Place the grid area over the wound. Position the top of the grid toward the patients head.
5. Trace around the edge of the wound using a fine point permanent marker.
6. If the wound is too large to fit within the grid area of one tracing grid, overlap two grids and trace the wound across both grids.

7. Remove the contaminated wound contact layer from the tracing grid and dispose as clinical waste.
8. Place the tracing grid on the tablet – placing the holes over the pegs. If available, place the coversheet on top of the tracing grid and secure over the pegs on tablet.
9. Place the stylus at a point on the wound tracing and press the switch on the stylus and wait until the tracing symbol appears in the display.
10. Trace around the wound outline, without lifting the stylus.
11. The tablet will “beep” When the tracing is complete, and display the area measurement on the digital display.

### **Statistical Analysis:**

The results of this study were analyzed using SPSS. V.16 program as means, standard deviation and comparing means between groups and within groups using independent t- test and paired t-test respectively are calculated.

### **3- Results:**

Twenty nine patients with diabetic ischemic foot ulcers were recruited to the present study (Eight females and twenty one males). Patients were randomly assigned to experimental group, consisted of 15 patients and control group consisted of 14 patients.

The sites of ulcers in patients' feet varied being in the lateral plantar 5<sup>th</sup> ray, big toe, heel, medial and lateral malleolus, and dorsum of the foot or the hallux.

**Table (4):** show mean values of length, width and area of foot ulcer in both groups:

Group	Mean of ulcer length	Mean of ulcer width	Mean of ulcer area
Study group	1.4 cm.	1.95 cm	2.63 cm <sup>2</sup>
Control group	1.5 cm.	3.02 cm	4.08 cm <sup>2</sup>

**I) Within study group:**

Ulcers in eight patients were completely healed (53.0%); three ulcers healed at the end of two weeks and five healed after 4 weeks.

**Figures (4)** (A and B) show the ulcer size before and after the treatment.

(A)- Complete healing:



Figure 4(A) (Before treatment)

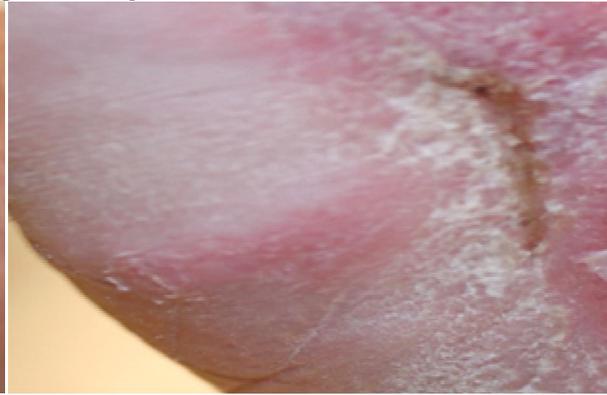


Figure 4(A) (After treatment)

B) - Approximately healed



Figure 4(B) (Before treatment)



Figure 4(B) (After treatment)

As shown in table (5) and figure (5) there was high significant differences between pre- treatment and two weeks post- treatment mean values of ulcer area, as p (0.019). The mean value of area of ulcer and S.D. before treatment was  $2.63 \pm 3.084$ , while the mean value of area of ulcer two weeks after treatment was  $1.10 \pm 1.01$ .

**Table (5):** Comparison between pre-treatment and 2weeks post-treatment within study group regard to VISTRİK measurement of ulcer area.

Visitrak Measurement of Ulcer Area	Study group		P- value	t-value
	Pre-treatment	2weeks post-treatment		
Mean $\pm$ SD	2.63 $\pm$ 3.08	1.10 $\pm$ 1.01	0.019**	1.67

\*\*High significant

Also, there was high significant difference between two weeks post- treatment mean value of ulcer area and four weeks post- treatment mean value of ulcer area as  $p$  (0.014) as shown in table (6) and figure (5).

**Table (6):** Comparison between the 2 weeks post-treatment and 4weeks post-treatment values within the study group regard to Vistrak measurement of ulcered area.

Vistrak measurement of Ulcer Area	Study group		P-value	t-value
	2weeks post-treatment	4weeks post-treatment		
Mean $\pm$ SD	1.10 $\pm$ 1.01	0.56 $\pm$ 0.82	0.014**	2.931

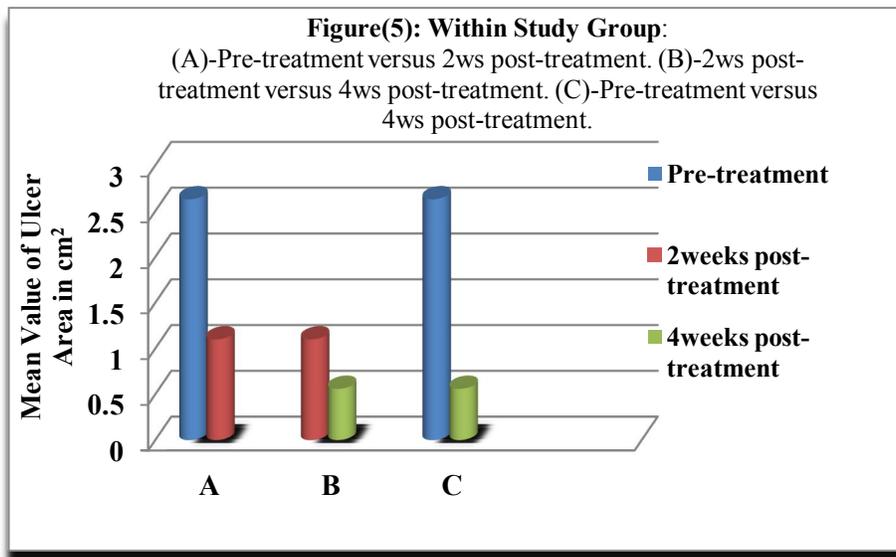
\*\*High significant.

As shown in table (7) and figure (5) there was significant differences between pre- treatment mean value of ulcer area and four weeks post- treatment mean value of ulcer area as  $p$  (0.032).

**Table (7):** Comparison between pre-treatment and 4weeks post-treatment within study group regard VISTRİK measurement of ulcer area

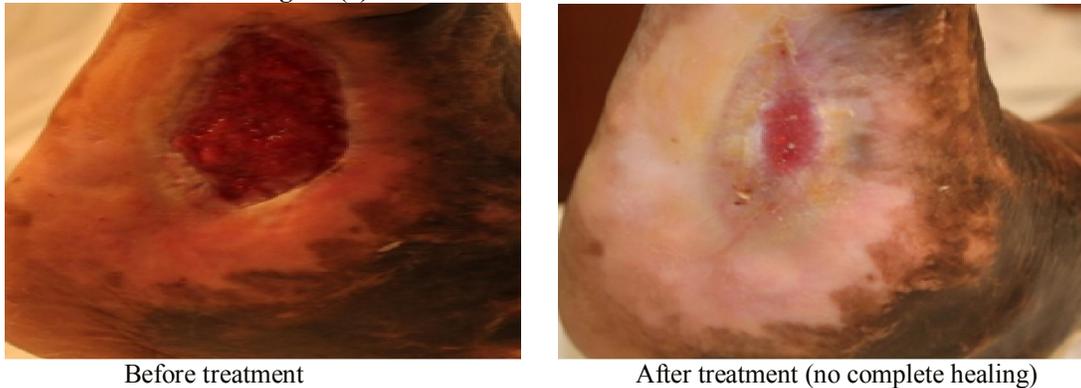
Vistrak measurement of Ulcer Area	Study group		P-value	t-value
	Pre-treatment	4weeks post-treatment		
Mean $\pm$ SD	2.63 $\pm$ 3.08	0.56 $\pm$ 0.82	0.032*	2.096

\*Significant



## II) Within control group:

No complete healing, and six ulcers deteriorated (enlarged area of skin redness, and increased wound size); four ulcers deteriorated at the end of the 2<sup>nd</sup> week and the two ulcers deteriorated at the end of the 4<sup>th</sup> week, as shown in figure (6):

**Figure (6):** Before treatment ulcer and after treatment.

**The independent t-test was applied to compare between groups, and the results showed that:**

The mean value and SD of total areas of ulcer before treatment was 4.08(3.40), the mean value and SD of total areas of ulcer two weeks after treatment was 8.76(10.72) and the mean value and SD of total

areas of ulcer four weeks after treatment was 7.38(10.19) as shown in tables (9, 10 and 11).

There was no significant difference between pre- treatment mean value of ulcer area and two weeks post- treatment mean value of ulcer area as  $p$  (0.179) as shown in table (9) figure (7).

**Table (9):** Comparison between pre-treatment and 2weeks post-treatment within control group regard to Visitrak measurement of ulcer area.

Visitrak measurement of Ulcer Area	Control group		P- value	t-value
	Pre-treatment	2weeks post-treatment		
<b>Mean <math>\pm</math>SD</b>	4.08 $\pm$ 3.40	8.76 $\pm$ 10.72	0.179	-1.2

There was very high significant difference between two weeks post- treatment value of ulcer area and four weeks post- treatment mean value of ulcer area as  $p$  (0.001) as shown in table (10) figure (7).

**Table (10):** Comparison between 2 weeks post-treatment and 4 weeks post-treatment within control group regard to VISTRİK measurement of ulcer area.

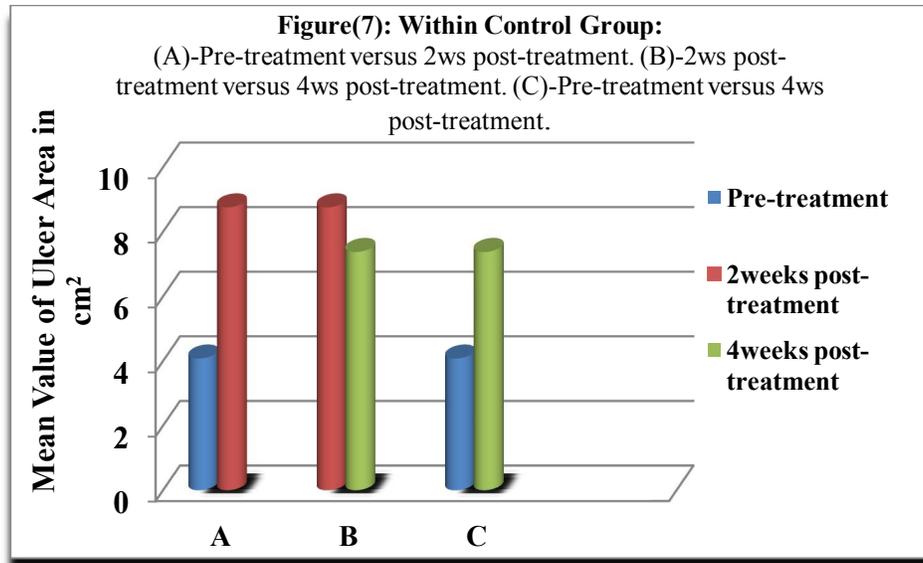
Visitrak measurement of Ulcer Area	Control group		P-value	t-value
	2 weeks post-treatment	4 weeks post-treatment		
<b>Mean <math>\pm</math>SD</b>	8.76 $\pm$ 10.72	7.38 $\pm$ 10.19	.001 <sup>***</sup>	1.91

\*\*\*Very high significant.

There was no significant difference between pre- treatment mean value of ulcer area and four weeks post- treatment mean value of ulcer area as  $p$  (0.19), shown in table ( 11 ) figure ( 7).

**Table (11):** Comparison between pre-treatment and 4weeks post-treatment within control group regard VISTRİK measurement of ulcer area.

Visitrak Measurement of Ulcer Area	Control group		P-value	t-value
	Pre-treatment	4weeks post-treatment		
<b>Mean <math>\pm</math>SD</b>	4.08 $\pm$ 3.40	7.38 $\pm$ 10.19	0.19	-.902



### III. Between groups:

The mean value of areas of ulcer and SD before treatment for control group was 4.08(3.40), while the mean value of areas of ulcer and SD before treatment for study group was 2.63(3.084)

The mean value of total areas of ulcer and SD two weeks after treatment for control group was 8.7600(10.72), while the mean value of total areas of ulcer and SD two weeks after treatment for study group was 1.10 (1.01).

The mean value of total areas of ulcer and SD four weeks after treatment for control group was 7.38(10.19), while the mean value of total areas of

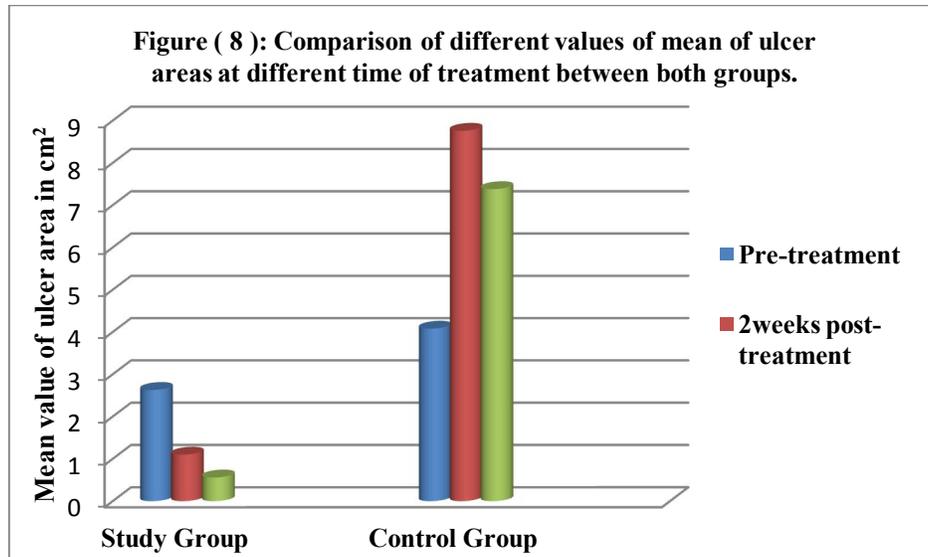
ulcer and SD four weeks after treatment for study group was 0.56 (0.82).

There was no significant difference between the study and control groups in mean value of ulcer areas before treatment as  $p$  (0.54), while there was highly significant difference between the study and control groups in mean value of ulcer areas after two weeks of treatment as  $p$  (0.014). There was significant difference between the study and control groups in mean value of ulcer area after four weeks of treatment  $p$  (0.008) as shown in tables (12) and figure (8).

**Table (12):** Comparison between study group and control (Pre-treatment, 2 weeks post-treatment and 4 weeks post-treatment).

Visitrak measurement of ulcer area	Study Group Mean± SD	Control Group Mean ± SD	$P$ (value)
Pre-treatment	2.63±3.08	4.08±3.40	0.54
2 weeks post-treatment	1.10±1.01	8.76±10.72	0.014**
4 weeks post-treatment	0.56±0.82	7.38±10.19	0.008***
$P$ (value)	0.019**	0.179	

\*\*High significant. \*\*\*Very high Significant



#### IV-Calculation of percentage (%) of surface area change (rate of healing):

The wound closure rate was expressed as the percentage of wound area compared with that on the last wound area measurement, calculation was done using Visitrak.

**Table (13): Rate of Healing**

	Study Group	Control Group
Healing rate after 2 weeks	-58.1%	+214%
Healing rate from 2 weeks-to 4 weeks	-49%	-1.5%
Healing rate after 4 weeks	-78.8%	+180%

Minus (-) means decrease in wound surface area.

Plus (+) means increase in wound surface area

#### 4- Discussion

Several maneuvers have been used to prevent the deterioration of ulcer. However, there were no modalities that promoted the healing of ulcer by increasing tissue microcirculation, which has been suggested to be beneficial for wound healing. In the present study, the effectiveness and safety of mechanical vibration that has been proven to improve tissue microcirculation hence improve healing.

To minimize situational bias, the same foot ulcer treatment and care regimen was conducted in both groups. Before the data analysis, researchers confirmed the equivalence of the regimen, including standard wound care maintaining moist environment such as normal saline and dress for ulcers by bactigras, gauze, soft band and rinkelastic three times / week without use of any granulation stimulus such as collagen or hormones. Regarding characteristics of the participants and ulcer dimensions there were no

statistically significant differences between the experimental and control groups, indicating that the 2 groups were comparable.

Mean value of ulcer area in control group increased from (4.08) to (8.76) as one ulcer deteriorated (enlarged area of skin redness, and increased wound size) while in study group, mean value of ulcer area decreased from (2.63) to (1.1).

So in control group there was no healing result as ulcer areas increased and statistically no significant difference before and 2 weeks after as  $p > (0.05)$ .

While in study group (mechanical vibration), there was perfect healing effect as ulcer areas decreased as one ulcer completely healed and statistically there was high significant difference before and 2 weeks after as  $p < (0.05)$ .

By comparing the results between groups, there was high significant difference between both groups

in mean ulcer area after 2 weeks so it confirmed the healing effect for (mechanical vibration) as study group.

The mean value of ulcer area in control group slightly decreased from (8.76) to (7.38) and there were sex ulcers deteriorated (enlarged area of skin redness, and increased wound size) while in study group, mean value of ulcer area decreased from (1.1) to (0.55).

So in control group there was slight healing result as ulcer areas slightly decreased and statistically there was significant difference between two and four weeks after treatment as  $p < (0.05)$  but statistically there was no difference before and four weeks after treatment as  $p > (0.05)$  as there was no complete healing.

While in study group (mechanical vibration), there was perfect healing effect as ulcer areas decreased as eight ulcer completely healed and statistically there was high significant difference between 2 weeks and 4 weeks after treatment, as  $p < (0.05)$ , in addition there was high significant difference between before treatment and 4 weeks after beginning of treatment, as  $p < (0.05)$ .

And by comparing the results between groups, there was high significant difference between both groups in mean ulcer area after 4 weeks so it also confirmed the healing effect for (mechanical vibration) as study group.

These findings show that mechanical vibration therapy facilitated the healing of diabetic foot ulcer by promoting the blood supply. Vibration has been reported to affect circulation of skin in a non-invasive manner. Two main mechanisms were considered to be responsible for the increase in blood flow with vibration. The first mechanism is the production of mechanical stresses including shear stress, compression, and stretching of endothelial cells. These induce vasodilation of venules via mechanotransduction, which is mainly regulated by nitric oxide (NO). Many studies have reported a relationship between NO productions or NO synthase (NOS) expression and mechanical stress created by flow stress or exercise (Griffin et al., 2006).

The second mechanism of vasodilation observed was nerve axon reflex-related microvascular vasodilation. Vibration may induce impulses via receptors widely distributed on the skin surface, resulting in the release of substances such as substance P and calcitonin that dilate the blood vessels. The vasodilation achieved by skin vibration may assist the healing of wounds (Caselli et al., 2006).

In previous studies; a significant increase in blood flow was observed in the 600 mVpp at 15 min after direct vibration of the skin at a frequency of 47

Hz. Another study showed that using a vibration frequency of 26 Hz demonstrated an increase in muscle blood volume. **Skoglund** showed that low-amplitude, high-frequency vibration induced vasodilation in human skin. These facts may point to a relationship between the intensity of vibration and blood flow rather than frequency (Tschakovsky and Sheriff, 2004).

**Kerschman-Schindl et al. (2001)** examined the circulatory responses of participants who stood on a platform (Galileo 2000, Novotec GmbH, Germany) vibrating at 26 Hz (3 · 3 min sets). Despite the brief duration of the exposure, mean blood velocity to the quadriceps and gastrocnemius muscles was doubled. Further, the resistive index of the popliteal artery was decreased compared with resting levels. According to the authors, the imposed vibration (amplitude = 3 mm, peak acceleration = 78 m/ 1s), evoked rhythmical muscle contractions which caused alterations in peripheral circulation without significant cardiovascular changes as indicated by a lack of change in HR and blood.

**Zhang et al. (2003)** used a brief (3 min) vibratory stimulus (LING V650; Ling Electronics, Anaheim, CA, USA) that emitted random acceleration of constant power density between 5 and 2000 Hz. Six healthy participants rested their foot against a vibrating plate and blood flow to the tibialis anterior muscle was quantified using photoplethysmography. Local muscle blood flow was increased by an average of 20% as a consequence of the brief vibration stimulus.

**Stewart et al. (2005)** provided additional evidence that vibration can be effective for the treatment of painful conditions such as osteoporosis. In their study, 18 women, aged 46–63 years), placed their right foot on a vibrating customized foot plate apparatus (McLeod, LDM Associates, San Jose, CA, USA), whilst in a supine position with a 35° upright tilt. The plate was attached to an actuator which delivered sinusoidal vertical displacements of up to 2 mm. A vibration frequency of 45 Hz for 5–7 min was sufficient to cause significant increases in calf blood flow of up to 46% as measured by strain gauge plethysmography. It was argued that plantar vibration enhances venous drainage as well as peripheral blood flow and lymphatic flow.

In the present study, the healing of one ulcer at the end of 2 weeks of treatment in the study group indicated that vibration therapy, the time required to heal could be shorter than 4 weeks. An improvement in the healing of diabetic foot ulcer decreases physical and economic burdens; it not only lightens the nurses' work load, but also improves patients' quality of life.

## Conclusions

Patients with diabetic foot ulcer grade (A1) received low mechanical vibration with a frequency of 47 Hz for 15 minutes 3 times / day 5 days/weeks for a month in a nonrandomized, controlled study design. Compared with the control group, healed ulcer area was significantly higher in the study group, so it can be concluded that low mechanical vibration therapy may improve healing of diabetic foot ulcer.

## Corresponding Author:

Dr. Omar Farouk Helal

PhD in Physical Therapy, Assistant Professor, Physical Therapy Department, Faculty of Applied Medical Sciences, Umm Al Qura University. KSA.

Email address: [dr.mon5@hotmail.com](mailto:dr.mon5@hotmail.com).

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