Laser Versus Ultrasonic Therapy in Accelerating Healing of Foot Ulcers in Diabetic Patients

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ABSTRACT

Purpose: *The purpose of this study was to compare the effect of low power laser with pulsed ultrasonic therapy on accelerating healing of foot ulcers in diabetic patients.* ***Subjects****: Sixty diabetic subjects (male and female) suffering from foot ulcers were participated in this study. Their age ranged from 46 to 65 years old with the mean values (57.4±7.6).* ***Methods:*** *Sixty diabetic Patients with foot ulcers were divided randomly into three groups of equal number.* ***Group-I:*** *Twenty patients received low power laser therapy at intensity of 4 J/cm^2 for 20 minutes every other day for three months and the conservative treatment of wound management.* ***Group-II:*** *Twenty patients received pulsed ultrasonic therapy and the conservative treatment. Pulsed ultrasound was applied around the perimeter area of the wound for 5 minutes 3 times/ week for three months with intensity of 0.5 W/cm^2, at a frequency of 3 MH, and the pulse ratio of 1:5.* ***Group-III:*** *Twenty patients received the conservative treatment only for three months. The surface area and the ulcer volume of the ulcer were measured before the intervention, and after three months of the treatment for each patient in the three groups.* ***Results:*** *The paired t-test proved that there were significant differences in the surface area and ulcer volume after treatment in group I and II only. The ANOVA analysis proved that there were not any significant differences before intervention among three groups but there were significant differences in the surface area and ulcer volume after treatment, there was non-significant differences between group-I and II.* ***Discussion:*** *These results may be due to that ultrasound encourages the growth of new capillaries in chronic ischemic tissue, and increases Ca^{++} flow across cell membranes. Laser therapy alters the level of prostaglandins, increases adenosine tri-phosphate synthesis, and accelerates collagen and fibroblasts synthesis.* ***Conclusion:*** *Low power laser or pulsed ultrasound therapy in addition to the conservative treatment significantly accelerates the rate of healing of foot ulcers in diabetic patients than the conservative treatment only.*

INTRODUCTION

Diabetes is associated with accelerated atherosclerosis development, and specific vascular complications as retinopathy, nephropathy and neuropathy. These are the most important aspect of the disease as they are major source of hazards to the patients. The interaction of these complications produces clinical findings ranging from disorders of the nails, callus formation and skin lesion to the involvement of muscles and bones as foot trauma may quickly lead to ulceration, infection, gangrene and amputation[2,27,32]. The advanced end products accumulated in diabetes may adversely affect extra cellular matrix, cellular function and cytokines production that prevent the prompt of wound healing[25,29].

Foot ulcers are often the results of repeated mechanical stress, peripheral neuropathy, loss of protective sensation, presence of peripheral vascular disease[1,17]. Sensory neuropathy impairs the neuro-inflammatory response which may contribute

to continue tissue injuries while Motor neuropathy results in weakness and changes in foot structure. Autonomic neuropathy impairs the normal maintenance of skin integrity, vascular tone, and the thermoregulatory response, all of which can interfere with normal wound repair[4,18].

It was estimated that about 15% of diabetic patients experience a foot ulcer in their life. Foot ulcers are a major predictor of future lower extremity amputation in patients with diabetes. The incidence of lower limb amputation in people with diabetes rises, thus appropriate techniques for wound care are essential preventive strategies[20,21,26]. The basic principals of surgical treatment of skin ulcer include relief of pressure, wound cleaning, enzymatic sharp debridement, and dressing[5,36]. Sharp debridement of the devitalized tissue has been shown to stimulate healing of the neuropathic wounds. There is evidence that any specific type of dressing enhances wound healing as the dressing prevents further trauma, and minimizes risk of infections[36]. These infections require antibiotic therapy as soon as the infection is diagnosed[3,37].

The cytokines and growth factors are released primarily from the platelets to promote wound healing. The release of vasodilator substances facilitates the migration of neutrophils into the wound and activation of monocytes to form tissue macrophages that are important cells in the immune response to chronic inflammation and suppression of bacterial growth[37].

In addition to the conservative treatment there are numerous physical therapy approaches were used for the wound healing as electrical stimulation, therapeutic ultrasound, ultraviolet radiation, electromagnetic therapy and low power laser therapy[15,24,28,30,31,33,34]. Electrical stimulation has been shown to enhance migration of fibroblasts, provide antibacterial effect and facilitate wound healing. Electrical stimulation enhances wound healing when used in conjunction with appropriate off-loading and local wound care[31].

Therapeutic ultrasound has a positive effect on collagen deposition and reduction in wound size in matched pairs of pigs[8,23]. Physical therapists currently use ultrasound therapy to treat wounds at intensity from 0.1 to 0.5 w/cm[2,15,28]. The application of low frequency ultrasound with low dose is a helpful treatment option in chronic venous leg ulcer, especially if they don't respond to conventional treatment[30]. Ultrasound combined with ultraviolet may reduce the time of ulcers healing in patients with spinal cord injury and allow faster return to rehabilitation programs, and leisure activities[15]. But the effect of ultrasound on ischemic diabetic ulcers is unknown.

The use of laser for wound healing is becoming increasingly attractive to physical therapists. Early researches suggest that laser therapy may have a role in hastening wound healing[24]. It is effective in the treatment of venous ulcers particularly those which are painful and resistant to other measures[36]. The combination of topical hyperbaric oxygen and low energy laser therapy is studied in patients with chronic diabetic foot ulcers and the authors found that this may be a safe modality for patients with diabetic foot ulcers[34] and further research is needed to assess the effectiveness of laser bio-stimulation on diabetic ischemic wound[24]. In addition to electrical modalities the hydrotherapy improved healing of the pressure ulcers and reduced the time of treatment significantly faster than the conservative treatment only[10].

The purpose of this work was to compare the effect of low power laser against pulsed ultrasonic therapy on accelerating

healing of ischemic foot ulcers in chronic diabetic patients.

SUBJECTS, MATERIALS AND METHODS

Subjects

Sixty male and female (38 male and 22 female) diabetic patients with foot ulcers were referred from the specialized physician to participate in this study at the clinic of physical therapy, faculty of Physical Therapy Cairo University. Their age ranged from 46 to 65 years old. All patients have foot ulcers with full thickness and the duration of their ulcers from one month to three months. Patients with surface area of ulcer more than six cm^2 were excluded from this study. They were under medical control (fifty five patients treated with insulin injection and five patients with oral hypoglycemic drugs).

Instrumentations

1) Low power laser therapy with frequency of 800 Hz.
2) Ultrasonic therapy apparatus was applied for its therapeutic effect on wound management.
3) Camera used to take photographs to the surface area of the ulcer.
4) Clean transparent films and pointed pins used to trace accurately the outline of the epithelial edge of the wounds.
5) Computer and scanner used to measure the ulcer surface areas.
6) Clean sterile syringe and solution of normal saline used to measure the volume of the wounds.

Procedures

Assessment procedure: The experimental protocol was explained in details for every patient. Each patient underwent the following assessment before and after intervention.

- Ulcer surface area was measured and analyzed by Computer Image analysis for the wound tracing, a baseline tracing of the ulcer perimeter was drawn on a sterile disposable transparence. The average of three measurements was taken and expressed as the ulcer surface area.
- Ulcer volume assessment using a syringe of five cubic centimeters filled with normal saline. Each patient rested in a comfortable position that allowed the wound to be filled with the solution which was injected into each wound until its filling .The amount of injected solution was detected in cubic centimeter.
- Side and site of the ulcer was determined.

Treatment procedures: The sample of patients was divided randomly into three groups of equal number '" twenty patients for each group".

Group-I: Twenty patients received low power laser therapy in addition to the conservative treatment. The distance was adjusted to provide a field to cover the ulcer and the surrounding tissue by 1 mm, each patient was treated for 20 minutes at intensity of 4 j/cm^2, 3 times per week for 3 months; after each session the ulcer was covered with sterile gauze.

Group-II: Twenty patients received the ultrasonic therapy in addition to the conservative treatment. The ultrasonic therapy was applied to the intact skin surrounding the wound for 5 minutes 3 times per week, for 3 months. The treatment was delivered at a frequency of 3 MHZ and at spatial average temporal average (SATA) with intensity of 0.5 w/cm^2 (1:5 pulse ratios).

Group-III: Twenty patients received the conservative treatment only for 3 months. The

conservative treatment was applied for three groups that included Systemic antibiotics, insulin therapy or oral hypoglycemic drugs, debridement and irrigation of the wound with normal saline and then the wound was dressed with cotton pads. All dressings replaced by first soaking them with normal saline for one minute then removing the moistened pad gently from the wound bed, all dressing were changed once daily.

Statistical Analysis

The collected data were statistically analyzed using paired t-test to detect the significance within each group. The ANOVA-test was applied to determine the significance among three groups before and after three months of intervention. This test was followed by post hoc tests (LSD) to detect the best group.

RESULTS

Sixty diabetic patients (male and female) with foot ulcers participated in this study. Their age ranged from 46 to 65 years old with the mean value (57.4±7.6). The mean values of the time from onset of diabetes to the onset of the foot ulcer were (16.2±5.8) years. The mean values of the duration of foot ulcers in days was (45±15).Forty five patients (75%)had foot ulcer on the planter surface and fifteen patients (25%)on the dorsal surface .There were 40 patients out of 60 have diabetic foot ulcer on the right side and 20 on the left side.

The mean values of the surface area of diabetic foot ulcer in group-I (laser therapy) were significantly reduced from (4.5±1.18) to (1.4±0.89) and in group-II (therapeutic ultrasound) from (4.4±1.27) to (1.4±0.91). While in group-III (treated with conservative treatment only) there was non- significant reduction from (4.6±1.13) to (4.4±1.02) (table 1, fig 1).

Table (1): The improvements in the surface area in square centimeters after treatment in the three groups.

Variables	Group-I		Group-II		Group-III	
	Pre	Post	Pre	Post	Pre	Post
Range	2-6	0-2	2-6	0-3	2-6	1.7-6
Mean	4.5	1.4	4.4	1.4	4.6	4.4
±SD	1.18	0.89	1.27	0.91	1.13	1.02
T-value	26.1*		12.8*		1.8†	

* significant (P< 0.05). † non significant (P> 0.05).

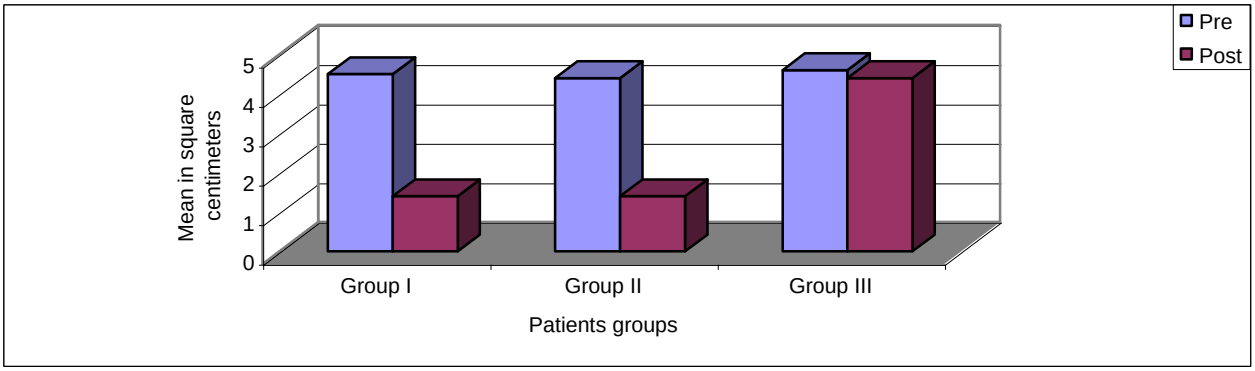

Fig. (1): The mean values of the surface area in square centimeter pre and post treatment in three groups.

The mean values of the ulcer volume of diabetic foot ulcer in group-I (laser therapy) were reduced from (3.6±1.02) to (1.8±1.14) and in group-II (therapeutic ultrasound) from (3.5±1.13) to (1.5±1.01). While in group-III (conservative treatment only) there was non-significant reduction from (4.1±1.09) to (3.9±1.2) (table 2, fig 2).

Table (2): The improvements in the ulcer volume in the three groups after treatment.

Variables	Group-I		Group-II		Group-III	
	Pre	Post	Pre	Post	Pre	Post
Range	1.6-5	0-3.6	1.6-5	0-3.6	1.6-6	2-6.5
Mean	3.6	1.8	3.5	1.5	4.1	3.9
±SD	1.02	1.14	1.13	1.01	1.09	1.2
T-value	6.76*		8.29*		1.89†	

*significant (P< 0.05). † non significant (P> 0.05).

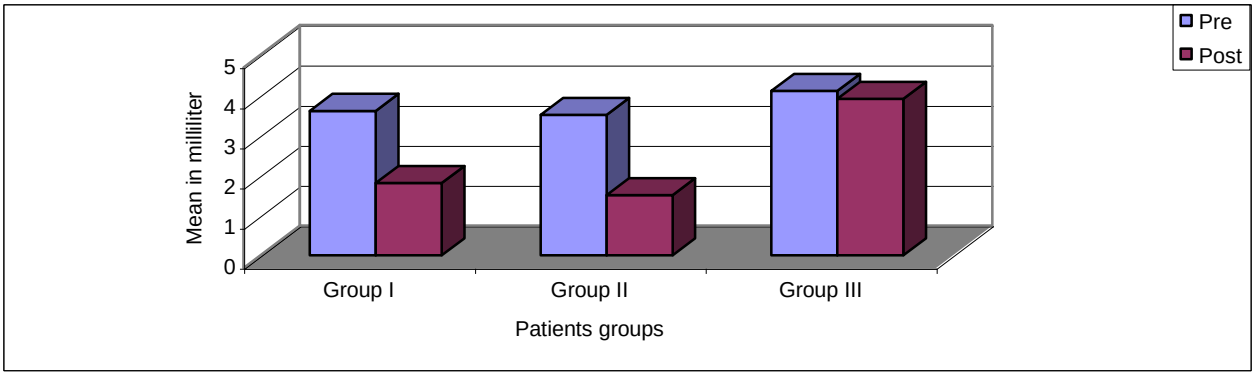

Fig. (2): The mean values of the ulcer volume in milliliters pre and post treatment in three groups.

The ANOVA analysis of the ulcer surface area showed that there were non-significant differences among three groups before treatment with the mean values in between (0.19±0.39), and within (1.43±81.7) (F-value 0.14) (P>0.05) while after treatment there were significant differences among three groups with the mean values in between (61.1±122.1), and within (0.95±54.8) (F-value 64.45) (P<0.05). Also in relation to the ulcer volume there were non-significant differences among three groups before treatment with the mean values in between (2.14±4.3), and within (1.18±67.2), (F-value 1.81) while after treatment there were significant differences among three groups with the mean values in between (34.1±68.1), and within (1.3±72.1) (F-value 26.9) (P<0.05), (Table 3).

Table (3): The ANOVA –test for the ulcer surface area and volume before and after the treatment in three groups.

Variables	Surface area in square centimeters				Ulcer volume in Milliliters			
	Pre		Post		Pre		Post	
	B	W	B	W	B	W	B	W
MS	0.19	1.43	61.1	0.95	2.14	1.18	34.1	1.3
SS	.039	81.69	122.1	54.8	4.28	67.2	68.1	72.1
F-value	0.14†		64.45*		1.81†		26.91*	

*significant (P<0.05). † non significant (P< 0.05) B: between W: within
SS: Sum of squares MS: mean square

Table (4): The Post hoc tests (LSD) for the three groups after treatment.

Variables	Comparisons	Mean diff	SE	F-value
Surface area in square centimeter	GI : GII	-1.0	0.31	0.75†
	GI : GIII	-3.1	0.31	0.85*
	GII : GIII	-2.98	0.31	0.00*
Ulcer volume in milliliters	GI : GII	-0.32	0.36	0.38†
	GI : GIII	-2.1	0.36	0.00*
	GII : GIII	-2.4	0.36	0.002*

*significant (P< 0.05). † non significant (P< 0.05).

DISCUSSION

The results of this study showed that there was significant reduction in the ulcer surface area and ulcer volume in group I (laser therapy) and in group-II (ultrasonic therapy) after three months of treatment. While in group-III (conservative treatment only) the reduction in the ulcer surface area or ulcer volume after treatment was not significant. The improvements after conservative treatment only were not significant and this may be due to short time of antibiotic application and some drugs that improve the peripheral circulation should be added. As the diabetic ulcer characterized by poor vascular area and absence of protective sensation and this may deteriorate the healing of the ulcer.

The improvements after ultrasonic therapy in addition to the conservative management was significant due to the therapeutic effect of ultrasound which encourages the growth of new capillaries in chronic ischemic tissue, and increases Ca^{++} flow across cell membranes. These intracellular changes might result in increased secretions, cell motility and synthesis of growth factors[11]. Beside the stimulatory effect of ultrasound on fibroblasts it stimulates the secretion of mitogenic factors from macrophages that are important cells in the immune response to chronic inflammation[8].

The results of this study were supported with other studies[8,9,12,13,15,23,30]. As the ultrasound accelerated the wound healing in 11 matched pairs of surgical induced incisions and the reduction in wound size after 7 days of intervention was significantly greater in the ultrasound group by 29% when compared with control group[8]. The combination of ultrasound with ultraviolet may have greater benefit in accelerating wound healing as it decreases the healing time of pressure ulcers and allows faster return to rehabilitation programs in patients with spinal cord injury[15]. The ultrasound/ultraviolet regimen consisted of five sessions per week, alternating ultrasound/ultraviolet daily used. Ultrasound was usually applied 3 times per week, as the dosage of the current study. Pulsed US used at a frequency of 3 MHz and the average intensity of 0.2 w/cm^2 (1:4 pulse ratio) for 5 minutes per 5 cm^2 of wound area. The ultraviolet 95% emission was calculated each session according to wound appearance[15].

In the literature the ultrasound was used with different modes and intensities in treatment of ulcers and wounds[9,12,13,23]. Three times weekly at 3 MHz with intensity of 0.2 W/cm^2 (1:4 pulse ratio)[12,13] or with a higher ultrasound intensity of continuous spatial average intensity 0.5 W/cm^2 once weekly at 1 MHz[9] or in a pulsed mode with (pulse ratio 1: 9)[23]. As in a comparative report the ultrasound used for ten minutes with 3MHz, 0.1 W/cm^2 three times/weak for 12 weeks on venous leg ulcers with hydrocolloid dressings and compression therapy in twenty four patients.

The reduction of the ulcer surface area of the control group was 16.5% whereas in the ultrasound group was 55.4% .The authors concluded that the application of ultrasound on chronic venous leg ulcer promotes the healing of varicose veins and pressure sores[39].

On the other side the results of the current study contradicted to Eriksson et al., study[14]. Eriksson et al., reported that there was not benefit from treating ulcers with ultrasound. The authors applied ultrasound twice weekly only at one MHz with a continuous spatial average intensity of 1.0 W/cm^2. The short period of treatment time, low frequency of the waves and the continuous mode of application may be the cause of their results. In the current study the ultrasound was applied in pulsed mode with average intensity of 0.5 W/cm^2 and three MHz. frequencies, three times per week for three months.

The significant improvement in patients treated with laser therapy and conservative treatment was coming in agreement with the literature[24,34,36]. Sugrue et al. (1990)[36] applied infrared laser irradiation for 12 patients with chronic venous ulcers unresponsive to conservative treatment for 12 weeks. They found that 2 ulcers healed completely and there was a 27% reduction in size of the remaining ulcers, and 44% increase in ulcer floor area occupied by healthy granulation tissue. They concluded that the most important finding of their study is that the laser treatment reduces the ulcer pain[36]. Schattner (2001)[34] evaluated the effect of a combination of the topical hyperbaric oxygen treatment and the low energy laser on ulcer healing in 100 patients with chronic diabetic foot ulcers for (3.2±1.7) months. He found that 81% healing of diabetic foot ulcers in patients who previously did not respond to a conservative treatment program. He reported that the topical hyperbaric oxygen treatment and the low energy laser could be considered safe and simple and inexpensive early adjunctive treatment for patients with chronic diabetic foot ulcers.

The explanation of how laser can assist the healing process is that the bio-stimulation of laser accelerates the inflammatory phase of wound healing by altering the levels of various prostaglandins, increasing adenosine tri-phosphate synthesis, enhancing electron transfer in the inner membrane of the mitochondria and accelerating collagen and fibroblasts synthesis[7,16]. Laser therapy can promote the defensive mechanism by increasing number of T- and B- lymphocytes cells in patient with immuno-suppressed system[34].

Regarding the patients characteristics in this study (75%) of patients had diabetic ulcer at the base of the first metatarsal bone. This may be due to that the highest shear stresses occurred under the first metatarsal corresponding to most frequent site of ulceration[22]. Also there was significant increase in the mediolateral component of the ground reaction force on the first metatarsal bone and this increased risk of foot ulcers[6]. Most of the diabetic ulcer occurs in the planter aspect of the foot due to the weakness of the intrinsic muscles of the foot leading to abnormal pressure distribution, or may result from penetrating wounds[33]. There was marked predominance of the incidence of the diabetic foot ulcer in male more than female (38 male and 22 female). This may be due to the difference of their duties during daily living activities[19]. The incidence of the diabetic foot ulcer in the right side more than in the left side, accounting for 67% on the right and 33% on the left and this may be due to the functional predominance of the right foot as the stress located on the right side (dominant leg) is more than that on left one[19]. From this

work it was concluded that pulsed ultrasound or cold laser plus the conservative wound management accelerates the rate of healing of diabetic foot ulcers than the application of conservative treatment only.

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الملخص العربي

الليزر العلاجي مقابل الموجات فوق الصوتية في تعجيل التئام قرح القدم في مرضى البوال السكري

تهدف هذه الدراسة إلى مقارنة تأثير أشعة الليزر منخفضة القوة و الموجات فوق الصوتية المتقطعة على تعجيل التئام قرح القدم في مرضى البوال السكري . تشمل هذه الدراسة ستون مريضا (من الذكور والإناث) بمرض البوال السكري يعانون من قرح بالقدم تتراوح أعمارهم بين 46و 65 سنة، تم تقسيم العينة عشوائيا إلى ثلاث مجموعات. المجموعة الأولى تشتمل على عشرون مريضا تم علاجهم بأشعة الليزر منخفضة القوة لمدة عشرون دقيقة بمعدل ثلاث مرات أسبوعيا بالإضافة إلى العلاج التحفظي للجروح لمدة ثلاثة شهور . المجموعة الثانية تشتمل على عشرون مريضا تم علاجهم باستخدام الموجات فوق الصوتية المتقطعة بتردد 3 ميجا هرتز وبشدة نصف وات لكل سنتيمتر مربع على المنطقة حول الجرح لمدة خمسة دقائق بمعدل ثلاث مرات أسبوعيا لمدة ثلاثة شهور بالإضافة إلى العلاج التحفظي للجروح. المجموعة الثالثة تشتمل على عشرون مريضا تم علاجهم بالعلاج التحفظي للجروح فقط لمدة ثلاثة شهور. ثم قياس مساحة سطح القرح بالسنتيمتر المربع وكذلك حجم القرح لكل المرضى قبل بداية العلاج ثم بعد ثلاثة شهور من العلاج. بينت النتائج الإحصائية عدم وجود فوارق إحصائية قبل بداية التجربة وأظفرت عن وجود نقص ملحوظ لكل من مساحة سطح القرح وكذلك حجم القرح في المجموعة الأولى والمجموعة الثانية بينما كان غير ملحوظ في المجموعة الثالثة التي تم علاجها بالعلاج التحفظي فقط كما انه لا يوجد فارق معنوي بين المجموعة الأولى و الثانية .يستخلص من نتائج هذا البحث أن استخدام أشعة الليزر منخفضة القوة أو الموجات فوق الصوتية المتقطعة بالإضافة إلى العلاج التحفظي للجروح يعجل في شفاء قرح القدم في مرضى البوال السكري اكثر من العلاج التحفظي للجروح فقط .