

# Efficiency of therapeutic ultrasound, low-level laser and compression therapy for healing of venous leg ulcers

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## Aim

To evaluate the efficiency of therapeutic Ultrasound, low level laser and compression therapy for healing of venous Leg ulcers and Compare the effect of modalities on the ulcers.

## Subjects and methods

Three groups were included in the study. Group I: 20 patients with leg ulcers treated with low level laser therapy. Group II: 20 patients with leg ulcers treated with ultrasound therapy. Group III: 20 patients with leg ulcers treated by compression therapy (four layer bandage) were used in this study. All patients were subjected to detailed history, clinical evaluation in addition to X-ray of legs and feet, and Doppler ultrasound of both legs. The main variables for follow up were the measurement of the area of the lesions under aseptic conditions at 0, 1, 2, 3 months and qualitative clinical evaluation of the ulcers by physician and by the patient. The results from group I, group II and group III were obtained and then compared with each others.

## Results

According to the size of the ulcer, some ulcers heal within 1 month which is (15.6%) in group I, (10%) in group II, and (28.5%) in group III. Some ulcers heal within 2 months which is (28%) in group I, (23.3%) in group II and (37%) in group III. The remaining ulcers heal within 3 months or more which are (56%) in group I, (66.6%) in group II and (34.2%) in group III. Thus the percentage of healing denoting that compression bandage technique used in group III is the most efficient in healing of chronic venous leg ulcer followed by laser therapy and lastly US therapy ( $P = 0.04$  at the end of the first month and  $P = 0.03$  at the end of the third month).

## Conclusion

Compression therapy is the most efficient treatment of venous leg ulcers. Low level laser therapy and Ultrasound therapy are useful methods as a conservative treatment of venous leg ulcers and can be used in ulcers of small size.

## Keywords:

venous ulcers, therapeutic ultrasound, low level laser, compression therapy

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## Introduction

Venous ulcers represent the most prevalent form of difficult-to-heal wounds. The incidence of venous ulceration is increasing with the increasing age of the general population. The most common cause of lower extremity ulcers is venous insufficiency, which accounts for almost 80% of all venous ulcers [1].

Risk factors for the development of venous ulcers include venous disease, obesity, immobility, family history of varicose veins, deep vein thrombosis, previous surgery for varicose veins, and congestive cardiac failure. Up to 50% of patients with chronic venous insufficiency have a history of leg injury [2].

Tissue healing, one of the main effects of low-level laser therapy (LLLT), is characterized by three main factors. First, there is an increase in the production of ATP. Second, there is a stimulus to microcirculation, which increases the delivery of nutritional elements. Finally, new vessels are formed from pre-existing vessels [3].

Application of ultrasound (US) may exert a number of biophysical effects on wound healing. These include alternations in cellular protein synthesis and release, blood flow and vascular permeability, angiogenesis, and collagen content and alignment. In the management of cutaneous wounds, frequencies from 0.5 to 3 MHz have been found to enhance the healing process in incisional lesions, and diabetic and venous ulcers [4].

Below-the-knee graduated compression from the toe (highest) to the knee (lowest), in the form of bandaging or stockings, is viewed as a key component of treatment when venous leg ulceration occurs in the absence of relevant arterial disease [5].

## Patients and methods

The study was approved by the Ethics Committee of the university and the patients were included in

the study after giving their informed consent after explanation of the purpose and procedures of the study.

### Patients

This study was carried out from January 2013 to January 2014 (Tables 1 and 2).

A total of 60 patients were included in the study.

Adult patients of both sexes with a diagnosis of chronic venous leg ulcers that were primarily caused by problems associated with deep venous thrombosis and varicose veins, classified as C6 according to the clinical classification of the CEAP classification, were recruited into this study.

The fundamentals of the CEAP classification include a description of the clinical class (C) on the basis of objective signs, the etiology (E), the anatomical (A) distribution of reflux and obstruction in the superficial, deep, and perforating veins, and the underlying pathophysiology (P), whether because of reflux or obstruction.

The patients were recruited from the inpatient and outpatient clinic of the Vascular Surgery Department.

### CEAP classification of chronic venous disease

#### Clinical classification

C0: no visible or palpable signs of venous disease; C1: telangiectasies or reticular veins; C2: varicose veins; C3: edema; C4a: pigmentation or eczema; C4b:

lipodermatosclerosis or atrophic blanche; C5: healed venous ulcer; C6: active venous ulcer.

#### Inclusion criteria

- (1) Age older than 30 years.
- (2) Either sex.
- (3) One or more venous ulcers larger than 1 cm<sup>2</sup> in area.
- (4) No evidence of arterial disease of the legs (ankle brachial pressure index > 0.8).
- (5) Patient not currently receiving any other form of treatment or resting for the ulcer.
- (6) Ability to provide written consent.
- (7) Patient with C6 according to the CEAP classification.

#### Exclusion criteria

- (1) Ulcers of infectious, pressure, or postoperative origin.
- (2) Patients with uncontrolled diabetes and diabetic sensory neuropathy, cellulitis, vasculitis or collagen vascular disease, and any concomitant illness.
- (3) Patients taking any medication that may affect wound healing, including corticosteroids and chemotherapy.
- (4) Active or suspected carcinoma.

The calculation of the area of the ulcer was carried out using graph papers to document the ulcer's perpendicular linear dimensions (typically in centimeters using graph paper); the maximum distance is length and perpendicular distance is width [6].

**Table 1 Demographic data of the studied groups**

Demographic data	Group I (N = 20)	Group II (N = 20)	Group III (N = 20)	$\chi^2$	P
Sex [N (%)]					
Male	7 (35)	9 (45)	11 (55)	1.62	0.45
Female	13 (65)	11 (55)	9 (45)		
Cause of the ulcer [N (%)]					
Incompetent communicating veins	3 (15)	5 (25)	2 (10)	1.68	0.43
Incompetent superficial venous system	4 (20)	3 (15)	3 (15)	0.42	0.89
Both incompetent communicating and superficial venous system	7 (35)	6 (30)	7 (35)	0.15	0.93
Previous DVT	6 (30)	6 (30)	8 (40)	0.60	0.74

DVT, Deep venous thrombosis

**Table 2 Associated comorbidities in patients of the three groups**

Comorbidities	Group I (N = 20) [N (%)]	Group II (N = 20) [N (%)]	Group III (N = 20) [N (%)]	$\chi^2$	P
Hypertension	8 (40)	5 (25)	3 (15)	3.24	0.19
Coronary heart disease	4 (25)	5 (25)	2 (10)	1.56	0.46
Renal disease	3 (15)	2 (10)	1 (5)	1.11	0.57
Hepatic disease	3 (15)	2 (10)	0	3.05	0.27
Lower limb edema	11 (55)	8 (40)	2 (10)	9.23	0.01

The progress of healing was measured every month and recorded as the percent of healing.

The patients were classified randomly into three different groups of treatment.

#### *Group I*

It included 20 patients treated by LLLT. There were 13 women and seven men.

#### *Group II*

It included 20 patients treated by US. There were 11 women and nine men.

Both group I and group II were treated at the Rheumatology and Rehabilitation Department.

#### *Group III*

It included 20 patients treated using four-layer compression bandaging. There were 10 women and 10 men.

Group III was treated at the Vascular Surgery Department.

### **Methods**

All patients were subjected to a thorough assessment of history and clinical evaluation.

Patients were assigned randomly to the different treatment groups.

#### *Group I*

All 20 patients were subjected to LLLT of the ulcer. The infrared laser was applied on the ulcer using the scanning method. It was applied for 4 min (980 nm; power: 200 MW; 4–6 J/cm<sup>2</sup>). The treatment was carried out for 3 months, three setting per week, with follow-up every month to detect improvements by measuring the diameter of the ulcer and detecting the progression of healing.

#### *Group II*

Twenty patients were treated with US (0.5 W/cm<sup>2</sup>, 1 MHz). The treatment was carried out for 3 months, three setting per week, with follow-up every month to detect improvements by measuring the diameter of the ulcer and detecting the progression of healing.

#### *Group III*

Twenty patients were treated by compression therapy.

### **Compression (bandaging) technique**

A multilayer graduated high-compression elastic system (four layer bandage) was used in our study.

The so-called four-layer bandage comprises:

- (a) A padding bandage (orthopedic wool) to redistribute pressure from bony prominences and to enable an even distribution of pressure under the compression bandages where the shape of the leg may militate against even graduated pressure,
- (b) A crepe inelastic bandage (to create a base for the compression), and (3 and 4) two mild-compression to moderate-compression elastic bandages.

### **Achieving effective pressure**

This four-layer bandage is an example of a multicomponent elastic system and is designed to apply a sustained sub-bandage pressure of 35–40 mmHg at the ankle for patients with an ankle circumference of 18–25 cm to reverse chronic venous hypertension; this is achieved using:

Laplace's law: theoretical pressures:

$$P = \frac{T \times N \times 462}{C \times W},$$

where, sub-bandage pressure P is dependent on: N = number of layers of bandage; the more the layers, the greater the pressure.

T is tension in the bandage – the greater the force applied, the greater the pressure. C is limb circumference – the smaller the circumference, the greater the pressure. W is width of bandage – the narrower the bandage, the greater the pressure. 4620 is the accepted constant.

### **Application of bandaging**

Bandaging can be applied using a spiral technique with 50% overlapping and run from the base of the toes to just below the tibial plateau to be changed every week to avoid decrease of the applied pressure and to avoid soaking of the bandaging.

By starting at the base of the toes, there is less chance of the bandage trapping interstitial fluid produced by normal systemic hydrostatic and osmotic pressure. In brief, if the bandages started further up the foot or at the ankle, there would be considerable swelling of the toes and forefoot. Application of the bandages up to the knee, just below the tibial plateau, ensures that the calf muscles are assisted in their pumping action, reducing superficial capillary and venous hydrostatic pressure by increasing the velocity of venous blood returning to the heart.

Follow-up every month to detect improvements by measuring the diameter of the ulcer and detect the progression of healing.

#### Assessment

To ensure the safe and effective application of bandages, competent practitioners should perform a holistic assessment of the patient before any bandages are applied; the assessment should include the following: circumference of the ankle, prominences of bones, level of activity of the patient, position and size of the ulcer, level of exudates, ankle brachial pressure index, signs of ischemia in the leg, history of cardiac disease, presence or absence of diabetes mellitus, and previous experience of compression bandaging.

#### All patients were subjected to the following investigations

- (1) Radiograph of the leg and feet.
- (2) Doppler US of both legs.

The results from group I, group II, and group III were obtained and then compared.

In our study, the patients were followed up at 3, 6, and 9 months after complete healing for the detection of recurrence.

#### The main variables for follow-up were as follows

- (1) Measurement of the area of the lesions under aseptic conditions at 0, 1, 2, and 3 months using a graph paper.
- (2) Qualitative clinical evaluation of the lesions.
  - (a) A qualitative clinical evaluation of the lesions was performed by a physician by inspecting the ulcer in terms of color, inflammatory signs, infectious signs, wound care, wound response, and recurrence.

A qualitative clinical evaluation of the lesions was also performed by the patient using the visual analogue scale.

#### Statistical methods

The data were coded and analyzed using SPSS version 16.0 (Upper Saddle River, NJ: Prentice Hall. Chapters 2,3).

For qualitative data,  $\chi^2$ -tests were used, which were represented as frequencies and percentages.

Means, SD, and range were used to describe quantitative data and analysis of variance was used to compare the means of the groups.

The test results were considered significant when  $P$  value less than 0.05.

#### Results

Thirty-two ulcers were treated in 20 patients in group I, which were distributed as follows: six patients had a single ulcer in one leg, four patients had a single ulcer in both legs, five patients had two ulcers in one leg, and two patients had two ulcers in both legs.

Thirty ulcers were treated in 20 patients in group II, which were distributed as follows: six patients had a single ulcer in one leg, three patients had a single ulcer in both legs, five patients had two ulcers in one leg, and two patients had two ulcers in both legs.

Thirt-five ulcers were treated in 20 patients in group III, which were distributed as follows: nine patients had a single ulcer in one leg, five patients had a single ulcer in both legs, four patients had two ulcers in one leg, and two patients had two ulcers in both legs.

This study was carried out from January 2013 to January 2014.

Thus, the percentage of regression of the total surface area showed that the compression bandage technique used in group III was the most efficient for healing of chronic venous leg ulcers, followed by laser therapy, and finally US therapy ( $P = 0.04$  at the end of the first month and  $P = 0.03$  at the end of the third month).

After 3 months of follow-up, there was recurrence in two (10%) patients in group I, four (20%) patients in group II, and one (5%) patient in group III, whereas after 6 months of follow-up, there was recurrence in three (15%) patients in group I, two (10%) patients in group II, and two (10%) patients in group III. However, after 9 months of follow-up, there was recurrence in two (10%) patients in group I, three (15%) patients in group II, and two (10%) patients in group III. Thus, the recurrence rate of chronic venous leg ulcers with the use of the compression bandage technique in group III was the lowest as the total number of recurrent cases was five (25%), followed by laser therapy used in group I as the total number of recurrent cases was seven (35%), and finally US therapy used in group II had a higher recurrence rate as the total number of recurrent cases was nine (45%) ( $P = 0.85$ , nonsignificant).

In the present study, five patients were lost to follow-up: two patients in group I, two patients in group II, and one patient from group III.

## Discussion

The chronic venous insufficiency of the extremities is a progressive disease where in the most severe class 6 (the CEAP system), active ulceration develops – *ulcus cruris venosum*. The venous ulcerations are located most often above the medial malleolus, are very hard to heal, and are associated with distinct pain syndrome. When the disease is not treated adequately, patients may develop various degrees of disability [7].

The complex approach combining medication and local treatment, limb elevation, and elastic compression is the only method that has proven effective in resolving the problem because the presence of an active ulcer is a contraindication against surgical intervention [8].

In this study, a four-layer compression bandage (35 to 40 mmHg at the ankle) applied in 20 patients with venous leg ulcers provided an effective physical modality for wound healing (group III), which was compared with LLLT applied in 20 patients (group I) and US therapy applied in patients in group II. For patients with isolated superficial reflux, the healing rate at 2 months was 9/14 (64%) in group I, 6/10 (60%) in group II, and 16/23 (69%) in group III. For patients with superficial and deep reflux, the healing rates were 3/5 (60%) in group I, 2/4 (50%) in group II, and 4/6 (66%) in group III.

Study assessment parameters included ulcer size, the presence of skin infection or inflammation, pain, and recurrence of ulcers. The primary outcome measures were the mean healing time. The mean healing time was 2 months as shown in Table 3; the healing was significant at the end of the first and the third month more with compression therapy in group III, followed by LLLT in group I, and finally, US therapy in group II.

In a study carried out by Taradaj and colleagues, it was concluded that the hemodynamic effect (improvement of arterial microcirculation inside the venous leg ulcer) is one of the most significant biophysical mechanisms of healing after clinically efficient compression therapy.

Hemodynamic reactions are not basic mechanisms of high-voltage stimulation and US therapy during the healing of venous leg ulcers. Computed thermography is a simple and useful tool to measure hemodynamic effects in wound healing [7].

It has been reported that LLLT can accelerate wound healing. These findings are supported by in-vitro examinations confirming that low-level laser irradiation significantly increases cell proliferation and collagen deposition [9]. A clinical trial was conducted on 131 patients with venous leg ulcers (ulcer surface >3 cm<sup>2</sup>; duration >3 months) who were randomized into three groups: group A included 42 patients who were treated using an open-toed, elastic, class III compression device knitted in tubular form (tubulcus); group B included 46 patients treated with a multicomponent bandaging system comprised of tubulcus and one elastic bandage; and group C included 43 patients treated with a four-layer compression bandaging system. The healing rate during the 26-week treatment period was higher in group C [10].

Another study compared the rate of healing, pain, and quality of life between medical compression stockings (MCS) (group I) providing 15–25 mmHg at the ankle and four-layer compression bandaging (group II) applying 35–40 mmHg at the ankle bandages. Healing was observed within 90 days in 36% of patients using MCS (group I) and in 48% of patients using four-layer compression bandages (group II). Healing within 180 days was observed in 50% of MCS (group I) patients and in 67% of patients with four-layer compression bandages (group II) [11].

Another study concluded that low-intensity laser therapy could be an effective treatment for patients with venous ulceration. Assessments of wound surface area, wound appearance, and current pain were completed by an independent investigator. The primary findings were changes in wound appearance and a decrease in the wound surface area (range 33.3–46.3%). Visual analogue scale scores showed a decrease of 15% at the end of the study [12].

**Table 3 Criteria of ulcer healing**

Duration of healing	Group I (N = 32 ulcers) [N (%)]	Group II (N = 30 ulcers) [N (%)]	Group III (N = 35 ulcers) [N (%)]	$\chi^2$	P
Size of the ulcer (cm <sup>2</sup> ): on admission to the study (cm <sup>2</sup> )					
<2	7 (21.8)	6 (20)	7 (20)	0.75	0.93
2–4	16 (50)	13 (43.3)	18 (51.5)	3.73	0.15
>4	9 (28.1)	11 (36.7)	10 (28.5)	0.40	0.82
Duration of healing of the ulcer					
First month	5 (15.6)	3 (10)	10 (28.5)	6.19	0.04
Second month	9 (28.4)	7 (23.3)	13 (37)	1.54	0.46
Third month	18 (56)	20 (66.7)	12 (34.5)	7.20	0.03*

Another study found that compression was more effective in healing venous leg ulcers than no compression, and multilayered high compression was more effective than single-layer compression. High compression was more effective than moderate compression in preventing recurrence of ulcers. There is generally insufficient reliable evidence to draw conclusions on the contribution of laser therapy, therapeutic US, electrotherapy, and electromagnetic therapy toward chronic wound healing [13].

A study was carried out that included 70 patients with venous leg ulcers divided into two groups. Group A included 33 patients who were treated with US, compression stockings, and drug therapy. Group B (control) included 37 patients who were treated with the compression stockings and drug therapy only. Ten patients in group A and 12 patients in group B showed complete healing. Comparison of the total surface area, length, width, and volume did not show any difference between the groups. Decrease in pus and greater promotion of granulation were observed in group A compared with group B. However, the changes observed did not have an influence on acceleration of therapy or on the final stage of the wound-healing process because no differences were detected in the epidermization rate of the ulcers in either group. Therefore, there are no specific indications that application of US promotes healing in patients after a surgical operation [14].

In this study, the recurrence rate of compression therapy was the lowest (25%) after 9 months whereas

the recurrence rate with US therapy was the highest (45%) as shown in Table 4.

In a clinical trial that was conducted on 136 patients subjected to a four-layer compression bandage with healed venous leg ulcers attending the outpatient clinics for follow-up, recurrence was observed in 32% of patients with ulcers after 12 months of complete healing [15].

However, in another trial conducted on 138 patients subjected to four-layer compression bandage with healed venous leg ulcers attending the outpatient clinic for follow-up, recurrence was observed in 34% of patients after 18 months of complete healing [16].

### Conclusion and recommendation

Venous surgery, followed by compression therapy is the most efficient treatment for venous leg ulcers. LLLT and US therapy are useful methods as a conservative treatment of venous leg ulcers and can be used for the treatment of small-size ulcers. More studies should be carried out with large numbers of patients using a combination of modalities.

### Acknowledgements

#### Conflicts of interest

None declared.

**Table 4 Qualitative clinical evaluation of the patient**

Parameters of evaluation	Group I (N = 20) [N (%)]	Group II (N = 20) [N (%)]	Group III (N = 20) [N (%)]	$\chi^2$	P
<b>Inflammatory signs</b>					
Preprocedure	18 (90)	19 (95)	18 (90)	0.83	0.44
During the procedure					
First month	12 (60)	17 (85)	16 (80)	0.15	3.73
Second month	6 (30)	10 (50)	9 (45)	0.41	1.78
Third month	2 (10)	7 (35)	2 (10)	0.06	5.57
<b>Infective signs</b>					
Preprocedure	15 (75)	13 (65)	14 (70)	0.49	0.48
During the procedure					
First 1 month	11 (55)	9 (45)	10 (50)	0.49	0.82
Second month	6 (30)	3 (15)	4 (20)	1.37	0.50
Third month	2 (10)	1 (5)	1 (5)	0.54	0.77
<b>Decrease of pain</b>					
First month	11 (55)	16 (80)	15 (75)	0.19	3.33
Second month	5 (25)	13 (65)	8 (40)	0.04*	6.85
Third month	1 (5)	7 (35)	1 (5)	0.07*	9.41
<b>Recurrence</b>					
Total	7 (35)	9 (45)	5 (25)	1.76	0.42
Within 3 months of follow-up	2 (10)	4 (20)	1 (5)	2.26	0.32
Within 6 months of follow-up	3 (15)	2 (10)	2 (10)	0.32	0.85
Within 9 months of follow-up	2 (10)	3 (15)	2 (10)	0.32	0.85

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