



## Full Length Research Article

### EFFICACY OF LOW LEVEL LASER THERAPY IN THE MANAGEMENT OF VENOUS LEG ULCER

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#### ABSTRACT

**BACKGROUND:** Chronic venous leg ulcers are major health problems in most countries with patients who suffer from chronic venous insufficiency. LLLT is most commonly used physiotherapy modality used as a tissue stimulator to improve wound healing and they also have anti inflammatory and an analgesic effect. Very few studies attempted to find the efficacy of LLLT in the management of venous leg ulcers.

**Study Design:** Pre and post with control group design.

**Materials and Methods:** 40 patients who diagnosed with venous ulcers in the leg are randomly arranged and allocated equally to either experimental or control group. 20 patients of the experimental group was treated with Low Level Laser Therapy (wave length 904nm), Power 0.5 to 4 J/cm<sup>2</sup>, Duration 2 min, along with routine medication and 20 patients of the control group were treated conservatively with routine medications. Both groups were treated 3 times a week for 4 weeks. The wound size is measured along grid system on the first day of treatment and at the end of four weeks for both the groups.

**Results:** At the end of the four weeks both LLLT and control group showed improvements in venous ulcer healing. But intergroup comparison shows that LLLT group wound size was 60.36 cm<sup>2</sup> before treatment and after treatment wound size was reduced to 46.71 cm<sup>2</sup> and in conservative group wound size 63.34cm<sup>2</sup> before the treatment and which has reduced only 62.07cm<sup>2</sup> at the end of the four weeks of treatment. So the result showed that LLLT group shows statistically significant improvement results (P<0.005) in venous leg ulcer healing.

**Conclusion:** From the results of the study we can conclude that Low Level Laser Therapy is an effective method of treatment for venous leg ulcer patients.

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## INTRODUCTION

Venous ulcers are wounds that are thought to occur due to improper functioning of valves in the veins usually of the leg. They are the major cause of chronic wounds occurring in 70% to 90% of chronic wound cases (Synder, 2005). The exact etiology of venous ulcers is not certain, but they are thought to arise when venous valves that exist to prevent backflow of blood do not function properly, causing the pressure in veins to increase. The body needs the pressure gradient between arteries and veins on order for heart to pump forward through arteries into the veins. When venous hypertension exists, arteries no longer have significantly higher pressure than veins, blood is not pumped on effectively into or out of the area and it pools

out (Deya Al-Kurdi *et al.*, 2008). The disease mainly effects people between 60 and 80 years old, with women affected 3 times more frequently than men (Mastoe, 2005). Chronic venous leg ulcers and a major health problem on most countries with patients who suffer from chronic venous insufficiency. Venous ulceration has two main etiologies. Firstly ulceration may be assorted with demonstrable varicose veins; secondly such ulceration may follow thrombosis and phlebitis in deep and perforating veins. The second group presents as an ulcerated edematous leg with demonstrable superficial varies in only about 1/3<sup>rd</sup> of cases (Das, Test book of surgery). The first choice of management of venous ulcers is medical management or non –operative and various other techniques has been used. The usual choice of treatment in physiotherapy is Low Level Laser Therapy and some of the studies reported that Low Level Laser has moderate influence

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Treatment	N	Gender	Age	Minimum	Maximum	Mean	Std. Deviation
Laser therapy	15	Male	Age	30.00	67.00	51.0667	12.70808
	5	Female	Age	51.00	63.00	57.8000	5.44977
Conservative treatment	15	Male	Age	25.00	69.00	44.9333	12.20343
	5	Female	Age	49.00	65.00	57.0000	6.67083

**Table 2: Wound size before and after the different modes of treatment at different interval of time. Values are expressed as Mean  $\pm$  S.D. n=20.**

	GROUP	Mean (cm <sup>2</sup> )	Std. Deviation	N
Before Wound Size	LASER THERAPY	60.3625	26.22718	20
	CONSERVATIVE TREATMENT	63.3450	38.23580	20
	Total	64.6900	31.22932	40
First week	LASER THERAPY	57.1250	26.44949	20
	CONSERVATIVE TREATMENT	62.8625	38.38247	20
	Total	63.0208	31.35308	40
Second week	LASER THERAPY	53.3500	26.74937	20
	CONSERVATIVE TREATMENT	62.5200	38.53020	20
	Total	61.2567	31.55912	40
Third week	LASER THERAPY	49.4750	27.23846	20
	CONSERVATIVE TREATMENT	62.3575	38.73238	20
	Total	59.5608	31.98267	40
Fourth week	LASER THERAPY	46.7125	27.50829	20
	CONSERVATIVE TREATMENT	62.0795	38.95263	20
	Total	58.2140	32.35607	40

Medi on wound healing in venous leg ulcers (Kopera D. Kokol *et al.*, 2005). Current management of Venous ulcers involves prevention, Management, Surgical Management and Physical Therapy in chronic wounds particularly venous ulceration, are very difficult to heal. Because current therapies are variable in their ability to induce complete healing, these remain a need to develop adjunctive treatments that can improve or accelerate the healing process (Joseph *et al.*, 2008). In physiotherapy various methods of treatment can be given for venous ulcers namely Infra Red Radiation (Fleming *et al.*, 1999) Ultrasound therapy (Taradaj *et al.*, 2008) and Laser therapy. In the above mention modalities effectiveness of the Low Level Laser Therapy is being done. LLLT is most commonly used physiotherapy modality as bio stimulation to improve wound healing & they also have anti inflammatory and analgesic effect. Very few studies attempted to find the efficacy of LLLT in the management of venous ulcers, So this study is aimed to determine the effectiveness of LLLT on the management of venous leg ulcers.

## MATERIALS AND METHODS

This study was approved by the Nitte University Ethical Committee 40 patients from the department of surgery K.S Hegde Hospital diagnosed by the surgeons as venous leg ulcer was selected for the study. The diagnosis was confirmed by all the clinical interventions. The 40 subjects were recruited for this study including both females and males. The patients were randomly assigned to any of two groups of 20 each. All this patients selected for the study were in the age group 20-80

years. We included the subjects, Patients with venous ulcer, Dermatitis. We excluded the subjects with tumors, Deep Venous Insufficiency (DVI), Metal Implants, Photo allergy, Burns, Tuberculosis, History of long term steroid therapy & radiation; uncontrolled diabetics.

**Interventions:** Group 1 was treated with Low Level Laser Therapy with routine medical management. Laser was applied with the wavelength 904nm Dosage 0.5 to 4 joules/cm<sup>2</sup>, Duration 2min for cm<sup>2</sup> area, 3 times a week for 4 weeks. The base of the wounds is visually divided into square cm grids. The Laser probe is held perpendicular to the center on each square at the distance of 0.5 to 1cm from the wound surface and is swept in the entire cm<sup>2</sup> in a circular motion. Each square cm of involved tissue is stimulated equally for effective coverage of the entire tissue surfaces. Both patients and the therapist has to cover the eyes with Goggle. Group2 Patients getting conservative and medical management. In this we advise the patients to elevate the limb, up to 30<sup>0</sup> in supine lying position, passive movements to maintain mobility of the foot and ankle, Cleaning and daily dressing, Effective Analgesic and antibiotic used as advised by the surgeons.

**Outcome Measures:** All the subjects were evaluated for the wound measurement before starting of the treatment. Post outcome measurements were done at the end of 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> weeks. The area of venous ulcer was traced by sterile transparency paper (cleaned with spirit). The area of venous ulcers was measured by maximum length and width measurement with ruler and by digitizer.

**Table 3: Intergroup comparison of different modes of treatment Values is expressed as Mean difference  $\pm$  Standard Error. N=20**

Multiple Comparisons						
Measure: Treatment						
Post hoc / Bonferroni ANOVA						
(I) Treatment	(J) Treatment	Wound Size Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
LASER THERAPY	CONSERVATIVE TREATMENT	7.8067 <sup>*</sup>	.92095	.000	5.5351	10.0784
CONSERVATIVE TREATMENT	LASER THERAPY	-7.8067 <sup>*</sup>	.92095	.000	-10.0784	-5.5351

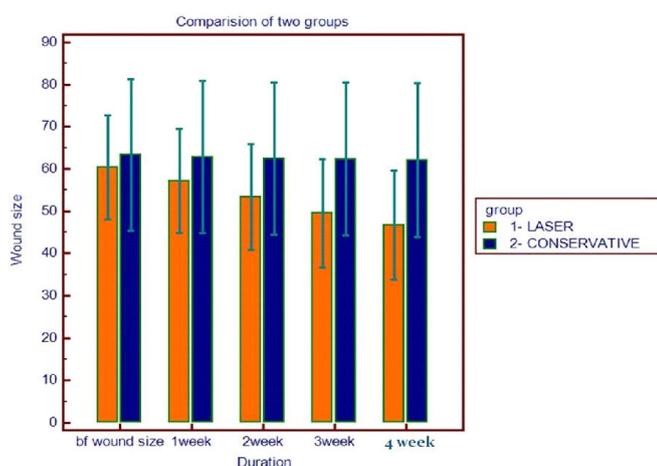
Based on observed means.  
The error term is Mean Square(Error) = 8.482.

\*. The mean difference is significant at the .05 level.

**Statistical Analysis:** The collected data were analyzed using the statistical tests. Statistical analyses were done using IBM SPSS 21 software. Within group comparison were made using Mean and Standard deviation and between group comparison were made using one way ANNOVA. Post hoc Analysis was carried out to compare to difference in wound size between the weeks.

## RESULTS

The mean age for group I was male  $51.66 \pm 12.70$ , and for females  $57.80 \pm 5.44$  as shown in table 1. Group I consisted of 20 subjects (n = 20) with a gender distribution of 15 males (75%) and 5 females (25%). Group II also consisted of subject (n=20) and gender distribution is males (75% & females (25%)). The mean and standard deviation (SD) of pre and post measurement for both groups I and group II are presented in Table II & III. The post test mean for Group I was  $46.71 \pm 27.50$  and group II was  $62.07 \pm 38.95$ . The intergroup pre and post analysis worth different modes of treatment shows a mean difference in wound size was 7.80;  $p=0.000$  shows significance



Difference ( $P<0.05$ ) between two group. The mean and standard deviation of pre and post measurement for both group presented in Table I. The Intergroup pre and post comparison of wound size for group I and II represented in Table III.

## DISCUSSION

Present study showed a change on wound size in the Laser Therapy group from base line ( $60.36 \pm 26.22$ ) to 1<sup>st</sup> week ( $57.12 \pm 26.44$ ), to 2<sup>nd</sup> week ( $53 \pm 26.74$ ) to 3<sup>rd</sup> week ( $49.47 \pm 27.33$ ) and 4<sup>th</sup> week ( $46.71 \pm 27.50$ ) respectively. Present study showed a change in difference wound size in conservative group from base line ( $63.34 \pm 38.23$ ) to 1<sup>st</sup> week ( $62.86 \pm 38.38$ ) to 2<sup>nd</sup> week ( $62.52 \pm 38.53$ ) to 3<sup>rd</sup> week ( $62.35 \pm 38.73$ ) 4<sup>th</sup> week ( $62.07 \pm 38.95$ ) respectively. Physical Therapy such as infrared radiation ultrasound Therapy, Laser Therapy, active exercises includes in the management of Venous ulcers. However, conflicting finding have been reported in some studies and some investigation found no treatment effect on an accelerating the repair of wounds (Huseyin *et al.*, 2004). Laser treatment has been studied in wound healing; currently laser treatment is used for open wounds, grafts, incision, diabetic ulcers, venous ulcers, lacerations and burns (Huseyin *et al.*, 2004). Canan Tikiz *et al.* (2009) in the study found that Fibroblasts and collagen were found to be significantly increase in the laser group when compared to the other group on the 7<sup>th</sup> day ( $p<0.05$ ). Angiogenesis was found to be significantly increased only in laser group, when compared to the other group on the 15<sup>th</sup> day ( $P < 0.05$ ) Canan Tikoz (2009). For the better effect of Laser, increased patient population and frequency of treatments may help for the better reduction of ulcer size have been documented by studies conducted by Franck Marie *et al.* (2010).

Laser can be classified as surgical (High power) and non surgical (Low power) for therapeutic purposes. Non surgical lasers are widely used as tissue stimulator to improve wound repair. They also have anti inflammatory and analgesic effects. Laser wavelength of 632.8nm and 904nm Ga As are most commonly used in wound healing (Huseyin *et al.*, 2004). Therefore we have used the Ga As (Semiconductor infrared radiation source) with wavelength of 904 nm and power 0.5 to 4J/cm<sup>2</sup>. The result of this study also supports the other studies. LLLT will stimulate the Collagenogenesis Fibroblast generation and DNA synthesis activity (John Low and Reed, 2000). It also has anti-inflammatory effect (Aymann Nassif *et al.* 2002). The study showed that Low Level Laser

Therapy and conservative therapy both have beneficial effect on venous leg ulcer ( $p=0.000$ ) and when compare the effect between both the groups Laser therapy shows better results than the conservative therapy.

### Scope for the further study

A large sample size should be taken to improve the quality of the results. More research is necessary with larger group: Standardization of treatment interventions using more parameters of outcome measurement. Further study can be done between ultrasound therapy and Low Level Laser Therapy with a controlled group with larger samples size. Usage of other investigations for the knowledge of result like cellular contents granulation tissue formation and collagen deposition which give better and moresignificant results.

### Conclusion

From the result of the study we observed that Low Level Laser Therapy is found to be comparatively better than the conservative therapy in the management of Venous Ulcer.

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