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Photographic Assessment to Evaluate Effectiveness of Low-Level LASER Therapy in Wound Healing: A Randomized Controlled Trial

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Abstract

Introduction: Among the existing non-invasive therapies, Low Level LASER Therapy (LLLT) has been gaining interest as various studies have proved its effectiveness in the treatment of non-healing wounds but no studies have been done to report the effects within a shorter duration when compared to Standard Operating Procedure.

Aims: To evaluate the effectiveness of LLLT on ulcer dimensions using photographic assessment and simple ruler method. To compare effectiveness of Standard Operating Procedure and LLLT on ulcer dimensions using photographic assessment and simple ruler method.

Materials and methods: A randomized controlled trial was carried out on total of 30 subjects divided randomly into 2 groups of 15 each. Standard operating procedure was given to group A, whereas LLLT along with Standard Operating Procedure was administered to group B. Intervention was given for 6 days. Patients were assessed for ulcer dimensions using a simple ruler method and IMITO Measure app, and pain assessment was done using Visual Analogue Scale pre and post intervention of 6 days.

Results and discussion: Significant improvement in pain reduction was seen in both the groups ($p<0.05$). But when comparison was done between the groups, no significance was reported ($p>0.05$). There was no significant difference noted in the ulcer dimensions in both groups ($p>0.05$).

Conclusion: The study concludes that standard operating procedure is equally beneficial as in combination with LLLT. LLLT can be used in conventional therapy to lessen the pain of the patient.

Keywords: Low Level LASER Therapy, Photographic assessment, Standard Operating Procedure, IMITO Measure

1. Introduction

A wound is defined as a disruption of normal anatomic structure and function resulting from pathologic processes commencing internally or externally to the involved organ [1]. The current estimated value of the population suffering from chronic wounds worldwide is 6 million [4]. A community-based epidemiological study in India related to wounds reported the prevalence of wounds to be 15.03 per 1000, lower extremity being the most common site for both acute as well as chronic wounds [5]. The wounds that heal in time and follow proper stages of healing, ensuring restoration for a longer duration of both anatomic and functional integrity are labeled as acute wounds while chronic wounds fail to heal without sustaining anatomic or functional integrity [1]. Wound healing is affected by various factors which are categorized as local and systemic. Local factors comprise of ischemia, infection, edema, venous sufficiency amongst others while systemic factors encompass diabetes mellitus, age, gender, hypothyroidism, hormonal balance, stress, obesity and others [4,5]. Foot ulceration is more prevalent in patients who have had a past history of ulceration or amputation [6]. In India, diabetes is rapidly gaining the status of a potential epidemic with more than 62 million diabetic individuals currently diagnosed with the disease [7]. Even though factors such as age, obesity, malnutrition, macro and micro vascular disease may play a role in affecting wound healing it cannot be denied that patients with diabetes experience more wound healing failures than the non-diabetic population [8].

The three risk factors related with DFUs are that pathological changes, anatomical abnormalities and environmental impacts, the conjunction of these factors might set off a chain of events that leads to ulceration [6]. In diabetic population, poor wound healing is attributed to various factors like hyperglycaemia which may increase nutrients to the bacteria and also alter local defense, poor angiogenesis, inhibition of responses of inflammation and fibroplasia and defects in collagen deposition and discrepancy of the extracellular matrix[9]. Many different therapies along with conventional therapy are said to be effective in wound healing. These therapies are ultrasound, electrical stimulation, hyperbaric oxygen therapy, Low Level LASER Therapy and other forms of photobiomodulations[10].

Planimetry , digital photography followed by computer software program analysis, direct measurement of 2D of the wound, dedicated Photography software (using a mobile application) and LASER technology are the main methods used in assessment of wound however, the most commonly used used are planimetry and computer software programs. The ideal method for assessment of wound should offer accuracy, reliability and feasibility[11]. In times, where technology is gaining interest and extensive use of smartphones for various reasons, IMITO MEASURE, a smartphone application provides an ideal, feasible and valid way for measuring wound dimensions[12,13]. Even with number of significant researches, there has been no study where photographic assessment is done to see the effectiveness of Low Level LASER Therapy on ulcer dimensions. There is dearth of evidence supporting photographic assessment of the wound and hence, the need arises to evaluate efficacy of photographic assessment on effectiveness of Low Level LASER Therapy and Standard Operating Procedure on ulcer dimensions within a short time span.

2. Materials and Method:

Ethics:

Ethical clearance was obtained from Institution ethical committee and all necessary COVID 19 precautions were taken following ICMR guidelines. The trial was registered prospectively in Clinical Trials Registry-India with CTRI number: CTRI/2021/09/036524

Study design:

This study is a randomized controlled trial having 30 participants randomly divided into 2 groups of 15 each. All were diagnosed cases of foot ulcers aged between 40-65 years, both males and females, having grade 1 and grade 2 ulcers on Wagner's classification. 4-7 years diagnosed cases of diabetes and having palpable peripheral pulses were included in study. The exclusion criteria comprises of those unwilling to participate, diagnosed cases of cellulitis, pressure sores, infected ulcers and medically unstable patients.

Outcome measure:

The participants were assessed on day 1 which was pre intervention and day 6 which was post intervention. Ulcer dimensions were assessed using simple ruler method and IMITO Measure mobile application. Length, width and depth were noted using simple ruler method while length, width, area and circumference were assessed using imito measure app. Pain was rated using visual analogue scale (VAS).

Intervention:

After inclusion of the participants, they were randomly separated to study and control group. In the control group only standard operating treatment care was administered to the participants while in the study group participants underwent standard operating care alongside with Low Level LASER Therapy. The intervention was given once daily for 6 days by the physiotherapist. Patient was asked to attain a comfortable position in such a way that the ulcer area is completely visible. Low Level LASER Therapy was administered using scanning and grid method. Time duration was calculated based on the area of the ulcer. Standard operating procedure included daily dressing, cleaning of the wound and debridement as and when needed.

Statistical analysis:

Statistical Package for the Social Sciences version 23 (SPSS 23) was used for statistical analyses. The data was entered into an excel worksheet, charted and subjected to statistical analysis. Normality of all continuous data was

checked using the Kolmogorov-Smirnov test which showed normal distribution. Unpaired t-test was used to analyze parameters between control group as well as the intervention group. Comparison of difference in pre and post within group was done using paired t-test. Probability values was set at <0.05 considering statistically significant and <0.001 considering highly significant.

3. Results

Table I shows data analysis of the demographic details like age, gender, height, weight, BMI, years of diagnosis, type of ulcer, grade showed p value > 0.05, suggesting that the data followed a normal distribution.

Table II and III shows within group analysis while graphs I,II and III show comparison between the groups. Data analyses of ulcer dimension using ruler method which include length, width and depth in group A and group B when compared within the group showed improvement which was not significant. When compared between the groups, both the groups showed similar results which were statistically insignificant. Data analysis of length, width, area and circumference by IMITO Measure in group A and group B, when compared within the group showed improvement but *p*-value was insignificant. When compared between the groups, both the groups showed similar improvement with *p*-value being insignificant. Data analyses of pain scores in group A and group B, when compared within the group showed *p*-value being significant. When compared between the groups, both the groups showed *p*-value being insignificant ($p>0.05$)

4. Discussion:

Present study found that there was more male dominance over female as there were 60% of males in Group A and 86.66% of males in Group B whereas the average number of females in Group A were 40% and 13.33% in group B. Every day practices such as smoking, chewing tobacco and consuming alcohol indicated a larger percentage of individuals suffering from DFUs when compared to those who had normal habits[14]. Women are much less likely than men to develop foot ulcers, which may be due to less serious neuropathy, better joint mobility and reduced foot pressures[15]. In the present study, participant's age ranged from 40-65 years. Participant's mean age in our study was 53.33±10.37 in Control group and 59.20±11.37 in study group. In another study it was concluded that patients between 45–64 years old had the greatest percent of discharge from hospital for foot ulcers, whereas those younger below 45 years old had the lowest discharge probabilities[16].

Table I

Particular	Group	Mean	SD	p-value
Age	Group B	59.20	11.37	0.151
	Group A	53.33	10.37	
HEIGHT	Group B	155.13	4.27	0.134
	Group A	158.00	5.77	
WEIGHT	Group B	60.20	7.69	0.527
	Group A	58.13	9.86	
BMI	Group B	25.35	3.25	0.180
	Group A	23.57	3.80	
DM_YRS	Group B	7.00	3.09	0.096
	Group A	10.20	6.50	

* Significant at 5% level, Demographic profile

Mean BMI in our study for control group was 23.57±3.80 kg/m^2 and in study group was 25.35±3.25 kg/m^2. Even though India has lower rates of overweight and obesity, it seems to have a high diabetes prevalence than countries in the west, implying that diabetes can develop at a lower BMI in population of India than in populace in Europe[7]. In this study the control group had a mean BMI which indicated more of overweight individuals and the intervention group had more obese class 1 individuals. Obesity is considered as one of the risk factor in terms of diabetes which can further affect wound healing[7,8].

Our study results varies from many other studies done on LLLT where LLLT was proven to be effective in reduction of ulcer size or enhancing wound healing[10,17,18]. The probable reason for this could be the time

duration for which the LLLT was administered. In our study LLLT was set for 6 sessions whereas other studies it was administered over 15 days or more[18,19]. The other factor that could be the reason of the contrasting results could be the difference in the ulcer dimensions, like in the research by Kajagar et al where subject with ulcer size of 6×6 cm^2 or less were included whereas in our study no such generalization was done and patients with variant sizes were incorporated[10].

Our study results were in accordance to the systematic review done to investigate the efficacy of LLLT on chronic wounds in human subjects, the study concluded that there are no solid justifications for using LLLT to treat venous leg ulcers, decubitus ulcers or other chronic wounds on a regular basis[16].

Table II

Variable	Pre		Post		Diff		Effect size	z – value	p – value
	Mean	SD	Mean	SD	Mean	SD			
Manual length	4.89	1.41	4.98	0.45	-0.09	1.20	0.08	0.299	0.769
Manual width	3.09	1.65	2.81	1.35	0.27	0.59	0.46	1.791	0.095
Manual depth	0.69	0.76	0.68	0.77	0.01	0.05	0.26	1.000	0.334
IMITO length	5.40	0.77	5.17	0.56	0.23	1.01	0.23	0.888	0.389
IMITO width	3.09	1.41	2.94	1.32	0.15	0.73	0.21	0.799	0.438
IMITO area	11.99	6.32	9.64	4.38	2.34	4.91	0.48	1.848	0.086
IMITO circumference	14.14	3.50	13.31	2.64	0.83	2.81	0.30	1.143	0.272
VAS	3.97	2.97	3.32	2.49	0.65	1.07	0.60	2.339	0.035*

* Significant at 5% level, Pre and post paired t-test for Control Group

Table III

Variable	Pre		Post		Diff		Effect size	z – value	p – value
	Mean	SD	Mean	SD	Mean	SD			
Manual length	5.22	1.26	5.22	1.32	0.00	0.65	0.00	0.000	1.000
Manual width	2.61	1.06	2.55	1.10	0.06	0.24	0.25	0.951	0.358
Manual depth	0.35	0.73	0.35	0.73	NA	NA	NA	NA	NA
IMITO length	5.24	1.08	5.05	1.12	0.19	0.40	0.47	1.829	0.089
IMITO width	2.68	1.04	2.43	1.00	0.26	0.76	0.33	1.296	0.216
IMITO area	10.90	3.56	9.38	3.32	1.52	3.16	0.48	1.863	0.084
IMITO circumference	12.09	2.76	11.63	2.68	0.46	1.13	0.41	1.591	0.134
VAS	2.66	1.70	1.81	1.48	0.85	0.98	0.87	3.355	0.005*

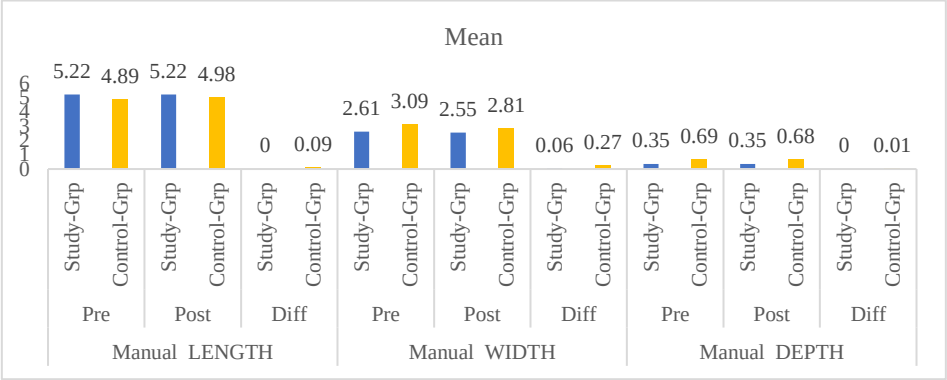
* Significant at 5% level, Pre and post paired t-test test for Study Group

A study done using the smartphone application suggested that it was accurate as compared to digital software[11]. Numerous researches have analyzed the effect of LLLT on repair using minor wounds[20]. whereas in our study the ineffective results can be contributed to the wound variability. In our study we included Grade 1 and Grade 2 ulcers according to Wagner's classification. In a study no noticeable variations were seen among the groups receiving the LLLT and sham groups until day 6, when the wounds were far into the soft tissue recovery phase, this results supports our study as we administered only 6 sessions of laser therapy[21].

According to medical knowledge, the pain associated with DFU might vary from mild to severe[22,23]. in one of the study 755 of the participants suffered from pain due to DFUs While some studies also reports that patient do not experience pain in DFUs[23,24]. Our study showed insignificant results in reduction of the pain when compared between groups. Similar to our finding one study reported that Laser treatment improved

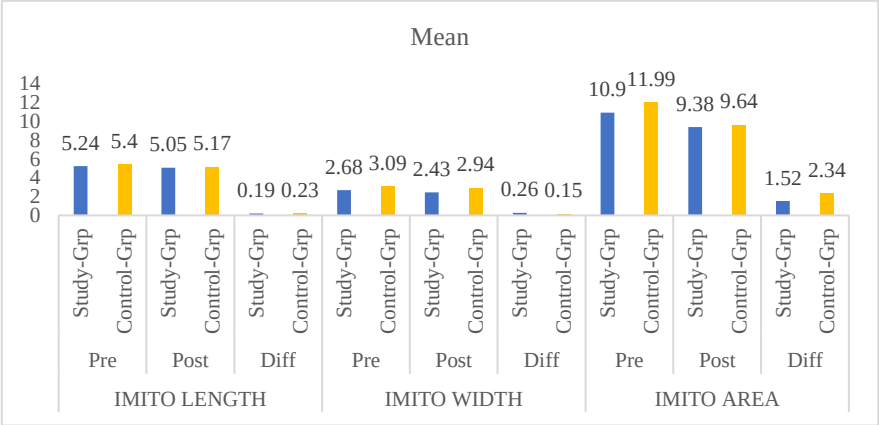
vascularization and expedited collateral circulation[25]. which could further explain and support the improvement in the pain reduction by Low Level LASER Therapy.

Graph I



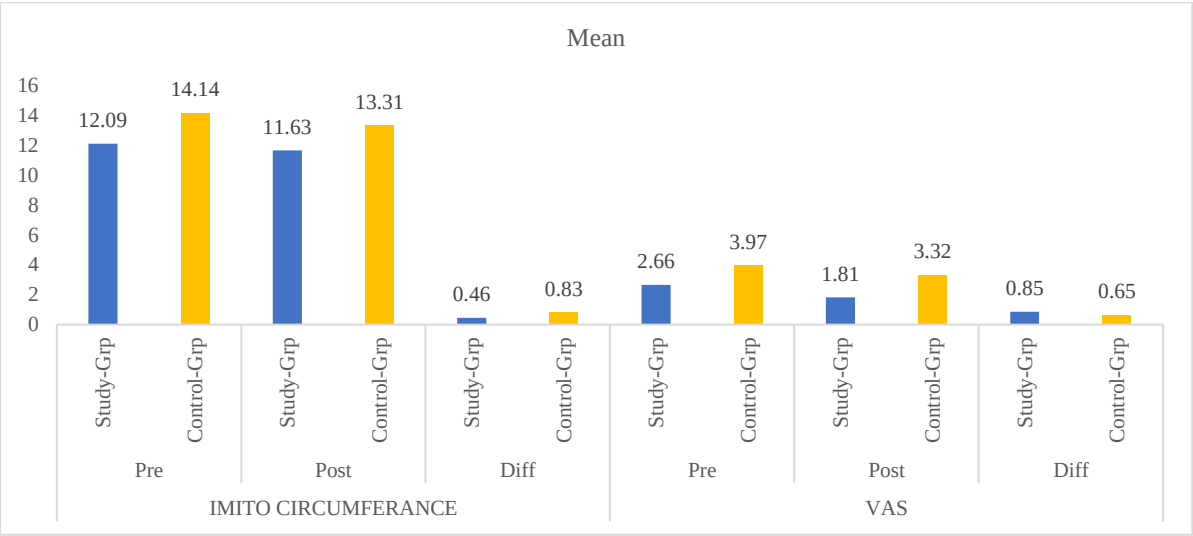
Between group comparison (1)

Graph II



Between group comparison (2)

Graph III



Between group comparison (3)

5. Conclusion:

The present study presented significant improvement in terms of pain reduction within the groups, however when compared between the groups, was insignificant. In case of reduction of ulcer dimensions, similar improvement was seen in both the groups which was statistically insignificant however it a high effect size. When compared between groups, both groups showed equal improvement. It can be concluded that standard operating procedure is as beneficial as given along with LLLT. LLLT can be used in conventional therapy to lessen the pain of the patient.

Conflict of Interest: None

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