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Photo-Biomodulation Therapy versus Saline Dressing in Wound Healing: A Prospective Comparative Study

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Abstract

Background: The process of wound healing is a standard physiological reaction to injuries, often resulting in the restoration of normal function and structure in affected tissues.

Objective: This work aimed to assess and compare the efficiency and safety of photo-biomodulation (PBM) therapy versus saline dressing in acute wounds.

Patients and Methods: This prospective comparative randomized clinical work had been performed on 40 participants aged from 16 to 40 years old, both genders, with acute wounds. Patients were divided into two equal groups: Group A (PBM side): Treated with diode laser and Group B (control side): Treated with saline dressing.

Results: Wound site, infection, size of the lesion at baseline and on 7th day were insignificantly different between both groups. Size of the lesion on the 14th day and duration of complete wound healing were significantly lower in group A than group B (p<0.05). Photographic wound assessment tool score at 14th day was significantly varied between both groups (p<0.001). Patient satisfaction and visual analogue scale were significantly varied between both groups (p<0.001). Complication was insignificantly different between both groups. Semi-quantitative histological scoring system on the 14th day was significantly different between both groups (p<0.001).

Conclusions: PBM wounds which received low level laser therapy exhibited advantages in various aspects, including less time needed for complete healing, reduced wound size, lower pain scores, along with favorable results in edges, skin color surrounding the wound, epithelization, granulation tissue, and overall wound assessment score compared to the control side.

Key Words: *Photo-biomodulation – Saline dressing – Wound healing – Low level laser therapy.*

Ethical Committee: Approval from Tanta University Hospitals' Ethics Committee Egypt, (code: 36184/12 /22).

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Introduction

The process of wound healing is a typical physiological reaction to injuries, often resulting in the restoration of normal structure and function in affected tissues. In certain illnesses, the process of wound healing results in a modified restoration of tissue structure and function, which is linked to the onset of remodelling and fibrosis [1].

Light treatment has its origins in ancient civilisations, including the Egyptians and Indians, who utilised sunshine (heliotherapy) for therapeutic and health-enhancing purposes [2].

Photo-biomodulation (PBM) treatments are a light-based therapy employing non-ionising light sources, that include lasers, broadband light and light emitting diodes (LEDs), throughout the spectrum of visible and infrared light. In order to start photophysical (both linear and nonlinear) and photochemical processes at various biological scales, this nonthermal technique uses endogenous chromophores [3].

A chromophore is a substance, either endogenous inside tissues or exogenous from external sources, that absorbs certain wavelengths based on its absorption coefficient [4].

It is becoming evident that interactions between light and biological tissues may elicit pathophysiological and anatomy-specific reactions. The four primary biological reactions elicited by PBM encompass pain and inflammation relief, an adjusted immune response, and tissue repair and regeneration [5].

PBM treatments may improve fibroblast matrix synthesis, wound contraction, inflammatory infiltration, macrophage phagocytosis, endothelial mobility and organisation for angiogenesis, epithelial migration and proliferation, and immunological monitoring [6].

Recent studies have demonstrated how well PBM treatment increases the activities of epithelial cells, especially their basal colony-forming units (stem/progenitor cells), which aid in the regeneration of skin appendages such as glands and hair follicles and re-epithelialization [7]. PBM was recognised for its efficacy in facilitating surgical wound closure in its first practical application [8]. The benefits of PBM treatments have since been demonstrated in human clinical trials for a variety of wound types, including diabetic, venous, pressure, and burns, among others [9]. PBM treatments have demonstrated clear therapeutic benefits in the effective treatment of burn injuries [10].

This work aimed to assess and contrast the efficiency and safety of PBM therapy versus saline dressing in acute wounds.

Patients and Methods

Forty individuals, both male and female, ages 16 to 40, with acute wounds such as second-degree burns, traumatic wounds, donor site of split thickness skin grafts, and degloving injuries of the extremities, participated in this prospective comparative randomised clinical study. After receiving clearance from Tanta University Hospitals' Ethics Committee in Tanta, Egypt, the work was carried out between December 2022 and December 2023 (approval code: 36184/12/22). A written well-informed consent had been gathered from the patient or relatives of the patients.

Exclusion criteria were patients who were on medications containing steroids or chemotherapy, chronic diseases including diabetes mellitus, renal failure, pregnant or lactating women, bleeding disorders and have malignancy.

Randomization:

Patients were divided into two equal groups: Group A (PBM side): Include the patients treated with diode laser and Group B (control side): Include the patients treated with saline dressing.

Each patient had been subjected to complete history taking, general and local examinations and laboratory tests [complete blood count (CBC), C-reactive protein (CRP), virology, bleeding profile, liver and renal function tests].

Digital photographs were taken for each wound at the baseline, before every session and at the end of follow-up period. The evaluation was done on 7th day and 14th days. Wound swabs had been taken for microbiology culture at baseline, 7th and 14th days. A wound was deemed infected if the swab culture showed development of any pathogenic microbe and antibiotics would be taken according to culture.

Clinical assessment:

Patient satisfaction was assessed by 5-point Likert scale (with one being ''absolutely dissatisfied'', two being ''dissatisfied'', three being ''neither dissatisfied nor satisfied'', four being ''satisfied'' and five being ''absolutely satisfied'') at 14th day [11].

Photographic wound assessment tool (PWAT) [12] encompasses six domains: Size and depth of the wound, the edges of the wound, type and quantity of necrotic tissue, skin color around the wound, type and quantity of granulation tissue, and epithelialization.

Assessors awarded a score ranging from zero to four for each of the six domains. The overall PWAT score for each wound image was determined by aggregating the points allocated to the six domains. The overall PWAT scores ranged from 0 to 24, with 0 indicating a fully healed ulcer. Measuring wound surface area: Square counting involves delineating the wound contour on clear film and then quantifying the area of the delineation by manually tallying the number of squares of predetermined size inside the tracing after overlaying the film onto a printed grid [13]. The visual analogue scale (VAS) has been employed to assess pain on the 7th and 14th days. The scale is shown by a 10cm (100mm) line, with 0 indicating no pain, 1 to 3 indicating mild pain within manageable limits, 4 to 6 indicating discomfort that disrupted sleep, and 7 to 10 indicating severe pain that significantly impacted appetite and sleep. Patients were directed to indicate a spot on the line that corresponded to their pain at the specified time intervals. Complication as infection, itching and pigment changes were recorded.

Surgical technique:

Group A (PBM side): After cleaning the wound with sodium chloride solution (saline solution 0.9%), The participant was positioned comfortably and provided with protective goggles for phototherapy. A diode laser device [Metrum Cryoflex Salsa, 940 nm Sp. z o.o Sp.k. European Medical Manufacturer, Poland] was used in all cases. Fig. (1).

Fig. (1): Diode laser device.

The device was adjusted as follows: Power output: 50mW. Mode: Continuos. Exposure time: 60 seconds/cm^2. Spot size: 0.6cm. Dose: 5 J/cm^2. Non-contact application technique, 2mm away from the skin lesion. In order to prevent contamination of the treated region, the laser device's probe was placed over the wound at a distance of 2mm from the skin lesion (non-contact) for 60 seconds/cm^2 with a power output of 50mw and a dosage of 5 j/cm^2. The probe was wrapped with sterile plastic wrap. Then gauze dressing (dry) was applied over the wound. Therapy was repeated 3 times per week until complete wound healing. If infection is suspected, systemic antibiotics were given according to swab culture.

Group B (control side), application of sodium chloride (saline solution 0.9%) soaked dressing only over the wound. Dressing was repeated 3 times per week until complete wound healing. If infection was suspected, systemic antibiotics were given according to the swab culture.

A written consent for performing the punch biopsy (3mm in diameter) specimen for histological assessment was obtained from all patients. The punch biopsy specimens were taken from all patients from the center of lesions at baseline and on 7th, and 14th days under completely sterilized conditions and local infiltrative anesthesia (2% lidocaine). Fig. (2).

All specimens were stained with hematoxylin and eosin as a routine histologic examination **[14]**. The histological evaluation was performed by the economic division at the pathology academic department of the faculty of medicine.

Fig. (2): Punch biopsy from degloving injury.

A microscopic examination of regularly stained paraffin sections with haematoxylin and eosin was conducted to assess the healing process, and photos were captured with a digital camera. Using a semi-quantitative scoring approach, the degree of re-epithelialization, the presence of fibroblasts, polymorphonuclear leukocytes (PMNL), and newly formed vasculature were assessed blindly **[15]**.

Absent is represented by zero, minimal by one, mild by two, moderate by three, and severe by four. 0 means there is no epithelization, no fibroblasts, PMNL, or newly formed blood vessels; 1 means the cut edges of the epithelium are thicker, there are fewer fibroblasts, PMNL, or newly formed blood vessels; 2 means that the epithelium is migrating, there are moderately many fibroblasts, PMNL, or newly developed blood vessels; 3 means that the epithelium is bridging the incision, there are many fibroblasts, PMNL, or newly formed blood vessels; and 4 means that there is full epithelial regeneration, there are too many PMNL, fibroblasts, or newly developed blood vessels.

Statistical analysis:

Measurable investigation was finished by IBM SPSS programming bundle rendition 20.0. (Armonk, NY: IBM Corp) Subjective information was shown using numbers and rates. The Shapiro-Wilk test had been used to survey the ordinariness of appropriation. Quantitative information had been shown using range (least and most extreme), mean, standard deviation, middle and interquartile range (IQR). The meaning of the outcomes acquired was decided at the 5% level. The tests utilized were McNemar and Peripheral Homogeneity Test used to examine the importance between the various stages, WilCCO on marked positions test for unusually dispersed quantitative boundaries, to differentiate between two periods and matched *t*-test for ordinarily appropriated quantitative factors, to differentiate between two periods.

Results

Demographic data, wound etiology and procedural details of LLLT were enumerated in this table. Table (1).

Table (1): Demographic data, wound aetiology and procedural details of LLLT of the studied patients.

	N=40
Age (years)	28.0 (23.0-32.0)
Sex:	
Male	33 (82.5%)
Female	7 (17.5%)
Wound etiology:	
Burn 2nd degree	20 (50.0%)
Trauma	6 (15.0%)
STSG donor	13 (32.5%)
Degloving injuries	1 (2.5%)
Procedural details of LLLT:	
Onset of LLLT (days)	2.18±0.50
No. of sessions	7.25±1.08

Data are presented as mean ± SD or frequency (%) or median (IQR).
STSG: Split thickness skin graft.
LLLT : Low level laser therapy.
No.: Number.

Wound site, infection, size of the lesion at baseline (day zero) and 7th day were insignificantly different between both groups. The size of the lesion on the 14th day and duration of complete wound healing were significantly lower in group A than group B ($p<0.05$). Table (2).

PWAT score at 7th day was insignificantly different between both groups. PWAT score at 14th day was significantly different between both groups ($p<0.001$). Table (3).

Patient satisfaction and VAS were significantly different between both groups ($p<0.001$). Complication was insignificantly different between both groups. Table (4).

Semi-quantitative histological scoring system at 7th day was insignificantly different between both groups. Semi-quantitative histological scoring system at 14th day was significantly different between both groups ($p<0.001$). Table (5).

Table (2): Comparison between both areas according to wound site, infection, size of the lesion and duration of complete wound healing

	Area A (n = 40)	Area B (n = 40)	Test	*p*
Wound site:				
Right	31 (77.5%)	24 (60.0%)	$\chi 2=2.851$	MCN $p= 0.092$
Left	9 (22.5%)	16 (40.0%)		
Arm	5 (12.5%)	6 (15.0%)	–	–
Foot	3 (7.5%)	2 (5.0%)		
Forearm	3 (7.5%)	3 (7.5%)		
Hand	2 (5.0%)	2 (5.0%)	MH=0.00	0.082
Leg	5 (12.5%)	4 (10.0%)		
Thigh	22(55.0%)	23 (57.5%)		
Infection:				
Baseline	0 (0.0%)	0 (0.0%)	–	–
7th day	4 (10.0%)	5 (12.5%)	–	0.920
14th day	6 (15.0%)	7 (17.5%)	–	0.932
Size of the lesion:				
Baseline	18.03±2.57	18.29±2.62	t=1.336	0.189
7th day	14.85±2.79	15.35±2.93	t=1.955	0.058
14th day	5.61±1.50	8.37±1.84	t=10.634*	<0.001*
Duration of complete wound healing	16.93±2.47	19.13±2.92	t=9.040*	<0.001*

Data are presented as mean ± SD or frequency (%).

* Significant p-value <0.05.

MCN: Mcnemar and marginal homogeneity test.

t: Paired t-test.

Table (3): Comparison between both areas according to PWAT score at 7th, 14th days and their total.

	Area A (n = 40)	Area B (n = 40)	Test	*p*
At 7th day				
Edges:				
1	1 (2.5%)	5 (12.5%)	MH=41.50	0.251
2	37 (92.5%)	24 (60.0%)		
3	2 (5.0%)	11 (27.5%)		
Necrotic tissue type (0)	40 (100.0%)	40 (100.0%)	–	–
Necrotic tissue amount (0)	40 (100.0%)	40 (100.0%)	–	–
Skin color surrounding:				
1	12 (30.0%)	11 (27.5%)	MH=43.0	0.144
2	24 (60.0%)	18 (45.0%)		
3	4 (10.0%)	11 (27.5%)		
Granulation:				
1	15 (37.5%)	9 (22.5%)	MH=50.0	0.480
2	18 (45.0%)	26 (65.0%)		
3	7 (17.5%)	5 (12.5%)		
Epithelization:				
1	10 (25.0%)	4 (10.0%)	MH=30.0	0.637
2	20 (50.0%)	30 (75.0%)		
3	10 (25.0%)	6 (15.0%)		
At 14th day				
Edges:				
0	39 (97.5%)	0 (0.0%)	MH=20.0*	<0.001*
1	1 (2.5%)	39 (97.5%)		
2	0 (0.0%)	1 (2.5%)		
3	0 (0.0%)	0 (0.0%)		
Necrotic tissue type (0)	40 (100.0%)	40 (100.0%)	–	–
Necrotic tissue amount (0)	40 (100.0%)	40 (100.0%)	–	–
Skin color surrounding:				
0	39 (97.5%)	8 (20.0%)	MH=0.0*	<0.001*
1	1 (2.5%)	32 (80.0%)		
2	0 (0.0%)	0 (0.0%)		
Granulation:				
0	34 (85.0%)	2 (5.0%)	MH=19.0*	<0.001*
1	6 (15.0%)	32 (80.0%)		
2	0 (0.0%)	6 (15.0%)		
Epithelization:				
0	31 (77.5%)	4 (10.0%)	MH=25.0*	<0.001*
1	7 (17.5%)	25 (62.5%)		
2	2 (5.0%)	11 (27.5%)		
Total PWAT score:				
7th day	7.75±1.55	8.10±1.32	Z=1.379	0.168
14th day	0.0 (0.0–1.00)	4.0 (4.0–5.0)	Z=5.551*	>0.001*

Data are presented as mean ± SD or frequency (%) or median (IQR).

* Significant *p*-value <0.05.

PWAT: Photographic wound assessment tool.

Table (4): Comparison between both areas according to patient satisfaction, VAS and complication.

	Area A (n = 40)	Area B (n = 40)	Test	*p*
Patient satisfaction	4.63±0.49	3.13±0.61	Z=5.295*	>0.001*
Absolutely dissatisfied	0 (0.0%)	0 (0.0%)	MH=134.0*	>0.001*
Dissatisfied	0 (0.0%)	4 (10.0%)		
Neither dissatisfied nor satisfied	0 (0.0%)	28 (70.0%)		
Satisfied	15 (37.5%)	7 (17.5%)		
Absolutely satisfied	25 (62.5%)	1 (2.5%)		
VAS:				
7^{th} day	5.78±0.97	7.85±0.80	Z=5.580*	>0.001*
14^{th} day	2.48±0.75	5.15±0.77	Z=5.580*	>0.001*
Complication	17 (42.5%)	18 (45.0%)	$\chi2$=0.220	0.774
Itching	11 (27.5%)	10 (25.0%)	$\chi2$=0.238	0.774
Infection	6 (15.0%)	7 (17.5%)	$\chi2$=0.346	0.0852
Pigmentation	0 (0.0%)	0 (0.0%)	–	–

Data are presented as mean ± SD or frequency (%). * Significant *p*-value <0.05. VAS: Visual analogue scale.

Table (5): Comparison between both areas according to semi-quantitative histological scoring system at 7^{th} and 14^{th} days.

	Area A (n = 40)	Area B (n = 40)	Test	*p*
At 7^{th} day				
Epithelization:				
1	5 (12.5%)	4 (10.0%)	MH=22.0	0.527
2	22 (55.0%)	26 (65.0%)		
3	13 (32.5%)	10 (25.0%)		
PMNL:				
1	5 (12.5%)	8 (20.0%)	MH=25.0	1.000
2	28 (70.0%)	22 (55.0%)		
3	7 (17.5%)	10 (25.0%)		
Fibrosis:				
1	7 (17.5%)	8 (20.0%)	MH=38.50	0.467
2	24 (60.0%)	25 (62.5%)		
3	9 (22.5%)	7 (17.5%)		
New vessels:				
1	6 (15.0%)	11 (27.5%)	MH=32.0	0.074
2	25 (62.5%)	23 (57.5%)		
3	9 (22.5%)	6 (15.0%)		
At 14^{th} day				
Epithelization:				
1	0 (0.0%)	0 (0.0%)	MH=124.50*	<0.001*
2	0 (0.0%)	7 (17.5%)		
3	8 (20.0%)	31 (77.5%)		
4	32 (80.0%)	2 (5.0%)		
PMNL:				
1	0 (0.0%)	0 (0.0%)	MH=124.0*	<0.001*
2	0 (0.0%)	16 (40.0%)		
3	11 (27.5%)	23 (57.5%)		
4	29 (72.5%)	1 (2.5%)		
Fibrosis:				
1	0 (0.0%)	0 (0.0%)	MH=117.50*	<0.001*
2	0 (0.0%)	11 (27.5%)		
3	17 (42.5%)	20 (50.0%)		
4	23 (57.5%)	9 (22.5%)		
New vessels:				
1	0 (0.0%)	0 (0.0%)	MH=124.0*	<0.001*
2	0 (0.0%)	7 (17.5%)		
3	10 (25.0%)	30 (75.0%)		
4	30 (75.0%)	3 (7.5%)		

Data is presented as frequency (%). * Significant *p*-value <0.05. PMNL: Polymorphonuclear leucocytes.

Fig. (3): Burn on (A) 7th day, (B) 14th day (Area A) after application of low level laser therapy, (C) 7th day and (D) 14th day (Area B) after saline dressing.

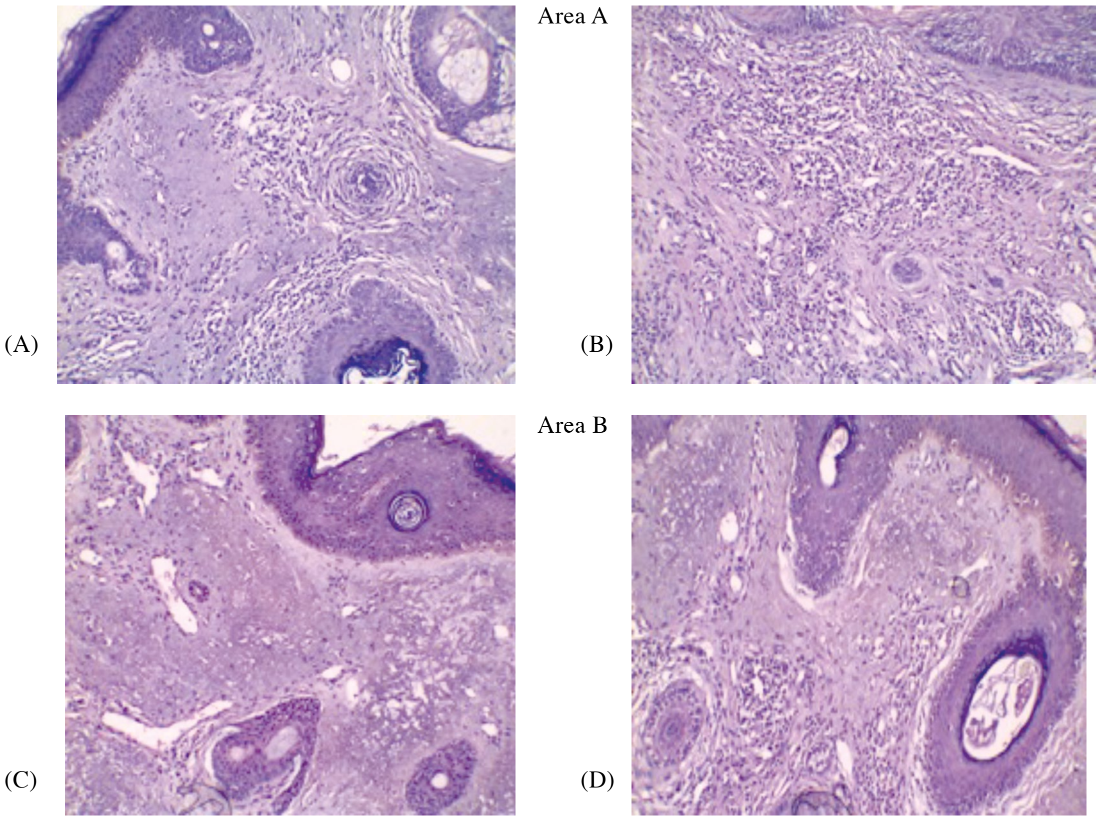

Fig. (4): Histological section H and E ×100 showed (A and D) moderate, (B) excessive, (C) few numbers of inflammatory infiltrate composed of lymphocytes, macrophages and neutrophils.

Discussion

The ability of skin lesions to recover is one of humanity's ongoing problems [16]. The goal of the process of healing is restoring the integrity and functionality of the wounded skin through a complicated physiological response that includes multiple cellular and molecular activities [17]. In our study the device of 940nm diode laser was adjusted as follows (power output 50mw, continuous mode, exposure time 60 seconds/cm^2, spot size: 0.6 cm, dose 5 j/cm^2 and non-contact at the distance of 2mm from the skin lesion). Light exposure over the wound was 3 times per week until complete healing. Unlike our study, Kazemikhoo et al. [18] used a 650-nm laser on the deep burn ulcer every other day until complete healing was accomplished. The laser's specifications were as follows: Power 150mW, spot size 0.6cm^2, duration 10 sec, and energy point 1.5 J. The study carried out by Vaghardoost et al. [19] used PLP in contact, continuous mode, providing 2 J/cm^2, at 650nm, 150mW, with a treated area of 0.25 cm^2, and a power density of 0.6 W/cm^2, to treat donor sites of STSG in patients with grade 3 burn wounds. Laser treatment was performed on operating days 0, 3, 5, and 7.

In agreement with our result about duration of healing of lesions, Gupta et al. [20] discovered that it took an average of 11.75 days (SD 2.86) for areas with second-degree superficial burns to fully recover. On day six, one person was treated; on day ten, ten people; on day thirteen, six people; and on day seventeen, three people.

Carboni et al. [21] discovered no substantial distinction between both of the groups.

In our study the size of wound in the PBM side exhibited a decrease in wound size on the 7th day but didn't achieve a significant difference, while there was significant reduction as compared with the control side on 14th day.

Unlike our study, Vaghardoost et al. [19] found that donor site size significantly decreased in both the laser and control groups on day 7. Notably, the reduction was significantly higher in the laser group, contrasted to the control group.

Also, in work by Mowafy et al. [22] demonstrated a highly significant reduction in burn surface area in cm^2.

Our study suggests that the PBM side exhibited lower VAS on the 7th and 14th days contrasted to control side, highlighting the potential effectiveness of laser therapy in decreasing pain. In meta-analysis, Enwemeka et al. [23] determined that LLLT is an exceptionally effective intervention for alleviating pain and enhancing tissue healing.

In our study on the 7th and 14th days, the PBM side demonstrated superior outcomes in wound edges compared to control side using PWAT score. Interestingly, early non-significant on the 7th day but latter on significant on the 14th day, disparities were observed in necrotic tissue type and amount, and the skin colour surrounding the wound, all indicative of more favorable results in the PBM side. Furthermore, the PBM group exhibited enhanced outcomes in granulation tissue, epithelization and overall wound assessment scores on the 14th day in comparison to control side. This comprehensive assessment confirms the potential efficacy of LLLT Therapy in promoting a more favorable wound healing environment. Carboni et al. [21] found that no significant change was seen in the Bates-Jensen scale; the means on day 1 and day 3 were comparable, although these means were considerably elevated compared to those on days 5 and 7.

Additionally, the LED group's average was lower than the control groups. Unlike our research, Gupta et al. [20] found no conclusive evidence of its positive effect on wound healing speed. However, its advantages are promising, and more thorough multicentric research is suggested.

Our study demonstrated non-significant improvement on the 7th day and significant improvement on the 14th day in all histological values in the PBM sides as compared to the control sides in reepithelization, fibrosis, inflammatory cells and neovascularization.

Our findings were also congruent with those of De Oliveira et al. [24] indicated that histopathologic study reveals that treated regions with LED exhibited enhanced epithelialization, characterized by increased proliferation of keratinocytes and fibroblasts, resulting in elevated collagen production compared to the control group.

In our study, as regards complication in group A, 17 cases (42.5%) with complication had 11 patients with itching (27.5%) and 6 patients with infection (15%) and no pigmentation. And in group B, 18 cases (45) with complication had 10 patients with itching (25%), 7 patients with infection (17.5%) and no pigmentation. Unlike our study, Gupta et al. [20] found that no laser related adverse effect in any patient. In a related research, Trajano et al. [25] discovered that the neoepidermis thickness of the first laser group was significantly higher than that of the control group. Ten days after the fire, there was a noticeable increase between the early and late groups. Ten days after the burn, the late laser group showed a significant increase in granulation tissue in comparison to the control and early laser groups. Both the early and late laser groups showed a similar significant increase in granulation tissue area compared to the control group 21 days after the burn.

Concerning epithelialization in laser groups, a substantial variation existed between the studied groups. Concerning necrotic tissue type and amount, no substantial variation existed between the two groups. On 10th day, laser group displayed better wound size and depth outcomes, along with favorable results in exudate quantity and type, skin colour around wound, peripheral tissue edema, granulation tissue, and overall total wound assessment score, the total score was significantly decreased in Laser group than it in control group. compared to control group. These findings collectively suggest that laser therapy contributes to improved wound healing and scar management outcomes.

Also found that regarding 5th day VAS, no substantial variation existed among both groups. Regarding 8th day VAS, no substantial variation existed among both and on 10th day VAS, a substantial variation existed among both groups.

Limitations of the work involved that the sample size was relatively small. So, we recommended that longitudinal assessment by extending the study duration or conducting follow-up assessments beyond the 14th day for a more thorough understanding of the long-term effects of laser treatment on wound healing. This approach would capture potential delayed responses and variations in healing trajectories over time. Establish standardized laser treatment protocols. Clear and standardized protocols for laser treatment applications are recommended to ensure consistency across interventions. This would facilitate the replication and validation of findings, contributing to the development of clear and reproducible guidelines for clinical practice.

Conclusions:

PBM sides that received LLLT exhibited advantages in various aspects, including less time needed for complete healing, reduced wound size, and lower pain scores, along with favorable results in edges, skin color surrounding the wound, epithelization granulation tissue, and overall wound assessment score compared to the control side. These findings collectively suggest that PBM therapy contributes to improved wound healing and pain management outcomes.

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