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Photo-Biomodulation on Irritant Dermatitis Post Ileostomy Surgery

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ABSTRACT

Background: Among the highest prevalent complications of ileostomy surgery is irritant contact dermatitis as a common early form of peristomal skin complications.

Purpose: This study aimed to evaluate the effect of Photo-Bio Modulation on Irritant Dermatitis Post-Ileostomy Surgery.

Subjects and methods: Sixty-eight patients from both genders following ileostomy surgery who suffered from irritant dermatitis were randomly distributed into two groups equal in number. **Group (A)** received photo-biomodulation therapy [Low level laser therapy (LLLT)] in addition to routine skin care, while **group (B):** received placebo photo-biomodulation (LLLT) in addition to routine skin care. Each group underwent treatment over eight weeks (three sessions per week).

Results: Irritant dermatitis was evaluated before and after the intervention using Ostomy Skin Tool and Dermoscopy, respectively. Both groups A and B exhibited significant improvements in all parameters of dermoscopy including erythema, scaling, excoriations, and ostomy skin tool total score ($p<0.001$). However, group A achieved greater improvements in all measurements compared to group B ($p < 0.001$).

Conclusion: Photo-biomodulation had a beneficial effect in decreasing the incidence of irritant dermatitis after ileostomy bag insertion.

Keywords: Irritant dermatitis, Photo-biomodulation therapy, Ileostomy surgery, Dermoscopy, OST scale.

INTRODUCTION

As part of the surgical management of both benign and malignant disorders, surgeons often create abdominal stomas, also known as ostomies [(1)]**.** States colostomies, ileostomies, and urostomies account for the majority of surgically created stomas [(2)]**.** According to **Lyon *et al*.** [(2)] intestinal stomas are created when a portion of the gastrointestinal system is cut open and exposed to the skin in order to drain the stoma effluents**.** Based on the research conducted by **Claessens *et al.*** [(3)], the most common medical disorders that need the use of an intestinal stoma are colorectal cancer, inflammatory bowel diseases (IBDs), fecal incontinence, radiation damage, penetrating bowel injuries, ischemic colitis, and diverticular disease with blockage.

To avoid passing through the larger intestine, a surgeon performs an ileostomy, which involves suturing the small intestine to the abdominal wall. Stoma, an artificial hole in the body, allows waste products of digestion to leave the body. Ileostomy bags collect the watery feces that travels through this opening [(3)].

The risks associated with this procedure include peristomal skin problems, stenosis, retraction, granuloma development, necrosis, and parastomal and prolapsed hernias [(1)]**.** The majority of adverse events after ostomy surgery are peristomal skin problems (PSCs**)** [(4)]**.** Because of its warmth, darkness, and susceptibility to leaks and immunocompromised states, peristomal skin provides a perfect setting for yeast multiplication [(5)]**.**

Peristomal skin integrity loss may cause skin breakdown and subsequent skin problems [(6)].

Based on past research, a skin issue categorization is proposed to be (1) Chemical injury, such as irritant dermatitis caused by effluent, (2) Mechanical destruction or trauma from stripping, tearing, or pressure, (3) Infectious conditions, such as bacterial, fungal, or viral infections, (4) Immunological reactions, such as allergic contact dermatitis and (5) Disease-related conditions, such as pyoderma gangrenous (PG) or psoriasis [(6)].

The most common types of peristomal dermatitis, according to **Cressey *et al.*** [(7)] include irritant contact dermatitis, mechanical dermatitis and allergic contact dermatitis**.** This skin condition can develop in response to contact with various substances such as urine, feces, medications, ostomy pouch systems, and stoma skin care products. Symptoms may include reddening, swelling, possible vesicles, maceration, and a decrease in skin integrity. Because ileostomies produce more liquid and the bilious small intestine contents are more acidic, they are more likely to irritate the skin around the stoma than colostomies [(8)].

A vicious cycle may ensue when skin issues create adhesive failure, which leads to leakage, which in turn produces stubborner skin problems [(9)]**.** Medical experts advise using stoma skin care products that are specifically formulated to avoid irritating the peristomal skin in order to keep it protected [(10)]**.** Immunomodulators, antihistamine creams, and topical steroids are the primary methods of treating atopic dermatitis (AD) [(11)].

There are a number of therapies available, but none of them have shown to be very helpful without the possibility of side effects. Consequently, a multimodal

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approach is usually necessary for cases of atopic dermatitis, and new treatments should be sought after to enhance management and treatment. Particularly, treatments with minimal side effects, like low-level laser therapy (LLLT), a type of phototherapy, should be prioritized [12]. According to **Zecha *et al.*** [13] photobiomodulation treatment (PBMT) involves the use of visible or near-infrared light from lasers or LEDs to promote wound healing, decrease inflammation, and alleviate pain.

Increasing researches in recent years, supports efficacy of PBM application in treating various dermatologic diseases as a non-surgical alternative to conventional treatments [14]. PBM has been shown as one of the most effective uses of PBM in dermatology problems resulting from cancer therapy, such as radiation dermatitis or mucositis to mitigate the severity, increasing deterioration, and discomfort of radiation dermatitis [14, 15]. Recent meta-analyses concluded that evidence supports PBM as a preventive intervention against severe radiation dermatitis [16, 17]. Numerous studies have shown substantial decreases in the quantity of inflammatory lesions [18]. The use of PBM in skin rejuvenation is warranted by its evident remodeling action via the synthesis of type 1 and type 3 collagen and elastin [19].

Because previous studies lacked sufficient quantitative data on the effects of photo-biomodulation therapy on irritant contact dermatitis in patients with stoma bag. This one was designed to fill that gap and evaluate the irritant dermatitis resulting from prolonged exposure to effluent by using of two assessment methods OST and dermascope.

MATERIALS AND METHODS

Study design: A double-blind, controlled investigation was conducted at Kafr El-Sheikh University Hospital from March 2024 to January 2025.

Participants: This study included sixty-eight individuals (male and female) who had irritating dermatitis after ileostomy bag insertion. The subjects were split up evenly into two groups of almost equal size.

Inclusion criteria: Patients with irritative dermatitis involving the ileostomy bag was seen in all cases. There were no other skin problems in any of the individuals.

Exclusion criteria: Individuals afflicted with difficulties in communication. Individuals who underwent radiation therapy or who refused to participate in this therapy and patients with other skin disorders.

Sample size calculation: The G*POWER statistical software (version 3.1.9.2; Franz Faul University Kiel, Germany) is employed to calculate the sample size, which is based on the findings of **Maiya *et al.*** [20]. The requisite sample size for this investigation was 34 subjects in each group. The calculation was conducted with a power of 90%, an effect size of 0.8, and an alpha of 0.05.

Randomization: Upon signing the permission forms, demographic data were collected. An independent researcher then allocated the 60 participants randomly and evenly divided to either group A or group B using computer-generated random cards with sealed and opaque envelopes. The envelopes were numbered consecutively to guarantee disguised distribution, ensuring participants remained oblivious to their group assignment.

Outcomes measures: Measurements were conducted before to and after to the eight-week intervention. Clinical examination and medical history taking to diagnose patients and weed out those who weren't eligible for the study, a doctor performed a comprehensive clinical examination and took a patient's history. All the participants followed identical management steps according to the national and international protocols.

A) The ostomy skin tool:

The severity of peristomal skin diseases (PSCs) was evaluated clinically through the principles of the Ostomy Skin Tool Based on the work of **Martins *et al.*** [21].

Criteria for OST scores are: Two components make up the OST: the DET score and the "Assessment," "Intervention," and "Monitoring" (AIM) guidance. According to **Martins *et al.*** [21] there are three standardized categories that make up the DET score for aberrant peristomal skin: discoloration (D), erosion (E), and tissue overgrowth (T**).** The area and severity values for each of these domains range from 0 to 3, for a total domain score of 0-5 and when added together, the scores for all of the domains provide a DET [22]**.** The DET score is a composite number between zero and fifteen, with zero representing normal skin and fifteen representing the most severe and extensive mix of symptoms. Three tiers of seriousness are being introduced. mild' (DET<4, moderate' (DET≥4<7, severe' (DET≥7**)** [23]**.**

B) Dermoscopy:

The system to grade the severity of contact dermatitis based on its dermoscopic characteristics. A score of 0 indicates no erythema, 1 indicates slight erythema, 2 indicates severe erythema, and 3 indicates erosion. From 0 (no scaling), 1 (faint scaling), 2 (moderate scaling), and 3 (severe scaling), the degree of scaling was graded. There was also a grading system for excoriations, with 0 indicating no excoriations, 1 indicating slight excoriations, 2 indicating moderate excoriations, and 3 indicating severe excoriations. Next, the aforementioned grades—erythema, scaling, and excoriations—were added together to generate a score. This score could be anywhere from 0 to 9, with 9 being the most severe and 0 indicating the absence of any of these symptoms. To measure the efficacy of the treatment, we compared the

dermoscopy score of the same region before and after the completion of low-evil therapy sessions to the baseline value [24].

Interventions:

A) Photo biomodulation [Low Level Laser Therapy (LLLT)] [helium-neon (**He-Ne) laser (ASA, Terza-via Alessandro, Italy)]:** For eight weeks, patients in the study group underwent three sessions of Low Level Laser Therapy weekly in addition to standard medical treatment under the following guidelines: Treatment parameters, the scanning He-Ne laser will provide the patient with a continuous wave of 86.5 mW, a frequency of 25 Hz, and an energy density of 2.5 J/cm^2. The wavelength of the laser was 632 nm. A scanning laser, held 30 cm away and perpendicular to the afflicted abdomen skin, was used to treat it. The patient was prepared for LLLT therapy by reclining supine in a comfortable posture and then being cleansed with saline on the afflicted area. The gadget will be examined to make sure it is turned off before the therapy begins. Turn on the gadget. Protecting their eyes from the laser light, both the patient and the therapist donned safety goggles for the whole session [25].

B) Placebo low level laser therapy:
Along with their regular medical care, the control group's members received three weekly sessions of placebo low level laser therapy for eight weeks Although the laser was not turned on in this group while covering the scanner with aluminum foil and asking the patient to wear sunglasses, the same procedures were followed and completed as in the laser group to create a sham effect.

Ethical approval: The Ethics Committee of Scientific Research at Cairo University's Faculty of Physical Therapy approved the study's protocol (permit No:P.T.REC/012/004835). All participants received information on the study's features, aim and advantages along with their ability to withdraw or refuse participation at any time. Patients provided their informed consent to participate before the study began. The study followed The Declaration of Helsinki through its execution.

Statistical analysis

An unpaired t-test was used to compare subjects' characteristics across groups. A Chi-square (Fisher exact) test was used to compare the distribution of sex and pathology across groups. Due to the non-normal distribution of the data, Mann–Whitney test was used. A U test was used to compare OST and dermoscopy across groups, while Wilcoxon signed-rank test was utilized to assess pre- and post-treatment differences within each group. The significance was established at $p \leq 0.05$. All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) version 25 for Windows (IBM SPSS, Chicago, IL, USA).

RESULTS

Subjects' characteristics: Table (1) presented the characteristics of subjects in groups A and B. No significant differences were seen between groups for age, BMI, time since operation, sex, and pathological distribution ($p > 0.05$).

Table (1): Comparison of subject characteristics between group A and B

	Group A	Group B	MD	t- value	p-value
Age (years)	44.68 ± 9.34	44.24 ± 7.82	0.44	0.21	0.83
BMI (kg/m^2)	30.81 ± 2.06	31.09 ± 2.30	-0.28	-0.39	0.69
Time since surgery (weeks)	5.24 ± 1.48	5.12 ± 1.61	0.12	0.31	0.76
Sex, N (%)					
Female	15 (44%)	17 (50%)	($\chi^2 = 0.24$)		0.63
Male	19 (56%)	17 (50%)			
Ulcer grade, N (%)					
Adenocarcinoma	6 (17.6%)	8 (23.5%)			
Hemorrhage intensity	5 (14.7%)	3 (8.8%)			
Infection intensity	4 (11.8%)	6 (17.6%)			
Ischemia hemorrhage	1 (2.9%)	4 (11.8%)			
Ischemic intensity	3 (8.8%)	2 (5.9%)	(Fisher's Exact Test = 8.19)		0.32
Perianal fistulas	5 (14.7%)	5 (14.7%)			
Sigmoid colon	5 (14.7%)	6 (17.6%)			
Small bowel obstruction	5 (14.7%)	0 (0.0%)			

SD: Standard deviation**, MD:** Mean difference**, χ^2:** Chi squared value**, p value:** Probability value.

Effect of treatment on OST and dermoscopy between groups: Within group: Group A exhibited a substantial reduction in OST score post-treatment relative to pre-treatment ($p < 0.001$). No substantial alteration was seen in group B ($p = 0.10$). There was a significant improvement in all parameters of dermoscopy in group A post-treatment compared to pre-treatment including erythema, scaling, excoriations, and total score ($p < 0.001$). In contrast, group B showed no significant change in erythema ($p = 0.32$), scaling ($p = 0.09$), or excoriations ($p = 0.07$), while there was a significant decrease in the total score ($p = 0.03$) (Tables 2 & 3). **Between group:** Between-group comparisons post-treatment revealed a significant decrease in OST and erythema, scaling, excoriations, and total score dermoscopy of group A compared to group B ($p < 0.001$) (Tables 2 & 3).

Table (2) Median values of OST pre and post treatment of group A and B

	Pre treatment	**Post treatment**		
	Median (IQR)	**Median (IQR)**	**Z- value**	**p value**
OST				
Group A	8.5 (10-7)	3 (4-2.75)	-5.11	0.001
Group B	8.5 (10-7)	8 (10-7)	-1.63	0.10
U- value	572	25.5		
	p = 0.94	***p = 0.001***		

IQR: Interquartile range; **U- value:** Mann-Whitney test value; **Z- value:** Wilcoxon signed ranks test value; **p-value:** Probability value.

Table (3): Median values of Erythema, Scaling, Excoriations and total scores of Dermoscopy pre and post treatment of group A and B

	Pre treatment	**Post treatment**		
	Median (IQR)	**Median (IQR)**	**Z- value**	**p value**
Erythema				
Group A	2.5 (3-2)	1 (1-0)	-5.20	0.001
Group B	3 (3-2)	2.5 (3-2)	-1	0.32
U- value	569.50	8.5		
	p = 0.91	***p = 0.001***		
Scaling				
Group A	2 (2-1)	1 (2-1)	-4.041	0.001
Group B	2 (2-1.75)	2 (2-1)	-1.67	0.09
U- value	550.00	***321***		
	p = 0.70	***p = 0.***001		
Excoriations				
Group A	2 (3-2)	1 (1.25-0)	-4.93	0.001
Group B	2 (3-2)	2 (2.25-2)	-1.77	0.07
U- value	552.00	***217.5***		
	p = 0.72	***p = 0.***001		
Total score				
Group A	6.5 (8-6)	2.5 (4-2)	-5.39	0.001
Group B	6.5 (8-6)	6 (7-5)	2.34	0.03
U- value	576.50	***48***		
	p = 0.98	***p = 0.***001		

IQR: Interquartile range; **U- value:** Mann-Whitney test value; **Z- value:** Wilcoxon signed **ranks** test value; **p-value:** Probability value.

DISCUSSION

The study measured results using OST commonly used in clinical settings to assess peristomal complications, particularly irritant contact dermatitis and dermoscopy used in diagnosis of general dermatological disorders.

Erythema, scaling, and excoriations are clinical symptoms of peristomal dermatitis, a common and bothersome consequence for ileostomy patients [(26)]. Conventional treatment methods, which include barrier solutions and topical corticosteroids, aren't always effective, and they may have side effects or slow wound healing in some areas. An emerging non-invasive adjunctive method with potential benefits on cutaneous inflammation and tissue regeneration is photo biomodulation, previously known as low-level laser treatment (LLLT) [(27)].

In order to achieve therapeutic results in peristomal skin complications, the intervention, LLLT was given three times a week for eight weeks. This is a routine that is frequently employed in clinical practice. The literature on LLLT and its suggested mechanisms of action, which include lowering inflammation, enhancing tissue repair and altering dermatitis pathways, are in line with the frequency and length of treatment.

Reducing mast cell degranulation and the release of proinflammatory mediators is one of the many benefits of photobiomodulation. The management of allergic responses and the alleviation of severe atopic symptoms may benefit greatly from this impact. Photo biomodulation may help with the acute inflammatory reactions that are common in many atopic diseases by calming mast cells and decreasing histamine release [(28)]. **Dompe *et al.*** [(29)] showed that lasers may have a light biomodulation impact on tissues and cells, which aids in the enhancement of tissue healing processes by direct modulation of cell behaviors**.** Photo biomodulation using fluorescent light energy was shown in a canine model to be a noninvasive, rapid, and safe therapy for dermatitis at any stage of the illness [(30)]**.** It lent credence to initiatives aimed at stewarding antibiotic resistance as it was well-tolerated by patients and enabled them to forego systemic or topical antibiotics. As an added bonus, research by **Barolet *et al.*** [(31)] showed that light biomodulation may decrease inflammation after chemical peels, skin resurfacing, vascular and benign pigmented lesions, and other invasive cosmetic procedures, which speeds up the healing process**.**

Some of the well-known biomedical and clinical uses of low-level helium-neon (He-Ne) laser irradiation include treating chronic wounds with anti-inflammatory and anti-infective therapy, promoting wound healing

following surgery or scalpel actions, preventing and treating muscle damage through photo stimulation therapy, and photo biomodulation [32].

Our main findings indicated that patients who had low intensity laser treatment had a noticeably statistically significant improvement in peristomal skin complications grade compared to the control group. When comparing the two groups' median values of erythema, scaling, excoriations, and total scores before treatment, the present investigation found no statistically significant differences. The median values of erythema, scaling, excoriations, and total scores were significantly lower after treatment in the study group compared to pretreatment values. The control group, on the other hand, had a considerable decrease in total score but no discernible changes in erythema, scaling, or excoriations after therapy. After the intervention, the study group had much reduced median values of erythema, scaling, excoriations, and overall scores compared to the control group. This suggests that the intervention was beneficial. Post-treatment comparisons showed significantly greater improvements in dermatitis for group A compared to group B ($p < 0.001$). The results are consistent with other studies that showed LLLT to be effective in lowering inflammation. In the line of the current study results, **Gobbo *et al.*** [16] showed that light biomodulation treatment as a preventative measure may shield against the escalation of severe dermatitis**.** Research by **Khalkhal *et al.*** [33] corroborated this, one method of treating medical conditions is by using lasers to target certain areas of the body. Wound promotion, tissue damage prevention, and deeper tissue healing may all be achieved with the use of lasers**.** Laser irradiation may have analgesic and anti-inflammatory effects on the surrounding tissue, which may explain how it brings about an increase in vascularity and the re-epithelialization of damaged tissue [20]**.**

This jibes with the findings of **de Barros Pinto *et al.*** [34] who demonstrated that PBM treatment amplified the anti-inflammatory IL-10 levels while simultaneously decreasing levels of pro-inflammatory IL-1, IL-6, and TNF-α, and enhancing flap necrosis at all assessment points. The number of inflammatory cells in skin flaps was also significantly reduced after photobiomodulation therapy**.** This is in agreement with the findings of **Woo** [28] who also discovered that sun biomodulation considerably decreased skin inflammation, as seen by a decrease in erythema, edema, and epidermal thickness, Photo biomodulation anti-inflammatory characteristics reduce redness and swelling, and its encouragement of cellular repair processes speeds up the clearance of acne lesions**.** In addition, patients who had low intensity helium-neon (He-Ne) laser treatment had a noticeably decreased severity grade compared to the control group [20]**.** According to **Salman *et al.*** [35] photo biomodulation shows promise as an additional or alternative treatment option for inflammatory skin conditions**.**

STRENGTHS AND LIMITATIONS

This research illustrated the efficacy of Photo-biomodulation therapy, which was proven to be beneficial and devoid of harmful effects. It also facilitated their incorporation as an essential component of the therapy regimen for individuals with peristomal skin dermatitis. The study had limitations, including insufficient follow-up, a short treatment duration, and restricted generalizability owing to the small sample size. Additionally, no additional dermatological conditions were examined, nor were various treatment approaches evaluated. To enhance the evidence for photo-biomodulation in the treatment of irritating dermatitis, more research should include prolonged treatment durations, expanded sample numbers, and subsequent evaluations.

CONCLUSIONS

Improvements in erythema, scaling, excoriations, and overall skin condition were considerably better in patients with post-ileostomy dermatitis who received photo biomodulation in addition to regular treatment compared to those getting routine care with sham therapy.

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