Case Series

Blue Light Photobiomodulation as treatment for peristomal skin disorders: case series

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Antonini Mario[1], Gasperini Stefano[2]

[1]Stomal Therapy Nurse, USL 11 Ospedale San Giuseppe, Empoli, Italy
[2]MD, Medical Advisor, Pisa, Italy

Abstract: **Introduction.** Keeping the peristomal skin intact proves to be a challenge for stoma patients and the health care teams that work with them. Peristomal skin complications are shown to affect 36.3% to 73.4% of patients. They are often particularly difficult to treat with topical therapies since the topical medications available are cream-based or ointment type formulations that don't allow for perfect adhesion of the pouching system to the abdomen's skin. In this study a preliminary evaluation of the effectiveness of Blue Light Photobiomodulation in the treatment of peristomal skin disorders was performed.
Methods. Patients carrying ostomy with lesions of types L2, L3, L4, L5, LX (SACS 2.0 classification5) that had not experienced an improvement in 4 weeks of standard therapy were selected for Blue Light therapy. Blue Light treatment was performed twice a week for 4 weeks, in addition to standard therapy. Tissue repair was evaluated through Wound Bed Score and pain reduction.
Results. All the 11 patients enrolled responded to Blue Light treatment with an average WBS improvement of 8.3 points and a significant reduction in pain. Blue Light Photobiomodulation to be decisive in activating the healing process in three patients with pyoderma gangrenous.
Conclusions. The positive clinical results suggests that Blue Light Photobiomodulation could be a promising tool in the management of peristomal skin lesions.

Keywords: Peristomal Skin Disorders, Photobiomodulation, Blue Light, Wound Bed Score

Introduction

Peristomal skin disorders are common postoperative complications in people who undergo surgical procedures resulting in enterostomal formation[1]. They usually occur within the first two weeks of the creation of the stoma but they can also present as late complications, months or even years after the initial surgery[1]. Complications range from mild irritation to full thickness ulcerations and the international literature refers to an incidence ranging from 36.3% to 73.4% for such alterations[2]. Peristomal skin alterations represent a significant problem both for stoma patients' quality of life and for the health care system, as peristomal

skin lesions are the main reason for which stoma patients visit outpatient clinics, and, in severe cases of peristomal skin complications, costs for a patient with a stoma increases from two to five times[3]. The therapeutic approach ranges from using different pouching systems, to topical, systemic medications and surgery, and should be chosen according to the underlying cause of the complication1. According to international literature, 77% of diagnosed skin disorders are related to contact with stoma effluent[4]. To avoid this, it is essential that the ostomy bag remain attached to the patients' abdomen. One of the main limitations in the treatment of peristomal skin alterations is the lack of appropriate topical therapies since the topical medications available are cream-based or ointment type formulations that don't allow for perfect adhesion of the pouching system to the abdomen's skin[5]. Photobiomodulation has been shown to promote several therapeutic effects, including the mitigation of pain and inflammation, immunomodulation and promotion of tissue regeneration and healing[6]. For this reason, we have decided to apply PBM with Blue Light as new, non-invasive, contactless therapy on patients under treatment for peristomal skin complications at San Giuseppe Hospital, Empoli, Italy.

Patients and methods

This case series focuses on patients carrying ostomy with skin complications of types L2, L3, L4, L5, LX (SACS 2.0 classification[7]) that had not experienced an improvement in 4 weeks of standard therapy were included. According to the SACS 2.0 a skin complication classified as L2 is an erosive lesion with loss of substance as far as and not beyond the basal membrane; L3 is an ulcerative lesion beyond the basal membrane; L4 is an ulcerative fibrinous/necrotic lesion; L5 is an ulcerative lesion involving planes beyond the muscular fascia (with or without fibrin, necrosis, pus or fistula); LX is a proliferative lesion (neoplasia, granulomas, oxalate deposit). The reported clinical observations were the result of a product test, authorized by the Hospital. All patients have been asked for informed consent. Treatment was performed in addition to standard therapy, twice a week, for 120 seconds in cases of inflammatory lesions (such as pyoderma gangrenous) or for 60 seconds in all other cases; Blue Light therapy duration was 4 weeks. Tissue repair was evaluated through two parameters: Wound Bed Score (WBS)[8] and pain. The WBS is a classification system that has proven to have validity in predicting complete wound closure and in clinical practice is considered a useful tool to support adequate wound bed preparation, essential for the healing. Pain was measured through the Visual Analogue Scale (VAS). At the enrollment visit and during the check-up visit, 3 days after the last Blue Light treatment, photographic images were collected and data for WBS and VAS were recorded on a specific patient data form. For Blue Light PBM was used a portable medical device (EmoLED), equipped with LED sources emitting blue light in the interval of 400-430 nm, with a power density of 120 mw/cm^2 and a fluence of 7,2 J/cm^2, at 4 cm from the skin lesion.

Results and discussion.

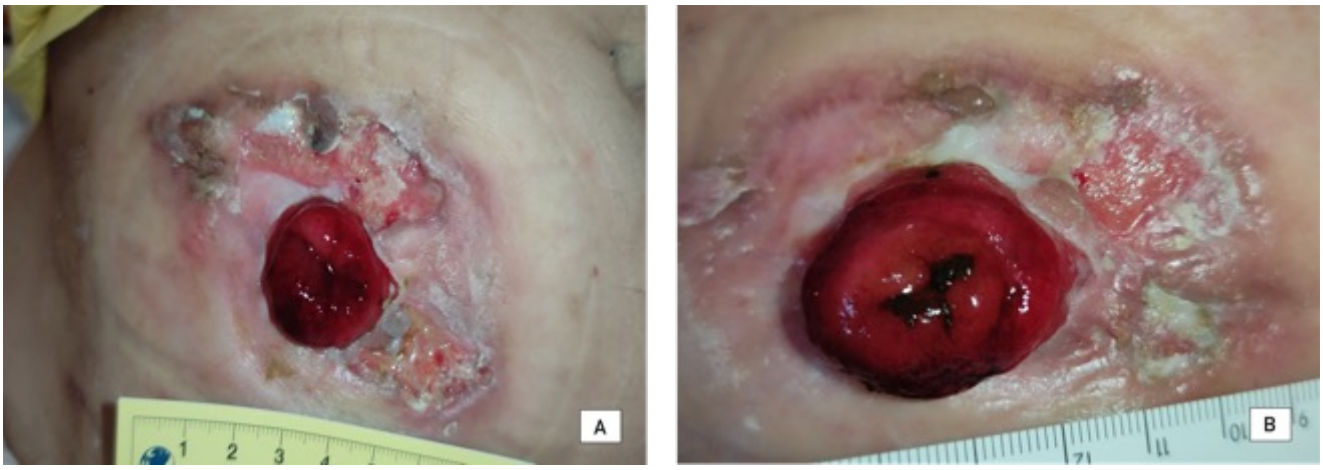
11 patients were enrolled. All patients responded to Blue Light treatment with an average WBS improvement of 8.3 points and a significant reduction in pain. Classification of the skin complications according to SACS 2.0 for each patient is reported in Table 1; in the table is also reported the quadrant of the abdominal region around the stoma where the skin complication was localized (T1=upper right; T2=upper left; T3=lower left; T4=lower right; T5=total). At the enrollment visit the average WBS was 5.9 (range 5-8) and the average VAS score was 5.4 (range 3-8). At the check up visit the average WBS had increased to 14.2 (range 10-16), where the maximum possible score (best score) is 16, and the average VAS value had dropped to 1.9 (range 0-3). The results obtained by each patient are reported in Table 1. Three clinically interesting cases of patients who had developed pyoderma gangrenosum are presented in figures 1, 2 and 3; pyoderma gangrenosum is a very painful ulcerations requiring a specific topical approach; in all three cases, Blue Light Photobiomodulation proved decisive in activating the healing process.

Tab 1 - Rating of the 16-items tool by five panelists; CVI: content validity index

Patient	Sex	Age (years)	Patology	Type of ostomy	
1	F	73	Rectal cancer	Ileostomy	
2	M	35	Diverticulum perforation	Left colostomy	
3	M	76	Right colon cancer	Ileostomy	
4	F	46	Rectal ulcerative colitis	Ileostomy	
5	F	67	Colorectal cancer anastomosis dehiscence	Ileostomy	
6	F	68	Rectal cancer	Ileostomy	
7	F	77	Rectal cancer Short bowel syndrome	Ileostomy	
8	M	51	Chron disease	Ileostomy	
9	M	80	Sigmoid colon cancer	Ileostomy	
10	M	77	Bladder cancer	Left ureterocutaneostomy	
11	M	88	Bladder cancer	Monolateral ureterocutaneostomy	

Figure 1 – Patient 4

A 46 years-old woman, who underwent total proctocolectomy for Ulcerative Colitis, with ileostomy formation and, subsequently, surgery and chemotherapy for breast cancer. Peristomal pyoderma gangrenous with presence of intense pain (developed during chemotherapy).
(A) Pyoderma gangrenous at enrollment; (B) The lesion after 4-weeks of standard therapy (cleansing with polyhexanide and betaine-based solution + Clobetasol ointment + protease-modulating matrix + Methylprednisolone (16mg) + Blue Light treatment (120 seconds twice a week).



	Peristomal Skin Complications					
	Classification (SACS 2.0)	**Timing after surgery (days)**	**WBS enrollment**	**WBS check-up**	**VAS enrollment**	**VAS check-up**
	L3 T2-4	3	5	16	3	2
	L3 T4	2	7	15	5	2
	L2 T3-4	3	6	15	6	2
	L3 T1-2-3	51	6	13	7	1
	L2 T1	7	5	14	3	2
	L4 T2-3-4	55	5	16	8	3
	L2 T3	55	7	13	8	2
	L4 T3	14	5	13	8	2
	L4 T4	15	6	15	5	2
	L2 T4	10	8	16	3	0
	LX T3-4	7	5	10	5	3

Figure 2 – Patient 6

A 68-year-old woman who underwent surgery for rectal cancer with sided ileostomy formation. Peristomal pyoderma gangrenous not responding to any therapy.
(A) Pyoderma gangrenous at enrollment; (B) The lesion after 4-weeks of standard therapy (cleansing with polyhexanide and betaine-based solution + Clobetasol ointment + protease-modulating matrix) + Blue Light treatment (120 seconds twice a week).

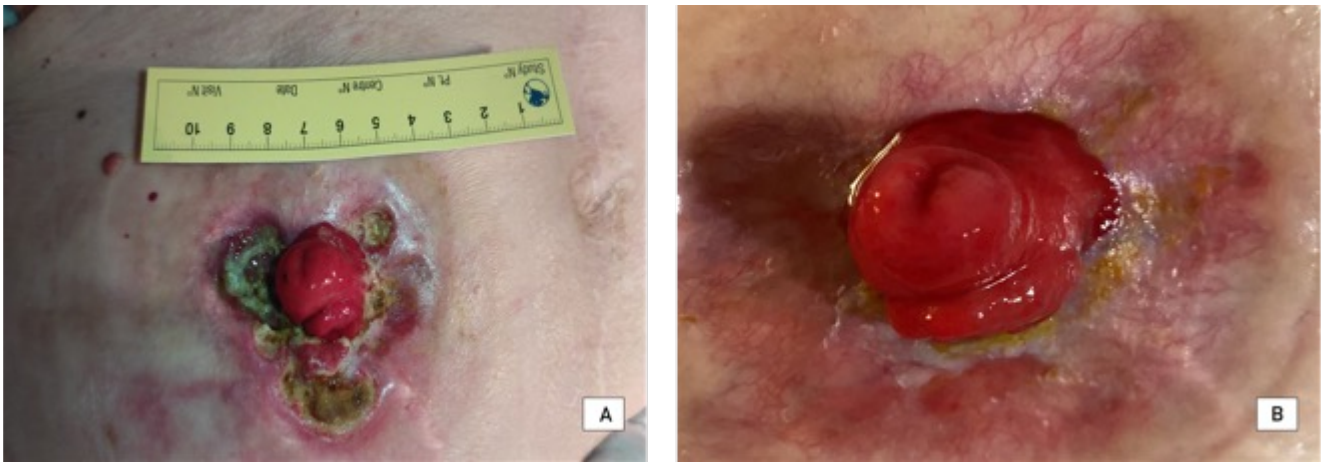
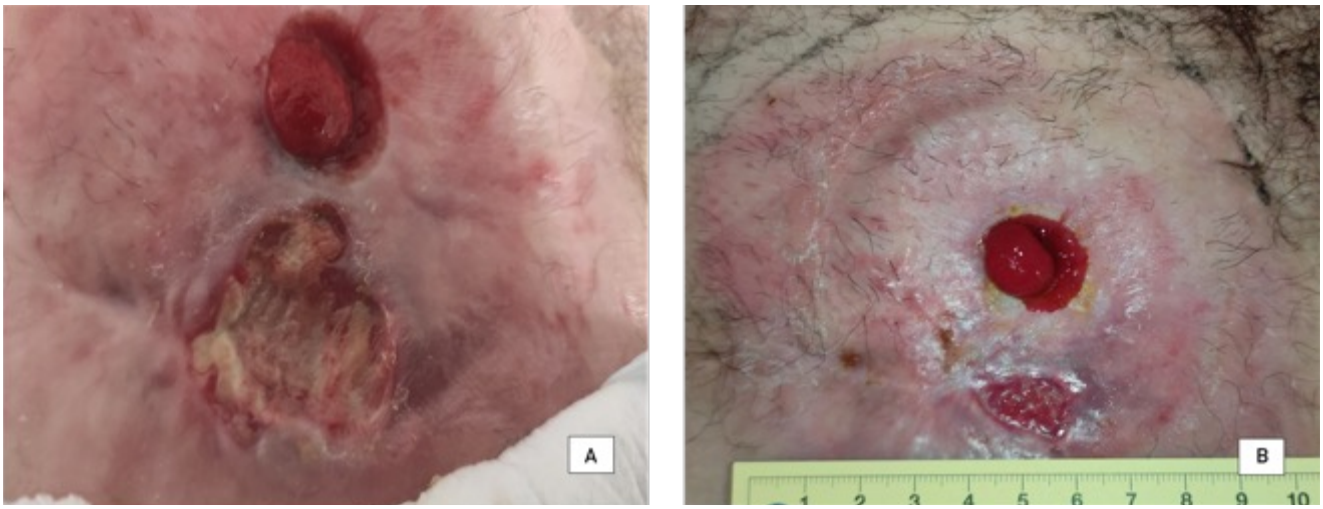


Figure 3 – Patient 8

A 51-year-old man who underwent total proctocolectomy for Chron's disease with ileostomy formation. Recurrent lesions recognized as pyoderma gangrenous.
(A) Pyoderma gangrenous at enrollment; (B) The lesion after 4-weeks of standard therapy (cleansing with polyhexanide and betaine-based solution + Clobetasol ointment + protease-modulating matrix) + Blue Light treatment (120 seconds twice a week).



The term Photobiomodulation6 define "a form of light therapy ... eliciting photophysical and photochemical events at various biological scales". A growing body of evidence supports the positive effects of Photobiomodulation on wound healing. Blue light PBM has been shown to modulate the oxidative state of Cytochrome C and thus influence the process of cellular respiration, which is more essential than ever in cells involved in tissue repair[9,10]. Furthermore, Blue Light acts on inflammation by stimulating a more rapid transition; this effect has been demonstrated in preclinical studies where early arrival of inflammatory infiltrate cells in the wound bed and an acceleration of the phenotypic switch of macrophages (M1 to M2), marking the transition to the proliferative phase, has been recorded in treated wounds[11,12]. These effects of Blue Light PBM are considered to be primally responsible for wound healing. Previous clinical results showed that Blue Light effectively promoted wound healing and reduced pain in patients with venous ulcers, vasculitis and traumatic wounds that did not respond to standard treatments[13,14,15]. In our experience, Blue Light PBM, in 4 weeks of therapy, has reactivated the healing of peristomal skin complications that did not respond to the standard therapy.

Conclusions

Blue Light Photobiomodulation is a non-invasive, safe, fast, and easy to perform therapy, non-interfering with the adhesion of the pouching system. In our experience Blue Light treatment has promoted the healing process and reduced pain of peristomal skin complications. Blue Light therapy can contribute to the management and healing of peristomal skin disorders, bringing a significant benefit to the quality of life of patients and to the economic sustainability of the healthcare system. Further investigations will be necessary to confirm our preliminary results.

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