Use of the Lumiheal device in the treatment of contaminated wounds

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ABSTRACT

Observational study on patients with chronic wounds of lower limb colonized or critically colonized treated with biophotonic therapy. Ten patients with venous or inflammatory ulcers were enrolled. All enrolled patients were treated once a week with a double application of the therapy. The treatment period was 6 weeks, and a final assessment was performed at 12 weeks. The data collected were: evaluation of the bacterial load using the Moleculight system; and bacterial load with semi-quantitative method via swab according to Levine. Four types of bacteria were studied, Staphylococci, Pseudomonas, Enterococci, and Proteus. Ph measurement and evaluation of the Cutting and Harding score for infections. Results show a good performance in the control of bioburden and a reduction of clinical signs in 2 weeks. The secondary point was a reduction of pain and an improvement of perilesional tissue. The reduction of the area was batter in venous etiology wounds by close to 40% and a healing rate of 33%, good result but lower in inflammatory wounds. The authors hypothesize a marked activity on factors linked to local inflammation.

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Introduction

BioPhotonic Klox (KBS) is an instrumental system used in the treatment of chronic skin lesions. The treatment is defined as Biophotonic and the system is composed of two parts. The role of low-energy photons in the healing process of wounds represents an innovative treatment for both wound healing and skin disorders, and it's made of two medical devices: an LED lamp (the main device)photo gel converter (secondary device). The topic gel contains specific chromophores, which are not absorbed by the skin, but when the gel is excited with the LED lamp it releases a micro-pulsed emission of photons in the form of fluorescence, whose energy provides wavelengths in the spectrum of visible light, between 500 and 610 nm. With the activation light (between 410 and 470nm), these low-energy photons clinically show a beneficial effect on the promotion of wound healing.[1,2] There are studies endorsing the effects of lights in the visible spectrum on tissue level[3-5] promoting: mast cell degranulation,[6] the proliferation of fibroblasts and keratinocytes,[7] and synthesis matrix[8] with the final effect of improving the quality of repaired tissues.[9] Skin exposure to low-level light increases the production of nitric oxide with the effect of vasodilation, and reduction of inflammatory phenomena and pain.[9] Chronic skin lesions are an increasingly emerging problem in health systems around the world, especially pressure ulcers and venous leg ulcers.[10-14] The study aimed to analyze the activity of a bacterial population in ulcers with colonization or critical colonization[15] of the Lumiheal device during clinical treatment. Available data in the literature show an important bactericidal activity *in vitro*.[16-18]

Materials and Methods

Ten patients were enrolled in the study, Table 1 shows inclusion and exclusion criteria. Data were gathered through paper cards, in addition to personal data also etiological data were gathered, and the evaluation of comorbidity through CIRs. The

analyzed parameters were: i) evaluation of bacterial load through the Moleculight system;[19] ii) bacterial load by semi-quantitative method through SWAB according to Levine's methods.[20] Results were divided into 4 identification groups with the + signs where 1+ meant a low bacterial load while 4+ meant a high bacterial load. Four types of bacteria were researched, Staphylococci, Pseudomonas, Enterococci, and Proteus;[21] iii) area measurement through the Silhouette system;[22] iv) pH measurement; v) evaluation of infection signs through Cutting ed Harding score;[23] vi) evaluation of wound bed through the WBP score proposed by Falanga;[24] vii) pain evaluation through NRS scale;[25] viii) the situation of perilesional skin.

All the patients enrolled were treated 1 time a week with a double application of lumiheal. The treatment period was 6 weeks, and a final evaluation was performed at 12 weeks. All the patients enrolled were treated according to the WBP guideline and locally depending on the TIME guideline.[26] The treatment protocol was: dressing removal, cleansing with saline solution, LumiHeal application, and dressing according to protocol with nonadherent gauze. At time 0, 21, 42 cleansing, SWAB and photograph, first treatment with Lumiheal, removal of gel, cleansing with saline solution, second treatment with Lumiheal, removal of gel, cleansing with saline solution, SWAB and photograph, dressing. At T84 only swab. At each application were measured: Bacterial charge (Moleculight), area (Silhouette system), Ph, Cutting & Harding Score, WBP score, and NRS.

Results

Table 2 shows characteristics of the enrolled population, 6 lesions were of venous origin while 4 were of vasculitis origin. The population in question has a high level of comorbidity and severity. The aim of the study was the evaluation of the efficiency of the lumiheal treatment on infection control, therefore we will begin with the result evaluation of this sector. During the study 28 swabs were executed before treatment: pseudomonas was isolated in 13 cases, staphylococcus was isolated in 9 cases, enterococcus was isolated in 4 cases, and proteus was isolated in 1 case. 28 swabs were executed after treatment: pseudomonas was isolated in 11 cases, staphylococcus was isolated in 8 cases, enterococcus was isolated in 4 cases, and proteus was isolated in 0 cases. Upon control 7 swabs were executed: pseudomonas was isolated in 5 cases, and staphylococcus were isolated in 2 cases, all the results are reported in Table 3. Supplementary materials, Figures 1 to 3 show graphs of the 3 main bacteria types that were found, divided based on bacterial charge, and if they were found pre or post-treatment, pseudomonas was the most isolated strain. The results obtained with the Moleculight camera are difficult to present because it is only a visual evaluation, but the reduction of the bacterial charge is noted by the clinicians, Supplementary materials, Figures 6 and 7 show 2 cases. The last parameter gathered, inherent

Table 1. Inclusion and exclusion criteria.

Inclusion	Exclusion
Age >18	Age <18
Obtainment of informed consent	Absence of informed consent
Ulcer older than 8 weeks	Ulcer younger than 8 weeks
Lesion <7x12 cm	Lesion >7x12 cm
Cleansed lesion / slough	Necrotic lesion / infected
Normal immune status	Syndromes with immunodeficiency or immunosuppressive drugs
Non light sensitivity	Light sensitivity
Availability for checks for a minimum of 4 weeks	Nonavailability for checks for a minimum of 4 weeks
Life expectancy >1 year	Life expectancy <1 year State of pregnancy Lesions with bone exposure

Table 2. Characteristics of enrolled population.

	Number	%	Range
Total patients	10	100	
Males	5	50	
Females	5	50	
Average age	66.6		39-81
Average wound's age (months)	26.8		8-60
Mean wound's area	6.88		2.4-23.4
Venous ulcers	6	60	
Vasculitic ulcers	4	40	
Mean ISV 14	0.75		0.5-1.1
Mean CM2	3.5		2-7

to the infectious problem, was the measurement of pH, it is indeed known that bacteria, ammonium producers, raise pH levels on the wound's surface. The result did not present great incisiveness on the parameter, with a rather low average reduction oscillating during the treatment period. Supplementary materials, Figures 4 and 5 Show the result of treatment with biophotonic treatment observed with Moleculight scan, before and after treatment in 2 cases. Supplementary materials, Figure 6 shows the detected values on the Cutting and Harding parameters, a sum of the different moments of treatment was done, this led to the construction of a line that has an important descent curve, value reaching 0 upon control. Supplementary materials, Figure 7 shows the clinical evaluation of the degree of infection defined by WUWHS classification, to be noted how in a short period there is a disappearance of clinical signs. Data regarding area are shown in Table 4 while Supplementary materials, Figure 8 shows the area evolution as a total in the 6 weeks of the study. The reduction during the treatment period was 30%. If we divide the cases based on the 2 aetiological groups (vasculitis pts 1,3,6,9) the differences in area reduction turn out to be 38.9% in venous ulcers during 6 weeks and 23.8% in the vasculitis group, data is shown in Supplementary materials, Figure 9. Pain results are shown in Table 5 and graphically in Supplementary materials, Figure 10, it is to be noted how the effect is quite rel-

Table 3. Results from swabs.

Swabs					
Patients number		**T0**	**T21**	**T42**	**T84**
01	PRE	Pseudo +++	Pseudo +++	Stafilo +++	Pseudo ++
	POST	NEG	Pseudo +++	Stafilo +	
02	PRE	Enterobatt +++	Pseudo +++	Pseudo ++	Pseudo ++
	POST	Enterobatt +	Pseudo ++	Pseudo ++	
03	PRE	Enterobatt +++	Enterobatt +++	Pseudo +++	Pseudo +++
	POST	Enterobatt +++	Enterobatt +	Pseudo +++	
04	PRE	Pseudo +++	Pseudo +++	Pseudo +++	Pseudo +++
	POST	Pseudo +	NEG	Pseudo +	
05	PRE	Stafilo +++	Stafilo +++	Stafilo +++	Stafilo +++
	POST	NEG	Stafilo +++	Stafilo +++	
06	PRE	Enterobatt +++ Stafilo +++	Stafilo +	Pseudo +++	//
	POST	Enterobatt +++ Stafilo ++	Stafilo +	Pseudo ++	
07	PRE	Proteus + Stafilo +++	Stafilo +++	Stafilo ++	Stafilo +
	POST	Stafilo +	Stafilo ++	Stafilo ++	
08	PRE	NEG	NEG	X	X
	POST	NEG	NEG	X	X
09	PRE	NEG	Pseudo +++	Pseudo +++	Pseudo +++
	POST	NEG	Pseudo +++	Pseudo +++	X
10	PRE	Pseudo +++	Pseudo +++	X	X
	POST	Pseudo +	Pseudo +++	X	X

Table 4. Wound's area evolution.

Area								
Patients number	**T0**	**T7**	**T14**	**T21**	**T28**	**T35**	**T42**	**T84**
01	5.5	4.0	3.6	2.7	3.5	3.0	3.3	4.3
02	12.7	12.3	12.9	10.4	9.7	9.4	7.8	8.9
03	7.5	6.8	7.1	6.8	6.2	7.3	6.4	7.5
04	3.2	2.7	3.1	3.3	3.7	3.7	3.7	4.1
05	5.3	5.0	5.0	5.3	4.9	4.7	5.0	//
06	23.4	21.3	22.6	20.9	21.1	21.9	17.5	//
07	2.4	2.3	2.5	2.2	2.4	2.3	2.0	1.2
08	3.2	2.4	0.1	HEALED				
09	2.6	2.6	2.2	2.2	2.9	2.7	2.9	//
10	3.0	2.2	0.5	HEALED				
Total	68.8	61,6	59.6	54.4	54.4	55	48.6	

evant in rather short times, especially considering how all the lesions had signs of infection upon enrolment. Results evaluation of wound bed evolution in terms of exudate and tissue according to WBP score, are shown in Table 6 and graphically in Supplementary materials, Figures 11 and 12. An effective preparation of wound beds is to be noted, especially regarding tissues. Perilesional skin turned out to have improved in every case and no allergic reaction was recorded. No adverse events were reported. Supplementary materials, Figure 13 shows an overall performance evaluation in terms of results.

Discussion

The results generally highlighted a better performance in venous ulcers, both in terms of infection control and in the control of signs and symptoms of inflammation. This is supported by the results obtained in the EUREKA study[2] and the data reported by Nikolis.[1] The authors believe that this result is determined by the concomitance of two factors: the reduction of the bacterial load and the control of inflammation. Starting from this point we believe that the control of inflammation reduces tissue damage and this would also justify the reduction of pain, supporting the work of Enwemeka,[8] where using energy transfer systems, an improvement in tissue trophism is obtained. This interpretation key would allow us to connect all the points obtained. Apart from this, the lack of changes in pH remains, and we believe that the use of a non-adherent dressing, therefore not capable of interacting with the microenvironment, led to this result.

Conclusions

This is an observational study of 10 patients in real life as it can be seen by either the inclusion and exclusion criteria, which are quite basic, and the data of CIRs and its indicators. As for the infection, the first objective of the study, results in both clinical terms, with a collapse of the signs of infection after 2 weeks, and instrumental terms based upon swabs have shown that the device is highly effective in treating infections in a non-advanced stage in chronic skin lesions. This result is independent of the aetiological cause.

As for the secondary parameters, the device has shown to

Table 5. Pain evolution during treatment period.

NRS								
Patients number	**T0**	**T7**	**T14**	**T21**	**T28**	**T35**	**T42**	**T84**
01	5	3	1	1	1	1	1	1
02	4	4	3	2	1	1	1	1
03	2	1	1	1	1	1	1	1
04	2	3	2	2	2	2	2	2
05	6	5	3	4	4	2	2	//
06	4	6	4	4	3	3	3	//
07	2	2	1	1	1	1	1	2
08	8	6	3	2				
09	8	6	4	4	4	4	4	4
10	4	2	1	1				
Total	45	38	23	22	17	15	14	11

Table 6. WBP score evolution.

WBP								
Patients number	**T0**	**T7**	**T14**	**T21**	**T28**	**T35**	**T42**	**T84**
01	C1	C1	B1	B1	B1	B1	A1	A1
02	C3	B3	B2	A3	A2	A2	A2	A1
03	B3	A3	A2	A2	A2	A2	A2	A1
04	A2	A2	A2	A2	A2	A2	A2	A3
05	C3	C2	C2	B3	B3	B3	B3	//
06	C3	D2	C2	B2	B2	C2	C2	//
07	B2	A2	A1	A1	A1	A1	A1	A1
08	C1	B1	A1	Healed				
09	C2	A2	A1	A1	A2	A2	A2	A2
10	B2	B1	A1	Healed				

be very effective on pain, leading to a constant and clear reduction, resulting in more effective in the group with lesions of venous origin. In terms of repair, we obtained a good result in venous ulcers, with an average beginning area reduction of 40% and a resolution of 33.3% (2/6); results were lower in vasculitic-inflammatory forms. The device has proven to be very effective in terms of wound bed preparation, especially in the first 2 weeks with fast results.

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Online supplementary materials:

Figure 1. Isolation of pseudomonas with Swab pre and post treatment.

Figure 2. Isolation of staphylococcus with Swab pre and post treatment.

Figure 3. Isolation of Enterococcus with Swab pre and post treatment.

Figure 4. Case 01 pre and post treatment, imaging with Moleculight (Pseudomonas).

Figure 5. Case 03 pre and post treatment, imaging with Moleculight (Staphylococcus).

Figure 6. Evolution of the Cutting and Harding score during the study.

Figure 7. Clinical evaluation of infection.

Figure 8. Global wound's area evolution.

Figure 9. Wound's area evolution by aetiology.

Figure 10. Pain evolution during treatment period.

Figure 11. Changing in wound bed tissue during treatment period.

Figure 12. Changing in level of exudate during treatment period.

Figure 13. Global performance.