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THE COLOUR
OF REGENERATIVE
SCIENCE

B.L.U.R. CLINICAL STUDY: INTERIM REPORT

B.L.U.R. - BLUE LIGHT FOR ULCERS REDUCTION

Multi-center study on the effectiveness of treatment with a blue light medical device (EmoLED) in the reduction of ulcer surface in 10 weeks.

A multi-center prospective, controlled study over **90 patients** is currently in progress. The study has the aim of verifying EmoLED clinical efficacy as remedy for CVI ulcers, through the measurement of the reduction percentage of the lesion area during 10 weeks of tretament.

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THE INNOVATIVE CARACHTER OF THE STUDY IS GIVEN BY THE USE OF THE SAME PATIENT TO COMPARE THE HEALING OF TREATED WOUNDS VERSUS UNTRETAED ONES.

In the figure an example of a half-divided ulcer. T is the half that will be treated, C the half used as control.

The data presented are obtained from a software analysis of wound images performed by the CNR Department of Clinical Physiology (Pisa, Italy) taken from the first 29 patients completing the study. The average age of the ulcers treated is 65 months (median: 6 months). No adverse events were recorded during the study.

Interim results show that EmoLED represents a valid and effective treatment for vascular ulcers compared to the standard treatment. Combining the profile of **clinical efficacy**, **safety** and **ease of use**, EmoLED presents all the necessary characteristics to become a real alternative in the management of chronic lesions.

PATIENTS:

WITH TWO LESIONS <5CM: the worse is treated with EmoLED while the other is used as control.

WITH ONE LESION >5CM: the lesion is splitted in two parts, one treated and the other used as control.

LESION'S ETIOLOGY:

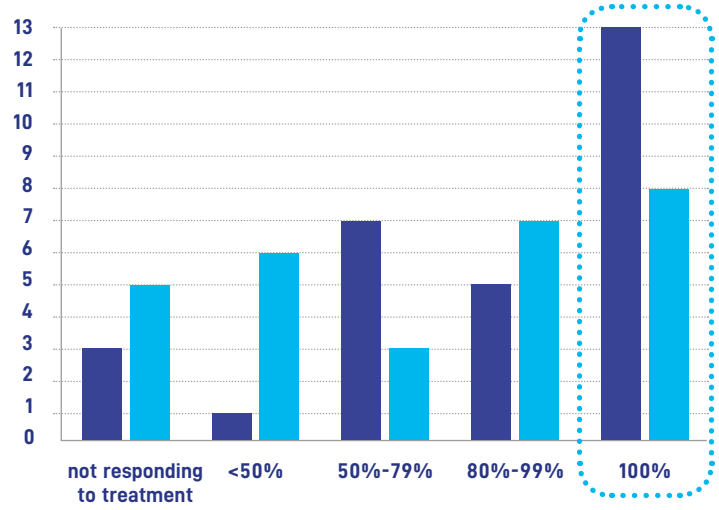
Venous, arterial and mixed skin lesions or surgical dehiscence lesions. Chronicity of the lesion: at least 8 weeks.

TREATMENT PROTOCOL:

TREATED LESIONS	CONTROL LESIONS
- Cleansing with physiological solution and debridment if needed.	- Cleansing with physiological solution and debridment if needed.
- Treatment with EmoLED performed at each visit for 60 seconds on the whole designated area.	
- Applications of hydrofiber dressing. If clinical signs of infection occur hydrofiber dressing with silver is applied.	- Applications of hydrofiber dressing. If clinical signs of infection occur hydrofiber dressing with silver is applied.

ENDPOINTS	EVALUATION METHODS
PRIMARY - Outcomes comparison in terms of reduction percentage of the surface area of the lesion treated with EmoLED versus the control at ten weeks.	Clinical observation of dimensions, depth, periwound skin, percentage of healing, exudate. Photographic image analysis with the use of a specific software developed and validate by the CNR- Clinical Phisiology Department.
SECONDARY - Evaluation of the healing time laps of the two areas.	
- Pain reduction.	VAS Scale
- Treatment safety.	Recording of any AE

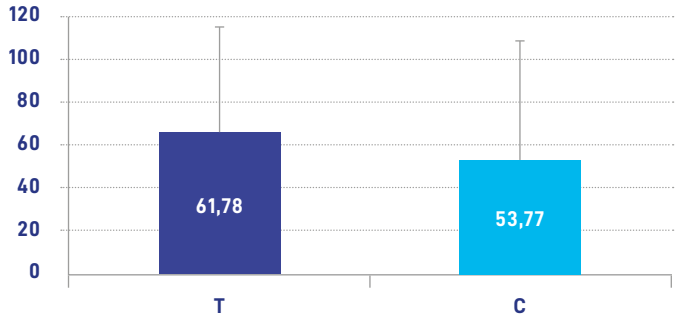
INTERIM RESULTS:



Number of patients distributed in healing percentage groups

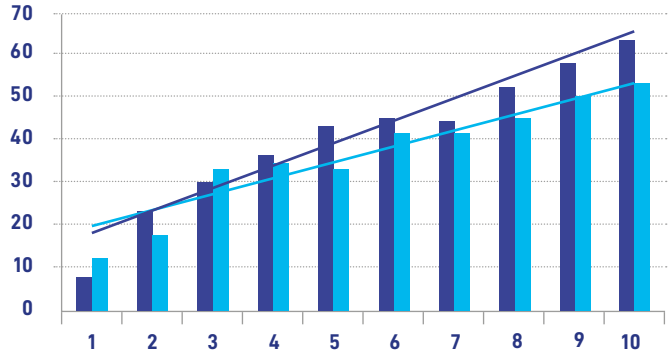
T C

At ten weeks the number of wounds healed completely is **60% higher** in the treated with EmoLED compared to control treated only with SOC.



Average area reduction (%)

The average ulcer area reduction is 15% higher in the treated wounds vs control.



Average area reduction (%) in non-healed wounds during 10 weeks.

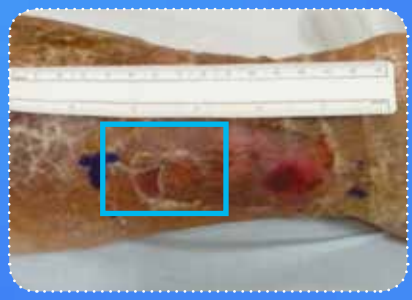
T Linear (T)
C Linear (C)

In the non-healing wounds has been recorded, nevertheless, an acceleration in the area reduction compared to control.

The following images show the evolution of four half treated ulcers. Is highlighted the half part treated with EmoLED.

enrollment time

end



Observation time: 3 weeks
Number of treatements: 2
Patients'age: 71 years
Ulcers'age: 6 months
Patology: CVI

enrollment time

end

Observation time: 10 weeks
Number of treatments: 9
Patients'age: 85 years
Ulcer's age: 15 years
Patology: mixed, venous prevalence, diabetic patient.

enrollment time

end

Observation time: 8 weeks
Number of treatments: 7
Patients'age: 78 years
Ulcers'age: 6 months
Patology: CVI

enrollment time

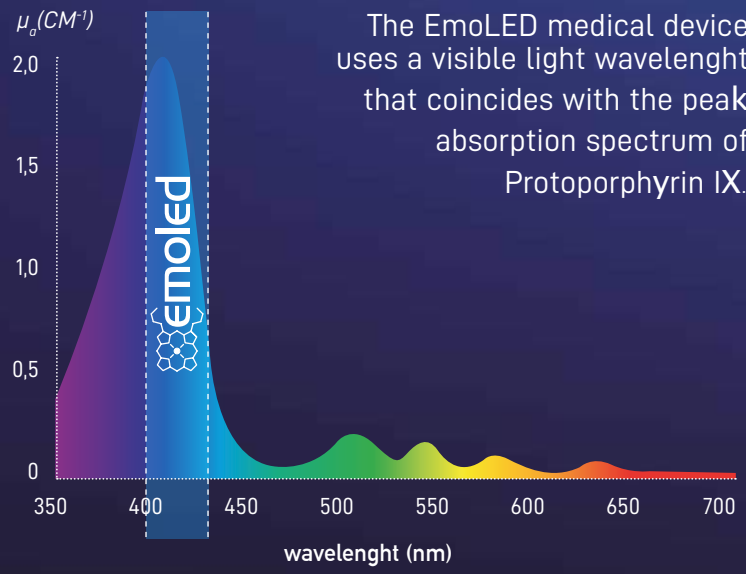
end

Observation time: 8 weeks Number of treatments: 7
Patients'age: 85 years
Ulcers'age: 4 months
Patology: CVI

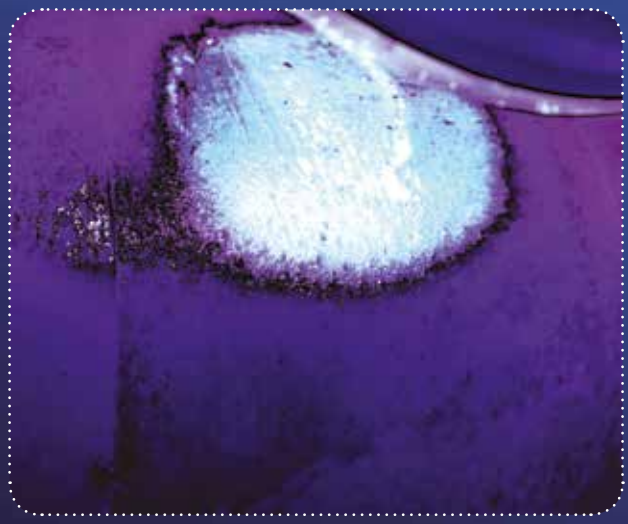
Light radiation characteristics:

Specific wavelengths of visible light in the blue range are able to activate the physiological healing process of skin lesions in a natural and non invasive manner; this is made possible by photoreceptors of such wavelengths present in blood and epithelial cells such as Protoporphyrin IX.

Absorption of visible light by PPIX:



The EmoLED medical device uses a visible light wavelenght that coincides with the peak absorption spectrum of Protoporphyrin IX.



The emitted radiation is generated by 6 LEDs and is made uniform over the entire irradiated area by the optical system of the device.

LIGHT EMISSION PARAMETERS

SPECTRAL BANDWIDTH:	400-430 nm
POWER DENSITY/IRRADIANCE:	120 mW/ cm2
IRRADIATED AREA:	20 cm2
TREATMENT DISTANCE:	3-5 cm
POWER OUTPUT:	2,3 W – max emission variation: 1%
ENERGY DENSITY/FLUENCE:	7,2 J/ cm2

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Emoled srl - Via di Rimaggio 141, int. 25 - 50019 Sesto Fiorentino (FI) - IT
www.emoled.com - t. +39 0550751960 - m. +39 3357408448

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