

BLUE LIGHT FOR ULCER REDUCTION

A new method to manage successfully difficult chronic wounds.

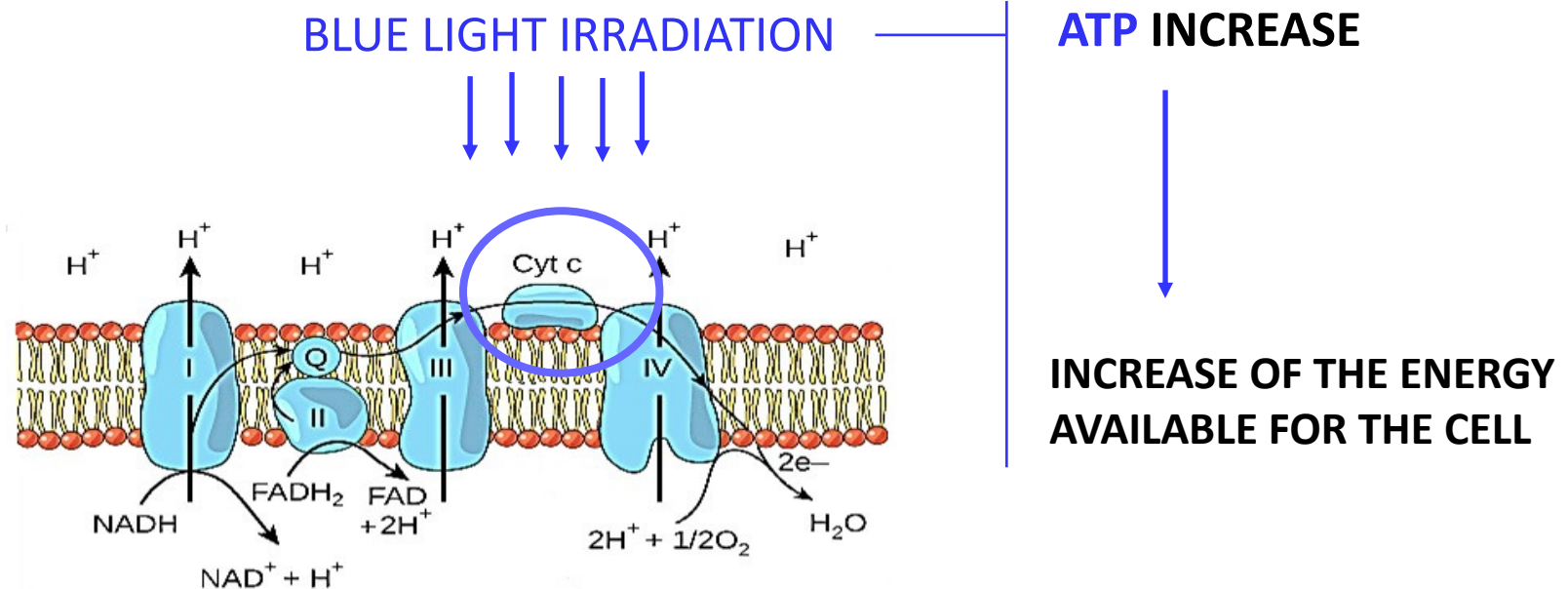
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AIM: To report on our experience on the use of a blue LED light Medical Device (EmoLED) with a wavelength between 410 and 430 nm for the healing of difficult chronic wounds.

METHOD: After pre-clinical trials on mice and rats and preliminary clinical observations, In May 2018 we started a multicentric study on 90 patients to verify the effectiveness of blue light treatment in surface reduction of ulcers. Inclusion criteria included wounds present for at least 8 weeks, vascular origin (arterial or venous ulcers) and wound dehiscence. Patients were given 1 minute treatment per week for 10 weeks.

Blue light has a beneficial effect on wound healing because it has a **photochemical effect on Cytochrome C**, present on the mitochondrial wall and on the Flavins. The action on Cytochrome C determines an increase in ATP production; while that on the Flavins determines an overcoming of inflammatory loop and angiogenesis.



PRIMARY ENDOPOINT

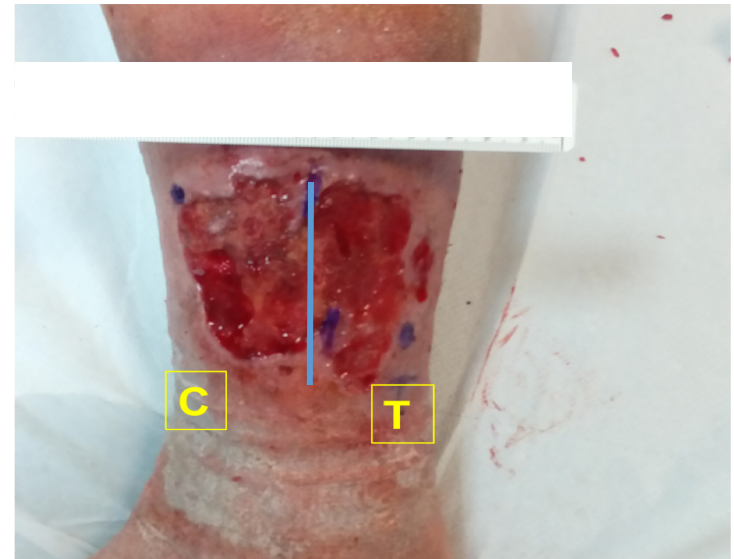
Outcome comparison intended as percentage of reduction of the lesion area treated with SOC+EmoLED versus the lesion treated only with SOC at ten weeks.

EVALUATION METHODS




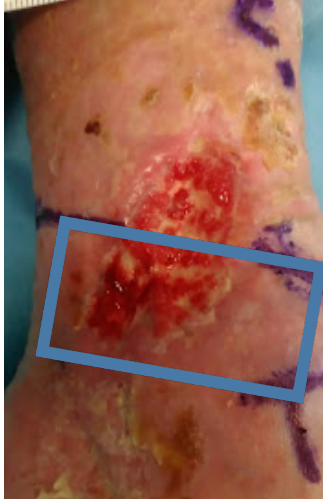
- Clinical observation of dimensions. Depth, peri-wound skin, percentage of healing, exudate, through data recorded on patient's Clinical Report Form
- Analysis of the photographic images acquired for each patient, performed by the CNR Department of Clinical Physiology (Pisa, Italy)

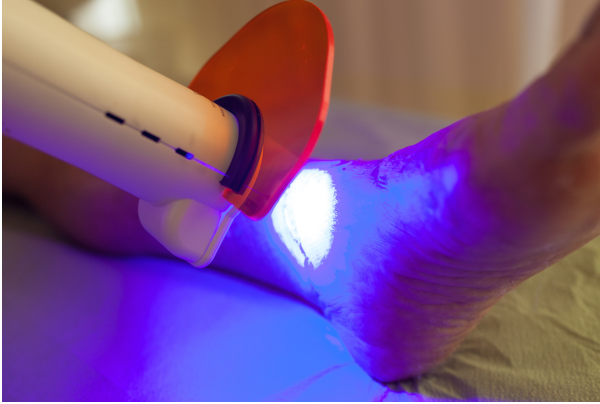
The innovative feature of the study is the use of the same patient to compare the healing of the treated wounds versus the untreated.

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



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enrollment time	end	
		<p>Observation time: 10 weeks Number of treatments: 9 Patients' age: 85 years Ulcer's age: 15 years Pathology: mixed, venous prevalence, diabetic patient</p>
		<p>Observation time: 10 weeks Number of treatments: 10 Patients' age: 75 years Ulcer's age: 2 years Pathology: venous ulcer</p> <p><i>NOTE. In figures T is the half lesion area that has been treated, C the half used as control.</i></p>



The **Blue LED Light Device** is portable, powered with rechargeable batteries and uses LED sources emitting Blue Light within the visible range of 400-430 nm, with a power density of 120 mW/cm² and a fluence of 7,2 J/cm² at target (= at distance of 4 cm from the light source).

RESULTS/DISCUSSION: Considering all the 60 patients that have completed the study (except for 4 drops out) the mean percentage reduction of the area in lesions treated with EmoLED at ten weeks is 51.52% compared to 31.15% of control lesions (treated only with SOC), recording a **difference in the mean percentage area reduction between treated lesions and control of 65.36%**.

CONCLUSIONS: Preliminary data from our study are very encouraging to demonstrate the effective use of Blue LED Light for successful management of difficult wounds.

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