Acne PhotoClearing (APC™) Using a Novel, High-Intensity, Enhanced, Narrow-Band, Blue Light Source

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INTRODUCTION

Acne, which results from the obstruction and inflammation of the sebaceous glands, is a condition that affects 80 percent of the human population (Leyden). Acne begins usually in adolescence, when hormonal changes cause the enlargement and then the obstruction of sebaceous glands in the skin. The obstruction of the gland openings causes the accumulation of sebum, which is followed by abnormal proliferation of the bacterial population, predominantly propionibacterium acnes (*P.acnes*). These pathophysiologic events result in the clinical expression of the painful, inflammatory pustules of acne. These lesions can heal with permanent scarring.

In spite of the various available treatments for acne, there are many patients who fail to respond adequately or who develop problematic side effects (Cunliffe). Topical acne medications are usually irritating to the skin and more than 40% of acne bacteria are insensitive to oral antibiotics. Therapy with Accutane is associated with possible severe side effects and is a costly treatment. Treatment time for responsive patients is usually at least three to four months.

Sun exposure is known to have some beneficial effects in up to 70% of patients with acne (Cunliffe). Although solar or artificial UV light has a mild camouflage effect on acne, its comedogenic and photoaging effects prevent its use in acne therapy.

It is known that *P.acnes* produce porphyrins during their normal life cycle, as part of their normal metabolism process. Visible light in the blue range, or to a less extent in the red range, induces a photodestructive effect on propionibacterium acnes that may take part in the decrease in acne severity during the summer. A moderate decrease in the number of acne lesions was achieved previously by exposure to light sources that produce red light (Konig), mixed violet and ultra-violet light (Meffert, Sigurdsson), or low intensity fluorescent light (blue and red).

This paper describes a novel, high-intensity, narrow-band, enhanced blue light system, which achieves over 60% clearance of acne lesions, following a total of eight bi-weekly 10-minute treatment sessions. This UV-safe acne photoclearing (APC) system is designed to operate above the threshold necessary to destroy the acne bacteria and at a rate that is quicker than the time needed for proliferation to occur.

MATERIALS AND METHODS

This acne photoclearing study utilized a high-intensity, 400W, UV-safe, enhanced blue (407-420 nm) metal halide lamp, which produced 90mW/cm^2 homogeneous illumination over an area of

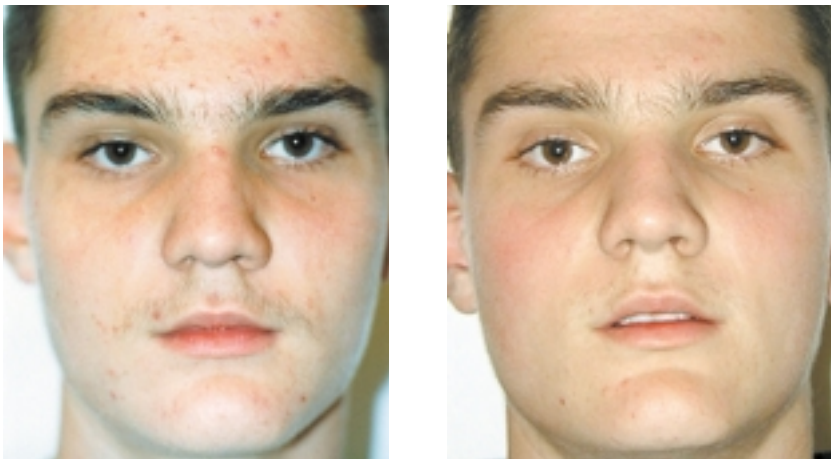

Fig. 1: Before and after 8 treatments; 2 months follow-up

20x20 cm^2 (ClearLight™ ESC Sharplan – ESC Medical Systems Ltd.). Fig. 2 shows the blue to near IR spectrum of the treatment source.

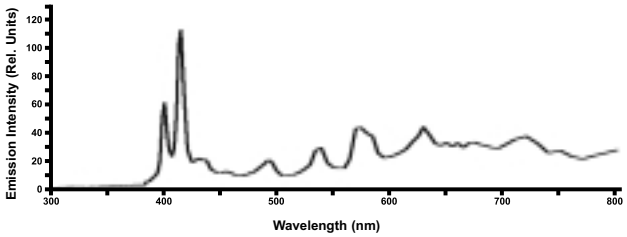

Fig. 2: Blue to near IR optical spectrum of the ClearLight™ high-intensity metal halide Acne PhotoClearing source

The 407-420 nm band matches the strongest porphyrin photoexcitation band (Fig. 3), whereas other wavelengths have a considerably smaller effect (Peng). Skin penetration of light at 420 nm is close to 1 mm, which targets exactly the surface and ductal *P.acnes*.

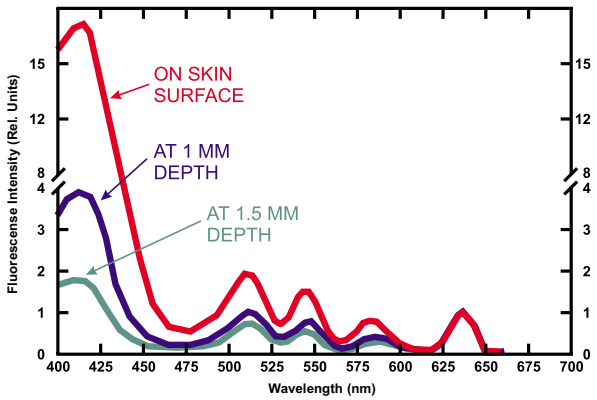

Fig. 3: Fluorescense excitation spectrum of protoporphyrin IX, demonstrating the essential role of the 407-420 nm blue-band in *P.acnes* photo-destruction

In Vitro Studies

Propionibacterium acnes cultures were grown for three days in anaerobic conditions. The level of endogenic porphyrins was determined by measuring fluorescence after extraction from the cells. The porphyrins produced by the bacteria were classified by HPLC elution patterns. Eradication of *P.acnes* by its endogenic porphyrins was examined after illumination with the intense narrow-band blue light emitting 20mW/cm^2 of narrow-band blue light (407-420nm).

In Vivo Studies

Skin Cultures

The effect of high-intensity narrow-band blue light on *P.acnes* of human skin was studied by Shalita et al. Ten patients were treated for inflammatory acne, either on the forehead or the cheek, during 20-minute sessions. *P.acnes* cultures were taken from both the treated and untreated symmetric areas, before therapy (baseline level) and after the 2nd, 4th and 6th treatments.

Clinical Studies

A clinical study was conducted to examine the effects of high-intensity, narrow-band, blue light on papulo-pustular acne. A total of 35 patients in three centers were treated twice a week, with the high-intensity, metal halide lamp that emitted 90mW/cm^2 of visible light. During each treatment, the patient's face or back was exposed to light for 10 minutes. Two months after the final treatment session, patients returned to the centers for clinical assessment.

RESULTS AND DISCUSSION

In Vitro Studies

Our data shows that *P.acnes* are capable of producing high amounts of endogenic porphyrins in the absence

Fig. 4: Before and after 8 treatments; 2 months follow-up

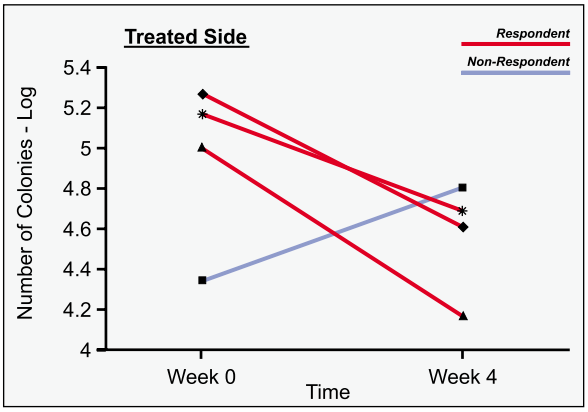

Fig. 5a: Photodestruction of facial *P.acnes* colonies with enhanced narrow-band blue light

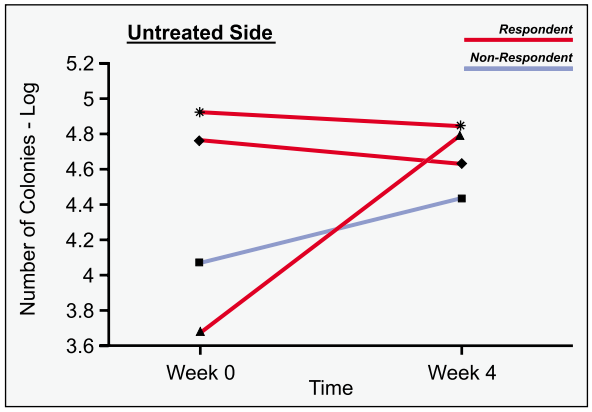

Fig. 5b: Proliferation of untreated *P.acnes* colonies

of trigger molecules. The porphyrins, which are produced by *P.acnes* are mostly uroporphyrin and coproporphyrin, as depicted from the HPLC elution patterns. The best photodestructive effects were obtained when cultures that grew anaerobically for 72 hours in liquid medium were illuminated twice for 60 minutes each, by intense, narrow-band blue light (fluence-20mW/cm^2, total light dose – 72 J/cm^2). The interval between treatments was 24 to 48 hours. Under these conditions, the viability of the culture was decreased by four orders of magnitude. This data demonstrates that eradication of *P.acnes* occurs with exposure to high-intensity, narrow-band blue light, as induced by its endogenic porphyrins.

In Vivo Studies

Skin Cultures

After six treatments, 60% (6/10) of the patients demonstrated a significant reduction in the levels of *P.acnes* (<1 log, P<0.05). These patients had a baseline level of *P.acnes* of >10^5 colonies/cm^2. The four patients, who did not show a significant change in *P.acnes* levels, had a low baseline level of *P.acnes* of 1 to 5 x10^4 colonies/cm^2. These results show a 90%, statistically significant reduction of *P.acnes* after therapy with high-intensity, narrow-band blue light. Based on these results, patients with higher surface *P.acnes* level (>10^5) would benefit more from the light treatment. Figures 5a & 5b present the results of blue band photodestruction of *P.acnes* colonies and a comparison to the proliferation of untreated colonies.

Clinical Studies

After eight bi-weekly treatments, 80% of the patients with mild to moderate papulo-pustular acne showed significant improvement of non-inflammatory, inflammatory and total facial lesions. Inflammatory lesion count decreased by a mean of 60%. Two weeks after the last treatment, the count had even further decreased to almost 70%. No side effects of the treatment were observed. External skin temperatures increased in a few cases by <1.5°C, however, this was not noticed by the patients. Twenty percent of the patients did not respond to the treatment. The lack of response in these patients may be attributed to the existence of deep acne cysts or to the existence of non-*P.acnes* bacteria.

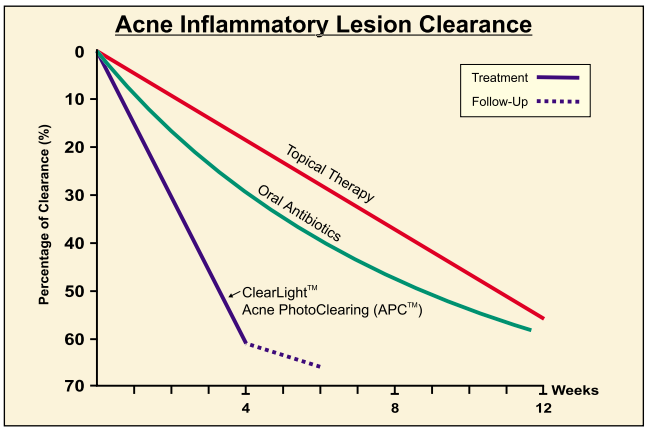

Fig. 6: Multicenter clinical results: inflammatory acne lesion counts for ClearLight treatments and comparison for conventional topical and oral antibiotic treatments

Fig. 6 presents a graphical summary of the clinical results. The level of acne clearance at one month after photoclearance is compared to a control group treated with 5% benzyl peroxide, one of the more potent conventional acne medications.

Figures 1 & 4 show before & after photos of two patients treated with ClearLight.

CONCLUSIONS

Propionibacterium acnes is a Gram positive, micro-aerophilic bacterium which takes a major part in the pathogenesis of inflammatory acne. *P.acnes* is capable of producing high amounts of endogenic porphyrins in the absence of any trigger molecules. These porphyrins are triggered by high-intensity blue light, thereby resulting in photodestruction of the acne bacteria. *In vitro* and *in vivo* studies with a novel, high-intensity, narrow-band, enhanced blue light system show 90% destruction of bacteria on human skin. Furthermore, there was a rapid response rate to the treatment, which resulted in a decrease in the number of acne lesions, as well as improvement in severity scores following the eight bi-weekly 10-minute treatment sessions. The amelioration of acne is comparable to the effects of oral antibiotics; however, the therapeutic effect occurs as early as four weeks after treatment (as compared to eight to twelve weeks after drug therapy) and without the side effects associated with topical or parenteral anti acne medications. Acne photoclearing (APC) by high-intensity enhanced narrow-band blue light is a promising non-invasive alternative to current topical and parenteral anti-acne remedies.

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