

Characterization of a New Light and Vacuum Device for the Treatment of Acne

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Introduction

We report on the development of a new device that combines broadband pulsed light with a vacuum suction technology for the treatment of mild to moderate acne, including pustular acne, comedonal acne, and mild to moderate inflammatory acne (acne vulgaris). This report includes an overview of the technology along with a discussion of early clinical findings.

Clinical Background

Pulsed light treatments have been used both alone and in combination with other modalities to rapidly reduce active acne [1, 2, 3, and 4]. Investigators postulated that a broadband light source would activate endogenous porphyrins resulting in a noticeable improvement being reported with these devices [5, 6]. The use of vacuum suction for the treatment of acne was first described in the dermatology literature by Moschowitz [7], who described the treatment of eight subjects with a rubber bulb to apply slight suction to acne lesions so as to cause localized hyperaemia.

Recently, a combination of pulsed light and vacuum has been proven clinically effective for the treatment of acne. A multicenter retrospective study by Shamban et al. [8] using a combination of pulsed light and vacuum demonstrated a physician-rated mean clearance of mild to severe acne ranging from 50% following a single treatment and up to 90% following four treatments. In the authors experience of performing over 150 treatments, marked improvement was seen after as few as two treatments spaced two weeks apart. Corroborating this, Gold et al. [9] administered four treatments to patients at three week intervals. At 91 days (one month after the final treatment), the median inflammatory lesion count (n=10 subjects with complete data) decreased from 22.0 (inter-quartile range [IQR] =11.2) to 10.5 (IQR=4.2). The difference was significant (P=.0196) by Friedman's AVOVA test. For noninflammatory lesions, the median counts decreased from 25.0 (IQR=19.0) to 10.0

(IQR=8.9) but the reduction was not statistically significant (P=.0956) as determined by Friedman's ANOVA test. The corresponding reduction percentages ($[(\text{baseline count} - \text{post treatment count}) / \text{baseline count}] \times 100$) were 78.8% (IQR=29.7) for inflammatory lesion counts and 57.8% (IQR=36.0) for non-inflammatory lesion counts. At 153 days (n=6 with complete data), reductions were significant for both inflammatory (P=.0137) and non-inflammatory (P=.0383) counts.

Wankiphakdeedecha et al. also studied 20 patients treated with mild to severe facial acne who were treated with a combination of pulsed light and vacuum and noted greatest improvement in patients with severe acne [10].

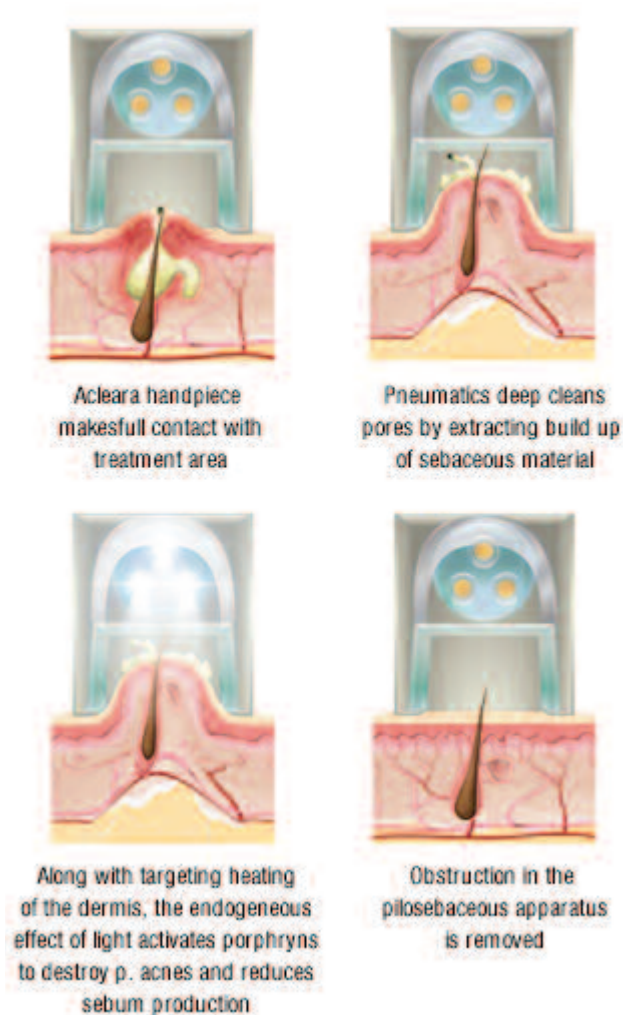
Device Overview

The Aclera™ Acne Treatment System (sold exclusively in the US by Palomar Medical Technologies Inc., Burlington, MA) is a technological advance over prior generation devices that deliver a combination of broadband pulsed light (500-1200 nm) simultaneously with the application of vacuum.

The Aclera Acne Treatment System is technologically based on solid physics and biological principals and functions by mechanically clearing congested follicles of the affected pilosebaceous apparatus using suction-applied tip while utilizing broadband light with a cut-off filter from 500 to 1200 nm to activate endogenous porphyrins in pathogenic bacteria. The device is capable of generating vacuum with up to 3 psi pressure in a confined treatment area which effectively lifts the dermal structures towards the epidermis and expels follicular contents onto the skin's surface.

Mechanism Overview

The device works by placing the treatment chamber over the area to be treated. When complete contact with the treatment surface is detected, a vacuum is applied drawing the treatment target into the treatment chamber. The effect of vacuum elevates the sebaceous gland toward the surface, momentarily stretches the skin 25 – 35%, and extracts the build up of sebaceous material. A series of flash lamps subsequently illuminate the treatment area. Along with targeting heating of the dermis, the endogenous effect of light activates porphyrins to destroy *P. acnes* and reduce sebum production. When this process is completed, the vacuum is released.



Therapeutic Effect of Vacuum: Extracting Build up of Sebaceous Material

The immediate and rapid pressure change on the sebaceous gland forces any blockages to open up evacuating sebum onto the surface of the skin.

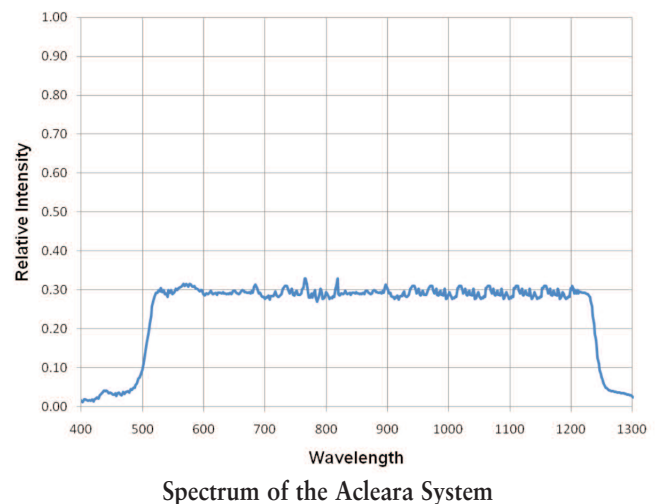
When sebum is extracted from the clogged pilosebaceous duct, various bacteria living in the sebum are also simul-

taneously extruded. In laboratory studies, researchers verified that mechanically extruding bacteria removed both antibiotic resistant and antibiotic susceptible bacteria. Much of the bacteria were antibiotic resistant and hence untreatable by many topical antibiotics. Mechanical extrusion of bacteria significantly reduced bacterial load on the sebaceous gland effectively allowing the patient's own immune response to overcome *p. acnes*.

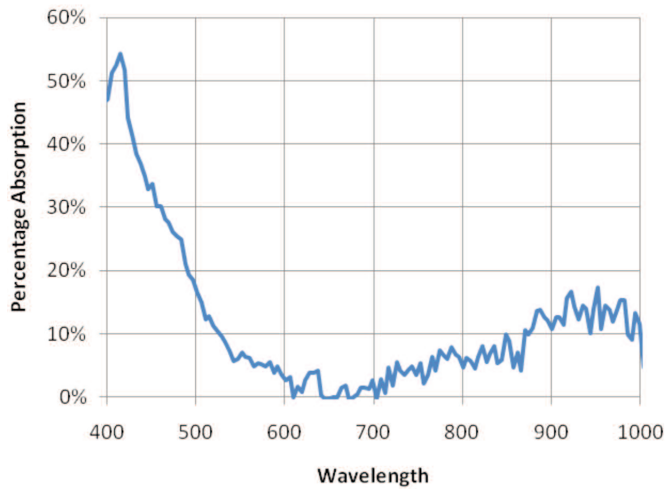
Endogenous Effect of Light

The Acleara system uses a series of xenon flash lamps that provide a broadband output ranging from 500 nm to 1200 nm.

An optical coating removes the shorter wavelengths that can potentially damage the heavily melanated epidermis of darker skin typed patients making the spectrum safe for the treatment of all skin types (I-VI). The treatment spectrum is shown in the figure below.



The sebaceous material that clogs the pilosebaceous duct causing inflammatory acne is composed of a variety of substances including sebum and tissue that once formed the epidermis. This includes keratin and melanin. Consequently its absorption spectrum is more complex than the absorption spectrum of porphyrins associated with *pAcne* bacteria. Investigators collected the extracted sebaceous material to determine its absorption spectrum [11]. The figure below shows the absorption spectrum of sebum closely resembling that of melanin. This is not surprising, as melanin is one of the major constituents of this extruded sebaceous material. There is also strong absorption in near infrared likely due to fatty acids that comprise the sebum.



Spectrum of the Material Extracted from the Pilosebaceous Unit

Comparing the spectral output of the Acleara system to the absorption spectrum of the material extracted from the sebaceous gland, light output between 800 – 1000 nm plays a major role in heating this material. Consistent with clinical literature, the broadband light source of the Acleara system activates endogenous porphyrins and also has an effect on peri-lesional erythema due to absorption in the 500–600 nm range.

Major Advantages of the Acleara System

The design of the treatment chamber of the Acleara system offers two several significant advantages compared to other products using similar technology. The first is the metallic walls of the chamber are dynamic-cooled by water. This prevents these walls from rising in temperature to a level that can readily burn any treatment tissue that contacts them. In other products, the metallic walls must be periodically cooled with a cryogen spray every five to ten pulses of light. The only indication that the walls have reached excessive temperatures is the response of the patient. In the Acleara system, the water flowing behind the reflective metallic walls keeps their temperature in a safe range and no external cryogen spraying is needed.

Eight advanced vacuum settings including a special soft vacuum mode allows for micro-adjustments making the treatment comfortable and reducing side effects on areas such as the forehead that were previously more prone to bruising.

Finally, the Acleara system eliminates the need to select treatment tips based on patient skin type. A highly optimized spectral output allows for a single light filter to treat all skin types including darker skinned patients.

Clinical Outcomes

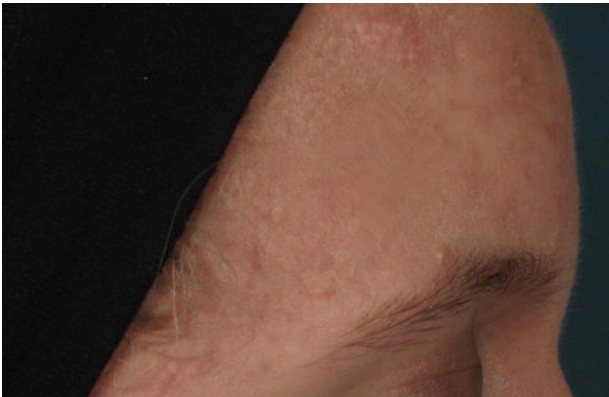
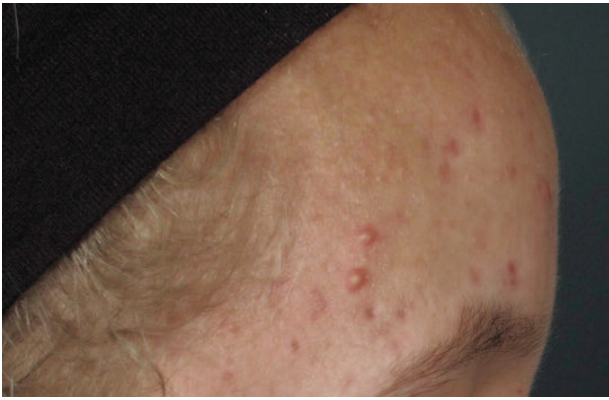
The Acleara system has been used for the treatment of mild to moderate inflammatory acne, comedonal acne, and pustular acne on all skin types. A sample of treatment outcomes are presented below.



1 week post first treatment

Photos courtesy of Colin Hong, MD

The patient above was treated at an energy level 5, and a vacuum setting of 3. Pulse duration was 25 milliseconds (ms) and a pulse delay of 750 ms. the double pulse setting was used. Two treatment passes were performed. Some lesions were spot treated with an additional pass.



After 4 Treatments

Photos courtesy of Girish Munavalli, MD

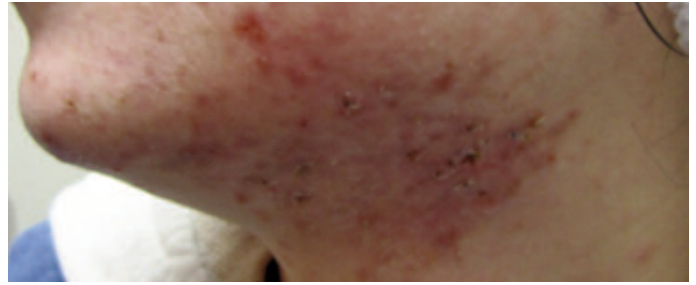
The patient above was treated at an energy level 4, and a vacuum setting of 2. Pulse duration was 3 ms and a pulse delay of 750 ms. The double pulse setting was used. Two treatment passes were performed.



1 week post 1st treatment

Photo courtesy of Colin Hong, MD

The patient below on the left was treated at an energy level 6, and a vacuum setting of 3. Pulse duration was 3 ms and a pulse delay of 750 ms. The double pulse setting was used. Three treatment passes were performed.



1 week post first treatment

Photo courtesy of Colin Hong, MD

The patient above was treated at an energy level 6, and a vacuum setting of 3. Pulse duration was 25 milliseconds and a pulse delay of 750 ms. The double pulse setting was used. Three treatment passes were performed.



After fourth treatment

Photo courtesy of Colin Hong, MD

The patient above was treated at an energy level 4, and a vacuum setting of 3. Pulse duration was 25 milliseconds and a pulse delay of 750 ms. The double pulse setting was used. Two treatment passes were performed and lesions were also spot treated for a third pass.

Treatment Protocol for All Patients

The treated areas were cleansed with a mild cleanser prior to treatment. Following a gentle cleanse, the treatment areas were steamed for 7 – 10 minutes prior to treatment. Steaming is not required but, in our experience, softens sebum facilitating the extraction of comedones. Energy settings were selected based on skin types. Vacuum settings were selected based on treatment areas with vacuum settings reduced when treating delicate areas such as the forehead. All patients were treated using a double pulse setting with two passes over the entire face with additional spot treatments as necessary. Patients were treated at weekly intervals for 4 – 5 treatments depending on the severity of acne.

Outcomes and Conclusions

Our experience to date demonstrates that Acleara treatments were well tolerated by patients and effective for the treatment of a wide range of mild to severe acne. There was little to no discomfort during treatments and no downtime. No anesthetics or numbing gels were used prior to treatment. Most noticeably, patients noted an immediate reduction in redness after the first treatment as is indicated by the photographs.

Immediate post-treatment skin reactions were limited to localized mild and transient erythema which resolved within 30 minutes after treatment. Patients reported satisfaction with outcomes.

While these initial findings warrant larger scale randomized studies, we do believe that the Acleara System is effective for the treatment of a wide range and severity of acne.

References

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11. Data measured by Ocean Optics™ Spectrometer (Ocean Optics Inc. Dunedin, FL)