An Advanced Vacuum and Light Technology for the Treatment of Acne Vulgaris

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INTRODUCTION: We report on the treatment of over 100 patients with acne using the new Acleara device. Patients were treated with mild to moderate acne vulgaris, including pustular, comedonal, and inflammatory variants. This report starts with an overview of acne therapies followed by a discussion of our clinical results with the Acleara.

Background and Overview

Acne is a disease of the pilosebaceous unit affecting both teenagers and adults. It is one of the most common disorders treated by the medical profession as well as self treatment using over the counter remedies. It can manifest itself as small comedones, blackheads, whiteheads, papules, pustules and deep cysts. There are numerous treatments available, which can vary from, but not limited too, systemic and topical antibiotics, retinoids, isotretinoin, and benzyl peroxide. Many of these treatments are effective if used for a sustained period of time. Most do not show immediate results which is often the goal of most patients.

All acne lesions start with the formation of a microcomedone created by hyperproliferation of the follicular epithelium [1]. At this very early stage, inflammatory processes and activation of the vascular endothelium are present. This initial inflammatory event may have multiple causes, some of which or all of which may be present. Changes in the concentration of the lipids in sebum may be one factor [2]. Peroxisome proliferator-activated receptor (PPAR) are transnuclear receptors responsible for generating peroxisome, which in turn are responsible for the catabolism of a variety of fats inside the cell. Studies linking androgens with PPAR in sebocytes suggest the increase production of free fatty acids and peroxidative squalene, both inflammatory compounds may be one cause [3]. Other evidence also links androgens linking to PPAR in sebocytes with increase sebocyte differentiation and lipid generation[3]. Free fatty acids in the cytoplasma of sebocytes also bind to PPAR leading to an increase in inflammatory compounds.

Increase in stress is often associated with an acne breakout. Recent scientific studies have shown that immunoreactive nerve fibers in close proximity to the sebaceous glands generate a neuropeptide called substance P that further stimulates the germative sebocyte cells leading to an increase in the number of these cells and in their differentiation [4].

The anaerobic bacterium pAcne can also be the source of the initial inflammation. Although studies have shown it is not necessary for pAcne to be present to start a microcomedone, its presence contributes to an inflammatory response [1][5]. In acne lesions, human β defensis-1 and -2 are upregulated and serve as a protective mechanism against pathogens such as bacterias [5]. It is reasonable to assume that pAcne bacteria is responsible for this increase in human β defensis-1 and -2. In addition Toll-like Receptors (TLR) manifested on macrophages are found in acne lesions. TLRs identify molecular patterns on bacteria and their presence is an indication that pACne bacteria have precipitated an inflammatory response.

The presence of inflammatory cytokines in the pilosebaceous unit creates hyperkeratinization, an excess of keratin [6]. This excess leads to an increase in the adherence or bonding of dead skin cells together resulting in a blocking of the hair follicle. A small cap is formed. The inflammatory cytokines will also cause the epidermal/dermal barrier between the infundibulum and the dermis to be compromised. Components of sebum will spill out into the dermis increasing inflammation, which is the main cause of scarring. The accumulation of sebum will also increase the food supply and improve the anaerobic environment for the pAcne bacteria leading to a surge in their population further exacerbating the problem.

Although the cause of the acne lesion is multifactorial, one major factor is an increase in sebum in the infundibulum unit. Removing the sebum/follicular contents is a sound method for reducing acne. By removing sebum/follicular contents, the level of pAcne population is immediately reduced. The various inflammatory cytokines contained in the sebum are extracted. The inflammatory free fatty acids and peroxidomes are removed.

How the sebum is removed is also important. Since the dermal/epidermal barrier is compromised, any method that applies pressure on the sebum without a corresponding pressure on the dermis will force sebum out of the infundibulum into the dermis. This can occur using the traditional extraction methods. The key is to apply pressure on the dermis, thereby squeezing the sebum out of the infundibulum on to the surface of the skin. A vacuum chamber placed over the acne lesion would apply the right kind of pressure to the dermis surrounding the lesion and to the sebum contained in the lesion.

Although secondary to removing the sebum, the inflammation caused by acne has a major vascular component. Very small capillaries, produced in response to the inflammatory signaling, proliferate around and below the acne lesions. This increase in vasculature is detected as redness. Pulsed light of the proper wavelength and temporal duration is an ideal energy source for removing these vessels. Since the hemoglobin and oxyhemoglobin in these capillaries have strong optical absorption in the green and yellow-orange portion of the spectrum, pulsed light in this spectral range would be ideal. Since the capillaries are very small, a short pulse duration in the millisecond range is preferred.

Devices

The discussion above describes the basis for a device that combines a vacuum chamber with short intensed pulsed green to yellow-orange light. Most of the devices associated with the treatment of acne have been primarily designed to destroy the pAcne bacteria while leaving the sebum in the infundibulum. Total destruction of the pAcne population is nearly impossible. The bacteria repopulate the infundibulum so long as its food source and protection from oxygen remain.

Blue Light Devices

Metal halide lamps with a wavelength of 405-420nm are being used to treat acne on a twice weekly basis. First used by Shalita et al, they have shown some improvement in treating facial acne [7, 8, 9, 10].

Porphyrins are organic compounds found in all biological systems. Produced by pAcne, they are one of many chemicals found in sebum. With very strong optical absorption around 400nm, blue light devices that emit light at this wavelength target this chromophore. The porphyrins located both in and around the pAcne bacteria absorb this light increasing the temperature and thereby destroying the bacteria. Transmitting sufficient blue light into the sebaceous gland, located as much as a millimeter below the surface of the skin, is problematic. Typically blue light in the wavelength range absorbed by porphyrins penetrates only 300 to 400 microns into the skin. In addition, in darker patient, melanin that accompanies the dead skin cells that have formed the comedone absorb much of this blue light, further attenuating it.

Sebum extracted from acne lesions has an optical absorption curve shown in Fig.1. Not surprisingly, it resembles melanin except in

the longer wavelength region where the absorption is greater than melanin. In this region, many of the lipids in the sebum start absorbing light.

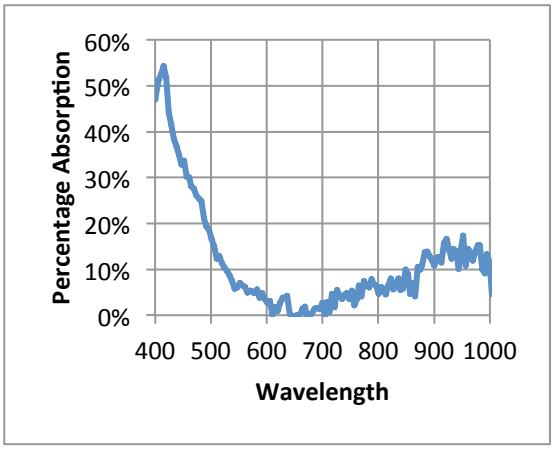


Figure 1. Absorption Spectrum of Sebaceous Material Extracted From Hair Follicle

Pulsed light combined with Aminolevulinic Acid (ALA)

Activation of aminolevulinic acid (ALA) by light is a form of photodynamic therapy. The ALA is applied to the skin surface, penetrates into the infundibulum and is converted to protoporphyrin IX (Pp IX). When it is photo excited by light, it destroys follicular bacteria. Several studies combing pulsed light with ALA have demonstrated a decrease in acne lesions, a decrease in sebum production and extraction and a reduction in the size of the sebaceous gland [11]. Several others have combined blue light with ALA and demonstrated improvement in acne lesions [12, 13]. ALA is slow to penetrate the sebaceous gland and can result in long incubation times. Following treatment, the patient is photosensitive and should remain out of sunlight for up to 48 hours. Compliance is difficult given the long incubation time and the photo sensitivity. In addition the ALA is expensive and not covered by insurance for this treatment.

Pulsed light devices (IPLs)

The porphyrins contained in and around the pAcne bacteria have absorption bands in other regions of the spectrum. Although the porphyrins are less absorptive in these bands compared to the absorption in the deep blue, the absorption is nevertheless sufficient. Intense pulse light devices cut-off filters above 500 nm target these absorption bands, heating the porphyrins and destroying the pAcne bacteria. Several studies reported improvement using such devices [14, 15]

These devices experience the same problems when treating acne. Even if the light reaches the porphyrins and destroys the pAcnes, it does not destroy all the pAcnes. Some is always viable and remains to immediately start repopulating the lesion. As long as there is sufficient sebum remaining, the conditions for the pAcnes population to rebound are ideal. The sebum is an excellent food supply and an excellent protector from oxygen required by anaerobic bacteria. Finally the inflammatory cytokines residing in the sebum remain to further stimulate the sebocyte to produce sebum and to differentiate.

The problem is the sebum/follicular content. Remove the sebum/follicular content, remove the problem.

Acleara: An Advanced Vacuum + Light Technology for the Treatment of Acne

Considering the absorption spectrums discussed above, broadband light sources found in pulsed light devices as well as continuous wave blue light devices should be more effective in treating acne than the results indicate. However, the strong absorption band for continuous wave blue light devices is in an area of the spectrum that does not penetrate very deeply into the skin. Pulsed light between 500nm and 600nm is highly attenuated before reaching a depth of 1mm or more. Finally, there is no still no force to mechanically or otherwise evacuate the blockage from the pilosebaceous unit.

The Acleara Acne Clearing System is a novel combination of filtered broad band light and vacuum. The device delivers broad band light in the 500 – 1200 nm range and delivers a gentle vacuum suction on the treatment area. When the vacuum activates, it generates 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 thereby clearing the pore. The effect of vacuum also stretches the skin 25 – 35%, reducing effective melanin concentration in the epidermis, which increases the transmission of energy to the targeted structures. This elevation of the

pilosebaceous unit results in more light delivered to target structures more efficiently as less energy is lost in the process of transmission.
Along with the targeted heating of the dermis, the endogenous effect of light activates porphyrins to destroy p. Acnes bacteria and reduce sebum production. The pressure caused by the vacuum combined with the heat generated by the absorption of light removes the follicular contents. Sebaceous material can be observed as it is forced out onto the surface of the skin. In addition to the sebaceous contents, pAcnes is removed both mechanically as well as thermally from the active acne lesion (Fig 2)

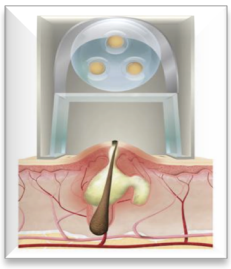
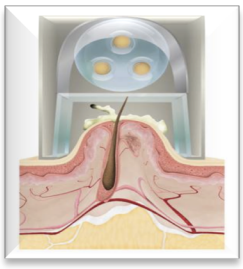
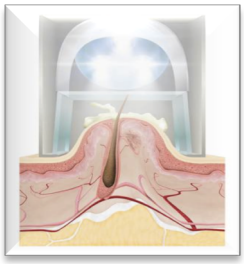
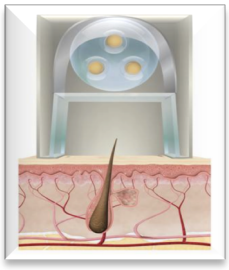
	
Acleara hand piece makes full contact with treatment area	Pneumatics deep cleans pores by extracting build up of sebaceous material
	
Along with targeting heating of the dermis, the endogenous effect of light activates porphyrins to destroy P. acnes	Obstruction in the pilosebaceous apparatus is removed and skin normalizes

Figure 2. Acleara Mechanism of Action

The light spectrum from the Acleara extends from 500nm to over 1200nm (See Fig 3). The light in the 500nm to 600nm is absorbed by the melanin in the sebaceous material. The light at the longer wavelengths is absorbed by the fatty acids in the same material. By removing light from the 400nm to 500nm portion of the spectrum, absorption by melanin in the epidermis is minimized making the treatment safe for the treatment of pigmented skin.

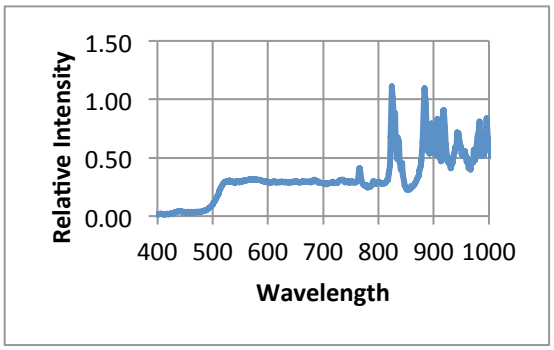


Figure 3. Output Spectrum of the Acleara System

Background of Acne in Our Practice

The Acleara system has been used for the treatment of mild to moderate inflammatory acne, comedonal and pustular acne lesions in all skin types.

Having performed more than 15,000 treatments with the Lux V (Palomar Medical Technologies, Burlington, MA)our office was familiar with the use of devices for treating acne. Initially patients being treated by the Lux V were switched to the Acleara. Advantages of the Acleara were immediately obvious. Comedonal acne lesions that did not respond to Lux V treatments responded well to the Acleara treatment. The patients also felt minimal discomfort with the Acleara and preferred it to Lux V treatments.

Treatment Protocol

The treatment area was first cleansed with a mild cleanser prior to treatment. All patients were photographed using the Visia Complexion Analysis System. While the manufacturer's treatment protocol suggests steaming as a way to soften sebum and facilitate the extraction of comedones, we did not steam patients as our patient volumes did not allow for that. Energy settings were selected based on skin types. Vacuum settings were selected based on treatment areas with vacuum settings for sensitive skin being used to treat delicate areas such as the forehead, temples and chest. All patients were treated using a double pulse with two passes over the entire face. Patients were treated at every two weeks for 4 – 5 treatments based on the severity of acne. No

external cool sprays, gels or anesthetics were used or required.

Although our results and the results of other users of the Acleara device on moderate to severe acne are especially dramatic, the majority of our patients are treated for comedonal acne, both open and closed. The results are equally dramatic, but difficult to display using photography. Patients, however, are very satisfied.

The importance of successfully treating comedonal acne cannot be understated. Based on the work of a variety of academics in the last ten years, micro-comedones are seen as the precursors of all acne. Starting with a microcomedone, acne lesions begin to develop due to a variety of factors causing an inflammatory response. This inflammatory response results in the sebaceous gland generating excess sebum, the weakening of the basal membrane in the infundibulum, and the establishment of an environment favoring the rapid growth of pAcnes bacteria. The end result is an inflammatory acne lesion.

Successfully treating the micro-comedones and comedones with the Acleara, something that could not be done with previous devices, lessens the potential for an inflammatory and or cystic acne lesion to develop. The mechanism for treating these small comedones is postulated to be the removal of the sebum by the vacuum combined with the destruction of the small micro vasculature by the light. This micro vasculature is developing in response to the higher than normal concentration of various inflammatory factors as part of the cascading process that would ultimately lead to an inflammatory lesion.

As stated earlier, after more than 15,000 treatments using the Lux V from Palomar, very few if any of these patients were successfully treated for small comedonal acne. Cystic inflammatory acne lesions responded consistently with the LuxV, but comedonal acne rarely responded. Now with the Acleara device, treatment of these comedonal lesions, as well as larger, cystic lesions can be accomplished.

Clinical Outcomes

100 patients manifesting mild to severe acne with Fitzpatrick Skin Types 1- 6 have been treated with the Acleara Acne Clearing System. Many of these patients were already undergoing treatment with the Lux V and were switched to the Acleara. None of the patients wished to return to treatment with the Lux V.

New patients, however, started with the Acleara and never were treated with the Lux V. To date, there are approximately 30 of these patients, many with comedonal acne. Approximately 15 new patients are added weekly. Due to the retrospective nature of the collection of data from the treating healthcare professionals, data was not uniformly recorded, and thus was not available, for all patients for all of the evaluation criteria.

The majority of patients noted a reduction in the number and severity of lesions post two treatments.

Treated patients also showed an improvement in the overall redness.

Perhaps the most dramatic visual improvement was in peri-lesional erythema with a sizeable majority showing an improvement in erythema post 2nd treatment.

The majority of treated patients also noted a reduction in oiliness of the skin and an improvement in overall skin texture.

Treatment providers noted a very dramatic reduction in blackheads and whiteheads that they had previously been unable to treat.

Patients were extremely satisfied with treatment outcomes and did not wish to return to previous treatment modalities. Treatment providers found the device fast and easy to use with a full face treatment taking about 10 minutes.

Side effects were transient and limited to the early part of our experience. The most common side effect was mild bruising which typically resolved within 48 – 72 hours post treatment. Once vacuum settings were adjusted and sensitive settings were used on areas such as the temples and forehead, no bruising occurred. Erythema typically resolved within 30 minutes of treatment.

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. Most important, however, is the new ability to treat both open and closed comedones, something no other device has been able to do consistently. Given the overwhelmingly positive outcome, we are investigating the use of the device as prophylactic on younger patients as a way to avert development of cystic lesions. By treating the micro-comedones before they can develop into inflammatory acne, we believe that Acleara may either avert the manifestation of acne or at least reduce severity when it manifests. Aclear most certainly will lessen the need for oral therapy.

Contributions:

The authors of this paper wish to thank the following individuals for their contributions to the work described in this study.

Erin Ward

Krista Woolsey

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