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Clinical and usability study to determine the safety and efficacy of the Silk'n Blue Device for the treatment of mild to moderate inflammatory acne vulgaris

MICHAEL H. GOLD[1,2], JULIE A. BIRON[1] & WHITNEY SENSING[1]

[1]*Tennessee Clinical Research Center, Nashville, TN, USA,* [2]*Gold Skin Care Center, Nashville, TN, USA*

Abstract

Introduction: Home devices for acne vulgaris have emerged as a way to utilize our current light based technology for the care of our patients suffering from acne vulgaris. *Materials and methods:* Patient received eight treatments with the Silk'n Blue device over a 4-week period. Follow-up visits were at 1 month and 3 months. *Results:* Seventeen subjects were entered into this institutional review board (IRB) approved clinical research project. There was a statistically significant decrease in mean acne counts from baseline through the follow-up visits, $p = 0.002$. Percent reduction was also statistically significant, $p = 0.041$. The study also showed that 36.4% of the patients had complete clearance with the study device. 100% of the patients showed full comprehension with the label for the device. There were no adverse events. Photos were captured. *Discussion:* The Silk'n Blue device has an array of 24 LEDs emitting a spectrum of light in the blue-violet range of light (405–460 nm). Subjects enrolled in this clinical trial clearly were able to understand the labeling for the device. *Conclusions:* The Silk'n Blue device is a safe efficacious at home device for the treatment of mild to moderate inflammatory acne vulgaris.

Key Words: *Silk N Blue Acne Vulgaris, Phototherapy*

Introduction

Acne vulgaris is one of the most common dermatologic entities seen in clinical practice (1). It has been estimated that above 70% of adolescents suffer from acne vulgaris and many of these same individuals have to continue with acne vulgaris into adulthood (2). Some have reported that up to 94% of all females have acne vulgaris at some point in their lives (3).

Acne vulgaris is a multifactorial skin disease with much of our therapy aimed at treating the causative bacterium, *Propionobacterium acnes (P. acnes)*. We are fortunate to have numerous therapeutic options available for our patients who suffer from acne vulgaris. These include topical and systemic therapies, as well as lasers and light therapy, including photodynamic therapy. The increased use of nonmedical therapy (lasers and light sources) has emerged as a more popular treatment due to the increased incidence of antibiotic resistance being seen with today's antibiotics and related medications (4).

Lasers and light sources are thought to treat acne vulgaris by three mechanisms of action. These include 1) the selective destruction of *P. acnes*, 2) the destruction of the sebaceous glands, and 3) by partial destruction of the sebaceous glands. Several recent reviews of lasers and light sources have been published (5,6); this manuscript will be evaluating a new blue light source for acne vulgaris, an at-home treatment for mild to moderate inflammatory acne vulgaris. This device works via the selective destruction of *P. acnes*.

P. acnes demonstrate a natural PDT response in the skin. During its growth, *P.* acnes produce porphyrins as part of their natural growth. The predominant porphyrins produced, are Protoporphyrin IX (PpIX) and Coproporphyrin III. These porphyrins have an absorption spectrum of light that is demonstrated in Figure 1 for PpIX (Coproporphyrin III has a similar absorption spectrum). From the graph,

Correspondence: Dr. Michael H. Gold, MD, Gold Skin Care Center, 2000 Richard Jones Rd #220, Nashville, TN 37215, USA. E-mail: research@tnclinicalresearch.com

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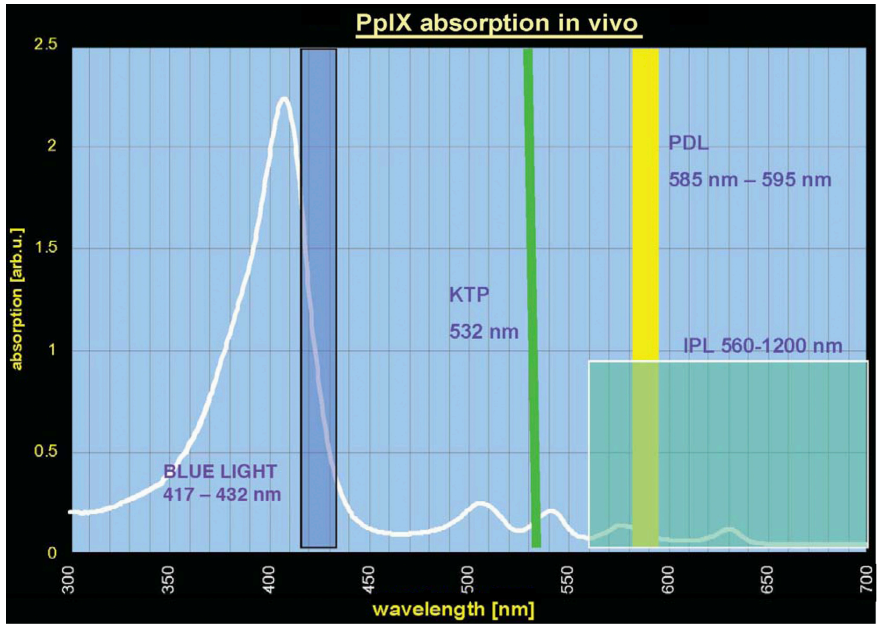

Figure 1. Absorption spectrum of PpIX.

the major peak for PpIX is in the blue range of light at 415 nm, and this peak is commonly referred to as the Soret band of absorption. Through this PDT response, as with all PDT responses, *in-vitro* irradiation of *P.* acnes with blue light leads to photoexcitation of endogenous bacterial porphyrin, singlet oxygen production, and selective bacterial destruction leading to acne vulgaris clearance (5–7). It has been studied extensively for use as an office based therapy and several blue light sources have recently been made available for home use.

The objective of this clinical research study was to evaluate the efficacy of the Silk'n Blue device to treat mild to moderate inflammatory acne vulgaris. The secondary objective was to determine if the average person is able to easily understand the label for use as described in the owner manual for the device.

Materials and methods

This was a single center clinical research project performed at Tennessee Clinical Research Center in Nashville, TN USA. The study was reviewed and approved by Essex Institutional Review Board, Inc. (Lebanon, NJ).

The Silk'n Blue device (Home Skinovations, Yokneam, Israel) is a battery operated hand-held device and is shown in Figure 2. It uses a low power light spectrum in the blue-violet absorption spectrum of light, from 405–460 nm. The device uses an array of 24 LEDs at the wavelengths of 405–460 nm to emit an optical power in a uniform

Figure 2. Silk'N Blue Device.

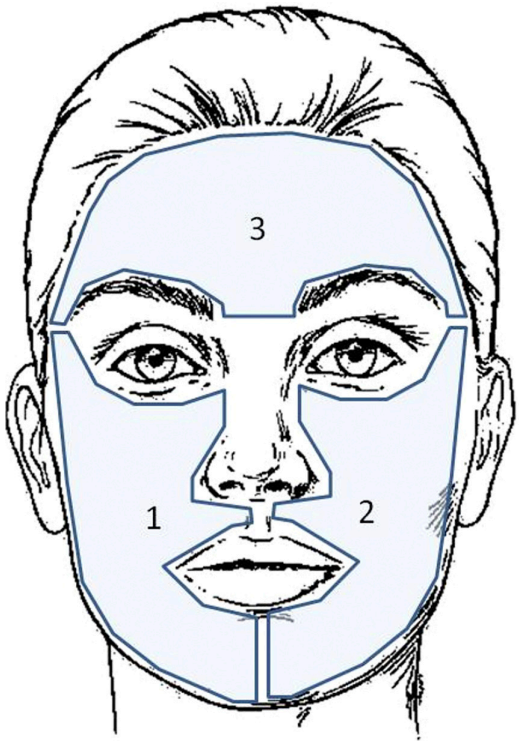

Figure 3. Patient treated with the Silk'n Blue device.

distribution with no associated hot spots. An on-off push-button is located on the applicator, as well as proximity sensor that turns on the LEDs only with skin contact. The device is equipped with two important safety features: 1) a safety switch that allows for emission of a light pulse only upon contact of the light head with the skin; and 2) a temperature sensor that shuts off power when the skin temperature reaches 41°C.

Each potential subject was required to sign an informed consent form prior to participation in this clinical research project. Inclusion criteria for participation in this study included the presence of mild to moderate inflammatory acne vulgaris; Fitzpatrick skin types I–VI; males and females who are between 21 and 65 years of age; and the willingness to follow the treatment schedule, post-treatment care, and have clinical photographs taken.

Exclusion criteria included the presence of a pacemaker or internal defibrillator; having a permanent implant in the treatment area, such as metal plates and screws or silicon; skin areas which have been injected with botulinum toxin, hyaluronic acid, collagen, fat injections, or any other augmentation method with a biodegradable product during the previous 6 months prior to the initiation of the study. Other exclusion criteria include having a current or history of skin cancer, or any other type of cancer, or pre-malignant lesions in the treatment area. All subjects had to have no significant medical diseases to be included in the trial or other skin conditions that could affect the treatment course with the medical device being studied. Medical therapy, including the use of previous cosmetic procedures, including facial dermabrasion, facial resurfacing, or deep chemical peels within 3 months of this clinical trial, received any lasers or light based therapy in the treatment area, including radiofrequency therapy within 6 months of the clinical trial. Finally, subjects could not have taken oral isotretinoin for 6 months before the beginning of this clinical trial. Subjects were also informed that they were free to discontinue their participation in the study at any time. All women of childbearing potential were given a urine pregnancy test prior to the start of the clinical trial.

As a secondary objective of the study, Subject questionnaires were administered to assure that all Subjects understood the labeling as described in the operator manual and that they were able to use the device properly. As a home use device, clear and precise written guidelines are mandatory.

Standard digital photographs were taken throughout the study. Each patient had photographs taken in frontal view, at 45° right and at 45° left.

The study involved 8 treatment sessions twice a week over a period of 4 weeks, where subjects treated themselves in-office with the Silk'n Blue device, and 2 follow-up visits to evaluate the results. These follow-up visits were 1 month after the eighth treatment and 3 months after the eighth treatment visit.

At each of the treatment visits (visits 1–8) the subjects were asked to arrive at the clinic wearing no makeup or other cosmetics. Subjects were asked to clean their skin with water prior to their clinic visit. The face was divided into three treatment zones: left, right, and forehead, according with the location of the acne vulgaris lesions. The Silk'n Blue device was placed on the skin and gently moved until it covered the entire area with acne vulgaris lesions. The zones of treatment are shown in Figure 3. The hand piece was moved over the skin slowly back and forth along the gravity lines or in circles to

Table I. Lesion count.

						Percentiles			
	N	Mean	SD	Minimum	Maximum	25	50	75	*p* value
Baseline	12	16.33	8.17	6	35	10.50	15.00	22.75	–
1 month	12	10.58	9.97	0	30	2.25	7.00	19.25	0.043
3 months	11	6.45	7.70	0	22	0.00	4.00	7.00	0.003

Table II. Percent of improvement in lesion count.

	N	Mean (%)	SD (%)	Minimum (%)	Maximum(%)	Percentiles 25	50	75	*p* value
Improvement 1 month	12	41.77	42.43	−66.67	100.00	23.00	48.33	71.79	0.108
Improvement 3 month	11	60.60	42.81	−33.33	100.00	30.00	72.00	100.00	0.041

Table III. General acne assessment at 1 month as compared to baseline.

	1 month							
	Clear		Mild		Moderate		Total	
	N	%	N	%	N	%	N	%
Baseline								
Mild	0	0.0	3	75.0	1	25.0	4	100.0
Moderate	1	12.5	3	37.5	4	50.0	8	100.0
Total	1	8.3	6	50.0	5	41.7	12	100.0

Table IV. General acne assessment at 3 month as compared to baseline.

	3 months							
	Clear		Mild		Moderate		Total	
	N	%	N	%	N	%	N	%
Baseline								
Mild	2	50.0	1	25.0	1	25.0	4	100.0
Moderate	2	28.6	4	57.1	1	14.3	7	100.0
Total	4	36.4	5	45.5	2	18.2	11	100.0

ensure uniform heating of the treated zone. Treatment time was 10 minute per zone. Following the treatment each subject was evaluated for any potential adverse reaction that could be associated with the treatment.

Acne vulgaris improvement was assessed by evaluating the 'before' photograph with the 'after photographs' taken during the clinical study. Safety was evaluated by monitoring immediate post-treatment affects and at each visit for any potential adverse events. Overall subject satisfaction from the treatments were measured on a 5-point scale where 1 = Not Satisfied, 2 = Somewhat Satisfied, 3 = Slightly More Satisfied, 4 = Satisfied, and 5 = Very Satisfied.

Results

Seventeen individuals were enrolled into this clinical trial to determine the efficacy of the Silk'n Blue device for the treatment of mild to moderate inflammatory acne vulgaris. The ages of the subjects enrolled were from 23 years to 65 years, with a mean of 38.75 years.

Four subjects withdrew consent for personal reasons, none related to the study treatment. One subject was lost to follow-up. Twelve subjects completed all of the study visits and the 1-month follow-up visit; eleven completed the 3-month follow-up visit. There were 11 female enrolled (91.7%) and one male enrolled (8.3%). There were 2 subjects with Fitzpatrick skin type II (16.7%), 8 subjects with skin type III (66.7%), 1 patient with skin type V (8.3%), and 1 patient with skin type VI (8.3%). No adverse reports were reported during the course of the clinical trial with the Silk'n Blue device.

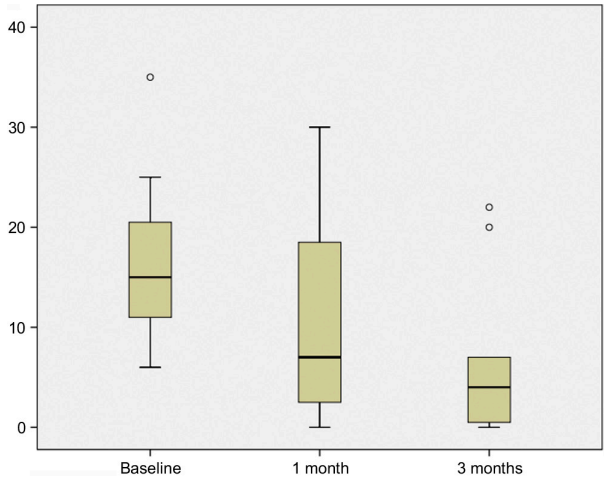

Figure 4. Graphically figure – lesion count.

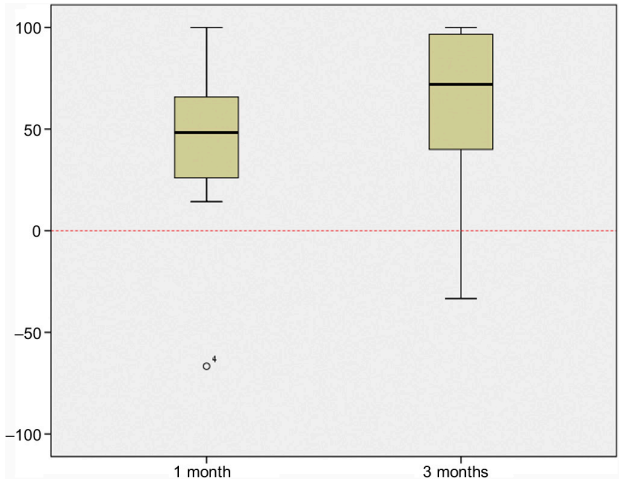

Figure 5. Precent of improvement in lesion count.

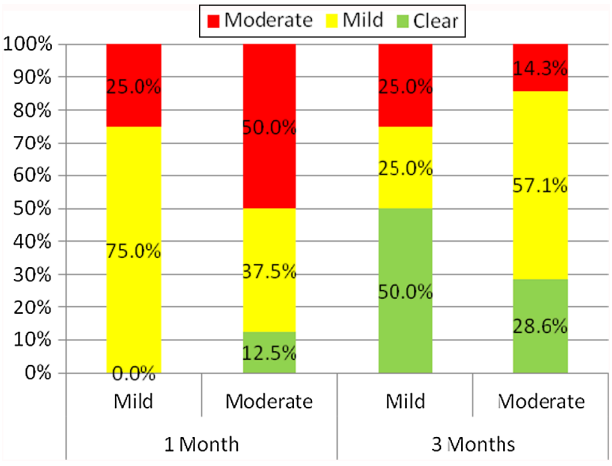

Figure 6. General acne assessment graphical representation.

Study results are shown in Tables I—IV, and Figures 4–6. Table I shows the actual acne vulgaris lesion counts at baseline and at the 1 month and 3 month following the last treatment lesion counts. As shown there was a decrease in mean acne vulgaris lesion counts from 16.33 at baseline to 10.58 at the 1-month follow-up to 6.45 at the 3-month follow-up visit. This is shown graphically in Figure 4. From these results, we can note a statistically significant change in actual acne vulgaris lesion count, $p = 0.002$. At the 1-month follow-up there was a statistically significant reduction in acne counts as compared to baseline, $p = 0.043$. At the 3-month follow-up visit, there was a statistically significant reduction in acne vulgaris lesion counts as compared to baseline, $p = 0.003$. Table II shows the percent improvement in acne vulgaris lesion counts, which is shown graphically in Figure 5. As shown, there was a statistically significant improvement, percent wise, at the 3-month follow-up visit, $p = 0.041$. Table III shows the general acne vulgaris assessment at the 1-month follow-up as compared to baseline; Table IV shows the general acne vulgaris assessment at the 3-month follow-up visit as compared to baseline. After 1 month, one subject (8.3%) demonstrated a completely clear face, with acne vulgaris lesion counts starting at 16 and ending at zero at the 1month follow-up period; this was maintained at 3 months. After 3 months, 4 subjects (36.4%) were clear from their acne vulgaris lesions. Figure 6 shows the general acne vulgaris assessment in a graphical representation.

Representative clinical photographs are shown in Figure 7(a–c).

As noted, the secondary objective of this clinical trial was to assess if the subject could clearly follow

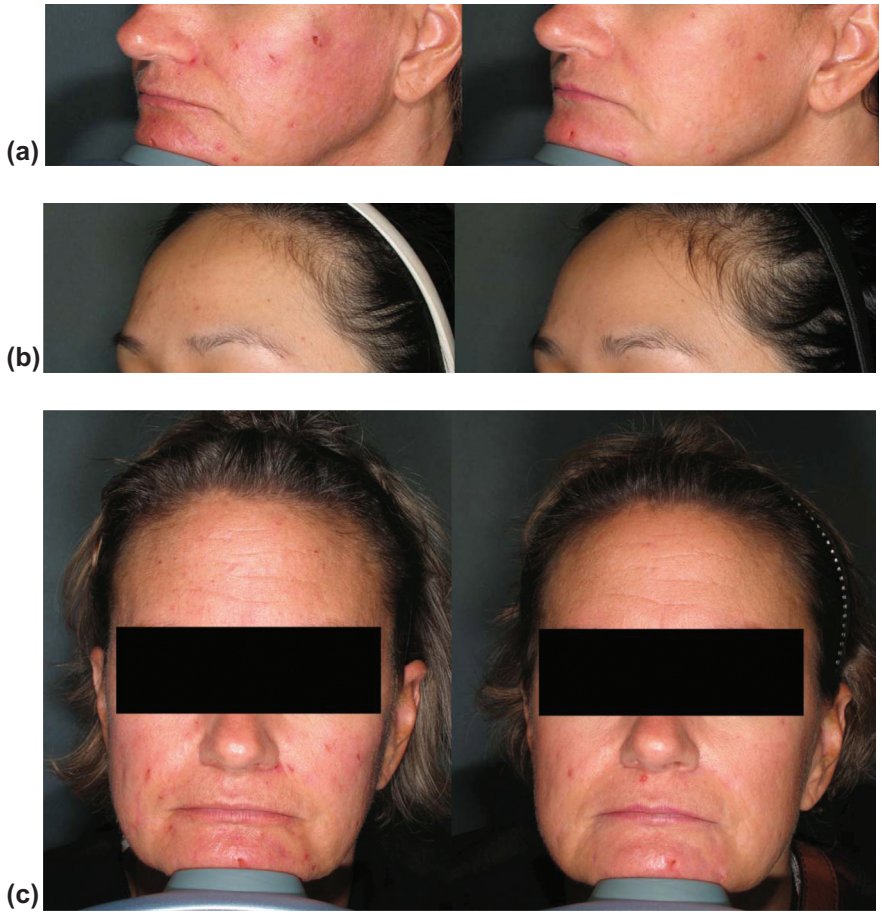

Figure 7. Clinical photographs. (a–c). Before and 3 Months after treatment.

the directions of use as seen on the commercial label of the Silk'n Blue device. All of the subjects (100%) were able to comprehend the directions, and their understanding was validated during the trial without any issues or reservations.

From the satisfaction survey performed during the clinical trial, 91.6% of the patients were satisfied (with a rating of 2 or above) and that 75% of the participants reported they were more than satisfied (rating of 3 or above) with the Silk'n Blue device.

Discussion

The clinical trial presented demonstrates a new and novel device for the home treatment of mild to moderate inflammatory acne vulgaris. The Silk'n Blue device has an array of 24 LEDs emitting a spectrum of light in the blue-violet range of light (405–460 nm). Subjects enrolled in this clinical trial clearly were able to understand the labeling for the device, use the device according to the label, and showed a reduction in acne vulgaris inflammatory lesions throughout the course of the clinical trial and in the follow-up periods.

Home devices for acne vulgaris have become more and more popular over the past several years. There have been numerous devices that have appeared on the market, the majority of which have no clinical trial evidence to support their effectiveness. With data produced form clinical trials such as this, people will have the educational tools to understand that not all home devices are created equally. The Silk'n Blue for mild to moderate inflammatory acne vulgaris has withstood clinical trials and peer-review.

Conclusion

With instructions proven to be easily executed by the general public, Silk'n Blue device for mild to moderate inflammatory acne vulgaris has shown effectiveness in acne vulgaris lesion reduction with proper use.

Declaration of interest: The authors report no declarations of interest with Home Skinnovations. The authors alone are responsible for the content and writing of the paper.

Dr Gold performs research and speaks on behalf of Home Skinnovations Ltd., Shaar Yokneam, Israel. This study was funded by Home Skinnovations/ Invasix.

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