Self-diagnosis of Mild-to-Moderate Acne for Self Treatment with Blue Light Therapy

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ABSTRACT

This study was an evaluation of self-applied, blue light, light-emitting diode therapy in the treatment of mild-to-moderate inflammatory acne on the face and associated labeling to determine if subjects are capable of self diagnosing their condition and whether they are capable of self-administrating treatment. Subjects included had no prior experience with the device. They were given the device and a copy of the labeling. Based on their own assessment, they were evaluated for their comprehension of the device and for its intended use. The study, which comprised 18 females and three males with an average age of 31, demonstrated that all participants (100%) were capable of correctly identifying their acne condition. The labeling, which was key to educating users in recognizing their acne type, included clear descriptions of different categories of acne. The study also demonstrated that the user was capable of self administering the treatment based solely on the device's labeling and without the supervision of a medical doctor.
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Patients who suffer from mild-to-moderate acne are generally treated with over-the-counter topical cleansers, astringents, and benzoyl peroxide preparations. For more severe flare-ups, patients may receive treatment with topical or systemic antibiotics from healthcare providers. Increasingly, *Propionibacterium acnes* has been reported to develop resistance to antibiotic treatment, making this modality less effective.[1] Moreover, patients often feel the psychological pain of the few effective treatments and of chronic persistence and reoccurrence of their acne.[2]

Phototherapy with visible light, specifically blue light, has been shown to improve skin condition in cases of acne and blemishes.[3] It is further reported to control the condition before an outbreak occurs. Blue light therapy is clinically shown to control acne without harsh chemicals or prescriptions and improves the skin's appearance.

MILD-TO-MODERATE ACNE

Acne vulgaris is a common skin condition, affecting 70 percent of adolescents[4] and frequently continues into adulthood.[5,6] The mainstay of treatment for acne is the use of topical or systemic antibiotics, benzoyl peroxide preparations, and topical or systemic retinoids.[6] Acne often improves after exposure to sunlight or artificially produced solar radiation. *P. acnes* produce mainly coproporphyrin III, which has an absorption spectrum peak at 415nm.[7]

In-vitro irradiation of *P. acnes* colonies with blue visible light leads to photo-excitation of endogenous bacterial porphyrin, singlet oxygen production, and bacterial destruction.[8]

Both *in vivo* and clinically it has been shown that acne may be treated successfully with blue visible light phototherapy.[5,6,9]

MATERIALS AND METHODS

Tända™ Clear Acne Light Therapy Treatment (Pharos Life Corporation, Cambridge, Ontario, Canada) is a 414nm, blue light emitting diode (LED) treatment that is scientifically and clinically proven to kill the *P. acnes* bacteria that cause mild-to-moderate acne.[10] The device can help improve existing blemishes as well as prevent future outbreaks.[6] Tända Clear (TC) is marketed for use in the treatment of mild-to-moderate inflammatory acne only. It is noninvasive, designed for self-care use, and is

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Figure 1. The Tända Clear device for self treatment

drug-free without any form of unfavorable side effects. It does not cause redness, flakiness, or dry skin (Figure 1). All 21 subjects included in the study were diagnosed as having mild-to-moderate acne (Tables 1 and 2). Subjects had no prior experience with the skin care system and fulfilled the inclusion criteria prior to recruitment to the study.

The evaluation looked at the subjective opinion and/or experience of the subjects on self diagnosis and blue light treatment administration with the device. The study verified if the intended user of the device was able to:

- Self select whether the device is appropriate for their condition
- Safely and adequately self administer the treatment per the device's labeling.

Subjects (N=21) at the Tennessee Clinical Research Center in Nashville, Tennessee, were included in the study according to the inclusion/exclusion criteria and after signing the informed consent form as approved by the institutional review board. All subjects were new patients and were either referred to the center by their physician or had come to the center on their own account during the recruitment phase.

After the subjects agreed to participate in the study, they were provided with instructions-for-use labeling and a TC device. The subjects were then asked to read the information and complete a questionnaire. The study looked at the following:

- The number of subjects who demonstrated correct understanding of the Acne Self Diagnosis Chart (Table 3) and were able to identify their condition correctly
- The number of subjects who demonstrated correct understanding of the device and its application
- The number of subjects who demonstrated correct understanding of the labeled warnings and precautions
- The number of subjects who demonstrated confidence in the use of the device without supervision by a doctor.

For observation purposes, the areas on the face were divided as follows: the left and right forehead, the left side of the face, the left chin, the right side of the face, and the right chin. After the subjects had performed the self diagnosis and had filled out the questionnaire, the clinicians performed assessments of the subjects' skin conditions. The results were compared and summarized. Significance tests were carried out at the five-percent significance level. Further statistical evaluation was performed using StatXact 5.0—double sided—α=0.05—paired sample with repeated measures analysis of variance (ANOVA) and student *t* test—unpaired with Mann-Whitney test for N=21. When subjects had expressed confidence in the ability to correctly and safely self apply TC, treatment was started under supervision of the clinician. The subjects then scored their findings regarding handling the device and performing self treatment.

TABLE 1. Types of acne

ACNE TYPE	DESCRIPTION OF CONDITION
No acne	Total absence of acne and blemishes
Subclinical acne	Small number of blackheads and whiteheads; barely visible; first sign of blemish
Comedonal acne	Blackheads and whiteheads (slightly inflamed—may be red); blemishes are visible
Mild acne	• Several inflamed pimples—red in color • Less than 20 whiteheads/blackheads or less than 15 inflammatory (red) lesions (pimples) or less than 30 total lesions (pimples) not all inflamed (red in appearance)
Moderate acne	• Many inflamed pimples (red in color) and pustules (visible accumulation of pus in skin) • 20 to 100 whiteheads/blackheads or 15 to 50 inflammatory (red) lesions (pimples) or 30 to 125 total lesions (pimples) not all inflamed (red in appearance)
Severe nodular acne	• Inflamed pimples and pustules (visible accumulation of pus in skin) with a few deep nodular lesions (solid mass can be felt under skin—can sometimes be raised) • Greater than 5 cysts (solid mass of skin like a knot, can be raised or felt under the skin) or total whiteheads/blackheads count greater than 100 or total inflammatory count greater than 50 or greater than 125 total lesions
Severe cystic acne	Many nodular cystic lesions (with signs of scarring)

TABLE 2. Definitions of lesions

LESION	DEFINITION
Comedo	Sebaceous follicle plugged with sebum, dead cells from inside the sebaceous follicle, tiny hairs, and sometimes bacteria. When a comedo is open, it is commonly called a *blackhead* because the surface of the plug in the follicle has a blackish appearance. A closed comedo is commonly called a *whitehead*; its appearance is that of a skin-colored or slightly inflamed "bump" in the skin.
Papule	Small (5mm or less), solid lesion slightly elevated above the surface of the skin. A group of very small papules and micro-comedones may be almost invisible but have a "sandpaper" feel to the touch. A papule is caused by localized cellular reaction to the process of acne.
Nodule	Dome-shaped or irregularly shaped lesion. Unlike a papule, a nodule is characterized by inflammation, extends into deeper layers of the skin, and may cause tissue destruction that results in scarring.
Cyst	Sac-like lesion containing liquid or semi-liquid material consisting of white blood cells, dead cells, and bacteria. It is larger than a pustule, may be severely inflamed, extends into deeper layers of the skin, may be very painful, and can result in scarring.

RESULTS

Twenty-one subjects concluded the study (18 female and 3 male with a mean age of 31 years). All of the participants (100%) accurately diagnosed their condition as "mild-to-moderate acne." Of those patients, 69.1 percent made an assessment that was virtually identical to that of the investigators in terms of lesion type and count. The remainder of the patients' self-assessments were somewhat different from that of the investigators. However, these patients still accurately assessed themselves as having either mild or moderate acne, and were thus part of the device's target population (Table 4).

Table 4 shows the subjects' estimates of their skin conditions and specifies the number of blackheads/whiteheads; red, inflamed pimples; and pustules on the face. After receiving instructions and reading the self-diagnosis chart, the subjects estimated their skin conditions. The answers given by the subjects were compared to the clinicians' estimates.

Of the 21 subjects, 71 percent (n=15/21) estimated having <30 lesions and 29 percent (n=6/21) estimated having between 30 and 125 lesions in total. Fifty-two percent (n=11/21) of the subjects judged their acne to be mild and 48 percent (n=10/21) estimated having moderate acne.

Estimations in numbers of blackheads (open comedones) and whiteheads (closed comedones) differed between subjects and clinicians for the estimated amounts that were <20 and >20.

The difference between subjects and clinicians for the estimation of blackheads and whiteheads of 20 to 100 and >100 was not significant. There was no significant difference noted for the estimated number of pimples observed by the clinicians and the subjects. Regarding the number of pustules on the face, the clinicians and subjects noted different estimates for 15 to 50 and >50 pustules. For the amounts of >15 and <15, there was no significant difference reported.

Figure 2 shows subjects' estimates of their skin conditions compared to the clinicians' estimates. Subjects demonstrated confidence in identifying their skin condition directly after receiving information. According to their opinion, the chart helped to identify their skin condition correctly. They expressed confidence in judging their type of acne correctly when using the chart. The chart was evaluated to be user friendly and suitable for use for identifying the type and severity of their skin condition (Table 5).

Subjects were of the opinion that the use of the device was easily understood after reading the instructions. They also expressed that the warnings and precautions given were clear (Table 6).

DISCUSSION

All of the participants (100%) accurately diagnosed their condition as "mild-to-moderate acne." Of those patients, 69.1 percent made an assessment that was identical to that of the investigators on the number of pimples present as well as the type of acne. The remainder of the patients' self-assessments differed somewhat for the noninflammatory lesions (whiteheads/blackheads) only.

These results could be due to subjects being well informed about their condition from various sources, such as the Internet. Moreover, it is assumed that the subjects were highly motivated to improve their skin condition, as some of the subjects came to the center on their own account during the recruitment phase of the study.

The subjects expressed the self-diagnosis chart to be clear. They had confidence in their own assessments even though, in some cases, their assessments showed some differences compared to the assessments performed by the clinicians. In general, the use of the self-diagnosis chart was regarded as positive. Subjects were of the opinion that the instructions provided for the use of the device were clear. Their expectations on the effect of the device for their condition were positive, and they felt that

TABLE 3. Self-diagnosis chart

ACNE TYPE	DESCRIPTION OF CONDITION	TC USE?
No acne	Total absence of acne and blemishes	Use of TC unnecessary
Sub-clinical acne	Small number of blackheads and whiteheads; barely visible; first sign of blemish	Yes
Comedonal acne	Blackheads and whiteheads (slightly inflamed—may be red); blemishes are visible	Yes
Mild acne	• Several inflamed pimples—red in color • Less than 20 whiteheads/blackheads, less than 15 inflammatory (red) lesions (pimples), or less than 30 total lesions (pimples) not all inflamed (red in appearance)	Yes
Moderate acne	• Many inflamed pimples (red in color) and pustules (visible accumulation of pus in skin) • 20 to 100 whiteheads/blackheads, 15 to 50 inflammatory (red) lesions (pimples), or 30 to 125 total lesions (pimples) not all inflamed (red in appearance)	Yes
Severe nodular acne	• Inflamed pimples and pustules (visible accumulation of pus in skin) with a few deep nodular lesions (solid mass can be felt under skin—can sometimes be raised) • Greater than 5 cysts (solid mass of skin like a knot, can be raised or felt under the skin), total whiteheads/blackheads count greater than 100, total inflammatory count greater than 50, or greater than 125 total lesions	No, consult your dermatologist for the best prescribed treatment
Severe cystic acne	Many nodular cystic lesions (with signs of scarring)	No, consult your dermatologist for the best prescribed treatment

TABLE 4. Subjects' estimates of their skin conditions compared to the clinicians' estimates

Subjects' estimates of total number of blackheads/whiteheads on face	*t* test two paired, same average	Subjects' estimates of total number of red, inflamed pimples	*t* test two paired, same average	Subjects' estimates of total number of pustules	*t* test two paired, same average
<20	0.004	<15	0.110	<15	0.181
>20	0.004	>15	0.5	>15	0.181
20–100	0.110	15–50	0.216	15–50	0.0151
>100	0.076	>50	0.169	>50	0.034

the device was safe and could be trusted.

Subjects found the use of the skin care system to be easy and did not expect any difficulties when administering self treatment without the supervision of a clinician.

CONCLUSION

The study showed that the self-assessment chart was appropriate for determining mild-to-moderate inflammatory facial acne, a condition suitable for TC self treatment.

Self administration of the device per the device's labeling was evaluated as being safe and adequate. Subjects included in the study were confident in safely administering the treatment themselves.

REFERENCES

1. Cunliffe WJ. Comedogenesis: some new aetiological, clinical and therapeutic strategies. *Br J Dermatol.* 2000;142(6):1084–1091.
2. Hanna S, Sharma J, Klotz J. Acne vulgaris: more than skin deep. *Dermatol Online J.* 2003;9(3):8.
3. Cunliffe WJ, Goulden V. Phototherapy and acne vulgaris. *Br J Dermatol.* 2000;142(5):855–856.
4. Krowchuk DP. Managing acne in adolescents. *Pediatr Clin North Am.* 2000;47(4):841–857.
5. James WD. Clinical practice. Acne. *N Engl J Med.* 2005;352(14):1463–1472.
6. Strauss JS, Krowchuk DP, Leyden JJ, et al. American

TABLE 5. Clarity of the self-diagnosis chart as evaluated by the subjects

CLARITY OF THE SELF-DIAGNOSIS CHART (N=21)	MEAN*	SD
Clear descriptions of types of acne are given	4.14	.73
Chart helps decide if device is right for acne type	3.95	.80
Information about use of chart was sufficient and easy	4.10	.88
Confidence about own judgment on type of acne	3.90	.77
Chart is user friendly	4.14	.98
General opinion about use of the chart	4.09	.88

Notes:
• Score range from 1 to 5, 1 = strongly disagree, 2= disagree, 3=neutral, 4=agree, 5=strongly agree.
• * = mean of the score (scale of 5)

Academy of Dermatology/American Academy of Dermatology Association. Guidelines of care for acne vulgaris management. *J Am Acad Dermatol.* 2007;56(4):651–663.

7. Lee WL, Shalita AR, Poh-Fitzpatrick MB. Comparative studies of porphyrin production in *Propionibacterium acnes* and *Propionibacterium granulosum*. *J Bacteriol.* 1978;133(2):811–815.
8. Arakane K, Ryu A, Hayashi C. Singlet oxygen (1 delta g) generation from coproporphyrin in *Propionibacterium acnes* on irradiation. *Biochem Biophys Res Commun.* 1996;223(3):578–582.
9. Kawada A, Aragane Y, Kameyama H. Acne phototherapy with a high-intensity, enhanced, narrow-band, blue light source: an open study and *in-vitro* investigation. *J Dermatol Sci.* 2002;30(2):129–135.
10. Sigurdsson V, Knulst AC, van Weelden H. Phototherapy of acne vulgaris with visible light. *Dermatology.* 1997;194(3):256–260.

TABLE 6. Subjects' evaluations of instructions and use of device (N=21)

	MEAN*	SD
Understanding of the skin care system	4.38	.59
Understanding warnings in given information	4.28	.56
Understanding precautions in given information	4.19	.60
Confident about use of device without a doctor	4.43	.50
Use of skin care system is easy	4.14	.57
Daily use of skin care system is easy for me	4.19	.51
Once-per-day use is easy for me	4.29	.56
Twice-per-day use is easy for me	3.76	.89
Expectation of performing the skin care system treatment correctly	4.38	.59
Self treatment is positive because of control	4.33	.48
The outcome will be positive	3.90	.62
The skin care system is medically effective and safe	4.10	.54
Satisfaction with the way the skin care system has to be applied	4.14	.57
The skin care system is safe for self treatment	4.05	.50
The skin care system will improve the facial skin condition	4.00	.70
Satisfaction with current treatment	3.10	1.17
Result with the skin care system is better than my current treatment	3.95	.67
General impression of the skin care system	4.14	.57

Notes:
• Score range from 1 to 5; 1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree.
• * = mean of the score (scale of 5)