Safety and Effectiveness of a New Blue Light Device for the Self-treatment of Mild-to-moderate Acne

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ABSTRACT

Objective: To assess the safety and effectiveness of treating acne for eight weeks using a new blue light device at a dose of ~2J/cm^2/day (representing typical full-face treatment) or ~29J/cm^2/day (representing the typical dose after localized spot treatment of acne). **Design:** Prospective, single-center, open-label study evaluating two levels of blue light in each subject. **Setting:** Subjects were recruited from the local community for self-treatment at home. **Participants:** Thirty-two subjects with mild or moderate facial acne vulgaris. **Measurements:** Inflammatory lesion count; number, severity, and redness of flares; improvement in skin characteristics (overall appearance, clarity, radiance, tone, texture, and smoothness); tolerability; subject satisfaction. **Results:** The blue light treatment was associated with significant reductions from baseline in inflammatory lesion count as early as Week 1 with ~29J/cm^2/day and Week 3 with ~2J/cm^2/day ($P \leq 0.01$). It was also associated with significant reductions in the number, severity, and redness of flares and with improvements in the skin's appearance, clarity, radiance, tone, texture, and smoothness. Overall, 53 percent of subjects considered the treatment much gentler than traditional acne treatments and 61 percent were satisfied. Three adverse events were probably related to treatment—minimal transient skin dryness (2) and minimal transient hyperpigmentation (1). **Conclusion:** The blue light treatment is effective and well tolerated, offering rapid, gentle, and convenient treatment of inflammatory acne. The blue light device offers a valuable alternative to antibiotics and potentially irritating topical treatments and can also be used adjunctively to complement other therapies.

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A new, handheld, blue light device for the self-treatment of mild-to-moderate inflammatory acne was cleared by the United States Food and Drug Administration (FDA) in January 2010.[1] Blue light is effective in the treatment of inflammatory acne because it results in photoexcitation of porphyrins within *Propionibacterium acnes* and this generates free radicals that are bactericidal to *P. acnes*.[2] Blue light treatment also appears to have anti-inflammatory effects on keratinocytes.[3]

The first blue light-emitting devices for acne therapy required patients to attend their physician's office for treatment once or twice weekly, and compliance suffered as a result. The new handheld device offers both the convenience of self-treatment at home and lower costs than in-office blue light therapy.

A study has been performed to evaluate the safety and effectiveness of using the blue light device—which emits blue light at ~412nm from light-emitting diodes—to self-treat mild-to-moderate inflammatory acne at two different doses in the home setting.

METHODS

Study design. This was a prospective, single-center, open-label study.

Subjects. Subjects were eligible for enrollment into the study if they had mild or moderate facial acne vulgaris, were 13 to 45 years of age, and were generally in good health. Mild-to-moderate facial acne was considered to consist of

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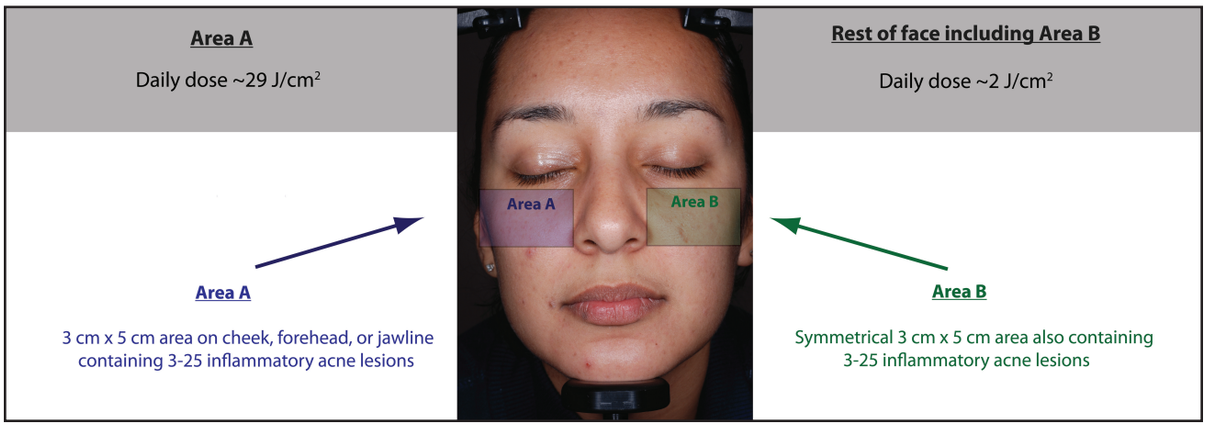

Figure 1. Blue light dosing

small (1–3mm) diffusely scattered inflammatory lesions (papules or pustules) together with noninflammatory lesions and no more than one small (2–4mm) nodular lesion.

They were also required to have one 3cm x 5cm target area on their cheek, forehead, or jawline containing 3 to 25 inflammatory lesions (Area A) and another 3cm x 5cm target area containing 3 to 25 inflammatory lesions located symmetrically on the other side of the face (Area B).

Exclusion criteria included the following: cystic acne; the use of prescription acne medication other than oral contraceptives; known light sensitivity; history of phototoxicity; sensitivity or allergic reaction to over-the-counter topical facial products; need to spend excessive time in the sun; psoriasis, vitiligo, or other conditions affecting the visual appearance of the face; history of herpes simplex virus or cold sores on the treatment area; and pregnancy, nursing, or planning to become pregnant. A washout period of eight weeks was required for previous facial cosmetic procedures (e.g., laser resurfacing, chemical peels, and dermabrasion) and six months for oral isotretinoin.

The protocol (TRIA-AC-030) was approved by the relevant institutional review board and conducted in accordance with the principles of the 2004 version of the Declaration of Helsinki. All subjects were recruited from the local community and signed informed consent (except if they were minors in which case they signed an assent and their parents or guardians signed informed consent).

Treatment regimen. Subjects were instructed to use the blue light device in a sweeping "paint the face" motion, twice daily for eight weeks. Treatment was given at two different doses—the higher dose on Area A and the lower dose on the rest of the face, which included Area B (Figure 1). The higher dose used on Area A (~29J/cm²/day) is representative of the dose that may occur during treatment of a localized outbreak of acne. The lower dose used on the rest of the face (~ 2J/cm²/day) is representative of the typical full-face treatment dose. After these treatments, and during the first two weeks of treatment only, subjects were additionally allowed to spot-treat by dwelling (holding the device) on one or more areas of acne to deliver an additional dose of 12J/cm² to such areas.

Subjects were instructed to cleanse their face before each treatment with an unscented soap or nonirritating facial cleanser provided by the sponsor. They were also instructed to apply a moisturizing noncomedogenic sunscreen with sun protection factor (SPF) 32 provided by the sponsor after each morning treatment as needed (for sun protection and to mitigate potential dryness and/or irritation).

Subjects were required to adopt the specified facial skin care regimen and avoid using any other facial skin care products for the duration of the study. Continued use of noncomedogenic make-up, perfume, and body spray was allowed, but the use of nonstudy facial astringents, cleansers, creams, and lotions was prohibited.

Outcome measures. Subjects were evaluated at Baseline and Weeks 1, 2, 3, 4, 6, and 8. The investigator assessed the inflammatory lesion count in Area A and Area B at all timepoints.

At the Baseline visit only, the subjects evaluated their level of frustration with flares and their level of concern over skin texture and skin tone and radiance (Table 1). At Baseline and/or Weeks 2, 3, 4, 6, and 8, the subjects also evaluated the number, severity, and redness of their flares; the improvement in the frequency and severity of their flares; the improvement in their skin's overall appearance, clarity, radiance, tone, texture, and smoothness; the improvement in their acne relative to their prior skin care regimen; and the speed of improvement in their acne relative to their prior skin care regimen (Table 1).

At all post-baseline timepoints, subjects were also asked to rate their level of agreement or disagreement with the following statements about the blue light treatment and its results: "it clears flares better than any other skin care product I've used," "it prevents flares better than any other skin care product I've used," "it is much gentler than traditional acne treatments," "it leaves my skin looking and feeling healthier than with any other skin product I've used," "my skin looks better than ever," and "my skin looks

TABLE 1. Scales used for evaluations

FRUSTRATION WITH FLARES	CONCERN OVER SKIN TEXTURE, SKIN TONE, AND RADIANCE	NUMBER OF FLARES	SEVERITY OF FLARES	REDNESS OF FLARES	IMPROVEMENT IN FREQUENCY OF FLARES, SEVERITY OF FLARES	IMPROVEMENT IN SKIN'S OVERALL APPEARANCE, CLARITY, RADIANCE, TONE, TEXTURE, AND SMOOTHNESS	IMPROVEMENT IN ACNE RELATIVE TO PRIOR SKIN CARE REGIMEN	SPEED OF IMPROVEMENT IN ACNE RELATIVE TO PRIOR SKIN CARE REGIMEN	SATISFACTION WITH THE BLUE LIGHT TREATMENT
Not frustrated at all	Not concerned at all	A few	Minimal flares	No redness	Dramatic improvement	Dramatic improvement	Significantly better	Significantly faster	Extremely satisfied
Somewhat frustrated	Somewhat concerned	Some	Mild flares	Minimal redness	Significant improvement	Significant improvement	Slightly better	Slightly faster	Very satisfied
Moderately frustrated	Moderately concerned	Quite a few	Moderate flares	Mild redness	Moderate improvement	Moderate improvement	As well as	As fast as	Satisfied
Very frustrated	Very concerned	Large number	Severe flares	Moderate redness	Slight improvement	Slight improvement	Worse than	Slower than	Slightly satisfied
—	—	—	—	Severe redness	No improvement	No improvement	—	—	Not satisfied

so much better that I reduced the amount of makeup I wear." Each of these was evaluated as strongly agree, moderately agree, neither agree or disagree, moderately disagree, or strongly disagree. Subjects also reported their level of satisfaction with the acne treatment at all post-baseline timepoints (Table 1).

Statistical analysis. Determinations of sample size were not based on a power analysis approach. Instead, using the results from previous clinical studies, the sample size was selected based on what was thought to be sufficient to demonstrate a statistically significant reduction in inflammatory lesion count in Area B at Week 8 relative to baseline.

All 32 subjects who enrolled and received at least one treatment with the blue light device were included in the intent-to-treat and safety analyses. A p value of <0.05 was considered statistically significant and p values were not adjusted for multiplicity. Within-group differences in lesion count reduction were evaluated using a paired t-test or Wilcoxon signed rank test. Changes from baseline in the number, severity, and redness of flares were analyzed using a Wilcoxon signed rank test.

RESULTS

Subjects. Of 32 subjects enrolled, 31 (97%) completed and one discontinued for nonstudy-related reasons. The majority of subjects were female (66%), of Fitzpatrick skin type III (44%) or IV (25%), and Caucasian (65% Caucasian, 7% Hispanic/Latino, 3% black/African descent, 26% other). Their mean age was 22 (±SD of 6.7) years. Areas A and B were located on the forehead in 47 percent of subjects, on the jawline in 28 percent of subjects, and on the cheek in 25 percent of subjects.

At Baseline, subjects had a median of five inflammatory lesions in each of Areas A and B. Overall, 97 percent of subjects were frustrated with acne flares—38 percent were very frustrated, 31 percent were moderately frustrated, and 28 percent were somewhat frustrated. In addition, 72 percent were concerned about their skin texture (22% very concerned, 34% moderately concerned, and 16% somewhat concerned) and 75 percent were concerned about the tone and radiance of their skin (25% very concerned, 22% moderately concerned, and 28% somewhat concerned). Other anti-acne treatments that subjects had tried previously were topical over-the-counter products (78% of subjects),

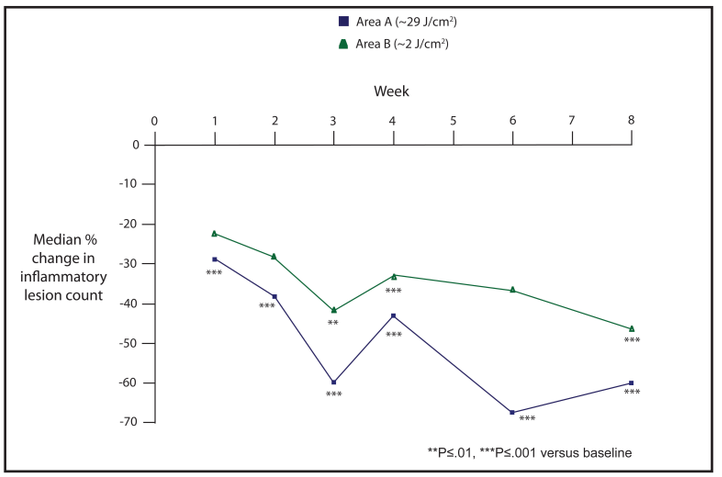

Figure 2. Reduction in inflammatory lesion count. Reproduced with permission from Wheeland RG, Dhawan S. Evaluation of self-treatment of mild-to-moderate facial acne with a blue light treatment system. *J Drugs Dermatol.* 2011;10:596–602

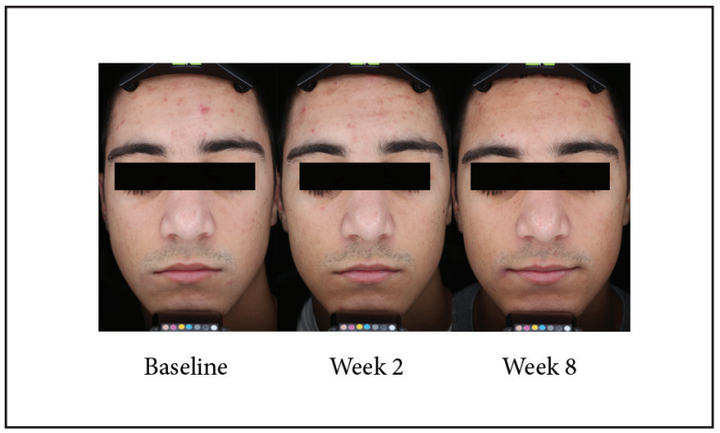

Figure 3. Clinical improvement after treatment with the blue light device. Area A was on the upper middle right forehead and received ~29J/cm²/day from the blue light device. The rest of the face received ~2J/cm²/day.

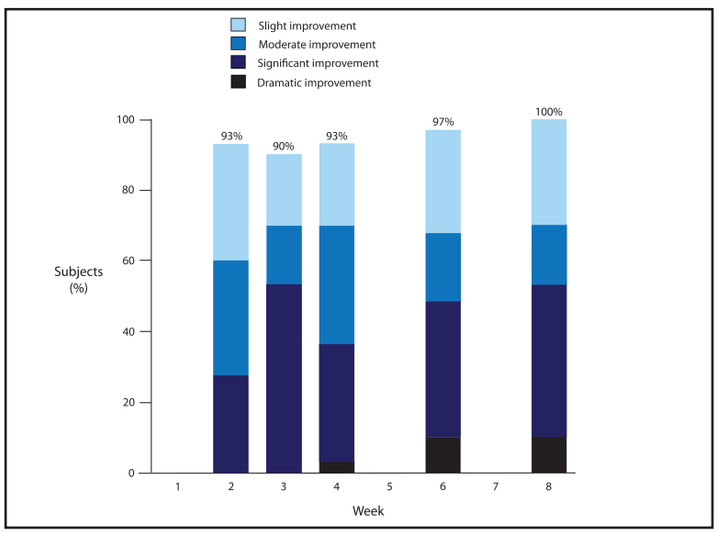

Figure 4. Proportion of subjects reporting improvement in severity of flares

topical prescription products (22%), oral medications (19%), oral contraceptives (6%), microdermabrasion (3%), and other (13%). The first subject started the study on May 26, 2009, and the last subject exited the study on August 26, 2009.

Investigator evaluations. The blue light treatment was associated with significant ($P \leq 0.01$) percentage reductions from baseline in inflammatory lesion count as early as Week 1 in Area A and Week 3 in Area B (Figure 2). The median reductions in inflammatory lesion count at Weeks 1, 4, and 8 were 29, 43, and 60 percent, respectively, in Area A, and 23, 33, and 46 percent, respectively, in Area B. Photographic documentation is shown in Figure 3.

Subject evaluations. Overall, 100 percent of subjects reported improvement in the frequency and severity (Figure 4) of their flares at Week 8 compared with baseline. The median number of flares declined from "some to quite a few" to "a few," the median severity declined from moderate to minimal, and the median redness declined from mild to minimal. The number of flares was significantly ($P \leq 0.05$) reduced from baseline from Week 3 onward, and the severity and redness of flares were significantly reduced from baseline from Week 4 onward. Also at Week 8, 53 percent of subjects agreed that the blue light treatment both cleared and prevented their flares better than any other skin care products they had used.

At Week 8, 100 percent of subjects considered their overall appearance was improved (Figure 5). High rates of improvements were also reported for clarity (97%), radiance (73%), tone (80%), texture (80%), and smoothness (83%) (Figure 5). At Week 8, the majority of subjects also reported better improvement than with their prior skin care regimen (77%) and "significantly faster" improvement than with their prior regimen (56%). In addition, 57 percent reported that their skin looked and felt healthier than with any other skin product they had used before, 37 percent reported that their skin looked better than ever, and 48 percent reported that their skin looked so much better that they had reduced the amount of makeup they wore. Overall, 61 percent were satisfied, very satisfied, or extremely satisfied with the blue light treatment.

Tolerability. At Week 8, 53 percent of subjects agreed that the blue light treatment was much gentler than traditional acne treatments (Figure 6). Three adverse events were probably related to treatment—minimal and transient skin dryness (2) and minimal and transient hyperpigmentation (1).

DISCUSSION

The results of this study demonstrate the effectiveness of the blue light device in reducing

the inflammatory acne lesion count and the frequency, severity, and redness of flares. Furthermore, the majority of subjects considered their blue light treatment achieved better and significantly faster improvement than their prior skin care regimen. Of additional benefit was the improvement in several other appearance-related skin parameters that are of great importance to many individuals—clarity, radiance, tone, texture, smoothness, and overall appearance. At baseline, a high incidence of subjects reported frustration with flares and concern over the tone, radiance, and texture of their skin. Therefore, the subsequent improvements in the frequency, severity, and redness of flares, and in the tone, radiance, texture, and other appearance-related characteristics of the skin were likely to be highly relevant and clinically meaningful.

The inflammatory lesion counts were statistically significantly lower than baseline at all timepoints for Area A and at Weeks 3, 4, and 8 for Area B. Even though the reductions in Area B were not *statistically* significant at some timepoints, the degree of reduction at these visits (23–37%) suggests that they were, nevertheless, *clinically* significant. The lower of the two dose levels of blue light used in this study was selected to investigate the effectiveness of treatment under recommended conditions of usage. The higher dose used (for treating Area A) was selected to investigate the safety and effectiveness of treatment when the device is also used to "spot treat" flares. Although it is not specifically recommended that users dwell on individual lesions, it is anticipated that they may tend to use a longer blue light exposure on their more troublesome areas of acne than on less affected areas of their face. The lack of troublesome adverse events suggests that the higher dose does not cause any additional safety concerns.

A similar study has been performed using the same blue light device as part of a treatment system (i.e., in conjunction with a proprietary cleanser and a proprietary serum, both of which contain salicylic acid).[4] It is not possible to make a meaningful comparison of results across two studies and a direct comparative study would be needed to make definitive comparisons. Nevertheless, the results from the two studies suggest that using the blue light device as part of a treatment system may further enhance the effectiveness of treatment, the appearance of the skin, and the likelihood of achieving subject satisfaction (Table 2).

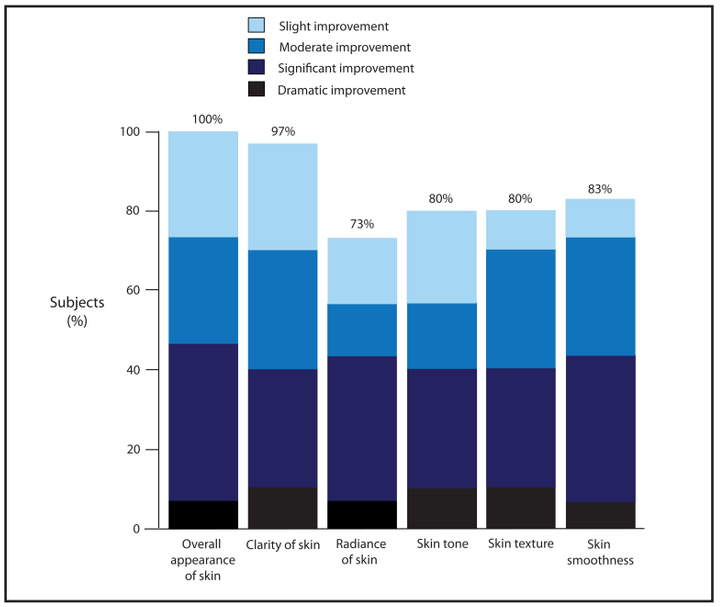

Figure 5. Proportion of subjects reporting improvements in their skin at Week 8

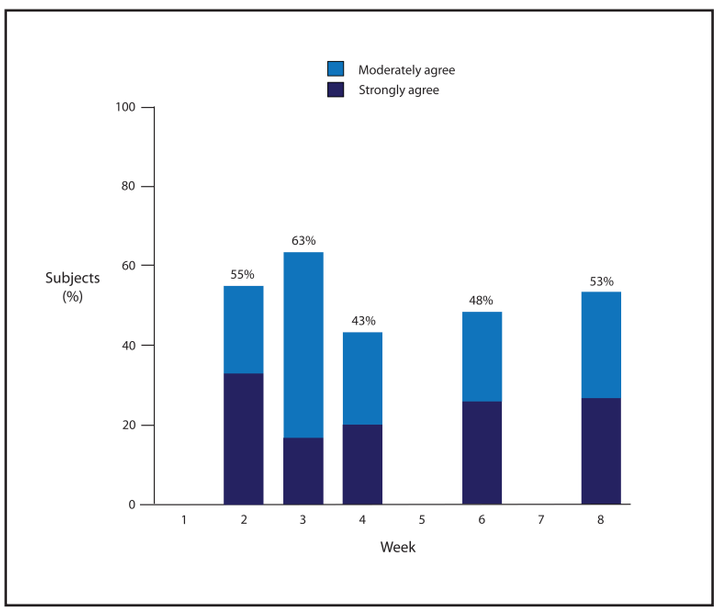

Figure 6. Proportion of subjects considering the blue light treatment was much gentler than traditional acne treatments

CONCLUSION

The blue light device treatment is effective and well tolerated, offering rapid, gentle, and convenient treatment of inflammatory acne, with the majority of subjects reporting that they were satisfied, very satisfied, or extremely satisfied with treatment. The blue light treatment is associated with significant reductions in the number, severity, and redness of flares and improvements in the skin's overall appearance as well as in clarity, radiance, tone, texture, and smoothness.

Because of its effectiveness against *P. acnes*, and its gentleness on the skin, the blue light device offers a

TABLE 2. Comparison of results at Week 8 from this study with those from another study[4] using a similar protocol except that the blue light device was used as part of a treatment system (i.e., in conjunction with a proprietary foaming cleanser and skin rebuilding serum, both of which contain salicylic acid)

	BLUE LIGHT TREATMENT ALONE (STUDY PRESENTED IN THIS MANUSCRIPT)	BLUE LIGHT TREATMENT + PROPRIETARY CLEANSER + PROPRIETARY SKIN REBUILDING SERUM[4]
Median reduction in inflammatory lesion count (%)	60% in Area A 46% in Area B	80% in Area A 67% in Area B
Subjects reporting reduced frequency of flares (%)	100%	100%
Subjects reporting reduced severity of flares (%)	100%	96%
Subjects reporting treatment cleared flares better than other skin care products they had used (%)	53%	71%
Subjects reporting treatment prevented flares better than other skin care products they had used (%)	53%	79%
Subjects reporting improvement in overall appearance (%)	100%	96%
Subjects reporting improvement in skin clarity (%)	97%	96%
Subjects reporting improvement in skin radiance (%)	73%	100%
Subjects reporting improvement in skin tone (%)	80%	96%
Subjects reporting improvement in skin texture (%)	80%	93%
Subjects reporting improvement in skin smoothness (%)	83%	93%
Subjects reporting better improvement than with prior skin care regimen (%)	77%	82%
Subjects reporting significantly faster improvement than with their prior regimen (%)	56%	56%
Subjects reporting skin looked and felt healthier than with any other product they had used before (%)	57%	71%
Subjects reporting skin looked better than ever (%)	37%	68%
Subjects reported skin looked so much better they had reduced the amount of make-up they wore (%)	48%	64%
Subjects who were satisfied, very satisfied, or extremely satisfied with their treatment (%)	61%	82%
Subjects considering study treatment was much gentler than traditional acne treatments (%)	53%	86%
Adverse events probably related to study treatment	3 (from group of 32 subjects)	11 related to topical products and 8 related to blue light device (from group of 33 subjects)

valuable alternative to antibiotics and potentially irritating topical treatments and can also be used adjunctively to complement other therapies.

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