Safety and Effectiveness of a New Blue Light Device for Self-Treatment of Mild to Moderate Acne

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INTRODUCTION

A new hand-held blue light device for the self-treatment of mild to moderate inflammatory acne was cleared by the US Food and Drug Administration 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 adherence suffered as a result. The new hand-held 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 to self-treat mild to moderate inflammatory acne at two different doses in the home setting.

METHODS

Main inclusion criteria

- Mild to moderate inflammatory facial acne
- One 3 cm x 5 cm target area on cheeks, forehead, or jawline containing 3-25 inflammatory lesions (Area A)
- Another 3 cm x 5 cm target area containing 3-25 inflammatory lesions, located symmetrically on the other side of the face (Area B)
- Aged 13-45 years

Treatment regimen

- Blue light device, with light-emitting diodes emitting blue light at ~415 nm, used twice daily for 8 weeks on:
  - The full face (~ 2 J/cm^2 per day, representing the typical full-face treatment dose)
  - Area A (~ 29 J/cm^2 per day, as may occur during treatments of a localized flare of acne).
- Subjects requested to:
  - Wash their face before each treatment using an unscented soap or facial cleanser provided by the sponsor
  - Apply moisturizing non-comedogenic sunscreen SPF 32 after each morning treatment as needed.
- Continued use of non-comedogenic make-up, perfume, and body spray was allowed.
- Use of non-study facial astringents, cleansers, creams, and lotions was prohibited.

RESULTS

Subjects

- Of 32 subjects enrolled:
  - 31 (97%) completed
  - 1 discontinued for non-study related reasons.
- Majority were:
  - Female (66%)
  - Fitzpatrick skin type III (44%) or IV (25%)
  - Caucasian:
    - 65% Caucasian
    - 7% Hispanic/Latino
    - 3% black/African descent
    - 26% other.
- Median of 5 inflammatory lesions in each of Areas A and B at baseline.

Efficacy

- The blue light treatment was associated with significant (P≤.01) reductions from baseline in inflammatory lesion count as early as week 1 in Area A and week 3 in Area B (Figure 1).
- The median reductions in inflammatory lesion count at weeks 1, 4, and 8 were:
  - 29%, 43%, and 60% in Area A
  - 23%, 33%, and 46% in Area B.
- Photographic documentation is shown in Figure 2.
- Between baseline and week 8:
  - 100% of subjects reported flares occurred less frequently
  - 100% of subjects reported reduced flare severity (from median grade of moderate to minimal) (Figure 3)
  - 100% of subjects reported reduced flare redness (from median grade of mild to minimal).

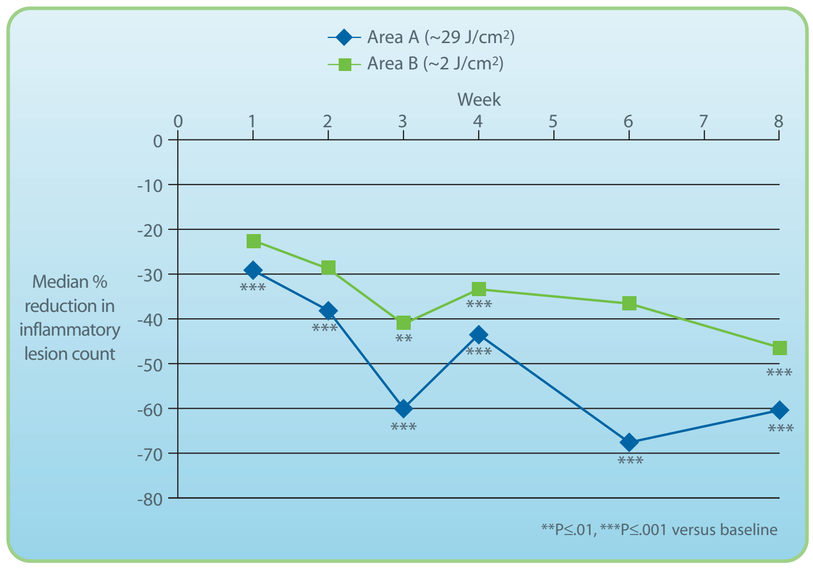

Figure 1. Reduction in inflammatory lesion count.

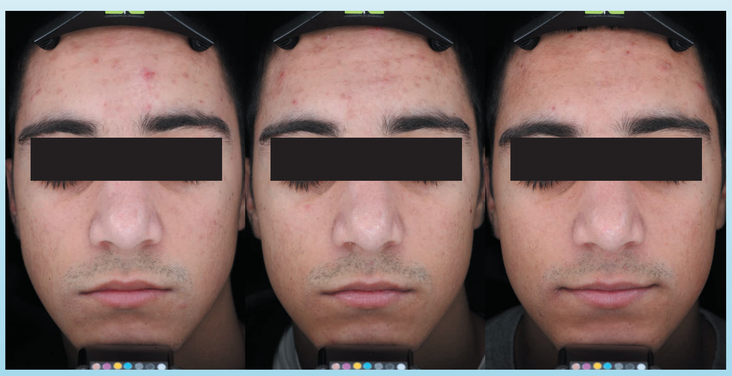

Figure 2. Clinical improvement after treatment with the blue light device. Area A was on the upper middle right forehead and received ~29 J/cm^2 each day from the blue light device. The rest of the face received ~2 J/cm^2 each day.

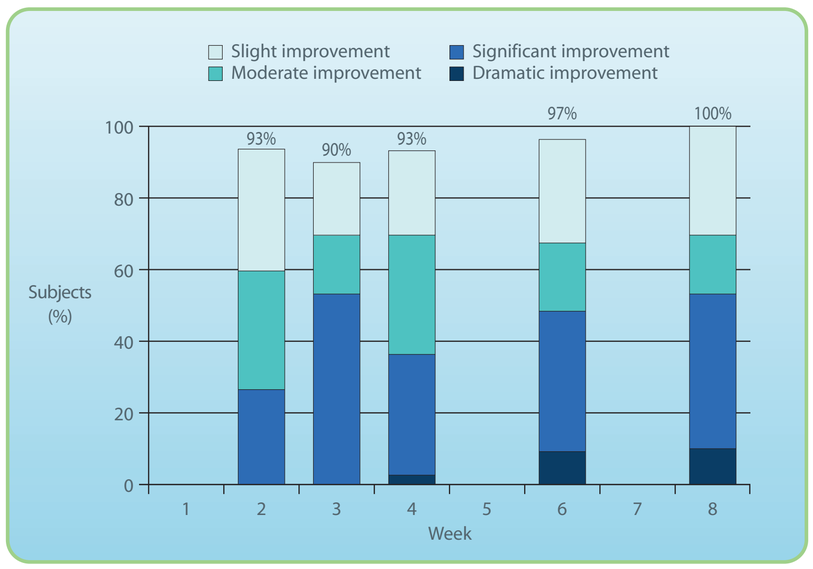

Figure 3. Proportion of subjects reporting improvement in severity of flares.

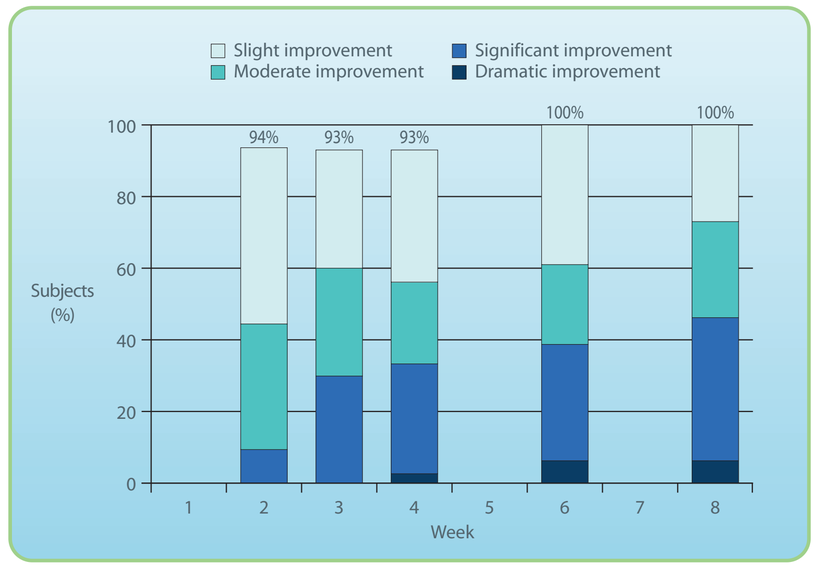

Figure 4. Proportion of subjects reporting improvement in the overall appearance of their skin.

- The proportion of subjects considering their skin was improved at week 8 in terms of the following parameters was:
  - 100% for overall appearance (Figure 4)
  - 97% for clarity
  - 73% for radiance
  - 80% for tone
  - 80% for texture
  - 83% for smoothness.
- At week 8, the majority of subjects also reported:
  - Better improvement than with their prior skin care regimen (77%)
  - Significantly faster improvement than with their prior regimen (56%).

Tolerability

- 3 adverse events reported were at least probably related to treatment:
  - Minimal and transient skin dryness (2)
  - Minimal and transient hyperpigmentation (1).

CONCLUSION

The blue light treatment is effective and well tolerated, offering rapid and gentle treatment of inflammatory acne with high levels of subject satisfaction. The blue light treatment is also associated with improvements in the skin's appearance, clarity, radiance, tone, texture, and smoothness, and reductions in the severity, redness, and frequency of flares. 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.

REFERENCES

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2. Ashkenazi H, Malik Z, Harth Y, Nitzan Y. Eradication of Propionibacterium acnes by its endogenic porphyrins after illumination with high intensity blue light. *FEMS Immunol Med Microbiol* 2003;35:17-24.
3. Shnitkind E, Yaping E, Geen S, et al. Anti-inflammatory properties of narrow-band blue light. *J Drugs Dermatol* 2006;5:605-10.

DISCLOSURE

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