A Novel Combined Light-Based Treatment of Acne Vulgaris With 1,450-nm Diode Laser and 450-nm Blue Light

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BACKGROUND Nonablative 1,450-nm diode laser (DL) and visible blue light (BL) have been effectively used for acne with superior safety profiles.

OBJECTIVE To evaluate synergistic effects of sequential DL and BL application for acne.

METHODS A 20-week, randomized split-face study was conducted to compare clinical courses between 2 facial sides either receiving sequential application of DL and BL or BL alone in 24 patients with mild to moderate facial acne vulgaris. Patients were scheduled to receive 3 consecutive sessions at 4-week intervals. Objective assessments, including revised Leeds grades, lesion counts, and sebum output measurements, and patients' subjective satisfaction were investigated.

RESULTS Both combination and BL sides demonstrated steady improvement of inflammatory acne lesions with 62.3% and 35.2% decreases at the 12-week follow-up visit compared with baseline respectively. For noninflammatory lesions and seborrhea, only combination regimen demonstrated improvement. Patients' subjective assessments paralleled objective findings. For safety profiles, no severe adverse effect was observed on both sides, and mild symptoms resolved spontaneously within a day.

CONCLUSION The combination regimen demonstrated synergistic efficacies for acne and seborrhea, with satisfactory safety profiles. Therefore, a few sessions of these light-based applications would be a viable option for acne treatments.

The authors have indicated no significant interest with commercial supporters.

Acne vulgaris is a nearly universal skin disease affecting more than 85% of adolescents and accounts for more than 30% of patients visiting dermatology clinics.[1,2] Current antiacne medications such as topical antibiotics and retinoids have demonstrated rather modest efficacy in mild to moderate acne, but they may be accompanied by various side effects such as antibiotic resistance and irritation.[3,4] In addition, considering high prevalence of acne, a substantial proportion of acne patients with underlying internal diseases or sensitive skin, and those preparing for pregnancy could not readily tolerate these medications.[5] With a growing medical demand for device-based treatments, light-based therapies including lasers, visible light, and intense pulse light have provided some clinical benefits.[6–8]

Among them, nonablative 1,450-nm diode laser (DL) and visible blue light (BL) have been effectively used for various acne lesions. Diode laser, with its wavelength in the infrared range, induces thermal damage to the mid-dermal skin layer, where sebaceous glands are located.[9,10] It leads to the subsequent impairment of sebaceous gland activity and associated inflammation. The concurrent incorporation of dynamic cooling device protects the epidermis from thermal damage.[11] Irradiation with visible BL has been also shown to improve acne lesions clinically, possibly by photoexcitation of bacterial porphyrins leading

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eventually to the destruction of *Cutibacterium acnes*.[12,13] Each set of wavelengths is believed to act by a distinct mechanism against multiple pathogenic factors of acne, with superior safety profiles in clinical practice.

Despite these advantages for light-based devices, previous studies have rarely evaluated whether sequential application of these devices have advantageous effects for the improvement of acne. In this study, the authors aimed to evaluate efficacy and safety of 3 consecutive sessions of combination treatment using DL and BL for acne and seborrhea through a prospective, randomized split-face comparison study.

Methods

Study Design

This study was designed as a 20-week, prospective, randomized split-face protocol that compared clinical courses between 2 facial sides receiving either sequential application of both DL and BL or BL alone for acne vulgaris. At the initial presentation, the severity of acne was evaluated by revised Leeds grade[14] and individual acne lesion counts from all enrolled patients. Then, each facial side was randomly assigned into either combination (both DL and BL) or BL alone treatment side. A simple random allocation sequence was created using computer-based random number generators to assign the treatment modality of each side. Randomization codes were secured in a safe until all data analyses were finished. Patients were scheduled to receive 3 consecutive sessions at 4-week intervals, with a follow-up visit 12 weeks after the final third treatment. An evaluation of each treatment session was performed after 1 week of every treatment. Two dermatologists evaluating the acne severity were blinded to the treatment assignment. At patients' each evaluation visit, photographic assessments by dermatologists, sebum secretion measurement, and patients' subjective assessments were conducted.

Subjects

This study was conducted in accordance with the Declaration of Helsinki and was approved by the institutional review board. Informed consents were acquired from all subjects before enrolments. Twenty-five participants (aged 18–39 years, 14 female and 11 male, 13 Fitzpatrick skin Type III and 12 Type IV) with mild to moderate acne vulgaris as defined by revised Leeds Score 2 to 6 (mean 4.4 ± 0.9) participated in this study. Subjects were not allowed to use any systemic, topical, or light-based acne treatment during the course of this study. The exclusion criteria were pregnancy, mental illness, intake of oral isotretinoin within 3 months, and application of other oral and topical acne medications, chemical peeling, and light-based treatments within 6 weeks. Baseline information is described in Table 1.

Devices and Treatment Protocols

An apparatus (Capri laser; Orotech R, Seoul, Korea) equipped with both DL and BL devices was applied through the study. According to the randomly assigned allocation, one half of the face was treated with DL followed by BL mode (combination regimen), and the other half with BL mode only. In local anesthesia, the face was cleansed with a mild soap and 70% alcohol, and a topical eutectic mixture of 2.5% lidocaine hydrochloric acid and 2.5% prilocaine (AstraZeneca AB, Sodertalje, Sweden) was applied to the entire face under occlusion 15 minutes before treatments. For the DL mode treatment, each half of the facial area received 2 passes of the stamp mode, which comprised 4 micropulses lasting a total of 280 ms with 5 cryogen spurts interspersed lasting a total of 35 to 40 ms (Figure 1). The spot size was 6 mm. Laser energies ranged from 5 to 7 J/cm^2 depending on patients' status and anatomical locations at the

TABLE 1. Baseline Characteristics of Enrolled Patients in This Study

	Patients' Clinical Characteristics
Number	25
Age (yr)	21.6 ± 7.8 (18–39)
Sex (F/M)	14/11
Skin phototype (III/IV)	13/12
Noninflammatory lesions	46.3 ± 15.8
Inflammatory lesions	32.1 ± 8.7
Mean Leeds revised scale	4.4 ± 0.9

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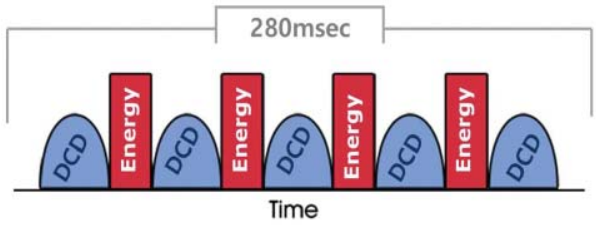

Figure 1. A timeline that shows the pulse sequence versus the cryogen spray sequence in a graphical manner. DCD, dynamic cooling device.

discretion of the operator. With the BL mode, treatment hand piece delivered symmetrical peak wavelengths; 450 nm for the BL. The irradiance range was 3.5 to 7.0 mW/cm^2 for the BL, with the radiant fluencies during a single treatment being 0.6 to 1.2 J/cm^2. Blue light was illuminated for 3 minutes throughout the face.

Clinical Outcome Assessments

Objective assessments of acne severity were conducted using individual lesion counts (inflammatory lesions: papules, pustules, and nodules; noninflammatory lesions: open and closed comedones) first. Leeds revised acne grading was also used for overall severity assessments. Two dermatologists not involved in treatments performed clinical evaluations. To ensure the reliability of the authors' evaluation, standardized digital photographs were also taken at baseline and each follow-up visit using identical camera settings (Nikon D70; Nikon Corp., Tokyo, Japan). To measure the sebum output level, both cheeks (the most prominent area of the zygoma) were selected for measurement areas. At least 5 hours after washing the face with soap, sebum was collected from each site on a plastic sebumeter strip (Skin-O-Mat; Cosmomed GmbH, Wetter, Germany) using a constant pressure for 30 seconds. After the face had been washed, further face washing, use of cosmetics, or any other topical products were not permitted until assessments. Patient's subjective assessments of satisfaction were also recorded at the final visit. Subjective evaluations were conducted for the improvement of acne, seborrhea, and skin textures/enlarged facial pores using a 5-point scale (0 = none, 1 = slight improvement, 2 = moderate improvement, 3 = good improvement, and 4 = excellent improvement). Subjects also recorded the mean duration of post-treatment responses including erythema, and edema with a 0-to-3 scale. Severe side effects including hyperpigmentation, secondary scarring, and infection were documented during treatment sessions in detail. The overall duration of subjective downtime during which the treatment meaningfully affects their quality of life was also recorded from each patient.

Statistical Analysis

The paired *t*-test or Wilcoxon signed-rank test and the McNemar test were used to compare the differences between before and after treatment and those between combination and BL treatment sides (SPSS version 24; SPSS Inc., Chicago, IL). A p-value <.05 was considered as statistically significant.

Results

Of the 25 patients who were initially enrolled, 24 (13 women and 11 men, aged 18–39 years; 12 Fitzpatrick skin Type III and 12 Type IV) patients completed the study; 1 patient withdrew for personal reasons. No patient withdrew secondary to treatment-related adverse events.

Evaluation of Acne Counts

For inflammatory acne lesion counts, both sides demonstrated significant improvement during 3 sessions of each treatment. At the final 12-week follow-up visit, the counts were decreased by 62.3% (from 16.3 to 6.1) in the combination side, and 35.2% (from 15.8 to 10.2) in the BL side, the difference of which was significant ($p < .05$). From the first session, reduction of combination side was more evident compared with BL side, and mean reductions of inflammatory lesions were observed just after the first session in combination side, and after the second session in BL side ($p < .05$) (Figure 2A). Noninflammatory acne lesions were reduced on the combination side (24.5%, from 22.4 to 16.9, $p < .05$) after the second session, while no significant change was observed on the BL side throughout the study period. The difference of improvements in mean lesion counts between 2 regimens was evident after the second visit ($p < .05$) (Figure 2B).

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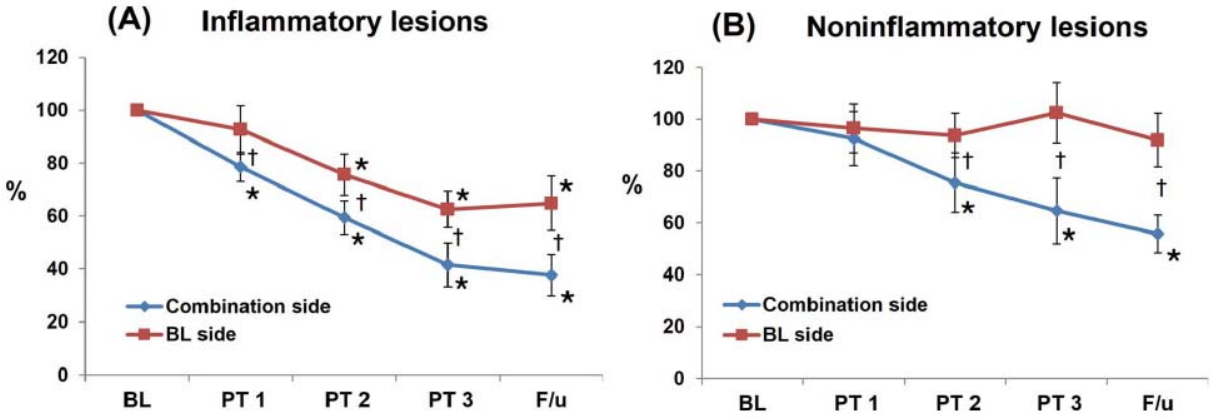

Figure 2. Percent changes in (A) inflammatory acne lesion counts and (B) noninflammatory acne lesion counts. *$p < .05$ versus baseline; †$p < .05$ between combination and BL sides. BL, blue light; PT, post-treatment.

Assessment of General Acne Severity and Sebum Secretion

Although there was no difference in the severity grading between the 2 sides at baseline (4.5 ± 0.8 vs 4.3 ± 0.9; $p > .05$), statistical differences in Leeds revised acne grades between different treatment sides were observed after the first session, consistent with results of acne counts. For the combination side, the mean acne grade was significantly decreased to 1.9 at the final visit and for BL side to 3.2 (Figure 3A) ($p < .05$). Figure 3B represents clinical photographs that illustrate improvements on the both sides and relatively better improvements on the combination side. Only combination side had demonstrated an inclination toward a gradual decrease in sebum output after the first session, while no decrease was observed on the BL side ($p < .05$) (Figure 4).

Patients' Subjective Evaluations

Patients' self-assessments for the degree of acne improvements generally paralleled physicians' evaluation. Patients' mean scores evaluated at the follow-up visit were 2.9 at the combination side and 2.0 at the BL side for acne, respectively ($p < .05$). Degree of seborrhea improvement was also consistent with sebumeter measurements (2.5 at the combination side and 1.3 at the BL side, $p < .05$). The moderate improvement in skin texture and enlarged pores

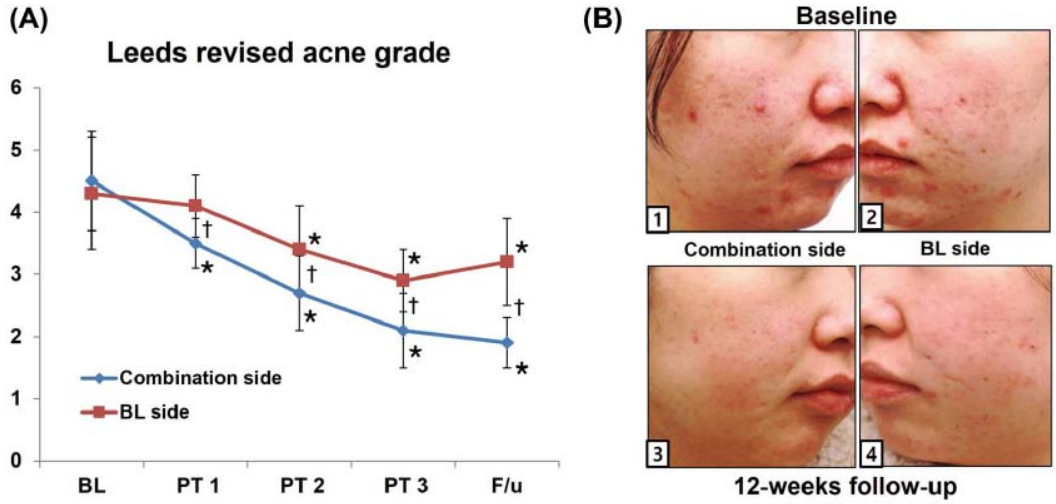

Figure 3. (A) Changes in the overall severity levels measured by Leeds revised acne grading system of the 2 sides. *$p < .05$ versus baseline; †$p < .05$ between combination and BL only sides. (B) Photographs of the combination side (1, 3) and BL side (2, 4) at baseline and after the 12-week lapse of the treatment. Clinical improvements were observed on both sides, but the degree of improvement was higher on the combination side. BL, blue light; PT, post-treatment.

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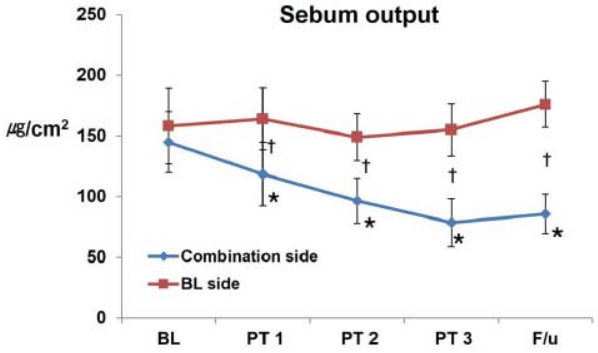

Figure 4. Changes in sebum output level with time. *$p < .05$ versus baseline; †$p < .05$ between combination and BL sides. BL, blue light; PT, post-treatment.

was observed only for combination side (2.0 vs 0.8, $p < .05$) (Figure 5). After finishing the whole study, the authors reinterviewed 15 participants by telephone or email. Among them, 11 patients (73%) answered that the improved state of acne and hyperseborrhea was maintained after the lapse of about 1 year. Nine of them were not using any concomitant treatments.

Safety Profiles

Various treatment-related side effects were thoroughly compared between 2 sides. For the degree of dryness and erythema, no statistical difference was observed between 2 groups. These symptoms resolved spontaneously within a day. Although postinflammatory hyperpigmentation was not observed in the BL side, 1 case (4%) with mild, localized pigmentations were observed in the combination side. No case of secondary scarring or infection was observed throughout the study. No flare of acne was observed from both groups. The average duration of downtime was 0.6 ± 0.6 days for the combination side and 0.5 ± 0.6 days for BL side, which was not significantly different ($p > .05$). Detailed information is shown in Table 2.

Discussion

Because even early acne lesions can evolve into permanent scars, early administration of effective therapy can reduce risk of scarring.[15] Although current guidelines mainly rate the quality of evidence supporting available medical options, a fair number of patients could not tolerate conventional medications.[16] Considering that acne originates from sebaceous gland and *C. acnes*, dermatologists can apply various light-based treatments based on characteristic physicochemical traits and chromophore activities in skin anatomy.[17–20] Accompanying intrinsically low systemic side effects, these treatments have demonstrated moderate efficacies against acne.[6–8] However, monotherapy of single wavelength may have limitations for the degree of clinical efficacy, rationalizing combination of multiple devices. However, related controlled studies with objective assessments have been still limited.

In this study, the combination of DL and BL demonstrated synergistic effects for the improvement of inflammatory and noninflammatory acne lesions, and hyperseborrhea. Although BL alone was effective against inflammatory lesions, the addition of DL

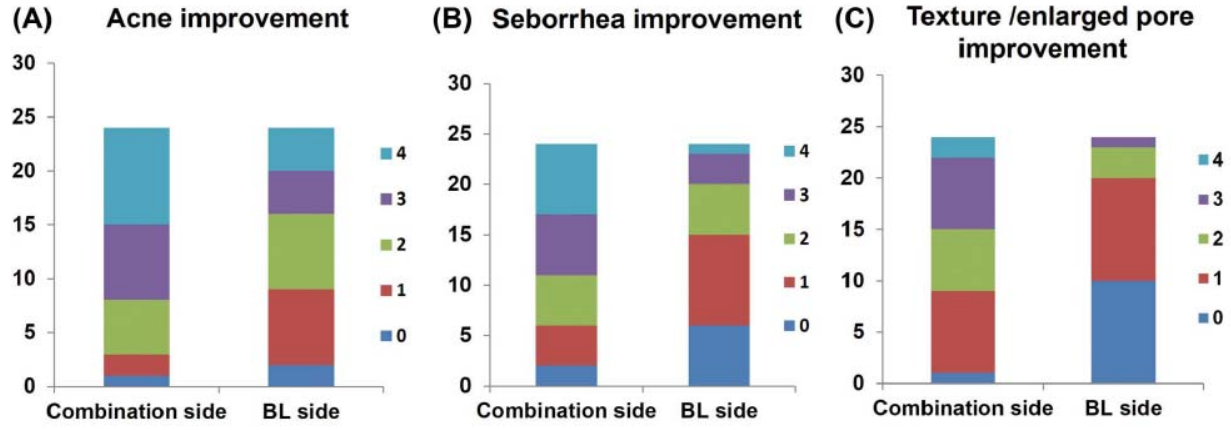

Figure 5. Patients' subjective assessments at the final follow-up visit for the improvement of (A) acne, (B) seborrhea, and (C) skin texture/enlarged pores using a 5-point scale (0 = none, 1 = slight improvement, 2 = moderate improvement, 3 = good improvement, and 4 = excellent improvement) between 2 regimens. BL, blue light.

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TABLE 2. Safety Profiles of Each Facial Side Treated by Either Combination or BL Only Regimen During Treatment Sessions

	Combination	*BL*	*Analysis*
Dryness (0–3 scale)	0.8 ± 0.4	0.6 ± 0.5	$p > .05$
Erythema (0–3 scale)	0.7 ± 0.5	0.5 ± 0.5	$p > .05$
Pigmentary changes	1/24	None	NA
Scar formation	None	None	NA
Secondary infection	None	None	NA
Acne flare during treatment sessions	None	None	NA
Average duration of downtime (d)	0.6 ± 0.6	0.5 ± 0.6	$p > .05$

BL, blue light; NA, not available.

reduced not only inflammation further but also sebaceous gland activities. Compared with topical agents and other light-based treatments, the improvement in inflammatory lesions of the combination regimen was generally satisfactory.[21,22] The maintenance of improvement for 3 months suggests potential prophylactic effects against acne recurrence, which may be an important advantage of this combination regimen. For the safety profiles, light-based treatments were much superior to the first-line topical medications, which will be beneficial to patient adherence.[23,24] Retinoid and benzoyl peroxide commonly used in first-line fixed combination regimen have potential irritation effects. Compared with Caucasians, Asians have complained of irritations more often after applying these topical agents.[23] Patients' subjective assessments for acne and seborrhea improvement paralleled objective findings. Mild and moderate improvement of skin texture was also observed in the combination regimen, which seems to be related with dermal remodeling effects of DL.[25]

Diode laser was initially designed for nonablative improvement of skin texture by stimulating procollagen production; meanwhile, histologic evaluation of the treated skin demonstrated coincidental damage to sebaceous glands.[17] At 1,450-nm wavelength, water is the principal chromophore, and the penetration depth of the laser is approximately 400 μa.[26] The presumed mechanism in vivo is through heating of the sebaceous gland and associated structures, subsequently leading to the impairment of sebaceous gland activity and associated inflammation.[17,27] This may elucidate significant improvement of noninflammatory lesions and seborrhea in this study. However, it is also true that sebaceous glands deeply located may not be directly affected by thermal damage of DL, suggesting other indirect mechanisms such as modulation of dermal microenvironment or induction of secondary cytokine expressions may also contribute to the improvement of acne and seborrhea. Recent studies have shown that a double-pass technique using relatively lower energy level as applied in this study is as effective, less painful, and better tolerated with less side effects.[28,29] In this study, the authors also confirmed comparable results in the perspective of pain and safety issues.

Blue light has been shown to be effective at activating coproporphyrin III and protoporphyrin IX, subsequently leading to the production of singlet oxygen and destruction of *Propionibacterium acnes*, responsible for inflammation.[19,30] The authors' previous study with BL and red light against acne has shown the downregulation of IL-1α, IL-8, and MMP-9 expression through NF-κB pathway, which leads to the mitigation of inflamed acne lesions.[31] Previous clinical studies have already reported that BL irradiation alone leads to significant improvement of inflammatory acne with mild side effects.[13,32] However, the relatively poor depth of skin penetration of this wavelength may limit its use as monotherapy, as partially confirmed in the authors' study. Considering that therapeutic mechanisms of these lights are distinct from traditional medications, these may be applied not only as a monotherapy for patients not tolerating conventional medications but also as a component of combination therapy for recalcitrant acne subtypes.

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There are some limitations in this study. First, all enrolled patients had an identical ethnic background. Second, additional studies would be needed to determine the most efficacious treatment parameters including energy level, the number of treatment sessions, and the interval between treatments. Finally, further studies regarding combination treatments using both these devices and antiacne medications against severe acne would provide clinically interesting data.

In conclusion, both DL and BL demonstrated efficacies for acne, and the combination of these 2 light-based treatments produced synergistic efficacies. Furthermore, demonstrating comparable efficacies, these novel light-based treatments have shown notable advantages in the safety profiles compared with currently used topical acne agents. Therefore, a few sessions of these devices, monotherapy or as a component of combination treatment, would be a viable option for acne treatments.

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