

Original Article



A Randomized, Split-Face, Comparative Study of a Combined Needle Radiofrequency/Intense Pulsed Light Device in Moderate-to-Severe Acne Patients

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ABSTRACT

Background: Radiofrequency (RF) and intense pulsed light (IPL) have been reported as efficient adjuvant treatment modalities for acne vulgaris.

Objective: We sought to evaluate the clinical efficacy and safety of a combined needle RF and vacuum IPL device for acne treatment without the use of other conventional topical or oral agents.

Methods: This randomized, split-faced study was designed to include patients with moderate to severe acne vulgaris. Comedone extraction was performed on both parts of the face prior to laser treatment. One side of the face was treated with RF and IPL in 2-week intervals, while the other side was left untreated as a control. Two independent blinded investigators evaluated the patients for improvement using clinical photographs. We also assessed for possible adverse effects.

Results: The study included 44 patients with acne vulgaris (27 men and 17 women). Their ages ranged from 19–39 years (average, 23 years). At the final 12-week follow-up visit, the acne reduction rate was 34.80% ($\pm 33.45\%$; range, 30.92%–19.03%) on the treated side and 13.76% ($\pm 37.58\%$; range, 28.26%–23.27%) in the control group compared to baseline, constituting a significant difference. The difference in reduction rate between the treated and control sides was 21.03% ($\pm 25.09\%$), with the treated side experiencing more significant improvement ($p < 0.05$). In the assessment of adverse events, one patient experienced mild surrounding erythema that spontaneously improved.

Conclusion: Combined treatment of needle RF and IPL could improve acne lesions.

Keywords: Acne; Intense pulsed light therapy; Microneedling; Radiofrequency therapy

INTRODUCTION

Acne can cause cosmetic problems, including persistent inflammatory erythema and scars. Therefore, there is an increasing

demand for effective acne management. Other than the many conventional treatment agents¹ for acne, various medical devices are being actively tested in clinical trials and demonstrate their efficacy by shortening the treatment time and reducing systemic

side effects². Many laser-/light-based modalities have been developed for acne treatment^{3,4}. Among treatment modalities of acne vulgaris, radiofrequency (RF) could act as an efficient alternative modality to topical and systemic medications. RF delivers current to the tissue to produce heat, denature hair follicles and sebaceous glands, and kill *Cutibacterium acnes*^{5,6}. RF also resynthesizes collagen through the wound-healing process⁷. Intense pulsed light (IPL) also helps to treat acne via anti-inflammatory effects through upregulation of transforming growth factor-beta 1⁸ and downregulation of tumor necrosis factor-alpha (TNF- α)^{9,10}. In addition, it destroys the blood vessels supplying the sebaceous glands⁹. The porphyrin produced by *C. acnes* absorbs light, resulting in the death of *C. acnes* by cytotoxic effect¹¹. A needle RF and IPL combination device was recently introduced to attain additive benefits from decreased sebaceous gland activity and anti-inflammatory effects. Few studies to date have assessed the effects of combination devices on acne vulgaris, and an animal study has been performed with a combination device. The aim of the present study was to demonstrate the clinical efficacy and safety of an RF and IPL combination device for the treatment of moderate to severe acne vulgaris.

MATERIALS AND METHODS

This was a randomized, evaluator-blinded, split-face, sham-controlled pivotal clinical trial. The needle RF device has an insulated needle with a depth of 1.2 mm, and the range of output energy is 2–52 W, which was divided into 10 levels (**Fig. 1A**). The IPL applicator was placed in contact with the skin to absorb energy into the skin under a vacuum. Then, pulsed light with a wavelength of 400–1,000 nm was irradiated at an energy in the range of 2–10.8 J/cm² (**Fig. 1B**).

Study patients

Patients with more than 20 acne lesions (inflammatory and non-inflammatory) on the face and those with inflammatory lesions with global assessment (Investigator's Global Assessment [IGA]) scale scores of 3 or 4 points were included in this study. The IGA scale was divided into five grades, with scores ranging from 0–4 points (**Table 1**).

The main exclusion criteria were as follows: 1) treatment history with oral retinoid or chemical peeling during the previous 6 months; 2) treatment history with oral anti-androgenic contraceptives during the previous 3 months; 3) treatment history with oral or topical antibiotics, topical retinoid, or systemic steroids during the previous 1 month; 4) implantable medical devices including a pacemaker, defibrillator, or leads; and 5) active dermatologic diseases such as connective tissue disorders or autoimmune diseases.

Treatment protocols

Comedone extraction was performed on both sides of the face. One side of the face was used as the control side, and the other side was treated with a combination device (dermaAKNE; Huons Medical Co., Ltd., Seongnam, Korea) providing insulated needle RF and IPL (400–1,000 nm) therapy. The side of the face to be treated with the device was determined by another independent investigator randomly. The treated side received RF at baseline, IPL at week 2, RF at week 4, and IPL at week 6. RF was performed with energy level three (4 W) and a 150 ms pulse width, and IPL was conducted with a 5.5 J/cm² energy level and 400–1,000 nm wavelength (**Figs. 1 and 2**). The patients were instructed not to use any topical or oral anti-acne agents during treatment.

Assessment of treatment outcomes

1) Clinical assessment

Digital photographs of the face were collected before treatment and at each visit. The global severity of each lesion was analyzed from the photographs by two independent dermatologists. The efficacy of the acne treatment was evaluated based on the number of acne lesions (inflammatory and non-inflammatory) in clinical photographs, adverse effects, and any additional acne scarring lesions after 8 and 12 weeks. The mean acne lesion reduction rate was used to evaluate the effectiveness.

2) Patient global assessment (PGA)

At 8 and 12 weeks post-treatment, subjects were asked to rate their satisfaction score on a 7-point scale (1=very dissatisfied, 2=dissatisfied, 3=somewhat dissatisfied, 4=indifferent, 5=somewhat satisfied, 6=satisfied, 7=very satisfied).

3) Safety assessment

All abnormalities occurring in this clinical trial were included in the safety evaluation. Local treatment-related adverse events, such as erythema, hyperpigmentation, edema, bulla, scarring, and pain, that occurred for 30 minutes after treatment with the needle RF and IPL combination device were evaluated.

Statistical analysis

Data were analyzed using SAS Analytics, version 1.0 (SAS Institute, Cary, NC, USA). Continuous data were expressed as mean $\pm$ standard deviation values, and categorical data were presented using frequencies and percentages. Descriptive statistics (mean, standard deviation, median, minimum, and maximum) for the difference in average acne lesion reduction rate (test vs. control groups) at 12 weeks after treatment compared to baseline and evaluated by an independent evaluator were presented. A paired t-test was used to determine whether there was a difference between the groups. When the normality distribution assumption was not

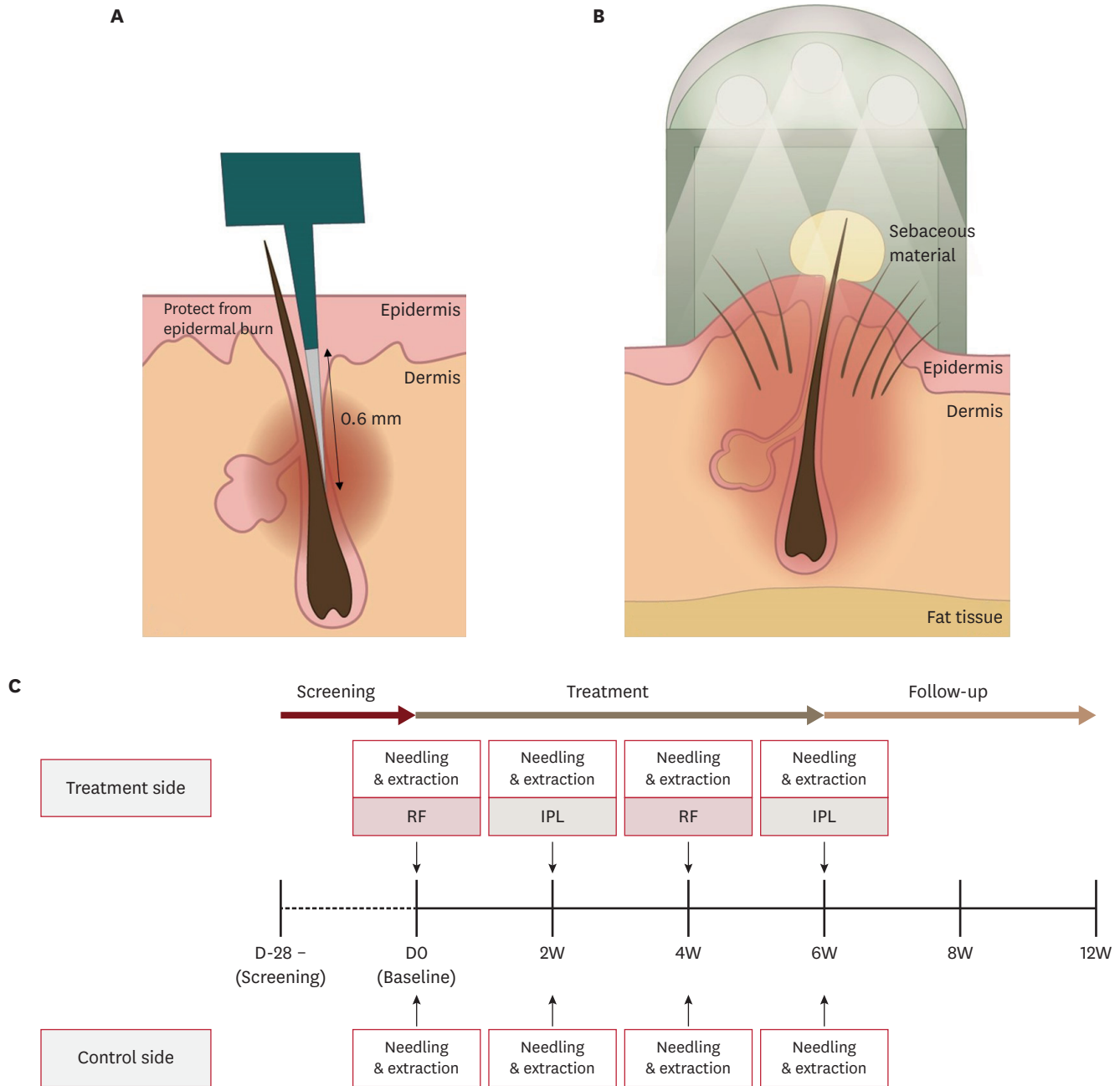


Fig. 1. Mechanism of needle RF and vacuum IPL. (A) Needle RF. (B) Vacuum IPL. (C) Treatment protocol. RF: radiofrequency, IPL: intense pulsed light.

Table 1. IGA scale

IGA scale	Description
Grade 0, clear	No inflammatory or non-inflammatory lesions
Grade 1, almost clear	Rare non-inflammatory lesions with no more than one small inflammatory lesion
Grade 2, mild	Some non-inflammatory lesions with no more than a few papular or pustular inflammatory lesions
Grade 3, moderate	Up to many non-inflammatory lesions and possibly including some inflammatory lesions, but no more than one small nodular lesion
Grade 4, severe	Up to many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions

IGA: Investigator's Global Assessment.

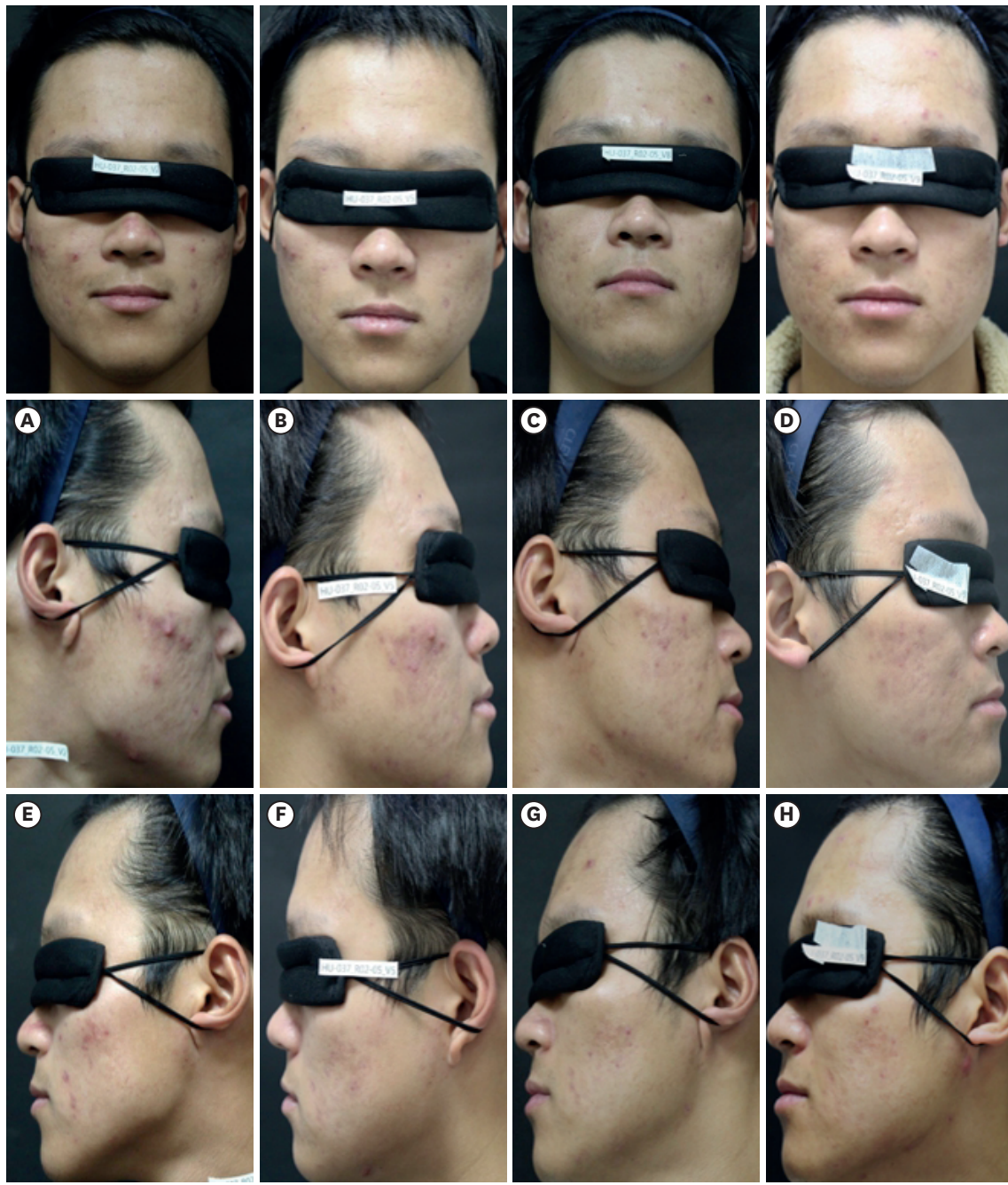


Fig. 2. Clinical photo (M/23). (A–D) treatment side and (E–H) control side. (A) Before and (B) after one treatment with monopolar RF and IPL and at (C) week 8 and (D) week 12. (E) Before and (F) after one treatment with extraction and at (G) week 8 and (H) week 12. Clinical photo (M/25). (I–L) treatment side and (M–P) control side. (I) Before and (J) after one treatment with monopolar RF and IPL and at (K) week 8 and (L) week 12. (M) Before and (N) after one treatment with extraction and at (O) week 8 and (P) week 12.
RF: radiofrequency, IPL, intense pulsed light.

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satisfied, the analysis was performed using Wilcoxon's signed-rank test. When $p < 0.05$, it was determined to be statistically significant.

Ethics statement

The study was conducted at the Departments of Dermatology of Hanyang University Hospital and Chung-Ang University Hospital

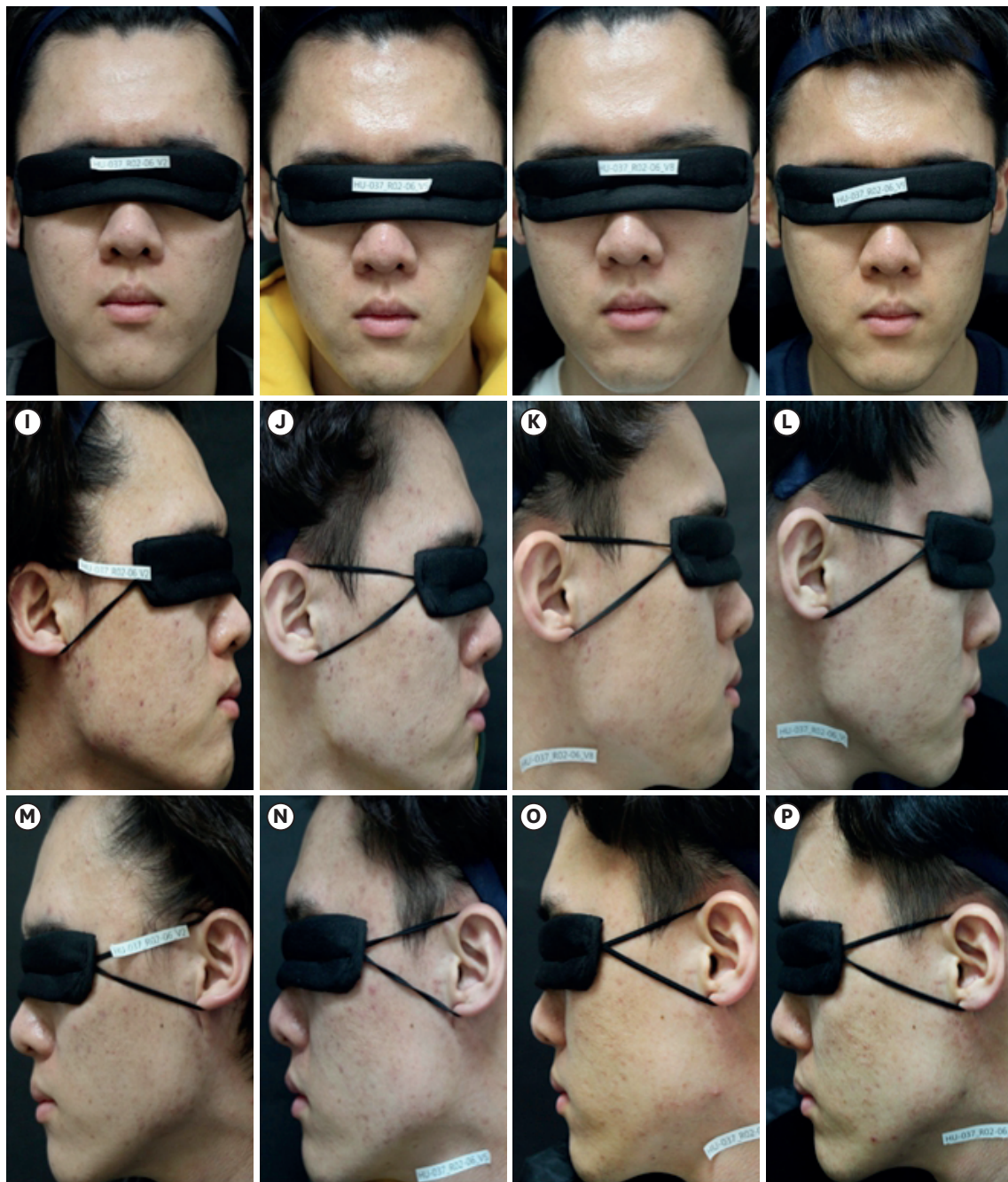


Fig. 2. (Continued) Clinical photo (M/23). (A–D) treatment side and (E–H) control side. (A) Before and (B) after one treatment with monopolar RF and IPL and at (C) week 8 and (D) week 12. (E) Before and (F) after one treatment with extraction and at (G) week 8 and (H) week 12. Clinical photo (M/25). (I–L) treatment side and (M–P) control side. (I) Before and (J) after one treatment with monopolar RF and IPL and at (K) week 8 and (L) week 12. (M) Before and (N) after one treatment with extraction and at (O) week 8 and (P) week 12. RF: radiofrequency, IPL, intense pulsed light.

in Korea, according to the Declaration of Helsinki. All patients provided written informed consent. The study protocol was approved by the institutional review boards of Hanyang University

Hospital (HYUH 2018-06-015) and Chung-Ang University Hospital (1741-007-279). Written patient consent has been obtained for publication for this report and for use of images.

RESULTS

Demographic data

A total of 44 patients with moderate to severe acne vulgaris were enrolled. Demographic information for the 44 patients enrolled in this study is presented in **Table 2**. A total of 27 men (61.36%) and 17 women (38.64%) were enrolled in the study. In the IGA assessment, the acne of 34 patients (77.27%) was classified as being of a “moderate severity,” while that of 10 patients (22.73%) was rated as “severe.” All of the patients had Fitzpatrick skin type III or IV. The Fitzpatrick skin type was grade III in 35 patients (79.55%) and grade IV in nine patients (20.45%).

Treatment outcomes

Treatment efficacy is summarized in clinical photographs (**Fig. 2**) and **Table 3** as the difference in average reduction in acne lesions at week 12 post-treatment versus that at baseline. The mean number of acne lesions was 30.92 (± 15.87) in the treatment group and 28.26 (± 14.69) in the control group, respectively, at baseline. After 8 weeks, this number was 22.41 (± 15.49) in the treatment group and 23.84 (± 15.65) in the control group. The reduction rate at week 8 compared to baseline was 27.29% ($\pm 31.29\%$) in the treatment group and 11.29% ($\pm 42.08\%$) in the control group. The difference in reduction rate between the two groups at 8 weeks was 16.00% ($\pm 29.56\%$), which was a statistically significant result ($p=0.0008$). After 12 weeks, the mean number of acne lesions was 19.03 (± 12.54) in the treatment group and 23.27 (± 14.69) in the control group. In addition, at 12 weeks after the first visit, the acne lesion reduction percentage was 34.80% ($\pm 33.45\%$) for the treated side and 13.76% ($\pm 37.58\%$) for the control side. The difference in reduction rate between the treated side and the control side was 21.03% ($\pm 25.09\%$), with the treated side showing a more significant improvement ($p<0.05$).

The PGA score was 5.98 points in the test group and 5.25 points in the control group at week 8 and 5.80 and 4.80 points, respectively, at week 12 (**Table 4**). The difference in PGA score between the treatment group and the control group was 0.73% ($\pm 1.21\%$) at week 8 and 1.00% ($\pm 1.29\%$) at week 12 ($p<0.0001$).

DISCUSSION

Four factors are important in the pathogenesis of acne¹², and needle RF is an effective way to treat three of them. First, needle RF is effective in reducing sebum and has a relatively selective thermal effect on the pilosebaceous unit. Selective electrothermolysis of the sebaceous glands reduces sebum secretion, resulting in long-term remission of acne¹³. Second, RF can reduce inflammation and the immune response. Volumetric heating of inflamed

Table 2. Demographic findings of enrolled patients

Characteristics	Total (n=44)
Sex	
Male	27 (61.36)
Female	17 (38.64)
Age (yr)	
Mean $\pm$ SD	24.34 $\pm$ 4.89
Median	23.00
Min, Max	19.00, 39.00
IGA (%)	
Grade 3	34 (77.27)
Grade 4	10 (22.73)
Fitzpatrick skin type	
Type III	35 (79.55)
Type IV	9 (20.45)

Values are presented as number (%).

SD: standard deviation, Min: minimum, Max: maximum, IGA: Investigator's Global Assessment.

Table 3. Difference in mean acne count reduction rate at 8 and 12 weeks after treatment compared to baseline

Number of acne lesions	Treatment side (n=44)	Control side (n=44)
Baseline		
Mean $\pm$ SD	30.92 $\pm$ 15.87	28.26 $\pm$ 14.69
Median	26.50	23.00
Min, max	8.00, 81.00	8.00, 73.50
Week 8		
Mean $\pm$ SD	22.41 $\pm$ 15.49	23.84 $\pm$ 15.65
Median	20.75	19.75
Min, max	5.00, 83.50	6.00, 66.00
% Change from baseline at week 8*		
Mean $\pm$ SD	27.29 $\pm$ 31.29	11.29 $\pm$ 42.08
Median	32.52	13.73
Min, max	-64.10, 81.67	-118.75, 87.23
Treatment difference†		
Mean $\pm$ SD	16.00 $\pm$ 29.56	
Median	11.79	
Min, max	-65.70, 95.45	
p-value‡	0.0008	
Week 12		
Mean $\pm$ SD	19.03 $\pm$ 12.54	23.27 $\pm$ 14.69
Median	14.50	19.50
Min, max	4.00, 56.00	5.50, 58.00
% Change from baseline at Week 12*		
Mean $\pm$ SD	34.80 $\pm$ 33.45	13.76 $\pm$ 37.58
Median	37.36	17.86
Min, max	-64.10, 83.33	-62.50, 75.44
Treatment difference†		
Mean $\pm$ SD	21.03 $\pm$ 25.09	
Median	19.26	
Min, max	-39.66, 83.33	
p-value‡	<0.0001	

SD: standard deviation, Min: minimum, Max: maximum.

Treatment side: DermaAKNE/control side: sham control.

*Reduction rate (% change) = (Lesion Count at Baseline – Lesion Count at 8th or 12th week)/(Lesion Count at Baseline) $\times$ 100.

†Difference = Treatment Side – Control Side.

‡Paired t-test.

dermal tissue surrounding follicles denatures collagen and causes neocollagenesis through the wound-healing process, including

Table 4. PGA* at weeks 8 and 12

PGA	Treatment side (n=44)	Control side (n=44)
PGA at week 8		
Mean ± SD	5.98±1.28	5.25±1.10
Median	6.00	5.50
Min, max	2.00, 7.00	2.00, 7.00
Treatment difference†		
Mean ± SD	0.73±1.21	
Median	1.00	
Min, max	-3.00, 4.00	
p-value‡	<0.0001	
PGA at week 12		
Mean ± SD	5.80±1.36	4.80±1.41
Median	6.00	5.00
Min, max	2.00, 7.00	2.00, 7.00
Treatment difference†		
Mean ± SD	1.00±1.29	
Median	1.00	
Min, Max	-2.00, 4.00	
p-value‡	<0.0001	

SD: Standard deviation, Min: Minimum, Max: Maximum

*7-point scale (1=very dissatisfied, 2=dissatisfied, 3=somewhat dissatisfied, 4=indifferent, 5=somewhat satisfied, 6=satisfied, 7=very satisfied).

†Difference = Treatment Side – Control Side.

‡Wilcoxon's signed rank test.

inflammatory reactions^{14,15}. A recent study revealed that RF energy also reduces levels of inflammatory mediators, such as TNF- α , in a rabbit ear model¹⁶. In addition, it leads to contraction of the dermis, tightening of the skin, and reductions in pore size. Third, RF energy successfully destroys *C. acnes*¹⁶. In addition, if RF acts on dilated blood vessels, it can congest them¹⁷ and reduce inflammatory cell infiltration¹⁸.

In our study, IPL was used to reduce post-inflammatory hyperpigmentation (PIH) and post-inflammatory erythema (PIE), but it was also helpful in the treatment of inflammatory acne. PIE occurs as a result of increased numbers of red blood cells in mildly inflamed and enlarged vessels^{19,20}. IPL works by targeted chromophore absorption of laser energy, causing selective photothermolysis. In erythema, oxyhemoglobin and deoxyhemoglobin are target chromophores²⁰. Oxyhemoglobin absorbs wavelengths of 418, 542, and 577 nm, and deoxygenated hemoglobin shows absorption peaks at wavelengths of 450 and 560 nm. Since the IPL of the test device had a proper range of wavelengths, it was also possible to improve the PIE without significant side effects. IPL can have a photodynamic effect that leads to the generation of reactive oxygen species and to photothermolysis of blood supplies to sebaceous glands²¹. A previous study suggested that IPL in a wavelength range of 530–700 nm would target small blood vessels that supply the sebaceous glands²². The IPL device used in the present study also applies a vacuum to the lesion under treatment. Upward compression is applied, and then skin structures are elevated. Therefore, pneumatic therapy could clean pores by extracting buildup of sebaceous material. Along with targeted

heating of the dermis, the endogenous effect of light activates porphyrins to destroy *C. acnes*^{23,24}. It is presumed that these effects combine to facilitate improvements in inflammatory acne.

An animal study has been performed with the intradermal RF and IPL combination therapy in acne¹⁶. The study found that, in combination, the two produce an additive effect on treatment compared to monotherapy. The intradermal RF treatment appears to markedly reduce lesion volume, while IPL appears to have an immunomodulatory effect. Some findings of the study suggested that when RF treatment is performed, the wound caused by needle insertion could be expected to heal quickly due to the anti-inflammatory and immunomodulatory cytokine enhancement effects of IPL. Our results showed that combination treatments have an additive effect in moderate to severe active acne lesions. Since this device can control most pathogenesis of acne, it is effective as a single treatment, especially for acne that recurs in the same location. However, as in this study, repeating the protocol is expected to reduce relapse. As the clinical pictures demonstrate, although there was no objective measure of erythema, the patients showed reductions in PIE and PIH on the treatment side. It was surmised that the test device can be considered cosmetically effective.

Our data revealed that the combination device could enhance clinical improvement with less downtime. In this study, the mean number of acne lesions at baseline was similar in the treated and control groups. At week 8, the rate of change was 11.29% ($\pm 42.08\%$) compared to baseline in the control group, while the rate of change was 27.29% ($\pm 31.29\%$) in the treatment group. At week 12, the rate of change was 13.76% ($\pm 37.58\%$) compared to baseline in the control group and 34.80% ($\pm 33.45\%$) in the treatment group. The control side showed some improvement because extraction with needling is one of the physical treatments for acne. However, the combination of needle RF and IPL has demonstrated superior effectiveness compared to the control group ($p < 0.0001$). As the number of acne lesions was reduced at 2 and 3 months after treatment, the treatment effect was maintained.

In this study, no patients used topical or oral anti-acne agents during our treatment protocols, and the results showed the combination device to be as effective as monotherapy for acne. Most medications available to treat acne have various drawbacks in terms of potential systemic adverse effects or inconvenience for the patients. In this respect, it is significant to prove the combined treatment efficacy of RF and IPL as monotherapy. In addition, if other medications are combined in real situations, better treatment outcomes can be expected.

According to the literature review, both monopolar RF and IPL treatment are efficacious for acne but have adverse effects, including erythema, burn, and bulla formation. However, minimal adverse effects were noted in our trial of the novel device.

Although this study was limited by a non-comparative design

and a small number of patients (44 patients), as it was a dual-center analysis, it remains a meaningful trial that evaluated the efficacy and safety of monopolar RF and IPL for treating acne. A further randomized, larger trial with a greater variety of subjects is needed.

Based on our results, the RF and IPL combination device reduced the number of acne lesions significantly, with few other significant side effects, compared to conventional treatment. This suggests its role as an effective therapeutic option for acne.

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CONFLICTS OF INTEREST

The authors have nothing to disclose.

DATA SHARING STATEMENT

The data that support the findings of this study are available on request from the corresponding author, upon reasonable request.

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