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ORIGINAL ARTICLE

Treatment of acne vulgaris with fractional radiofrequency microneedling

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ABSTRACT

Fractional radiofrequency microneedling is a novel radiofrequency technique that uses insulated microneedles to deliver energy to the deep dermis at the point of penetration without destruction of the epidermis. It has been used for the treatment of various dermatological conditions including wrinkles, atrophic scars and hypertrophic scars. There have been few studies evaluating the efficacy of fractional radiofrequency microneedling in the treatment of acne, and none measuring objective parameters like the number of inflammatory and non-inflammatory acne lesions or sebum excretion levels. The safety and efficacy of fractional radiofrequency microneedling in the treatment of acne vulgaris was investigated. In a prospective clinical trial, 25 patients with moderate to severe acne were treated with fractional radiofrequency microneedling. The procedure was carried out three times at 1-month intervals. Acne lesion count, subjective satisfaction score, sebum excretion level and adverse effects were assessed at baseline and at 4, 8 and 12 weeks after the first treatment as well as 4, 8 and 12 weeks after the last treatment. Number of acne lesions (inflammatory and non-inflammatory) decreased. Sebum excretion and subjective satisfaction were more favorable at every time point compared with the baseline values ($P < 0.05$). Inflammatory lesions responded better than non-inflammatory lesions ($P < 0.05$). Adverse effects such as pinpoint bleeding, pain and erythema were noted, but were transient and not severe enough to stop treatment. Fractional radiofrequency microneedling is a safe and effective treatment for acne vulgaris.

Key words: **acne vulgaris, fractional radiofrequency microneedling, laser, radiofrequency radiation, sebum excretion.**

INTRODUCTION

Fractional radiofrequency (RF) microneedling is different from conventional lasers because it does not affect skin color or transmit thermal energy to the dermis. At present, it is used to treat wrinkles, acne scars and hyperhidrosis.[1,2] There have been few studies evaluating the efficacy of fractional RF microneedling in the treatment of acne. A previous study concluded that fractional RF microneedling causes thermal damage to pilosebaceous glands and is an effective acne treatment. However, they did not back up their conclusions with objective parameters like the number of inflammatory and non-inflammatory acne lesions or the sebum excretion levels.[2]

We conducted this study to investigate the safety and efficacy of a fractional RF microneedling in the treatment of acne vulgaris using objective parameters.

METHODS

Twenty-five patients with moderate to severe facial acne were enrolled in a clinical trial after written informed consent had been obtained. The patient ages ranged 16–29 years. All patients had Fitzpatrick skin types ranging III–V. The patients were required to have no history of oral retinoid treatment within the past 6 months, no oral antibiotic treatment for the past 3 months, and no topical acne treatment such as retinoids, antibiotics or anti-inflammatory agents within the 1 month prior to the start of the study. Pregnant or lactating women and patients with a known history of photosensitive dermatitis were excluded. No other treatments for acne vulgaris were permitted during the study and for 3 months after the last treatment.

At the first patient visit, one dermatologist evaluated inflammatory skin lesions including papules, pustules, nodules, cysts and non-inflammatory skin lesions including open comedones, closed comedones and sebum excretions, and evaluated severity of acne from grade 1 to grade 5 following the global evolution acne (GEA) scale.

We used an INTRAcel (Jeisys Medical, Seoul, South Korea) for microneedle treatments. It has 49 partially insulated microneedles, and 1-MHz RF. We used 1.5-mm depth, 10-mm spot size, level 3 (12.5-W power, RF exposure time of 80 msec)

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settings. In addition, a Sebumeter (Courage+Khazaka, Cologne, Germany) was used to quantify sebum excretion. This device places 64-mm^2 segments of tape on the skin. In the presence of sebum, the tape becomes translucent, allowing light to pass through it. The device then evaluates the amount of light passing through the tape. The tape becomes translucent only in the presence of sebum, and does not react to water.

Patients washed their faces with mild soap, and cleaned with 70% alcohol. Then, we put 5% lidocaine-prilocaine cream on the face, and made it occlusive. We conducted two fractional RF microneedling passes with the INTRAcel (Jeisys Medical) using 1-MHz RF, 1.5-mm depth, 10-mm spot size, level 3 (12.5-W power, RF exposure time of 80 msec) settings through 49 microneedles in one visit. Patients received three such procedures at 1-month intervals, and follow up was conducted every month from before treatment to 3 months after the last procedure.

Facial photographs were taken using standardized camera settings (α350; Sony, Tokyo, Japan) at baseline and at each subsequent visit. Acne lesions were assessed by counting the number of inflammatory lesions including papules, pustules, nodules and cysts, and non-inflammatory open and closed comedones. Sebum excretion rates were measured using a Sebumeter (Courage+Khazaka). We told patients not to wash their faces for 6 h prior to sebum excretion measurements. Sebum measurement condition was controlled to a constant temperature of 21 ± 2.5°C and an average humidity of 46 ± 2.5%.

Side-effects such as pain, bleeding, erythema, edema, vesicles, infections and pigmentary change were recorded every month from before treatments to 3 months after the last treatment.

We assessed the degree of subjective satisfaction using a visual analog scale that ranged from 0 (worst imaginable acne state) to 10 (disease free) every month from 1 month after the first treatment to 3 months after the last treatment.

All data analyses were performed using SPSS version 17.0 for Windows (SPSS, Chicago, IL, USA). Statistical significance was defined as $P < 0.05$.

RESULTS

Twenty-five patients completed the study. There were 17 males and eight females, aged 16–29 years (average, 24.08 ± 3.13). Fitzpatrick skin type distribution included 16 patients with type III, seven patients with type IV and two patients with type V. There were 16 patients with GEA grade 3 (moderate) and nine patients with GEA grade 4 (severe) acne (Table 1).

Table 1. Patient demographics

Variable		No.	%
Sex	M	17	68
	F	8	32
Age, years	23.08 ± 3.13 (range, 16–29)		
Fitzpatrick skin type	III	16	64
	IV	7	28
	V	2	8
GEA scale	3	16	64
	4	9	36

GEA, global evolution acne.

The mean percentage decreases in inflammatory acne lesions were 47.18%, 65.13% and 84.91% 1 month after the first, second and third treatments, respectively. There was a statistically significant reduction at each time point compared with the baseline value. The reduction at 3 months after the last treatment was 90.11% compared to baseline, and the greatest 1-month interval reduction was after the first treatment ($P < 0.05$). The mean percentage decreases in non-inflammatory acne lesions were 40.86%, 55.16% and 70.82% 1 month after the first, second and third treatments, respectively. There was a statistically significant reduction at each time point compared with the baseline value. The reduction at 3 months after the last treatment was 76.46%. The greatest 1-month interval reduction was after the first treatment ($P < 0.05$). Inflammatory lesions responded better than non-inflammatory lesions ($P < 0.05$; Table 2,3, Figs 1–3).

The mean decrease in sebum excretion was 12.75%, 29.83% and 42.18% 1 month after the first, second and third treatments, respectively. Sebum levels increased slowly after treatment, and the mean decrease in sebum excretion was 36.99% 3 months after the last treatment ($P < 0.05$; Fig. 4).

Among 25 patients, five patients (20%) showed bleeding, four (16%) scaling, six (24%) crusting, eight (32%) swelling and eight (32%) erythema. Bleeding, swelling and erythema were most severe right after the procedure, but subsided in 1 week. Scaling and crusts were observed as soon as 1 day after the procedure, but subsided in 1 week. Hyperpigmentation, hypopigmentation, burns and scarring were not observed (Fig. 5).

Subjective satisfaction increased during treatment and was 3.32, 5.36 and 7.43 1 month after the first, second and third treatments, respectively. It then slowly decreased, but was still 7 at 3 months after the last treatment ($P < 0.05$; Fig. 6).

DISCUSSION

The pathogenesis of acne is attributed to four major factors: (i) sebaceous gland hyperplasia; (ii) abnormal follicular hyperkeratinization; (iii) *Propionibacterium acnes*; and (iv) inflammatory and immune reactions. Increased sebum secretion is a major cause associated with the development of acne. Conventional treatments include topical retinoids, benzoyl peroxide, azelaic acid, and oral antibiotics and retinoids. However, most of these treatments take a long time to achieve a cure and, recently, increasing resistance to antibiotics and isotretinoin's teratogenic potential have limited the use of traditional treatment. This is leading to increases in non-pharmacological treatment alone and combinations of non-pharmacological and pharmacological treatment.[3] Recently, various lasers including intense pulsed light, pulsed dye laser, infrared diode laser and potassium titanyl phosphate lasers, as well as photodynamic therapy, have been used to treat acne.[4,5] Pulsed dye lasers kill

Table 2. Changes in the numbers of acne lesions (inflammatory and non-inflammatory), sebum excretion and subjective satisfaction score after fractional radiofrequency microneedling in facial acne patients (mean ± standard deviation)

	Baseline	4 weeks	8 weeks	1-month follow up	2-month follow up	3-month follow up
Acne lesion						
Inflammatory	8.76 ± 3.45	4.62 ± 2.57	3.05 ± 2.39	1.32 ± 2.27	1.12 ± 2.46	0.86 ± 1.86
Non-inflammatory	13.49 ± 4.55	7.97 ± 4.37	6.04 ± 4.46	3.93 ± 3.88	3.70 ± 2.15	3.17 ± 2.68
Sebum excretion	162.71 ± 63.66	141.96 ± 67.19	114.17 ± 64.88	94.07 ± 46.37	101.12 ± 43.77	102.52 ± 40.33
Patient satisfaction score	–	3.32 ± 1.35	5.36 ± 1.19	7.43 ± 0.55	7.29 ± 1.93	7.00 ± 1.61

Table 3. Mean percentage changes of number of acne lesions (inflammatory and non-inflammatory) and sebum excretion from baseline to follow-up period

	4 weeks (%)	8 weeks (%)	1-month follow up (%)	2-month follow up (%)	3-month follow up (%)
Acne lesion					
Inflammatory	47.18	65.13	84.91	87.16	90.11
Non-inflammatory	40.86	55.16	70.82	72.57	76.46
Sebum excretion	12.75	29.83	42.18	37.85	36.99

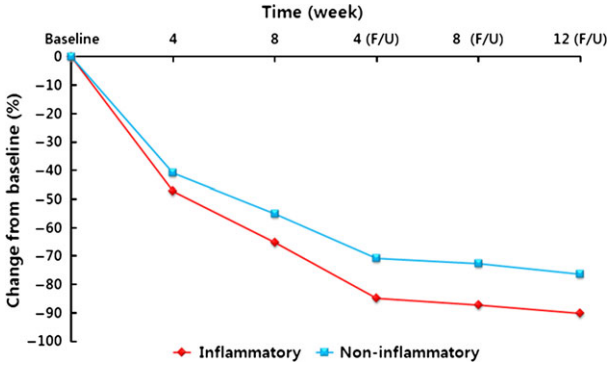

Figure 1. Mean percentage of inflammatory and non-inflammatory lesions was significantly decreased after each fractional radiofrequency microneedling and during 3 months of follow up. Results showed better responses in inflammatory lesions than in non-inflammatory lesions.

P. acne, one of the most important factors in the pathogenesis of acne, and decrease vascularity associated with inflammation, so they are used to treat inflammatory acne.[6] Non-ablative RF and Kobayashi needles cause thermal damage to sebaceous glands, and treat acne by decreasing sebum excretion.[7] Ruiz-Esparza *et al.*[8] treated 22 acne patients with a non-ablative RF device (ThermaCool TC; Thermage, Hayward, CA, USA), which delivers RF energy at 6 MHz. They showed 75% or better diminution of active acne lesion counts in 82% of the patients. Shah *et al.*[9] treated 20 acne patients with the same RF device and 44% of the patients showed significant improvement. However, some energy must be delivered to the dermis in order for these treatments to be effective. So, laser or RF treatments penetrate and tend to affect the epidermis, causing a number of side-effects. Some lasers generate pigmentary change due to absorption of a specific wavelength of the laser. Kobayashi needle treatments are also very time-consuming because of the small number of needles, and if the treatment area is large, they are difficult to use. Therefore, more effective and safe treatments are in demand.[10]

Fractional photothermolysis divides one laser beam into a number of microbeams, and targets 20–30% of skin tissue. The remaining normal epidermis and pilosebaceous units help wound healing. So, there are fewer side-effects and the recovery time is shorter than with conventional treatment.[11,12] In this study, we used RF radiation emitted by microneedles to achieve fractional photothermolysis. The INTRAcel contains 49 microneedles per cm^2 and the diameter of one microneedle is 100–200 μm. This limits epidermal damage from the microneedle itself, reducing crust and decreasing recovery time.

Because RF radiation has a short wavelength, there is little ion movement. It attacks polar molecules like water, amino acids and nucleic acids, and changes vibrating energy to thermal energy. Energy transmission changes according to the resistance of the tissue.[13] By imparting thermal energy, this radiation decreases activity of sebaceous glands and induces cytokines and growth factors, improving skin remodeling.[14,15] In contrast to laser therapy, it does not affect skin color, so it can be used on different types of skin and in people of different races. Despite these advantages, it can cause thermal damage to the epidermis.[8,16] However, in this study, we used insulated microneedles, which deliver RF radiation only at the tip. This targets thermal damage only to the intradermal region. We can put a microchip on this device that controls the depth to a range of 0.5–2.0 mm. Therefore, we can deliver high-intensity RF radiation without epidermal damage. Additionally, the large number of microneedles in the device can shorten the procedure time compared to other devices like

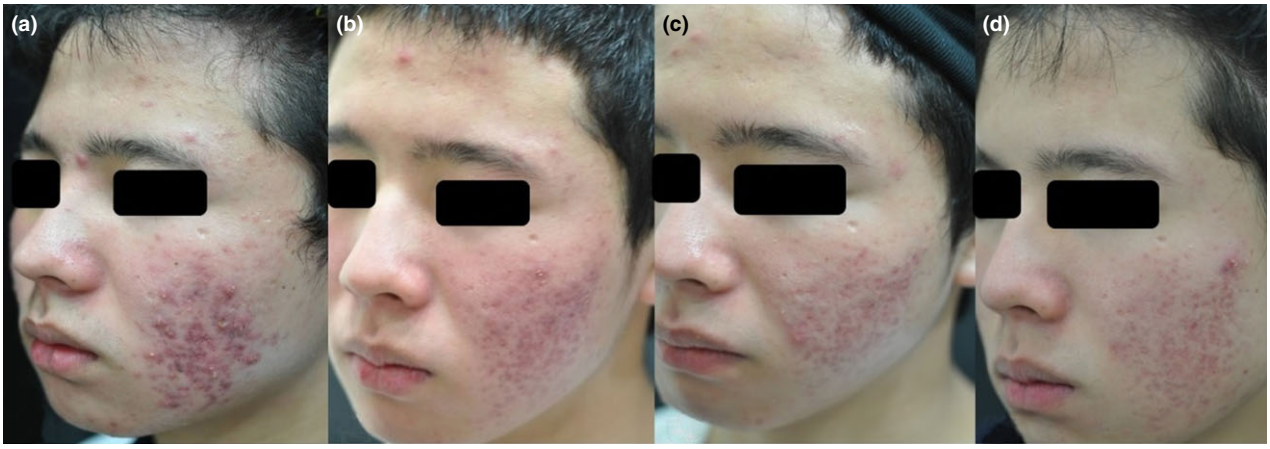

Figure 2. A 19-year-old male patient (a) before treatment, (b) after second treatment, (c) after 1 month of follow up and (d) after 3 months of follow up after fractional radiofrequency microneedling (case 3).

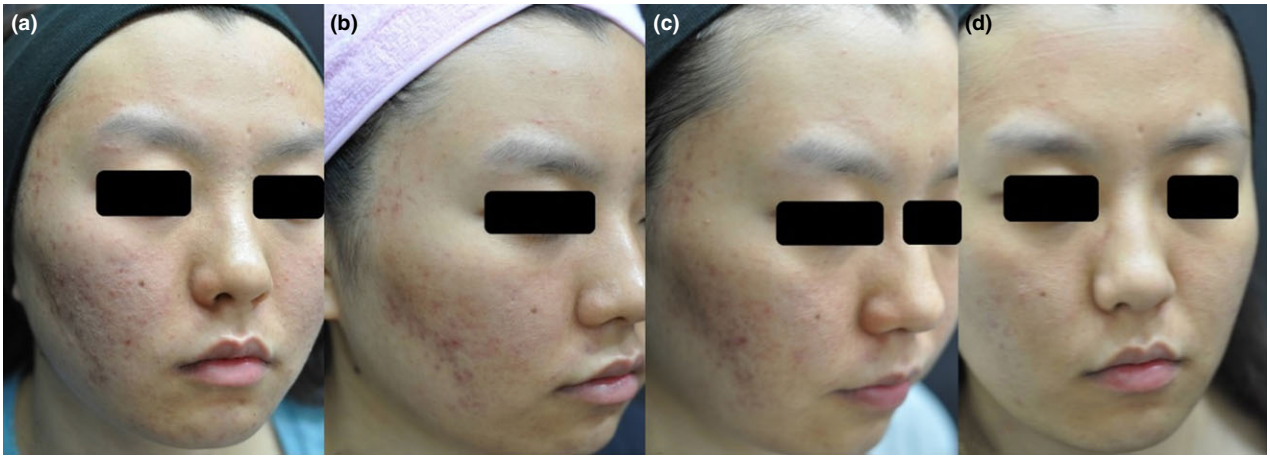

Figure 3. A 30-year-old female patient (a) before treatment, (b) after second treatment, (c) after 1 month of follow up and (d) after 3 months of follow up after fractional radiofrequency microneedling (case 10).

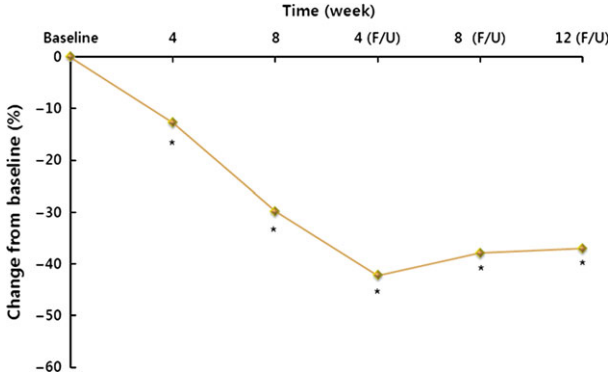

Figure 4. Mean percentage of sebum excretion was significantly decreased after each fractional radiofrequency microneedling (*$P < 0.05$).

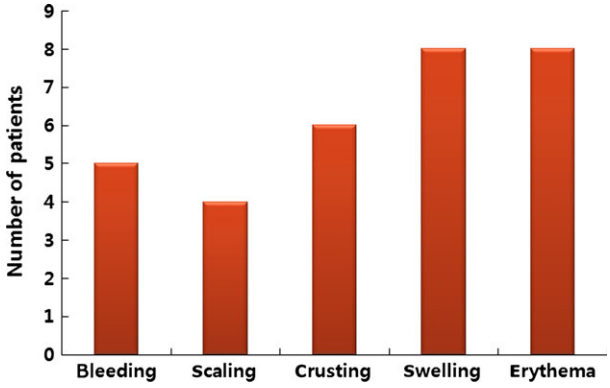

Figure 5. Number of patients who had each side-effect after fractional radiofrequency microneedling.

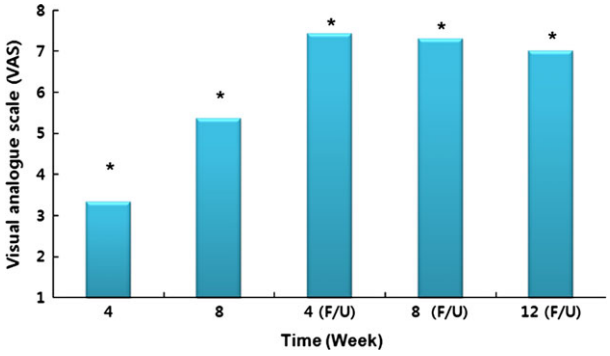

Figure 6. Mean changes in patient satisfaction score were statistically significant after each fractional radiofrequency microneedling and during 3 months of follow up (*$P < 0.05$).

the Kobayashi needle. The depth and intensity settings allow precise targeting of damage; at a given energy level, the damaged area is different according to the depth, and vice versa.[17]

The mechanism of fractional RF microneedling is thought to be similar to other kinds of laser or phototherapy. Prieto *et al.*[18] reported that combined therapy with RF radiation and pulsed light reduces the average area of sebaceous glands and perifollicular lymphocyte infiltrates. Hantash *et al.*[19] discovered that increases in transforming growth factor-β (TGF-β), matrix metalloproteinases-1 and -13, and heat shock protein 47 and 72, induce neocollagenesis and neo-elastogenesis. Ruiz-Esparza *et al.*[8] suggested that RF treatment-induced intradermal heating suppresses activity of sebaceous glands and facilitates skin remodeling. Therefore, in the treatment of acne it decreases the activity of sebaceous glands by imparting thermal energy, and subsequent remodeling of dermal structure produces clinical improvement.[14] The microneedle itself induces secretion of several growth factors, migration of keratinocytes and fibroblasts, and collagen synthesis.[20] Unlike with thermal damage, this induction is related to TGF-β.[14] Mechanical damage with microneedles also induces remodeling and generation of irregular and thick collagen bundles.[21]

There have been some studies that evaluate the effectiveness of fractional RF microneedling in the treatment of acne scar. However, there have only been a few reports regarding its efficacy on acne. Recently, Lee *et al.*[2] reported that fractional RF microneedling using a Scarlet (Viol, Sungnam, South Korea) containing 25 microneedles was safe and effective for the treatment of acne in 18 patients. Lee *et al.*[22] treated 20 acne patients with an Infini (Lutronic, Seoul, South Korea) containing 49 insulated microneedle electrodes in just one session, with follow up every 2 weeks from baseline to 8 weeks after the treatment. They showed 21.7% reduction in the number of acne lesions at 2 weeks after the treatment, but showed increase above baseline at week 4, and then showed 6% reduction at the end of the 8-week follow up. The casual sebum level decreased at 2 weeks after the treatment, and increased slowly but remained below the baseline until week 8. It is somewhat difficult to compare simply the result of their device with ours, because of the different number of treatment sessions and the different follow-up intervals. However, it was evident that their therapeutic effects remained shorter than ours, as compared with the results at 4 weeks after the first treatment of our study.

We treated 25 acne patients with an INTRAcel system containing 49 partially insulated microneedles a total of three times each at 1-month intervals, with follow up every month from before treatment to 3 months after the last procedure. The mean percentage decreases in inflammatory and non-inflammatory acne lesions at 1 month after the first treatment were 47.18% and 40.86%, respectively. There were statistically significant reductions in these lesions at each time point compared with baseline, to final reductions of 90.11% and 76.46%, respectively, at 3 months after the last treatment. Inflammatory lesions responded better than non-inflammatory lesions. The mean decrease in sebum excretion at 1 month after the third treatment was 42.18%, but sebum excretion increased slowly after treatment. At 3 months after the last treatment, the mean decrease in sebum excretion was 36.99%. Subjective satisfaction increased to 7.43 at 1 month after the last treatment, and was still 7 at 3 months after the last treatment.

Some side-effects were observed. Although the microneedles are small in diameter, there can be temporary bleeding. Bleeding occurred frequently when the procedure was conducted with a depth setting of 1.5 mm, but was uncommon in superficial procedures. The most severe complaint was pain. Topical anesthetics were not sufficient in patients with severe pain, but nerve blocking was helpful to reduce pain. If the laser tip was removed quickly, burns could occur due to current on the superficial epidermis, and postinflammatory hyperpigmentation could follow. In this study, transient bleeding, erythema and swelling were most severe right after the procedure, but subsided within 1 week. Hyperpigmentation, hypopigmentation, burns and scarring were not observed.

In the present study, 25 patients with moderate to severe acne were treated with fractional RF microneedling. Inflammatory and non-inflammatory acne lesion count, sebum excretion, subjective satisfaction score and adverse effects were assessed. Using objective parameters, we assessed safety and effectiveness. In conclusion, we suggest that fractional RF microneedling is safe and effective for the treatment of acne vulgaris.

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CONFLICT OF INTEREST: None declared.

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