

Evaluation of the Clinical Efficacy of Fractional Radiofrequency Microneedle Treatment in Acne Scars and Large Facial Pores

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BACKGROUND Fractional technology overcomes the problems of ablative lasers, such as inaccurate depth control and damage to the epidermis. Minimally invasive fractional radiofrequency microneedle devices allow for more-selective heating of the dermis.

OBJECTIVE To evaluate the clinical efficacy of fractional radiofrequency microneedle (ERM) treatment in acne scars and large facial pores.

MATERIALS AND METHODS Thirty patients with acne scars and large facial pores were enrolled. Bipolar radiofrequency energy was delivered to the skin through the electrodes of the FRM device. Skin lesions were evaluated according to grade of acne scars, Investigator Global Assessment of large pores, skin surface roughness, transepidermal water loss (TEWL), dermal density, microscopic and composite image, sebum measurement, and questionnaires regarding patient satisfaction.

RESULTS The grade of acne scars and Investigator Global Assessment of large pores improved in more than 70% of all patients. Skin surface roughness, dermal density, and microscopic and composite images also improved, whereas TEWL and sebum measurement did not change.

CONCLUSION Clinical improvement from FRM treatment appeared to be related to dermal matrix regeneration. FRM treatment may be effective in improving acne scars and facial pores.

The authors have indicated no significant interest with commercial supporters.

Unlike ablative lasers, fractional laser treatment has been shown to be clinically efficient in managing acne scars and other dermatologic diseases with cosmetic problems without causing direct damage to the epidermis.¹ Although conventional fractional treatment has some disadvantages of inaccurate depth control and possible indirect damage to the epidermis, a recently introduced minimally invasive fractional radiofrequency microneedle (FRM) device has been used to overcome such problems by creating radiofrequency thermal zones with minimal epidermal injury.²

After damage to the reticular dermis, long-term dermal remodeling, neolastogenesis, and neocollagenesis result in dermal thickening.³

Although previous studies on fractional lasers have confirmed their clinical efficacy in acne scars and large facial pores, the efficacy of FRM treatment in such skin conditions has not been fully elucidated.^{1,4}

This study was conducted to evaluate the clinical efficacy of FRM treatment of acne scars.

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Materials and Methods

Patient Selection

This study included 30 patients with mild to moderate facial acne scars and enlarged facial pores. There were of 12 men and 18 women aged 16 to 45. Exclusion criteria were concurrent systemic diseases (e.g., hematologic diseases with bleeding tendency or diabetes mellitus and atopic dermatitis affecting wound healing), currently taking anticoagulants or antiplatelet agents, pregnancy, previous history of frequent herpes simplex viral infection of the face, any esthetic procedures on the face within 6 months before the study, any implantable electronic device (e.g., pacemaker), active infection, and previous history of hypersensitivity to anesthetic creams. Only patients who consented to longitudinal follow-up during the study period were enrolled.

The Institutional Review Board of Kangnam Sacred Heart Hospital approved the protocol for the study. Informed consent was obtained from all participants.

Treatment Protocol

One day and 4 weeks after baseline measurements, patients underwent two sessions of radiofrequency treatment using a FRM device (INTRAcel; Jeisys, Seoul, Korea). The device uses bipolar radiofrequency technology to provoke plasma sparks, creating multiple partial thermal injury columns in the deep dermis. Bipolar radiofrequency energy is delivered through 49 microneedle electrodes in an area of 1 cm² and deployed into the deep dermis perpendicular to the skin surface. The entire needle electrode is nonconductive except the tip, beginning 0.3 mm from the distal end, to protect from radiofrequency heating at the insertion site. Radiofrequency energy is emitted to the dermis 0.2 seconds after microneedle insertion. The radiofrequency energy delivery durations differ according to energy levels. The currently available microneedles are 0.5, 0.8, 1.5, or 2.0 mm long. In

this study, only a 1.5-mm needle at a power of 500 W (maximum power 700 W) was used for treatment.

Immediately before treatment, all makeup was removed and the face was cleaned with facial foam cleanser and 70% alcohol. Topical lidocaine–prilocaine cream (EMLA Cream 5%; Korea AstraZeneca, Seoul, Korea) was applied under occlusion to both cheeks for local anesthesia 30 to 60 minutes before treatment. A full-face, double-pass treatment was performed using a FRM device with a depth of 1.5 mm. No epidermal cooling device was used simultaneously.

Clinical and Bioengineering Assessments of Facial Pores, Skin Roughness, Transepidermal Water Loss, Skin Density, and Sebum Quantity

Two dermatologists rated the acne scars as macular, mild, moderate, or severe: macular—erythematous, hyper- or hypopigmented flat marks; mild—mild atrophy or hypertrophy that may not be obvious at social distance of 50 cm or greater; moderate—moderate atrophic or hypertrophic scarring that is obvious at social distance of 50 cm or greater but can still be flattened by manual stretching of the skin; severe—severe atrophic or hypertrophic scarring that is obvious at social distances >50 cm and cannot be flattened by manual stretching of the skin.⁵ Gross photographic images were obtained using an Alpha 700 digital camera (Sony, Tokyo, Japan). The extent of enlarged facial pores was evaluated using the Investigator Global Assessment (IGA; 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, 4 = severe, 5 = very severe) based on photographic documentation. Other bioengineering measurements were made as follows: skin surface roughness using the GFM PRIMOS pico (GFM, Berlin, Germany), transepidermal water loss (TEWL) of two acne lesions and one control site using the Vapometer (Delfin, Kuopio, Finland), dermal density of the right cheek using Dermascan Ultrasound (Cortex Technology, Hadsund,

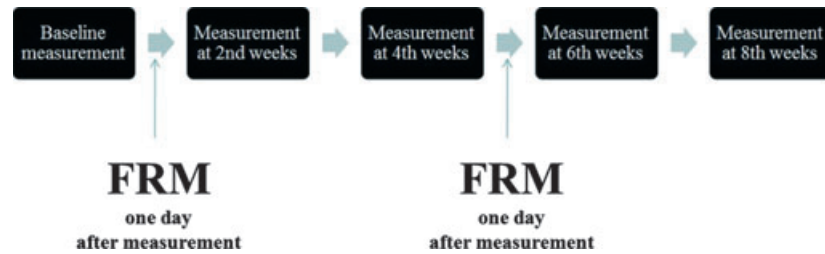


Figure 1. The schedules of skin measurements and fractional radiofrequency microneedle (ERM) treatment in this study.

Denmark), microscopic and composite images of the right cheek (depth of image, 100 μm ; original magnification $\times 30$) using confocal reflectance microscopy using a Vivascope 1500 (Lucid, Rochester, NY), and sebum measurement at an acne lesion and the control site using a sebumeter (SM 810; Courage + Khazaka electronic GmbH, Köln, Germany). The area of the facial pores in three 1- by 1-mm confocal microscopic images were measured using ImageJ 1.43u (National Institutes of Health, Bethesda, MD). These measurements were taken at baseline and weeks 2, 4, 6, and 8, except for microscopic and composite images, which were obtained only at baseline and weeks 4 and 8 (Figure 1).

At 12 weeks of follow-up, each patient filled out a questionnaire. Patient satisfaction was classified as very satisfied, satisfied, ordinary, dissatisfied or very dissatisfied. The questionnaire contained questions regarding pain during treatment (severe, moderate, mild, and none) and adverse events associated with the treatment, such as persistent pain, folliculitis, erythema, edema, hyperpigmentation, or hypopigmentation.

All statistical analyses were conducted using SPSS 12.0 for Windows (SPSS Korea, Inc., Seoul, Korea). The results were analyzed using Student *t*-tests or R-by-C crosstabs. Significance levels for all analyses were set at $p < .05$.

Results

Eight weeks after two sessions of FRM treatment, the grade of acne scars improved in 22 patients

(73.3%), did not change in seven (23.3%), and became aggravated in one (3.3%) (Figure 2). Of these 22 patients, one improved two grades from baseline, and 21 improved one grade. Enlarged pores improved in 21 patients (70%), did not change in seven (23.3%), and became aggravated in two (6.7%) (Figure 3). These results were not significantly different between sexes or between

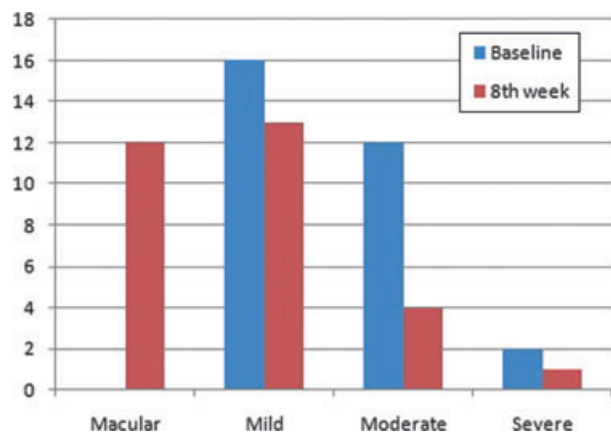


Figure 2. Changes in the grade of acne scars before and after treatment.

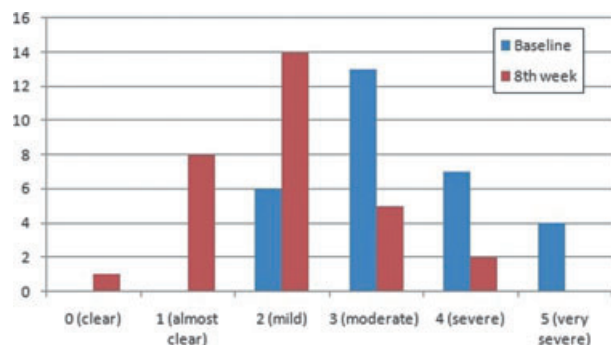


Figure 3. Changes in Investigator Global Assessment on large pores before and after treatment.

age groups. Clinical photographs taken in the eighth week showed improvement in acne scars and large pores (Figure 4).

Skin surfaces roughened slightly 2 and 4 weeks after treatment and softened 8 weeks after treatment (Figure 5A). These images were converted to the roughness parameters arithmetic average height and 10-point height.⁶ Both parameters increased during the procedures and decreased at completion of the procedure, although there were no significant differences ($p > .05$) (Figure 5B).

TEWL was decreased 2 weeks after treatment, but there were no significant differences between the

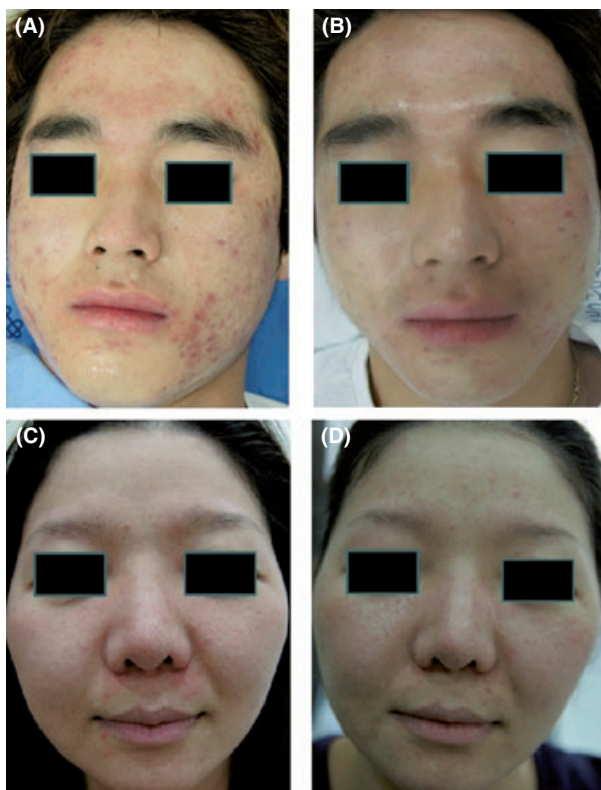


Figure 4. Atrophic acne scars and large facial pores in a 22-year-old man before (A) and 8 weeks after (B) two treatment sessions. The grade of acne scars and Investigator Global Assessment of large pores both changed from severe (4) to mild (2). Mixed atrophic and hypertrophic acne scars and large facial pores in a 32-year-old woman before (C) and 8 weeks after (D) two treatment sessions. The grade of acne scars changed from moderate (3) to mild (2), and Investigator Global Assessment of large pores changed from moderate (3) to almost clear (1).

acne lesions and control sites ($p > .05$). No significant changes in TEWL were noted (Figure 6). Dermal density decreased 2 and 6 weeks after treatment but increased 8 weeks after treatment, without significant differences ($p > .05$) (Figure 7A,B). On microscopic and composite images of the right cheek taken 8 weeks after treatment, enlarged pores became smaller and more even (Figure 8A). Image analysis revealed that the area of facial pores decreased 58.7%, with significant differences ($p < .001$) (Figure 8B). The size of the facial pores decreased in 22 patients (73.3%), did not change in seven (23.3%), and increased in one (3.3%). These results were consistent with IGA in 27 patients (90%) ($p < .001$). The sebum measurements were not significantly different between the acne lesions and the control sites after FRM treatment ($p > .05$). No significant changes in sebum measurements were noted (Figure 9).

Patient satisfaction at 12 weeks of follow-up was very satisfied in 12 patients (40%), satisfied in 14 (46.7%), ordinary in three (10%), dissatisfied in one (3.3%), and very dissatisfied in none (0%). Pain during the treatment was severe in two patients (6.7%), moderate in four (13.3%), mild in 18 (60%), and none in six (20%). The mean duration of visible erythema after treatment was 7.8 ± 2.6 days. Pain persisted for longer than 1 day in 10 patients (33.3%) and for longer than 3 days in five (16.7%). Folliculitis was observed in two patients (6.7%), but these lesions were mostly mild.

Discussion

Acne scars are one of the most distressing chronic dermatologic conditions and affect patients physically and psychologically because the lesions usually appear on the face.^{7,8} The negatively affect quality of life and can cause psychological problems such as depression and social avoidance.⁹ All efforts have been made to improve scars using chemical peels, intense pulsed light, nonablative and ablative lasers, fractional photothermolysis,

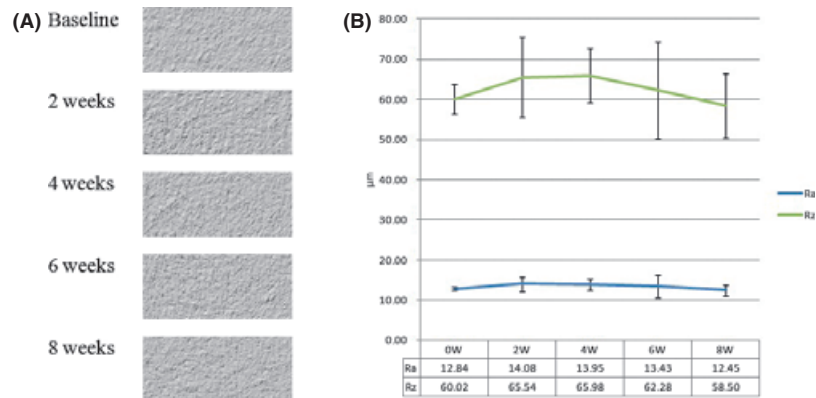


Figure 5. Three-dimensional images of skin surface roughness as assessed using GFM PRIMOS pico (A). Skin surface roughness was slightly roughened 2 to 4 weeks after treatment and softened 8 weeks after treatment. Laser treatment was performed the day after measurements at baseline and at 4 weeks. Ra, arithmetic average height; Rz, 10-point height.

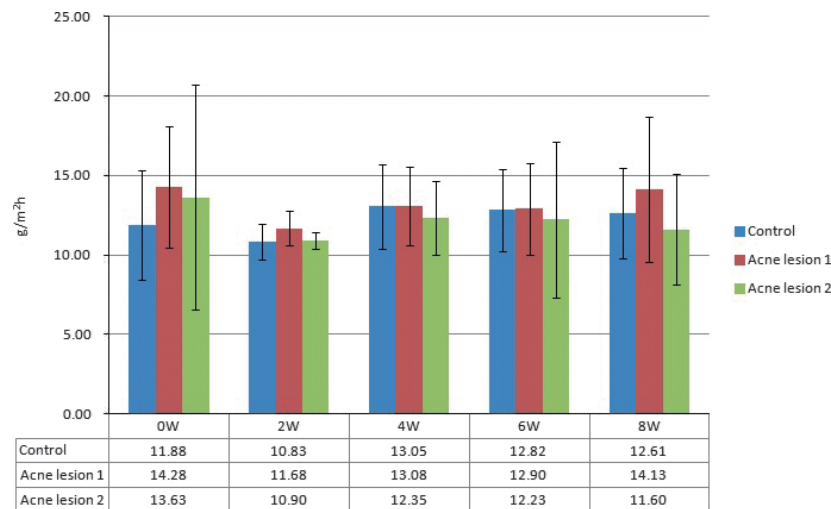


Figure 6. Transepidermal water loss was decreased 2 weeks after treatment, but the differences between the acne lesions and the control sites were not statistically significant. The overall changes in transepidermal water loss during the study was not statistically significant. Laser treatment was performed the day after measurements at baseline and at 4 weeks.

intralesional corticosteroid injection, and surgical removal,¹⁰ but some procedures have poor clinical outcomes, and others have disadvantages including pain during the procedure, long downtime, and a high rate of adverse events.

Enlarged facial pores that, in the past, were regarded as an irreversible aging process rather than a correctable cosmetic problem are now arousing new interest in dermatology with significant advances in dermatologic devices. Previous

studies have shown that pore size is associated with high sebum output level (seborrhea), aging, sex, genetic predisposition, chronic ultraviolet light exposure, and vitamin A deficiency.¹¹ Previous studies have indicated that enlarged pores are attributable to skin aging caused by changes in the dermal matrix.^{12,13} In skin aging, photoaging, one of the most important extrinsic factors, changes dermal thickness and disorients the dermal matrix, including collagen and elastin, by upregulating the matrix metalloproteinases.¹⁴ It

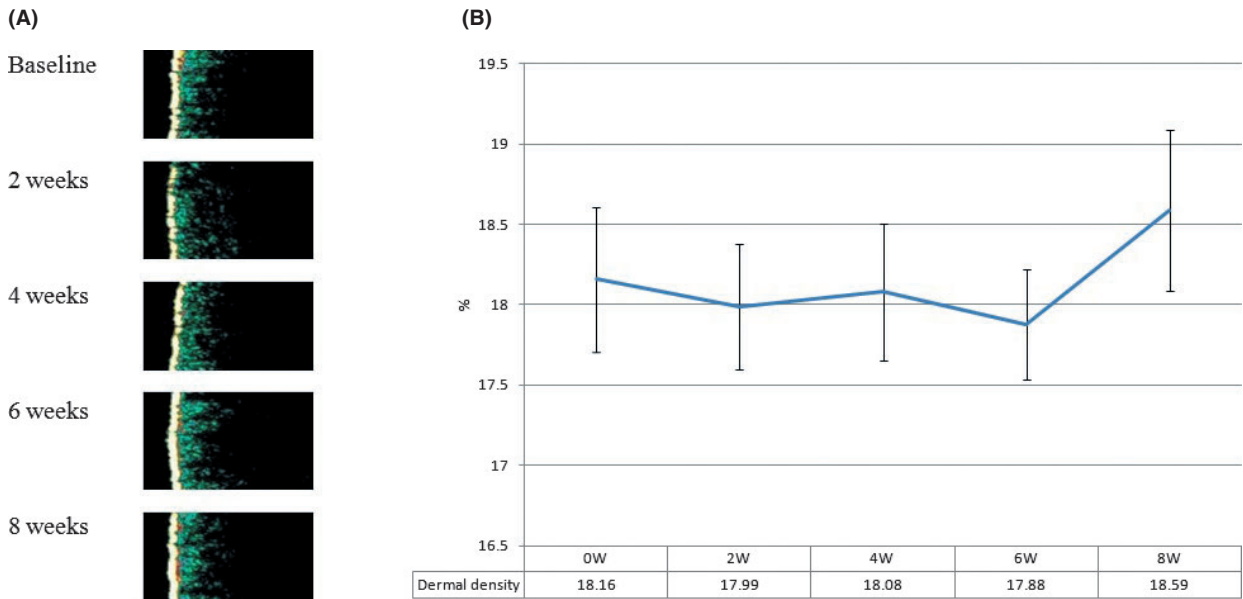


Figure 7. Images of dermal density of the right cheek (A). Dermal density decreased 2 and 6 weeks after the initial treatment, returned to baseline 4 weeks after treatment, and increased 8 weeks after treatment (B). Laser treatment was performed the day after measurements at baseline and at 4 weeks.

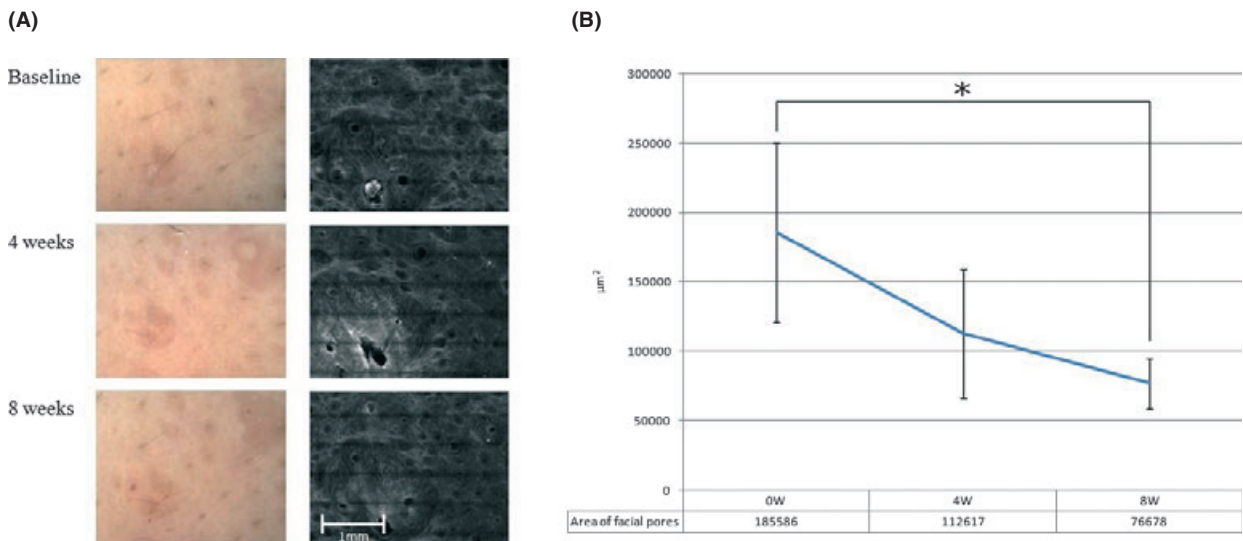


Figure 8. Microscopic and composite image of the right cheek showing changes in large pores (left, microscopic image; right: composite image; depth of image, 100 μm ; magnifying power $\times 30$) (A). The average total area of the facial pores decreased 58.7% ($*p < .001$) (B). Laser treatment was performed the day after measurements at baseline and at 4 weeks.

has been suggested that large pore size is more significantly associated with increased sebum output level than with sex or age.¹⁵ Excessive sebum excretion has been also accepted as one of the most important etiological factors in acne vulga-

ris, and patients with acne tend to have enlarged facial pores.¹⁶

Several previous studies have demonstrated the good clinical efficacy of fractional lasers in treating

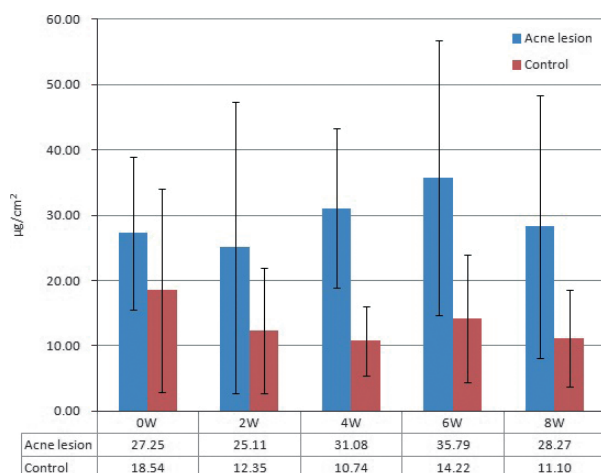


Figure 9. There were no significant differences in the amount of sebum between the acne lesions and the control sites. Laser treatment was performed the day after measurements at baseline and at 4 weeks.

acne scars and large facial pores,^{1,4} but these lasers can cause indirect damage to the epidermis, such as burns, and adjustments of the depth of radiofrequency thermal zones are imprecise. The newly introduced, minimally invasive FRM device is expected to overcome these limitations.^{2,17}

FRM treatment showed good outcomes in improving acne scars and large pores. Physician evaluation (grade of acne scars and IGA of large pores) and patient satisfaction showed overall improvement of more than 70%. There were temporary exacerbations of skin surface roughness and dermal density that had reversed by 8 weeks after treatment. Previous studies on the wound healing process after FRM treatment have shown that radiofrequency thermal zones containing denatured collagen were maintained in the reticular dermis for longer than 28 days after treatment, although new dermal tissue partially replaced the zones, and that various wound healing genes involved in dermal remodeling, such as tropoelastin and procollagen, steadily increased until 28 days after the procedure.³ This result is in accord with ours, which showed immediate regression by coagulation of the dermal matrix, as well as gradual remodeling by neoelastogenesis and neocollagenesis. Dermal density decreased 2

and 6 weeks after the 2-week treatment and increased 4 and 8 weeks after the 4-week treatment. In contrast, there were no significant differences in TEWL between the measurements before and after treatment. Because TEWL is mainly correlated with the skin barrier function of the epidermis, especially the stratum corneum, our results mean that FRM treatment could lead to only marginal changes in epidermal barrier function.¹⁸ Although microscopic and composite images showing minimized facial pores were consistent with IGA, they were in disagreement with sebum measurements showing insignificant changes. This indicates that changes in sebum excretion did not decrease the size of the facial pores. Instead, an increase in the dermal matrix by FRM treatment contributes to dermal thickening, increases the amount of collagen that had previously been decreased by photoaging, and rejuvenates the enlarged pores. It has been suggested that changes in facial pores may be attributed to dermis remodeling rather than a decline in sebum production.⁴

Although the adverse events from FRM treatment were infrequent and only transient, most patients complained of pain during the treatment and even intractable pain in some cases. The pain rarely persisted for several days, but it could influence patient adherence. Detailed description of side effects and adequate local anesthesia before treatment is necessary. The downtime of our treatment device seemed to be shorter than those of previous fractional lasers, even though there have been no comparative studies between the FRM device and other fractional lasers. When the needles are directly inserted into pores, they may increase pore size. Because the proportion of the large pores to all facial pores was small, there was low probability that the microelectrode would enter a large pore. Furthermore, because the treatment promotes dermal matrix regeneration, patients with predominantly hypertrophic acne scars may have a poor response or high complication rates. We did not experience any serious complications. Most of

our patients were satisfied with the treatment outcome.

This study evaluated the efficacy of FRM treatment using various noninvasive bioengineering tools. These recently developed tools are more physiologic than those used in previous studies. Moreover, our method is noninvasive. Although some measurements showed no statistical significance, probably because of small sample size, our FRM treatment improved skin lesions.

In conclusion, the results of this study suggest that FRM treatment could be effective in the treatment of acne scars and large facial pores, without significant adverse events, and may have some advantages in patient safety and a short down time.

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