ORIGINAL REPORT

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Comparison of Non-insulated Microneedle Fractional Radiofrequency and Ablative Fractional Carbon Dioxide Laser for the Treatment of Facial Atrophic Acne Scarring: A Pilot Randomized Split-face Clinical Study

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A study was undertaken to compare the effectiveness and adverse effects of non-insulated microneedle fractional radiofrequency (NIMFRF) and ablative fractional carbon dioxide ($AFCO_2$) laser on facial atrophic acne scarring in a randomized split-face model. Thirty subjects with facial atrophic acne scarring were enrolled. Each side of the face randomly received 1 session of NIMFRF or $AFCO_2$ laser. Photographs were taken by VISIA Complexion Analysis System at baseline, 1 month, 2 months, and 6 months after treatments. Subjective evaluations included Échelle d'Évaluation Clinique des Cicatrices d'Acné (ECCA) score, global improvement, and self-satisfaction. Potential adverse effects were also recorded. Skin melanin index and erythema index were measured. NIMFRF and $AFCO_2$ laser showed comparable efficacies on atrophic acne scarring ($p > 0.05$). ECCA scores decreased significantly at each follow-up visit, compared with baseline ($p < 0.05$). Approximate 95% of subjects achieved "satisfied" or "very satisfied" improvement. Pain was more obvious on the $AFCO_2$ laser side. Significantly increased red area value, melanin index and erythema index levels were seen on the $AFCO_2$ laser side at one month or 2 month, compared with the NIMFRF side ($p < 0.05$). NIMFRF has milder adverse effects with shorter recovery period than $AFCO_2$ laser. NIMFRF may be preferable for some patients due to its favourable adverse effect profile.

Key words: non-insulated microneedle fractional radiofrequency; ablative fractional carbon dioxide laser; atrophic acne scarring.

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SIGNIFICANCE

Facial acne scarring badly affects the quality of life and mental health of patients. Ablative fractional carbon dioxide laser has been used for the treatment of facial atrophic acne scarring. However, its adverse effects such as sharp pain, post-inflammatory hyperpigmentation, prolonged erythema, and substantial downtime limit its better application. Non-insulated microneedle fractional radiofrequency is a safe and efficient treatment for facial atrophic acne scarring. This study is the first to compare the clinical effectiveness and adverse effects of non-insulated microneedle fractional radiofrequency and ablative fractional carbon dioxide laser on facial atrophic acne scarring. Moreover, a randomized split-face model was employed. Non-insulated microneedle fractional radiofrequency and ablative fractional carbon dioxide laser are comparably effective for improving facial atrophic acne scarring. Non-insulated microneedle fractional radiofrequency has much milder adverse effects and a shorter recovery period than ablative fractional carbon dioxide laser.

Acne scarring is a common complication of acne vulgaris that can cause permanent disfiguration, occurring in up to 90% of acne patients to varying extents (1–4). The pathogenesis of atrophic acne scarring most probably relates to thickened bands of collagen that result in a retraction of the skin surface (1). Atrophic acne scarring on the face can have seriously negative effects on psychological well-being and patients' quality of life. Several modalities have been implicated as monotherapy and/or combination therapy to treat acne scarring, including punch subcision, excision, graft, chemical peels, laser (non-ablative and ablative) and radiofrequency (RF) (1, 3, 5–12). Although improvements in atrophic acne scarring can be achieved with these techniques, the advantages and disadvantages of each modality should be weighed (13).

Ablative carbon dioxide (CO_2) laser was once considered to be the criterion standard for skin resurfacing via the mechanism of thermal injury to induce neocollagenesis (14–18). Owing to its unacceptable adverse effects, ablative fractional laser was developed. Unlike classical CO_2 laser, ablative fractional CO_2 ($AFCO_2$) laser creates regions of columnar ablative thermal damage from the epidermis to reticular dermis, known as the microthermal treatment zones (MTZs), which stimulate re-epithelization via induction of wound healing, collagen production, and dermal remodelling. Among MTZs, there are intact microbridges that enable quicker recovery of surrounding epidermis to alleviate potential adverse effects (15–18). Nevertheless, to achieve sufficient clinical results in atrophic acne scarring, $AFCO_2$ laser still carries the risks of sharp pain, post-inflammatory hyperpigmentation (PIH), prolonged erythema, and substantial downtime (13).

RF is a type of alternative to atrophic acne scarring treatments (19–23). In contrast to lasers that target specific chromophore, RF is chromophore independent and has better penetration to the dermis and hypodermis as compared with light-based technologies (24). In a newly developed non-insulated microneedle fractional RF (NIMFRF) system, the needles are inserted into the skin by an electronically controlled smooth motion motor (25). When the needles reach the pre-defined insertion depth, RF is emitted with a fractional pulse model to selectively heat the dermis while sparing the epidermis. RF delivery over the whole dermal portion of the needle allows for effective coagulation, resulting in minimal or no bleeding as well as deep dermal heating (25).

Previous studies have demonstrated significant improvements in the treatment of atrophic acne scarring by $AFCO_2$ laser (26). NIMFRF was reported to be safe and efficient for atrophic acne scarring (27–29). However, a direct comparative study of the 2 approaches has not been carried out. Therefore, the present study was conducted to compare the clinical efficacy, safety, and adverse effects of NIMFRF and $AFCO_2$ laser on atrophic acne scarring in a randomized split-face model.

MATERIALS AND METHODS

Subject enrolment

The study period was set from March 2021 to October 2021. The ECCA (Échelle d'Évaluation Clinique des Cicatrices d'Acné) grading scale was used to evaluate the degree of scarring (30), and the facial atrophic acne scarring subjects with an ECCA score of more than 80 were set as enrolled criteria. Thirty Chinese subjects aged 18–40 years with Fitzpatrick skin types III and IV were enrolled.

The exclusion criteria were as follows: underwent concomitant acne scarring treatments in the previous 6 months, had a history of keloidal tendency or photosensitivity, had any other skin diseases or any systemic diseases, or were in varying stages of pregnancy and lactation. During the study period, the subjects were not permitted to receive any other facial cosmetic treatments.

Devices and treatment

The closed-envelope technique for randomization was used to determine which side of the face would receive 1 session of NIMFRF (Intensif, EndyMed, Caesarea, Israel), and the other side was treated by 1 session of $AFCO_2$ laser (Ultrapulse, Lumenis, Santa Clara, USA).

The specific parameters were set and adjusted based on skin type, skin thickness, acne scarring severity, and skin reaction immediately after treatments. For NIMFRF, needles with 25 non-insulated gold-plated microneedle electrodes were set at a penetration depth of 1.5–2.5 mm; the pulse duration was 80–110 ms with 2 to 3 passes and the intensity 12–17 W. For $AFCO_2$ laser, a DeepFX Handpiece with micro spot diameter of 0.12 mm and ActiveFX Handpiece with micro spot diameter of 1.25 mm were used. The parameter settings of the DeepFX Handpiece were energy of 10–12.5 mJ, density of 5%, and frequency of 500–600 Hz. The parameter settings of the ActiveFX Handpiece were energy of 100–125 mJ, density of 4–5%, and frequency of 500–600 Hz.

Before treatments, lidocaine cream was applied for topical anaesthesia and 75% alcohol was used for sterilization. Immediately after treatments, desonide cream, fusidic acid cream, and recombinant human epidermal growth factor gel was topically applied as previously (17,18). Subjects were advised to wear broad-spectrum sunscreen and moisturizing cream every day (17,18).

Clinical evaluations

Photographs of each subject were taken at baseline, and 1, 2, 3, and 6 months after the treatments (M1, M2, M3, M6), using a digital camera (Canon EOS 6D, Tokyo, Japan) and VISIA Complexion Analysis System (Canfield, Fairfield, USA). Based on the photographs, 2 unbiased dermatologists who were blinded to the randomization and treatment evaluated the acne scarring degree using the ECCA grading scale (30). Another 2 dermatologists, who were unaware of the side to which NIMFRF and $AFCO_2$ laser was given, evaluated the efficacies by using a 5-point clinical scale, i.e., 0%, 1–25%, 26–50%, 51–75%, and 76–100% improvement. Subjects evaluated their satisfaction in the improvement of acne scarring on each side of the face, respectively, using a 4-grade scale (dissatisfied, somewhat satisfied, satisfied, very satisfied).

The possible adverse effects, which included pain, burn sensation, pruritus, erythema, effusion, oedema, crust, PIH, hypopigmentation, infections, acneiform eruption, blisters, erosion, or worsening of scarring, were recorded. Pain was assessed using visual analogue scales (VAS, from 0 = no pain to 10 = worst pain ever).

Noninvasive measurements

At each time point, a Mexameter (MX18, Courage+Khazaka, Cologne, Germany) was used to measure melanin index (MI) and erythema index (EI), and a Sebumeter (SM810, Courage+Khazaka) was applied to measure skin sebum levels respectively. MI, EI, and skin sebum levels were measured in triplicate on each side of facial sites including the forehead, temporal area, cheekbone, cheilion, and chin to calculate the mean values.

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Statistical analysis

Statistical analyses were performed using SPSS 19.0 software (IBM Corp, Armonk, NY, USA). The Kruskal–Wallis test and Mann–Whitney *U* test were used for intragroup comparison or intergroup comparison. A *p*-value of less than 0.05 was considered statistically significant.

RESULTS

Subjects' baseline characteristics

In total, 30 subjects (14 males and 16 females) aged 19 to 37 years (average 26.9 ± 5.7 years) with Fitzpatrick skin types III (18 subjects) or IV (12 subjects) completed the entire study. The duration of facial atrophic acne scarring ranged from 1 to 10 years (median 6 years). Of the 30 subjects, 4 subjects underwent ablative laser treatment and 3 subjects underwent non-ablative laser treatment, more than 6 months ago (Table SI).

ECCA grading scale

On the NIMFRF side, the mean ECCA score was 118.37 ± 15.92 at baseline, which decreased significantly to 94.65 ± 18.65 at M1 ($p < 0.01$), and decreased continuously to a very low level of 76.38 ± 13.61 at M6 ($p < 0.01$). The mean decreases from baseline ranged from 24.43 ± 7.15 to 39.27 ± 9.67 at various follow-up visits. Significant difference was seen between M1 vs M3 ($p < 0.05$) and M1 vs M6 ($p < 0.05$). No difference was seen between other comparisons.

On the $AFCO_2$ laser side, the mean ECCA score was 113.89 ± 16.32 at baseline, obviously reduced to 88.23 ± 15.76 at M1 ($p < 0.01$), and continuously descended to a very low level of 77.63 ± 15.23 at M6 ($p < 0.01$). The mean decreases from baseline ranged from 25.42 ± 7.34 to 36.23 ± 10.15 at various follow-up visits. A significant difference was seen between M1 vs M3 ($p < 0.05$) and M1 vs M6 ($p < 0.05$). No obvious difference was seen between other comparisons.

There was no difference between the NIMFRF side and the $AFCO_2$ laser side either at baseline or at each follow-up visit. The mean ECCA scores and mean decreases in ECCA scores on the 2 sides are shown in **Fig. 1**. The representative clinical photographs of subjects treated by NIMFRF and $AFCO_2$ laser are presented in **Fig. 2**.

Global improvement evaluation

All subjects, whether receiving the NIMFRF treatment or the $AFCO_2$ laser treatment, were not graded 0% improvement or 76–100% improvement at any follow-up visit. Only 1 subject achieved 51–75% improvement after both the NIMFRF treatment and the $AFCO_2$ laser treatment at M1, and the good efficacy was maintained from M2 to M6. All the other 29 subjects were rated as 1–25% improvement or 26–50% improvement treated by the 2 devices at all follow-up visits. For the NIMFRF, the subjects who achieved 26–50% improvement were 53.34% at M1, and ranged from 46.67% to 56.67% from M2 to M6. For the $AFCO_2$ laser, the subjects who achieved 26–50% improvement were 36.67% at M1, and fluctuated around 50% at other follow-up visits. No differences were seen among different follow-up visits, on either the NIMFRF side or the $AFCO_2$ laser side.

When comparing the numbers of subjects who achieved 1–25% improvement and 26–50% improvement using the NIMFRF and the $AFCO_2$ laser, no difference was seen between the 2 treatments at any time points. The detailed results of global improvement evaluation were presented in Table SII.

Subject satisfaction

No subject rated as being dissatisfied with the NIMFRF treatment or the $AFCO_2$ laser treatment, and only 1 to 2 subjects rated as being somewhat satisfied. For NIMFRF, 60.00% subjects rated as being very satisfied at M1, and

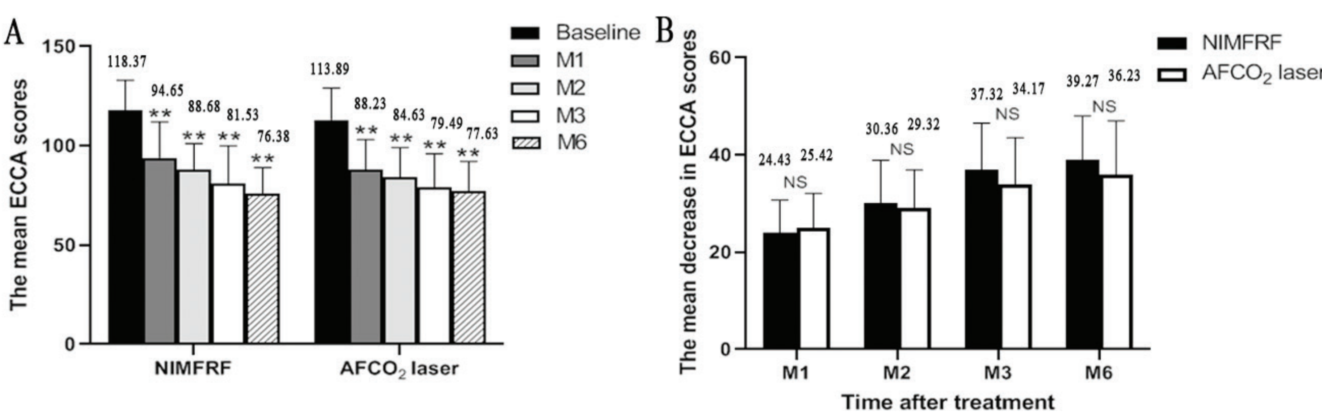

Fig. 1. Mean ECCA scores and mean decreases in ECCA scores on the NIMFRF and $AFCO_2$ laser sides. (A) Both on the NIMFRF side and $AFCO_2$ laser side, the mean ECCA scores were significantly decreased compared with the baselines. (B) For the mean decreases in ECCA scores, there was no difference between the NIMFRF side and the $AFCO_2$ laser side either at baseline or at each follow-up visit. $^{**}p < 0.01$; NS, $p > 0.05$.

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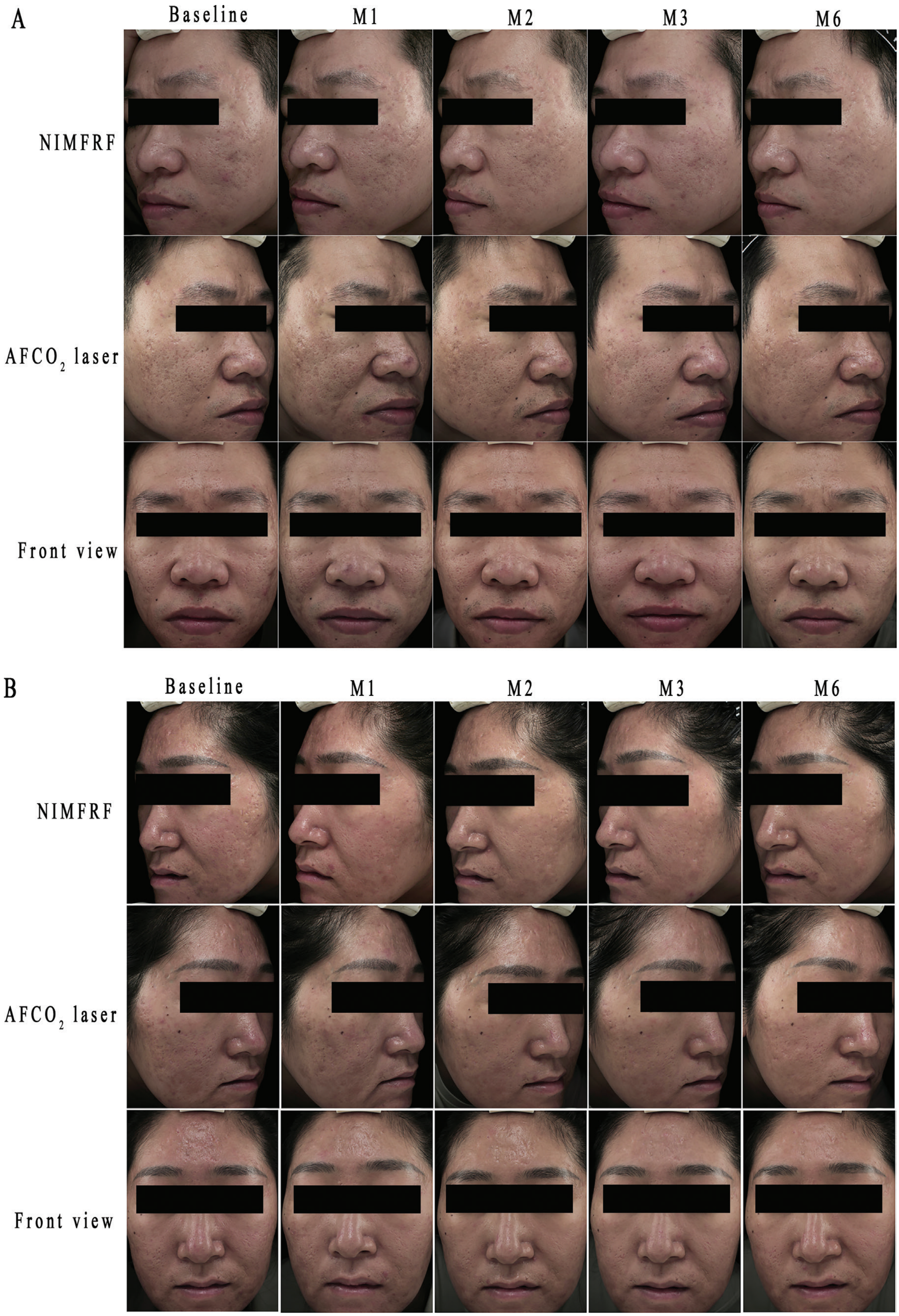

Fig. 2. Representative clinical photographs of (A) a 25-year-old man and (B) a 32-year-old woman before and after treatment with NIMFRF and AFCO$_2$ laser. After NIMFRF and AFCO$_2$ laser treatment, facial atrophic acne scarring was significantly improved. Both modalities achieved similar therapeutic effect.

the subjects' percentages were sustained above 53% from M2 to M6. For AFCO$_2$ laser, 40.00% subjects rated their satisfaction as very satisfied at M1, and the subjects' percentages were 53.33% to 56.67% at other follow-up visits. No differences were seen among different follow-up visits on either the NIMFRF side or the AFCO$_2$ laser side. In all, approximate 95% subjects were satisfied to very satisfied with either NIMFRF or AFCO$_2$ laser, and no difference was found between these 2 modalities. The detailed results of subject satisfaction evaluation are presented in Table SIII.

Non-invasive measurements

Eight indexes including pores, texture, wrinkles, spots, UV spots, brown spots, porphyrins, and red areas were measured by VISIA. At baseline, the values of red areas were 2.81 ± 0.76 and 2.79 ± 0.84 on the 2 sides. The values remained unchanged on the NIMFRF side and significantly increased to 3.99 ± 0.85 on the AFCO$_2$ laser side ($p < 0.05$) at M1, and the latter was significantly higher than the former ($p < 0.05$). Other comparisons of red areas were not statistically different (**Fig. 3**, **Fig. 4**A). Comparing with baseline (3.54 ± 1.09 and 3.71 ± 1.26 on the 2 sides), the values of pores significantly descended to 2.55 ± 0.67 on the NIMFRF side and 2.68 ± 0.54 on the AFCO$_2$ laser side at M1 ($p < 0.05$), and were maintained at similarly low levels at the M2, M3, and M6 follow-up visits. No differences were found among the 4 follow-up visits for the NIMFRF side or the AFCO$_2$ laser side. Also, no difference was found between the NIMFRF side and the AFCO$_2$ laser side at each time point (Fig. 4B). Meanwhile, the comparisons of skin texture, wrinkles, spots, UV spots, brown spots, and porphyrins were not significantly different among diverse time points or between the 2 treatments (data not shown).

Significant increases in MI and EI values were seen on the AFCO$_2$ laser side at M1 and M2. There was a significant difference in increased MI values between these 2 treatments at M1 (NIMFRF 10.03 ± 3.77 vs AFCO$_2$ laser 61.90 ± 26.14, $p < 0.001$) and the difference still existed at M2 (NIMFRF 7.30 ± 6.74 vs AFCO$_2$ laser 24.53 ± 9.68, $p < 0.05$) (Fig. 4C). There was also a significant difference in increased EI values between these 2 treatments at M1 follow-up (NIMFRF 16.20 ± 9.20 vs AFCO$_2$ laser 81.57 ± 35.17, $p < 0.05$). There were no differences at other time points (Fig. 4D). The skin sebum levels significantly decreased to about 40% at M1 and recovered to the baseline levels at M2 (Fig. 4E). The decrease in value of NIMFRF was 59.43 ± 23.38 and that of AFCO$_2$ laser was 53.20 ± 24.03 at M1, and the difference produced by the 2 devices was not statistically significant (Fig. 4E). No other differences were seen for MI, EI, or sebum content.

Adverse effects

Generally, all the reported adverse effects were observed on both sides of the face and tolerable, during and/or after the 2 modalities. The degrees were much milder and the lasting times were threefold to sevenfold shorter on the NIMFRF side than the AFCO$_2$ laser side ($p < 0.05$) (Fig. S1, **Table I**). Pains, burning sensation, erythema, oedema, and crust were found in all subjects. Pruritus was reported by 3 subjects on the NIMFRF side and by 10 subjects on the AFCO$_2$ laser side. Effusion was observed

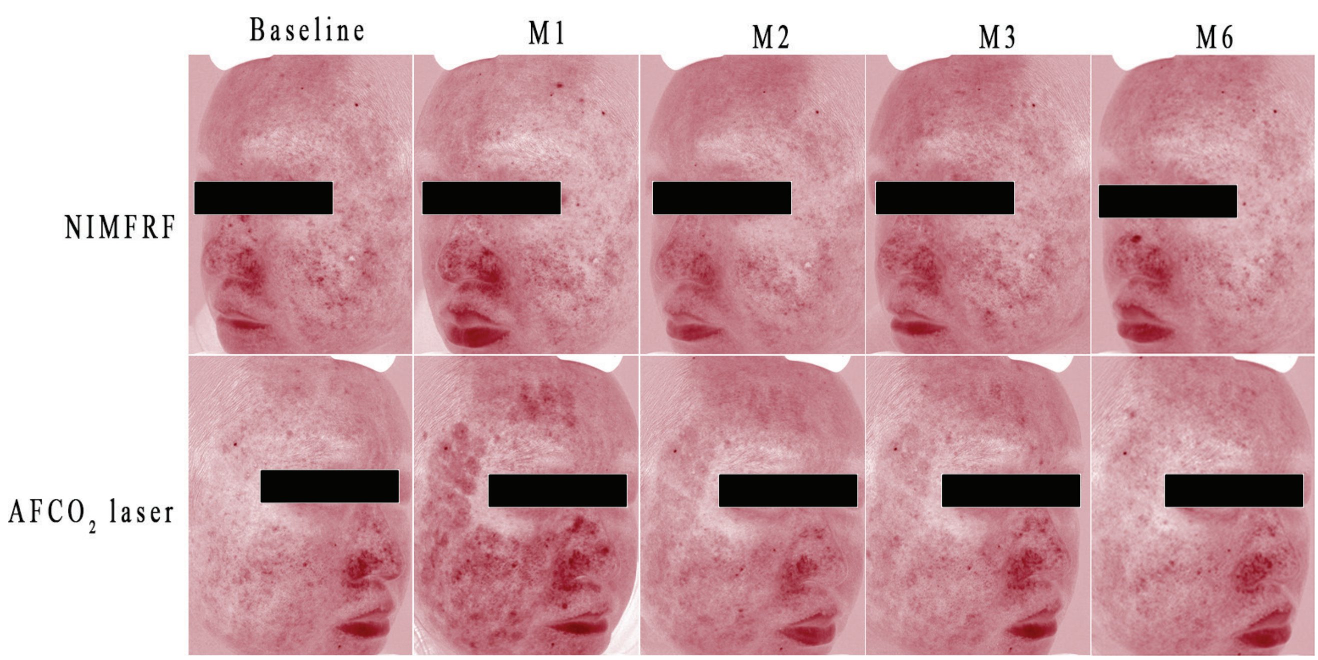

Fig. 3. Changes in red area under VISIA Complexion Analysis System on the NIMFRF and AFCO$_2$ laser sides. The erythema of the AFCO$_2$ laser side was more severe than the NIMFRF side at M1, and comparable at other follow-up visits.

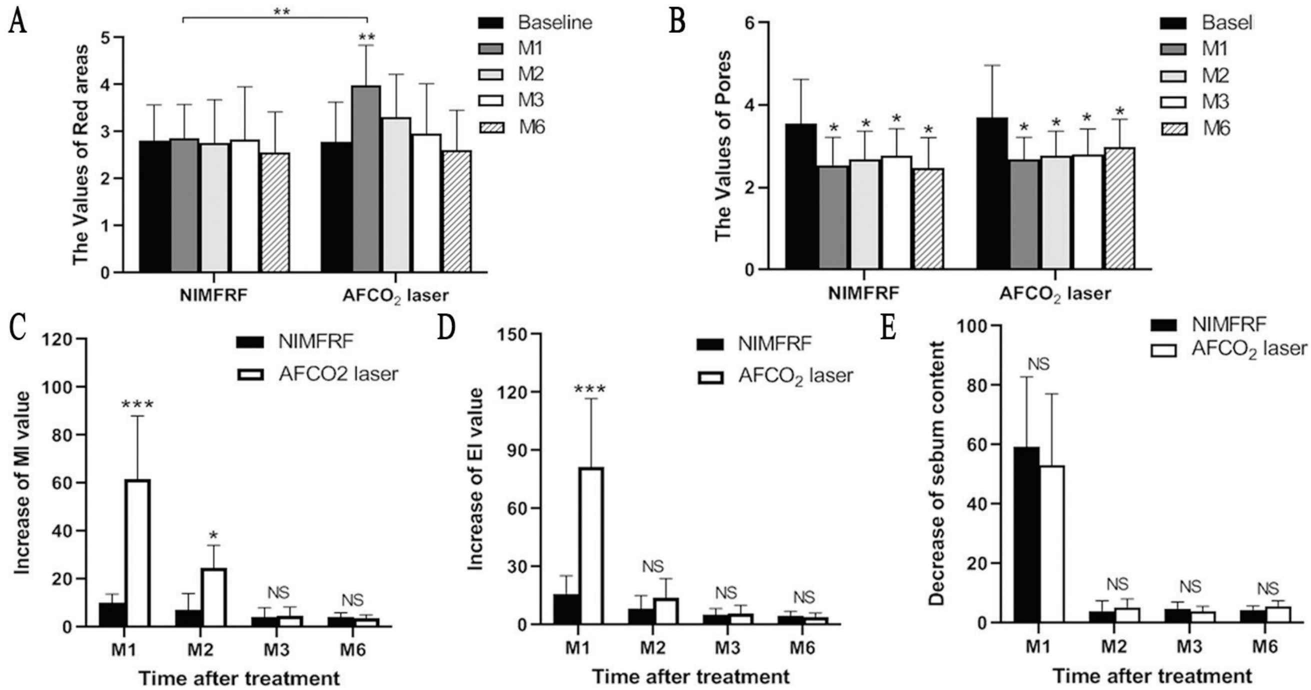

Fig. 4. Measure indexes using VISIA Complexion Analysis System: changes in MI and EI values and skin sebum content on the NIMFRF and AFCO$_2$ laser sides. (A) The values of red areas on the AFCO$_2$ laser side were significantly higher than that of the NIMFRF side at M1, and no differences were seen at other time points. (B) The values of pores significantly decreased after NIMFRF and AFCO$_2$ laser treatments and the difference in the 2 devices was not statistically significant. Significant increases in MI and EI values were seen on the AFCO$_2$ laser side at M1 follow-up visit. (C) The increases in MI value were much higher on the AFCO$_2$ laser side than the NIMFRF side at M1 and M2. (D) The increase of EI value was much higher on the AFCO$_2$ laser side than the NIMFRF side at M1. No significant difference was seen at other time points. Significant decreases in skin sebum content were seen on both the NIMFRF and AFCO$_2$ laser sides at M1. (E) The changes of skin sebum content were not significant between the 2 sides at any other time point. ***$p < 0.001$, **$p < 0.01$, *$p < 0.05$; NS, $p > 0.05$.

in 5 subjects on the NIMFRF side and 19 subjects on the AFCO$_2$ laser side. PIH was observed in 2 subjects on the NIMFRF side and in 11 subjects on the AFCO$_2$ laser side. No hypopigmentation, infections, acneiform eruption, blisters, erosion, or worsening of scarring were seen on either the NIMFRF side or the AFCO$_2$ laser side.

DISCUSSION

Atrophic acne scarring, one of the common complications of acne, can be physically challenging and psychologically devastating (26). AFCO$_2$ laser has been regarded as a criterion standard of skin resurfacing and widely applied to treat atrophic acne scarring since its invention (7, 15–17, 31–33). When newly developed technologies for atrophic acne scarring need to be justified, AFCO$_2$ laser can be used as a reference (31, 34). Besides, the split-face manner is the most direct method to compare 2 modalities. Previously, 2 split-face studies compared RF with AFCO$_2$ laser in the treatment of atrophic acne scarring, and the RF devices belong to fractional RF or microneedle fractional RF (31, 35). With the development of RF technology, the NIMFRF we used here is an upgrading type of fractional RF or microneedle fractional RF. Two disadvantages of previous fractional RF or microneedle fractional RF are significant micro-bleeding during the treatment and/or the need for many passes at different depths to cover the entire dermis (23, 24). In current study, we first compared NIMFRF with AFCO$_2$ laser for the treatment of atrophic acne scarring in a split-face manner. No subject developed micro-bleeding by NIMFRF, as RF emission delivered over the whole needle length allows better coagulation and heating of higher volumes of dermal tissue (23, 24).

In our study, the ECCAs descended by approximately 20% at M1 and further decreased about 30% at M6 from baseline with treatment by either NIMFRF or AFCO$_2$ laser, indicating a long-term process of collagen resynthesis and remodelling. Reductions of enlarged pores, showing about 28% decrease in pore values, further con-

Table I. Adverse effects of NIMFRF and AFCO$_2$ laser treatments (median)

Item	NIMFRF	AFCO$_2$ laser	p-value
Pain (VAS)	3	8	< 0.0001
Pain (hours)	4	16	< 0.0001
Burning sensation (hours)	2	8	< 0.0001
Pruritus (days)	1	3	< 0.01
Erythema (days)	2	7	< 0.001
Effusion (days)	1	3	< 0.01
Oedema (hours)	3	9	< 0.001
Crust (days)	1	7	< 0.0001
PIH (days)	3	21	< 0.0001

NIMFRF: non-insulated microneedle fractional radiofrequency; AFCO$_2$: ablative fractional carbon dioxide. Pain was assessed using visual analogue scales (VAS, 0 = no pain and 10 = worst pain ever). PIH: post-inflammatory hyperpigmentation.

firmed the collagen regeneration induced by treatments. About 40% decreased sebum secretion was also helpful for improving enlarged pores; however, the reductions were temporary and recovered to the baseline levels after M1 on both the $AFCO_2$ laser and NIMFRF sides. The results indicated that compared with decreased sebum secretion, collagen regeneration contributed more to pore improvement. As the reason for skin sebum production decreased, we speculated that $AFCO_2$ laser and NIMFRF exerted their effects through bulk heating of the dermis, which in turn damaged the sebaceous glands, resulting in a decrease in sebum production. Other studies also observed similar results after laser and radiofrequency treatments (36, 37). The global improvements as assessed by dermatologists showed that about 40–50% of subjects achieved 26–50% improvement and another 50% achieved only 1–25% improvement. In one previous split-face fractional microplasma RF vs $AFCO_2$ laser comparison study, the improvement rate was nearly 60% by each modality (31). The mean ECCAs of enrolled subjects in that study were around 50, and each subject received 3 sessions of treatments at average intervals of 8 weeks (31). In contrast, the subjects enrolled in our study were more severely affected, with a mean ECCA score of more than 110, and only 1 session of treatment was applied to each subject. Nevertheless, about half of the subjects rated being satisfied to very satisfied with both modalities. We consider that when more sessions are applied in future, greater improvements will be achieved.

The efficacies of the NIMFRF and the $AFCO_2$ laser treatment were comparable without significant difference in the present study. In another split-face trial, microneedle fractional RF (MNRF) vs $AFCO_2$ laser was also equally effective at improving acne scarring (35). Meanwhile, there a prospective study (38) and a retrospective study (39) indicated that fractional carbon dioxide laser and MNRF showed equivalent efficacy in the treatment of acne scarring.

Although efficacies were comparable, the adverse effects of $AFCO_2$ laser were relatively more severe and longer than those of NIMFRF. The objective results of increased MI, EI, and red area values at M1 or M2 conformed to the subjective recordings. Fortunately, the adverse effects were transient and endurable, and no serious adverse effects developed. Thus, the adverse effects of the $AFCO_2$ laser treatment did not frustrate the subjects' willingness to attend the next session. Other problems exist with the NIMFRF device. The sterile treatment tip is a disposable consumable, which means a tip can be used for only 1 subject for 1 session of treatment. Therefore, the cost of a patient undergoing NIMFRF is higher than that of using the $AFCO_2$ laser. Moreover, the whole treatment duration of NIMFRF is longer than that of $AFCO_2$ laser. However, it needs more patience on the part of the conductor and also the patient. Clinically, doctors should fully discuss with patients the choice of NIMFRF or $AFCO_2$ laser, by weighing efficacies, expense, and adverse effects of the 2 modalities.

In conclusion, in this study, we not only confirmed that both NIMFRF and $AFCO_2$ laser were effective and safe for the treatment of facial atrophic acne scarring, but also for the first time demonstrated that the 2 modalities achieved comparable clinical outcomes. Moreover, NIMFRF had milder adverse effects with shorter downtime than $AFCO_2$ laser. The limitation of our present study was the small number of patients and the absence of histological investigation. In the future, larger scale randomized controlled trials (RCTs) with more sessions of treatments need to be done to verify the current results.

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Data availability statement: The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethical approval: The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of the First Hospital of China Medical University (protocol code 2021-216-2; date of approval 8 March 2021).

Informed consent statement: Informed consent was obtained from all subjects involved in the study.

The authors have no conflicts of interest to declare.

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