Fractional Microplasma Radiofrequency Technology for Non-Hypertrophic Post-burn Scars in Asians: A Prospective Study of 95 Patients

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Background: Laser and other energy devices are emerging, minimally invasive treatments for scars. Among the various techniques, fractional microplasma radiofrequency technology (FMRT) has proven to be an effective treatment option for various types of scars and skin conditions such as rhytids, striae distensae, and hyperpigmentation.
Objective: This prospective clinical trial was designed to evaluate the efficacy and safety of FMRT for treating non-hypertrophic post-burn scars in the Asian population.
Method: All patients underwent three to five treatment sessions at various intervals of 8–16 weeks. The Patient and Observer Scar Assessment Scales (POSAS) [20] were used to evaluate changes in burn scars pre-and post-FMRT treatment.
Results: A total of 95 patients completed the study. The overall response rate was 86.3% (82/95). The total POSAS scores before and after 6 months of treatment were 53.41 ± 6.28 and 46.35 ± 5.30, respectively. There was statistically significant improvement in scar color, thickness, and pliability. There was no improvement in vascularization, pain, or itching. Complications included prolonged post-inflammatory hyperpigmentation, acne eruption, herpes simplex eruption, and abnormal hair growth. No severe adverse events, such as acute skin infection, hypertrophic scarring, or depigmentation, were observed.
Conclusion: FMRT is an efficacious, safe treatment for non-hypertrophic burn scars in the Asian population. Lasers Surg. Med. © 2017 Wiley Periodicals, Inc.

Key words: burns; cicatrix; micro-plasma; radiofrequency; scars; lasers

INTRODUCTION

Burns are a global public health concern, causing millions of cases of disability and disfigurement worldwide each year [1]. Current treatment methods for burn scars are complex and comprehensive [2,3]. Because most non-hypertrophic burn scars do not cause dysfunctional problems, the primary goal of treatment is to improve the patient's appearance. Hence, surgical treatment (e.g., flap transplantation, skin grafts, tissue expander implantation) tends to result in patient dissatisfaction due to unsatisfactory postoperative appearance, major donor-site morbidity, and prolonged treatment duration.

Laser therapy has been considered as a safe, effective, and minimally invasive treatment for burn scars. Techniques include the use of fractional CO_2 laser, 2940-nm Er: YAG laser, pulsed dye laser, and non-ablative fractional laser [4–7].

Fractional microplasma radiofrequency technology (FMRT) is a novel treatment that creates "plasma," a state of matter in which a portion of gas molecules are ionized [8]. Plasma sparks provoked at a small distance on the skin surface produce a crater-like microscopic treatment zone [9] and induce subsequent dermal remodeling and maturation [10]. Clinical application of FMRT has shown positive results with fewer adverse events than ablative lasers on acne scars, hyperpigmentation, rhytids, striae distensae, and skin graft contracture [11–15].

Post-inflammatory hyperpigmentation (PIH) has been considered as a major adverse event associated with laser therapy, especially in patients with darker skin [16]. A randomized split-face study, however, showed that PIH was greatly reduced on the FMRT-treated side compared with that on the CO_2 laser-treated side [17]. Another application of FMRT involves transepidermal drug delivery (TED) through dermal channels caused by plasma sparks. Combined FMRT and TED technology has shown positive results for treating hypertrophic scars and acne scars [18,19]. The purpose of this study is to evaluate the efficacy and safety of FMRT for treating non-hypertrophic post-burn scars in an Asian population.

Rui Jin and Jiying Dong contributed equally to this work as co-corresponding authors.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Forms for Disclosure of Potential Conflicts of Interests and none were reported.

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MATERIALS AND METHODS

Patients

From March 2012 to May 2014, a total of 108 Chinese patients with ≥1-year-old non-hypertrophic burn scars in various anatomic areas were enrolled in this study. Exclusion criteria included pregnancy or breastfeeding, history of hypertrophic scars or keloids, dermabrasion, or laser treatment within the past 6 months, and/or the presence of a cardiac pacemaker or other metallic implant near the treatment site. Each patient underwent a routine medical history and physical examination.

Informed consent was obtained from each patient. The study was performed in accordance with the guidelines of the 1964 Declaration of Helsinki. The study protocol was approved by the local institutional ethics review committee.

Treatment Protocols

A mild cleanser of 70% alcohol, 5% Lidocaine Hydrochloric Gel (Beijing Ziguang Medication Manufacture Corporation Ltd, Beijing, China) was applied to the entire scar surface of the patient under occlusion for 60–90 minute prior to FMRT treatment for local anesthesia. Fractional micro-plasma radiofrequency treatment (Pixel RF, Accent XL; Alma Lasers, Caesarea, Israel) was applied using a roller tip at 50–80 watts. Three or four passes were made in different directions over each affected area with a high rolling speed of roughly 5 cm/s and a delay of 5–10 seconds between passes. All patients attended three to five treatment sessions at intervals of 8–16 weeks. The same senior physician (J.D.) conducted all treatment sessions. This treatment was accompanied by an air cooler (Cryo 5; Zimmer, Warsaw, IN) for pain control and reduction of excessive thermal injury. Cold air is blown across the treatment site in 10 seconds intervals with ten seconds of break in between at a distance of 15–30 cm. For subjects who experienced PIH, the next treatment session occurred after the PIH had completely subsided.

Postoperatively, ice packs were applied to the treated areas intermittently for 30–60 minutes. Sterile saline and moisturizer (Flamigel, Aspen, Australia) were applied to the treated area twice daily for 7 days to facilitate epithelialization. Patients were instructed not to scratch the treated areas before decrustation and were encouraged to use SPF 50 sunscreen for 3 months after epithelialization.

Evaluation

The Patient and Observer Scar Assessment Scales (POSAS) [20] were used to evaluate changes in the burn scars pre and post treatment. POSAS, a modification of the Vancouver Scar Scales, is a combined patient and physician evaluation of the scar according to six patient parameters: pain, itching, color, stiffness, thickness, relief; and five physician (observer) parameters: vascularization, pigmentation, pliability, thickness, relief. Each parameter is scored on a scale of 1–10, with one indicating that the scar similar to normal skin and 10 indicating the worst situation imaginable. Two independent board-certified physicians who did not participate in patient recruitment or treatment performed the POSAS scoring through patient interview and evaluation of photographs (S.W., R.J.).

Data Collection

The patient's basic clinical data—age, sex, type, and time of injury, history of treatment—were recorded prior to treatment. Immediately after treatment, energy settings and a relative pain score using a visual analogue scale (0–10) were recorded. Before the next treatment session, patients were asked about any experienced side-events—pain, edema, erythema, infection, dyschromia, hypertrophic scar formation—and their answers were recorded.

All patients were photographed before treatment, 2 months after each treatment session, and 6 months after the final session. The same photographer took standard photographs from all of the patients using the same digital camera (Canon 450D; Canon, Tokyo, Japan) in a controlled setting. Controls included the following: (i) fixed location, posture, and background; (ii) distance of 1 meter between camera and patient; (iii) camera held at the level of the treated area; (iv) fixed exposure time, aperture size, and white balance settings; (v) fixed intensity and position of the light source; (vi) sharp definition of the photograph.

Data Analysis

Statistical analysis was performed using the Paired Student's t-test to determine if the POSAS showed a statistically significant change between the baseline and the final scar evaluation. Differences were considered statistically significant at $P < 0.05$. The rating of each POSAS parameter was compared to determine the FMRT treatment effects. SPSS version 16.0 software (SPSS, Inc., Chicago, IL) was used for the statistical analyses.

Fractional polynomial regression analysis was used to estimate the effects of background variables (i.e., patient age, scar age, number of treatments, energy settings) on variations in the POSAS score. Subgroup analysis was used to detect possible sources of heterogeneity according to different causes of the wounds, wound sites, skin types, patient's sex, and whether or not the scar area had been pretreated.

RESULTS

Among the 108 patients, 95 (88%) patients completed the follow-up while the other 13 (12%) patients did not. All 95 patients (40 male patients, 55 female patients; mean age 22.9 years, age 12–55 years) completed three to five treatments according to the protocol and were included in the final analysis. The ages of the burns ranged from 1 to 30 years (average 5.7 years). The characteristics of the patients are shown in Table 1.

The differences in both the Patient Scar Assessment Scale and the Observer Scar Assessment Scale were statistically significant ($P < 0.05$). The total POSAS scores

TABLE 1. Characteristics of Patients and Burn Scars

Age (years)	22.9 (12–55)
Sex (n)	
Male	40
Female	55
Skin type (n)	
I	0
II	10
III	36
IV	41
V	8
VI	0
Duration of burn scar (years)	5.7 (1–30)
Etiology of burn (n)	
Fire	51
Scalding	40
Cheminal	4
Precious treatment (n)	
Non	74
Flap transplantation	3
Skin grafting	11
Steroid injection	0
Surgical excision	7
Anatomical location (n)	
Face	60
Trunk	17
Extremities	18

before treatment and 6 months after final treatment were 53.41 ± 6.28 and 46.35 ± 5.30, respectively. The total scores of the Patient Scar Assessment Scale before treatment and 6 months after treatment were 32.27 ± 5.40 and 28.61 ± 5.93, respectively. The total scores of the Observer Scar Assessment Scale before treatment and 6 months after treatment were 21.13 ± 3.26 and 17.74 ± 2.29, respectively (Table 2).

For the patients' ratings, the mean pain, itching, color, relief, thickness, and stiffness scores were 1.07 ± 0.39, 1.11 ± 0.37, 7.72 ± 1.54, 7.45 ± 1.76, 7.27 ± 1.84, and 7.64 ± 1.89, respectively, before treatment, and 1.04 ± 1.32, 1.06 ± 0.35, 6.37 ± 1.92, 7.25 ± 1.84, 6.18 ± 2.30, and 6.71 ± 2.32, respectively, after treatment.

Using a paired Student's *t*-test to compare parameter scores, a statistically significant improvement in the patient's assessment of the color, thickness, and stiffness of the scar but not in the pain, itching, or relief categories was observed ($P = 0.28$, 0.25, 0.07, respectively) (Fig. 1). For the observer's scores, the mean vascularization, pigmentation, thickness, relief, and pliability scores were 3.93 ± 1.53, 5.12 ± 1.15, 4.28 ± 1.01, 3.92 ± 1.01, and 3.88 ± 0.98, respectively, before treatment, and 3.71 ± 1.20, 3.92 ± 1.17, 3.41 ± 0.84, 3.44 ± 4.83, and 3.27 ± 0.274, respectively, after treatment. A statistically significant improvement in pigmentation, thickness, relief, and pliability but not in vascularization was observed ($P = 0.06$) (Fig. 2).

TABLE 2. Patient and Observer Scar Assessment Scale (POSAS) Before and After Treatment

	Before treatment	After treatment	*P*
PSAS			
Pain	1.07 ± 0.39	1.04 ± 0.32	$P = 0.28$
Itching	1.11 ± 0.37	1.06 ± 0.35	$P = 0.25$
Color	7.72 ± 1.54	6.37 ± 1.92	$P < 0.05$
Relief	7.45 ± 1.76	7.25 ± 1.84	$P = 0.07$
Thickness	7.27 ± 1.84	6.18 ± 2.30	$P < 0.05$
Stiffness	7.64 ± 1.89	6.71 ± 2.32	$P < 0.05$
Total PSAS Score	32.27 ± 5.40	28.61 ± 5.93	$P < 0.05$
OSAS			
Vascularization	3.93 ± 1.53	3.71 ± 1.20	$P = 0.06$
Pigmentation	5.12 ± 1.15	3.92 ± 1.17	$P < 0.05$
Thickness	4.28 ± 1.01	3.41 ± 0.84	$p < 0.05$
Relief	3.82 ± 1.01	3.44 ± 0.83	$P < 0.05$
Pliability	3.88 ± 0.98	3.27 ± 0.74	$P < 0.05$
Total OSAS Score	21.13 ± 3.26	17.74 ± 2.29	$P < 0.05$
Total POSAS Score	53.41 ± 6.28	46.35 ± 5.30	$P < 0.05$

PSAS, Patient scar assessment scale; OSAS, Observer scar assessment scale.

Patients were deemed responsive to treatment if their overall POSAS scores decreased. After analyzing the collected data, the overall response rate was 86.3% (82/95). Regression analysis was performed to estimate the effect of background variables (i.e., patient age, scar age, number of treatments) on the variation of total POSAS scores. The regression curve indicated that the number of treatments and the fluence of the radiofrequency affected the POSAS score. The regression curve trends showed that the POSAS score variation increased as the number of

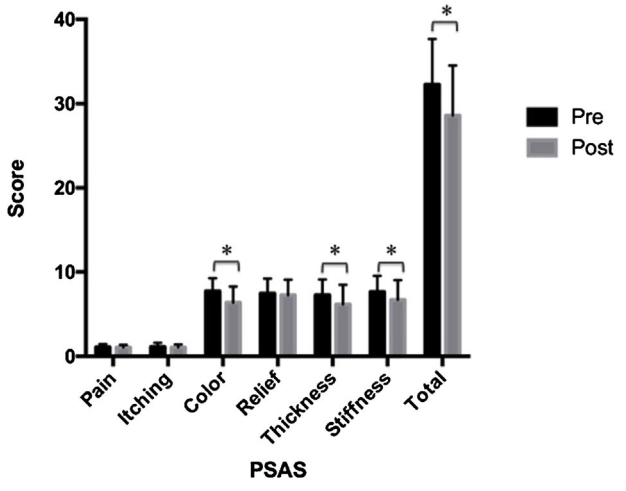

Fig. 1. Evaluation of burn scar improvement using POSAS grading scales—the Patient Scar Assessment Scales part. The bar chart showed a statistically significant ($P < 0.05$) reduction of PSAS score in scar color, thickness, stiffness, and total score; improvement was not statistically significant ($P > 0.05$) in pain, itching, nor relief. $^{*}P < 0.05$.

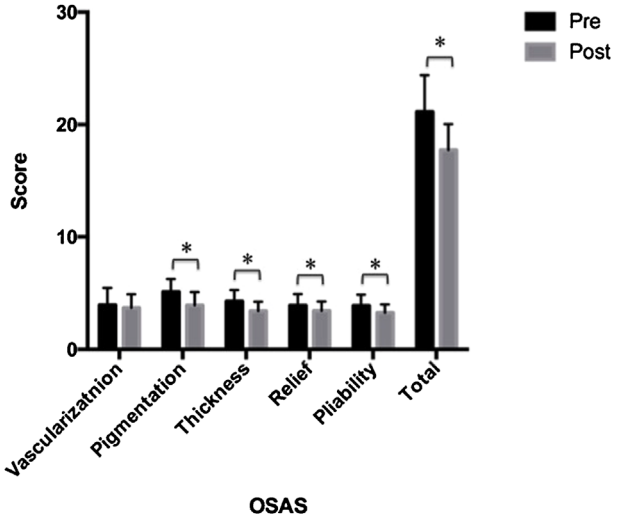

Fig. 2. Evaluation of burn scar improvement using POSAS grading scales—the Observer Scar Assessment Scales part. The bar chart showed a statistically significant ($P < 0.05$) reduction of OSAS score in scar pigmentation, thickness, relief, and pigmentation and total score; improvement was not statistically significant ($P > 0.05$) in scar vascularization. $^{*}P < 0.05$.

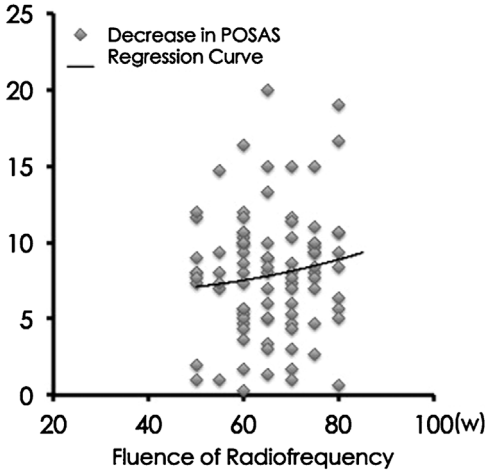

Fig. 4. Fractional polynomial regression of radiofrequency fluence versus variations in the POSAS score. The trend of the regression curves suggested that the POSAS score variation increased as the radiofrequency fluence increased. w: watt.

treatments and radiofrequency fluence increased (Figs. 3 and 4). Conversely, the flat curve of the regression analysis showed no significant correlation between the POSAS score and patient's age or the scar age.

Subgroup analysis was used to compare response rates subgroups of different causes of the wound, wound sites, skin types, patients' sex, and whether or not the scar had been pretreated. No significant differences were observed between these subgroups ($P = 0.37$, 0.21, 0.19, 0.35, and 0.53, respectively).

Adverse Events

Adverse events included pain during the treatment, post-therapy erythema, PIH, abnormal hair growth, and herpes simplex eruption (Table 1). The mean visual analog scale pain score was 4.70 ± 1.04 with topical anesthesia. The mean durations of post-therapy edema and erythema were 4.86 ± 0.79 and 10.62 ± 1.47 days, respectively. Overall, 26 subjects (27.37%) experienced prolonged PIH (>30 days). The duration of PIH was 23.46 ± 5.81 days (range of 16–98 days). Seven patients experienced acne eruption in the treated area within 1 month post-treatment, but the condition subsided without treatment. Four patients experienced abnormal hair growth in the treated areas. Diode laser (Soprano; Alma Lasers, Caesarea, Israel) was used 3 months after the final treatment to remove the hair. One patient experienced herpes simplex skin eruption in the treated area 3 weeks after the second treatment, but the condition subsided within 1 month. No infection, recurrence, or hypertrophic scar formation was observed during follow-up visits (Table 3).

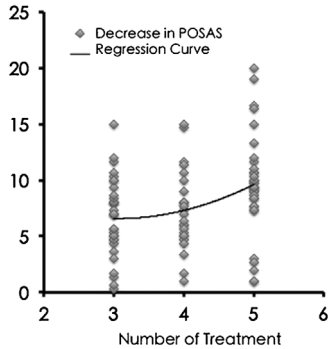

Fig. 3. Fractional polynomial regression of treatment number versus variations in the POSAS score. The trend of the regression curves suggested that the POSAS score variation increased as the number of treatments increased.

DISCUSSION

During the past decade, the role of lasers and other energy devices has steadily changed from a secondary treatment option to a primary treatment option for scar management. Current types of laser treatment devices extend treatment availability and options to most scar categories [21]. Adequate evidence-based findings has confirmed the safety and efficacy of several lasers, such as pulsed dye laser and fractional CO_2 laser [22]. FMRT is an emerging, minimally ablative technology that combines the ablative effect of plasma and the thermal effect of radiofrequency. This novel technology is capable of inducing mild ablation of superficial epidermis and neocollagenesis and remodeling of the dermis [23]. Histological studies have shown that FMRT produces much smaller thermal ablative and coagulative areas than fractional CO_2 laser [9]. In addition, another study suggested that the PIH rate was much lower with FMRT than with CO_2 laser. Hence, FMRT is considered to be a relatively safe laser treatment for the skin of individuals of Asian descent and has proved to be beneficial for pigmented burn scars in an Asian population [12]. However, there is still a lack of

TABLE 3. Adverse Events After Treatment With Factional Microplasma Radio Frequency Therapy

Immediate AEs	
Pain (VAS/mean + SD)	4.70 ± 1.04
Edema (D[a]/mean + SD)	4.86 ± 0.79
Erythema (D/mean + SD)	10.62 ± 1.47
Temporary AEs	
Acute skin infection (n)	0
Induced acne eruption (n[b]/%)	7 (7.37%)
Herpes simplex eruption (n/%)	1 (1.06%)
Abnormal hair growth (n/%)	4 (4.21%)
PIH >30 days (n/%)	26 (27.37%)
Long-term AEs	
Hypertrophic scarring (n)	0
Depigmentation (n)	0

SD, standard deviation; VAS, Visual analogue scales.
[a]D, Duration, days.
[b]n, Number of patients.

direct evidence from a high-quality randomized controlled study comparing the efficacy of FRMT and ablative lasers to guide clinical decision making.

Fractional Micro-plasma Radiofrequency is a technology that has been recently used in the treatment of skin conditions such as acne scar, rhytids, and striae distensae and showed promising results. To date, there is only one study published on the use of FMRT in post-burn scarring treatment [1]. The study found that after 3–5 fractional micro-plasma radiofrequency treatments, hyperpigmentation improved significantly in the majority of included patients (32 in 35 patients) without severe adverse events. However, this study only focused on hyperpigmentation of post-burn scars, other indicators of burn scars were not considered for primary outcomes. Our results provide evidence that FMRT improves the overall appearance of non-hypertrophic burn scars. Specifically, FMRT significantly improved the color (Fig. 7), thickness (Figs. 5 and 6), and pliability of burn scars, although it had no significant on contracture, pain, or itching. More recently, a case reported by Ding and Wang [14] suggested that FMRT has great potential for treating secondary skin graft contracture. However, our results indicated the opposite on scar contracture in a similar treatment protocol. This difference is possibly attributed to the fact that their research focused on early thin split-thickness skin graft contracture (less than 0.2 mm and 2 months), whereas the subjects of our study were mature and had relatively deeper burn scars.

No severe adverse events were observed during our study. Early complications included pain during the treatment, post-therapy erythema, and PIH. PIH rate of our study was 27.37%, which was relatively high compared to other similar FMRT studies [12,17] (0%). The primary reason for the high PIH rate of our study was that the PIH observation for each patient was made 30 days after each treatment. Other comparable studies [12,17] made the PIH observation for each patient 60 days after each treatment. Abnormal hair growth and herpes simplex eruption were infrequent complications and curable. Based on multiple regression analysis of the POSAS scores, we found that the positive effects of FMRT increased with the increased number of treatments. Therefore, we have evidence to believe that FMRT gradually improves the appearance of scars through both ablative and thermal effects, therefore we recommend repeated treatment. Although higher energy (between 50 and 80 watts) also resulted in more desirable results, more intensive treatment may have a higher chance of complications such as PIH and hypertrophic scar formation.

With our research findings and relevant literature, we propose the following recommendations for treating scars:

1. The findings show that FMRT was beneficial for treating scar thickness, color, and pliability but not for pain relief, itching, or scar contracture. Therefore, surgical correction is recommended for severely contracted scars prior to plasma treatment.
2. Several animal studies confirmed that the penetration depth of plasma on skin is 2–4 mm, depending on the energy settings [9,10]. Clinical observations also suggested that scars thicker than 4 mm often requires a higher energy setting and more treatment sessions. Therefore, FMRT is more recommended for scars thinner than 4 mm.

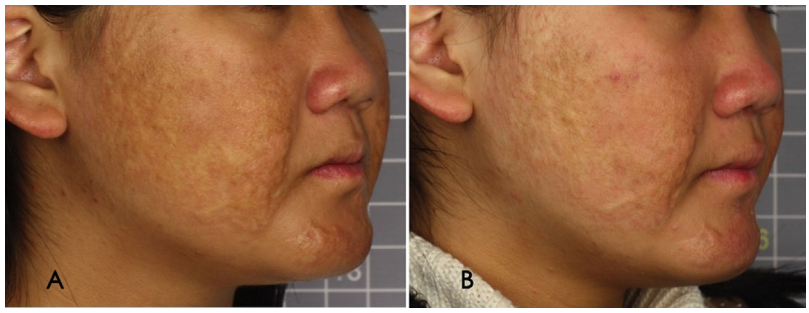

Fig. 5. This 22-year-old woman had a facial scar caused by an acid burn. **A**: Before treatment. **B**: Six months after four treatments. Color and irregularity of the scar are improved.

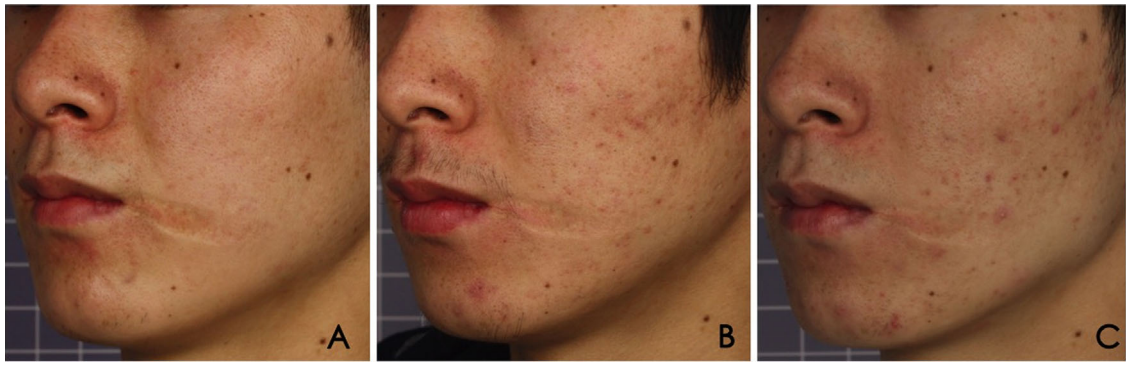

Fig. 6. A 26-year-old man had a facial scar from a metal burn. **A**: Before treatment. **B**: Two months after the first treatment. **C**: Two months after three treatments. Depression of the scar is diminished, and the scar margin has blurred.

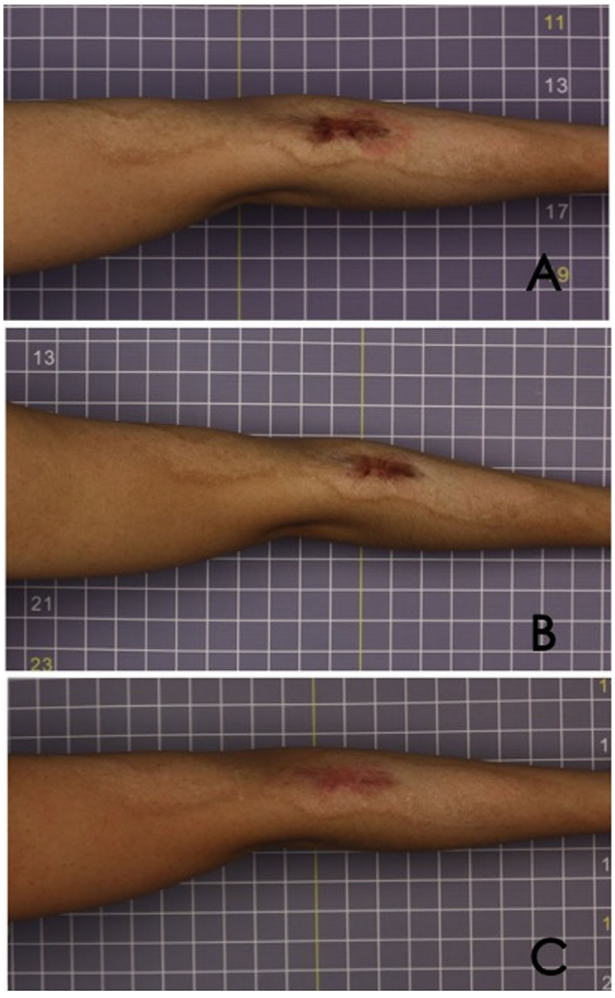

Fig. 7. A 21-year-old woman had a scalded right arm. **A**: Before treatment. **B**: Two months after the first treatment. **C**: Two months after five treatments. The hyperpigmentation of the scar is greatly improved.

3. As post-treatment erythema occurred in most patients and vascularization did not improve after FMRT, an erythematous scar should be treated with caution. We recommend two to three sessions of long-pulse Nd-YAG 1064 nm or pulsed dye laser treatment to improve scar vascularity prior to plasma treatment.
4. In consideration of thin eyelids and the high water content of eyes, scars on eyelids should be excluded from plasma treatment. In contrast, other laser choices, including fractional Er-YAG or CO_2 lasers, are relatively safer treatment options.
5. The recommended energy setting for patients of Asian descent is 50–80 watts with three or four passes. A high rolling speed of 5 cm/s and uniform energy coverage of the entire treated area are crucial in obtaining expected results with a lower chance for complications.

There were several limitations in the current study. First, the high lost-to-follow-up rate resulted in a high attrition bias. The intention-to-treat analysis showed that the response rate would have declined to 75.9% from 86.3% if all dropout patients had been included in the final efficacy evaluation. Second, our study was designed to be an interventional study. Thus, a major drawback of our study is that we did not have a control group. Finding a comparable control group is difficult because the morphology, color of scars, and/or different parts of a same scar, vary widely. Third, the follow-up duration of 6 months was relatively short for scar intervention, therefore, the long-term impact of FMRT on non-hypertrophic scars could not be determined. Fourth, the range of scar age was very large, which may increase selection bias in our research because young scars are expected to have more improvements in texture, pliability, and erythema compared to old scars. Randomized control trial still needed to clarify effect of FMRT on different scar age. Finally, the current scar assessment scale is not accurate enough to reflect the degree of improvement. The widely used Vancouver Scar Scale is imprecise and not applicable for non-hypertrophic burn scars. On the other hand, the POSAS is a subjective rating scale, so patients' assessments of the severity of

scars are often at odds with those of the objective indicators. Thus, the establishment of a more precise, credible scale for non-hypertrophic scars continues to be an urgent need in the realm of scar treatment.

CONCLUSION

Our results provide evidence that FMRT is efficacious and safe for treating non-hypertrophic burn scars in the Asian population. Specifically, FMRT significantly improved color, thickness, and vascularity of burn scar, although it had no significant effect on its contracture, pain, or itching.

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