

The Fate of Active Acne and Acne Scars Following Treatment With Fractional Radiofrequency

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ABSTRACT

Introduction: Acne vulgaris (AV) is a common skin disorder that may result in long-lasting acne scars. Techniques such as delivering fractional radiofrequency (RF) energy through miniature pins or needles have been utilized to manage active acne and acne scars. Skin restoration through dermal remodeling, neo-collagenesis, neo-elastogenesis, and epidermal re-newal are typical results of such treatments.

Methods: 15 subjects suffering from acne received 3 sessions of facial treatments, 3-4 weeks apart, using a fractional RF device with 24 pins tip of 2500µm in length. The treatment's safety and efficacy were evaluated up to 6 months after the last treatment.

Results: Facial photos and classifications of active acne, acne scars, and overall skin appearance demonstrated improvements in follow-up visits compared to baseline. No significant or unexpected adverse events were detected.

Conclusion: The current study supports the safety and efficacy of the fractional RF treatment modality for acne condition.

J Drugs Dermatol. 2019;18(12):217-221.

INTRODUCTION

Acne vulgaris (AV), one of the most common skin disorders is a prevalent condition mostly affecting adolescents and young adults.¹ For some patients, acne continues to be a problem beyond adolescence, persisting well into adulthood.² Studies on the psychosocial impact of acne have documented dissatisfaction with appearance, embarrassment, self-consciousness, and lack of self-confidence.³ Furthermore, acne is associated with feelings of anxiety, depression, anger, less satisfaction with the body, lower self-esteem, and social dysfunction.⁴ For many patients, acne may lead to permanent scarring and disfigurement, further aggravating the existing psychosocial aspects of this condition.^{5,6} It is therefore crucial to effectively treat AV in order to avoid scarring. The pathogenesis of acne relates to increased sebum production in the setting of aberrant follicular keratinization, *propionibacterium acnes* proliferation and significant perifollicular inflammation.⁷ This process leads to a local tissue damage, resulting in activation of a wound healing cascade. Imbalance in collagen deposition and matrix degradation may result in permanent scarring.⁸

Various therapeutic measures such as chemical peeling, dermabrasion, and fillers have been performed to improve acne scarring, but with sub-optimal outcomes. Various lasers, each with variable reports of success and advantages, as well as limitations, were also adapted to overcome acne effects.⁹

The potential of ablative lasers such as Er:YAG or CO₂ lasers in producing significant improvement was promising; however, these technologies were found to be associated with long recovery times and side effects such as post-inflammatory hy-

perpigmentation and scarring.¹⁰ More recently, newer methods have been developed to minimize adverse effects by treating the skin fractionally, leaving healthy areas to promote and improve the healing process. Ablative fractional resurfacing, using the CO₂ fractional laser system has demonstrated significant beneficial effects on atrophic acne scars and minor side effects comparing to non-fractional CO₂ laser.¹¹ Newer techniques such as delivering fractional radiofrequency (RF) energy through miniature pins or needles have been clinically proven effective for skin rejuvenation with high margins of safety.¹²⁻¹⁵ Improvement of skin conditions such as wrinkles, lax skin, and acne scars following fractional RF treatments is achieved through dermal remodeling, neo-collagenesis, and neo-elastogenesis with controlled epidermal renewal.¹⁵

The current study was focused on evaluating a fractional RF device for simultaneous treatment of acne scars and active acne and for overall skin appearance improvement.

METHODS

A prospective, open label, single center clinical study was conducted in our clinic, following IRB approval. The study was intended to evaluate the safety and efficacy of a fractional RF applicator (Fractora, InMode Ltd., Israel) for the treatment of active acne and acne scarring.

Fifteen subjects, 13 females and 2 males, average age 27.9 years (range 13-53 years), with Fitzpatrick skin types II-VI, having active acne lesions and acne scars were recruited. Subjects signed informed consent forms prior to enrolment in the study.

FIGURE 1. Fractora 24 pin tip.

Information on medical history, demographics, and baseline photographs were gathered at baseline screening visit.

Exclusion criteria included pacemaker or internal defibrillator, other implanted metallic or electronic devices, permanent metal or silicone implants in the treated area, current or history of cancer, pre-malignant conditions, cardiac disorders, and any severe concurrent disease, pregnancy or lactating, impaired immune system, current or history of diseases stimulated by heat, uncontrolled diabetes, active skin condition in the treatment area, skin disorders, any facial treatment or surgery performed within 3 months prior to treatment, any therapies or medications that may interfere with the use of the study device, or compromised health as determined by the study doctor.

Patients received 3 sessions of facial treatments, 3-4 weeks apart (according to individual condition and physician decision), using the Fractora fractional RF tips (InMode Ltd., Israel). The tip, which is in contact with the skin, is composed of an array of 24 RF conducting pins (Figure 1) and each pin is 2500 μ m in length, with or without insulating coating, along 2000 μ m. The insulated tip was used according to therapist discretion for dark skin types. Safety and efficacy of the treatment were evaluated at 3 follow-up visits, 1, 3, and 6 months after the last treatment.

Treatment was conducted according to the instructions in the device operator manual. A test spot was performed in a non-conspicuous area of the treatment site, prior to each session. Topical anesthesia was applied for the desired time and the area was then cleaned and dried. Fractional RF energy levels ranged between 15-38, starting with the low values, and increasing gradually as the treatment protocol proceeded. Lower parameters were applied on sensitive or bony areas and on darker skin types. One or two stacks were performed in each site and 1-2 passes were applied to the full treatment area. Parameters were adjusted according to individual condition, skin response and tolerance.

Safety was evaluated after each treatment and at follow-up sessions. Frontal and 45° left and right-side photographs were taken at standard conditions before and after each treatment and at follow-up time points. Evaluation goals were rating the degree of active acne, acne scars, and overall skin appearance improvement.

Acne scars classification was done using the following 5 scores scale:

- None (0) = Normal
- Trace (1) = Barely perceptible
- Mild (2) = Shallow
- Moderate (3) = Medium depth
- Severe (4) = Deep

Active acne classification was done using the following 5 scores scale:

- None (0) = Normal
- Trace (1) = Barely visible and localized
- Mild (2) = Somewhat visible and diffuse
- Moderate (3) = Visible and diffuse
- Severe (4) = Extremely visible and dense

Overall skin improvement was evaluated using the following 5 scores scale:

- None (0) = No change
- Mild (1) = Slight change
- Moderate (2) = Moderate change
- Good (3) = Considerable change
- Extreme (4) = Major change

RESULTS

Twelve subjects completed the study by attending the 6 months follow-up visit. One subject withdrew after the first treatment and 2 subjects attended either 1- or 3-months follow-up visits, but did not appear for the last, 6 months follow-up visit.

Evaluations of acne scars, active acne and overall skin appearance demonstrated progressive improvement in follow-up visits compared to baseline.

The acne scars score was reduced from an average of 2.80 to average of 0.80, active acne score was reduced from an average of 2.93 to an average of 0.75, and overall skin appearance improved from a score of 1.45 after one treatment to a score of 3.50 at 6 months follow-up visit. Figure 2 demonstrates the scores reduction at follow-up visits compared to baseline.

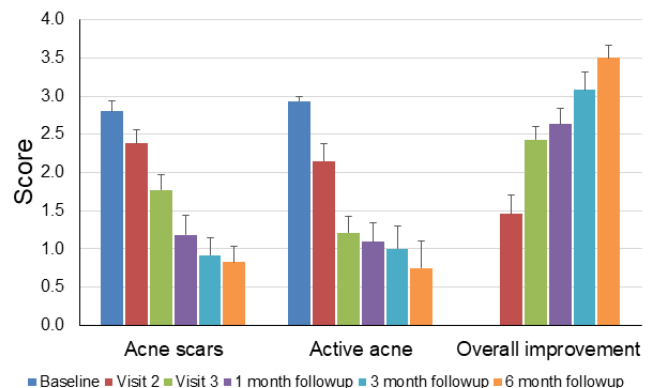
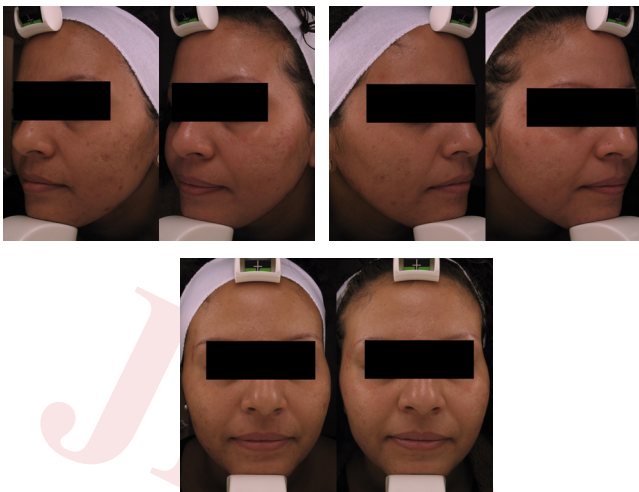
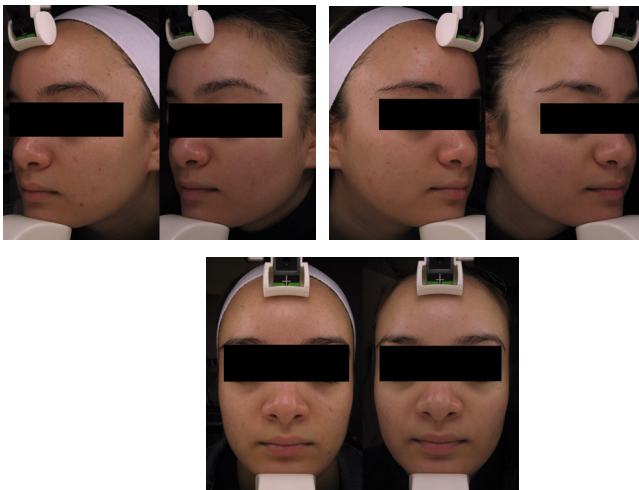
FIGURE 2. Histogram representing progress of changes in scores of acne scars, active acne and overall skin improvement as treatment progresses and at 1, 3, and 6-month follow-up visits, compared to baseline.

FIGURE 3. Acne treatment photos and classifications of a 31 years subject, skin type IV at baseline (left), and at 6 months post 3 treatments with 24 pins non-insulated tip (right).



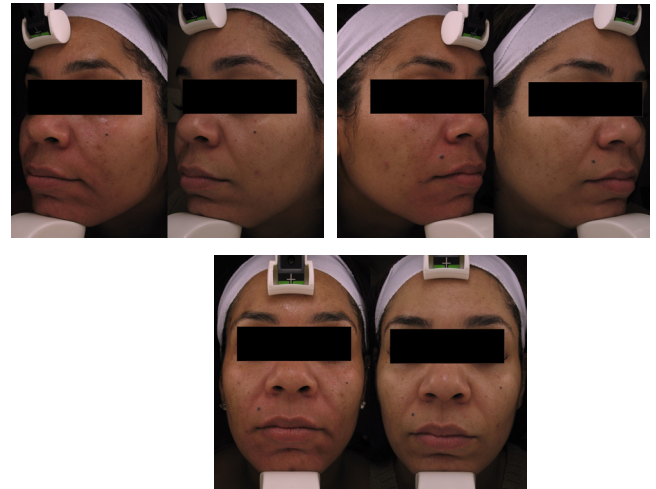
Classification	Baseline	6 months follow-up
Acne scars	2 = Moderate	1 = Trace
Active acne	3 = Moderate	0 = None
Overall skin improvement		4 = Extreme

FIGURE 5. Acne treatment photos and classifications of a 25 years subject, skin type III, at baseline (left), and at 6 months post 3 treatments with 24 pins non-insulated tip (right).



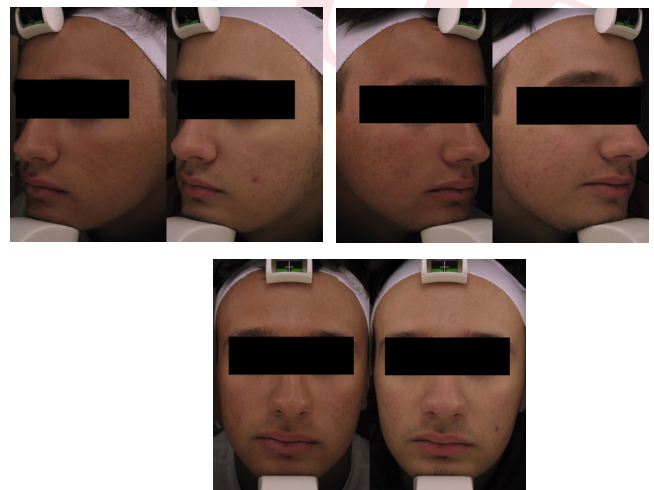
Classification	Baseline	6 months follow-up
Acne scars	2 = Moderate	0 = None
Active acne	3 = Moderate	2 = Mild
Overall skin improvement		3 = Good

FIGURE 4. Acne treatment photos and classifications of a 41 years subject, skin type IV, at baseline (left) and at 6 months post 3 treatments with 24 pins insulated tip (right).



Classification	Baseline	6 months follow-up
Acne scars	3 = Moderate	0 = None
Active acne	3 = Moderate	0 = None
Overall skin improvement		4 = Extreme

FIGURE 6. Acne treatment photos and classifications of an 18 years subject, skin type II, at baseline (left) and at 6 months post 3 treatments with 24 pins non-insulated tip (right).



Classification	Baseline	6 months follow-up
Acne scars	4 = Severe	1 = Trace
Active acne	3 = Moderate	2 = Mild
Overall skin improvement		4 = Extreme

Figures 3-6 demonstrate examples of patients' photos at 6 months follow-up compared to baseline. Improved acne condition, acne scars, and overall skin appearance post fractional RF treatment is noticeable in follow-up photos and classifications.

Assessments of safety of the Fractora treatment after each treatment and at follow-up visits indicated high safety profile with no unexpected or significant adverse events. Skin responses such as mild to moderate erythema and edema, a few pinpoint bleedings and acne flare up were transient and resolved spontaneously with no intervention.

DISCUSSION

Fractional RF skin treatments are well accepted as a safe and effective modality for skin resurfacing, tightening and rejuvenation.¹⁶⁻²⁰ Various skin conditions such as wrinkles, macropores, sagging and lax skin in face, neck, and décolletage areas are successfully treated, resulting in a gradual skin renewal process with minimal down time. The fractional treatment principle is creating thermally ablated and coagulated microscopic zones of the dermal layer. The non-ablated zones in the uninjured surrounding tissue serve as a reservoir of cells that accelerate and promote rapid healing.

Clinical studies have shown that acne scars are an additional major skin problem, that greatly improved following fractional RF treatments.²¹⁻²⁵

The fractional handpiece tips composed of an array of 24 RF pins is designed to deliver RF energy to the skin surface in a fractional manner. The energy is delivered to the skin through bipolar arrays of 24 insulated or non-insulated pins and results in localized heating and ablation of the skin that is in direct contact with the pins. Ablation and the resultant coagulation of the treated skin promotes skin renewal while untreated skin between the pins enables faster healing of the tissue. There is also the contribution of sub-necrotic, non-ablative, non-coagulative dermal matrix heating that promotes volumetric expansion of the dermis, as well as regeneration of fibers, leading to clinically apparent skin contraction. The InMode System with the Fractora Handpiece with the 24-pin tip has been cleared by the FDA (K151273).

Previous articles published about these treatments present clinical, histological and long-term results from the simultaneous treatment of active acne and acne related scarring.²⁶⁻²⁹ Patients were treated with the 24 pins tip, while for dark skin types, the tips used featured the insulating coating to provide additional epidermal protection for a high level of safety.²⁹

Results were followed for long term of up to three years and demonstrated clinically and histologically significant advantages in treating simultaneously acne scars and active acne.^{27,28} The

advantages were the minimally invasive nature of the procedure, the relatively very short downtime and safety.

The current study further demonstrates the progress of simultaneous active acne and acne scars improvement, following Fractora 24 pins tip treatment. Patients were treated with the coated or non-coated pins tip according to their Fitzpatrick skin type. Patients were followed for up to 6 months post 3 treatments. The treatment was found to be safe with no cases of significant or unexpected adverse events. Average scoring demonstrated a clear pattern of improvement in active acne, acne scars, and overall skin appearance. Improvement was progressive as collagen and elastin regeneration and the resultant skin renewal is a process that occurs over time.

In summary, results of the current study further support the safety and efficacy of fractional RF technology for the simultaneous treatment of active acne and acne related scars.

DISCLOSURES

Dr Bruce Katz has received funding for the clinical study referred to in this article.

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