

Clinical Evaluation of Safety and Efficacy of Fractional Radiofrequency Facial Treatment of Skin Type VI Patients

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ABSTRACT

Introduction: It has been well established that patients with darker skin types (Fitzpatrick skin types IV-VI) have an increased incidence of thermal induced side effects from laser and radio frequency (RF) treatments. Complications include a higher risk of post-inflammatory hyperpigmentation, hypopigmentation, and scarring, leading to unsatisfactory clinical outcomes. Fractional technologies improve the safety when treating patients with skin of color by treating only fractions of the skin while leaving a healing reservoir of untreated skin that improves the healing process. Fractional RF tips with coated pins may offer a more advantageous safety profile, particularly in the skin-of-color population (Fitzpatrick skin types IV-VI) by increasing the protection of the epidermal layer by minimizing epidermal heating. The current study was intended to evaluate the safety and efficacy of fractional RF technology for the treatment of patients with Fitzpatrick skin type VI.

Methods: 35 subjects with skin type VI received 3 sessions of facial treatments, 4 weeks apart using a fractional RF device with 24 pin coated tip. The treatment's safety and efficacy were evaluated at 2 follow-up visits, 6 and 12 weeks after the last treatment.

Results: Skin characteristics evaluations, including Fitzpatrick Wrinkles Classification, acne scars, and overall facial appearance demonstrated improvement in follow-up visits comparing to baseline. No significant unexpected adverse events were detected.

Conclusion: The current study proves the safety and efficacy of the fractional RF treatment modality with coated pins tips for skin rejuvenation treatments resulting in improved wrinkles, acne scars, and overall skin appearance, in patients with skin type VI.

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INTRODUCTION

Fractional skin resurfacing with non-ablative near-infrared laser wavelengths were introduced more than 10 years ago, in an effort to deliver high non-ablative columns of energy into the dermis. This treatment resulted in micro-coagulation zones formation and in collagen remodeling but left a significant portion of the adjacent skin untreated to act as a healing reservoir of cells for the non-ablative micro-coagulation zones.¹ In order to produce more significant results, ablative technologies like CO₂ used a fractional approach to create ablation columns with depth up to 2mm. These fractional ablative lasers provided the outcome advantages of ablative technique, but with improved recovery and minor risk of side effects. Fractional CO₂ and other fractional ablative wavelengths have shown excellent improvement in wrinkles, photo-aging, and acne scars.^{2,4}

Although these modalities can be effective, they may be associated with prolonged recovery and adverse effects. Complications, such as post inflammatory hyperpigmentation (PIH), hypopigmentation, and scarring are at higher risk of occurring in patients with Fitzpatrick skin types IV-VI.⁵ These potential adverse effects can all lead to decreased use of resurfacing procedures when treating patients with skin-of-color.

More recently, fractional RF technology was introduced for skin resurfacing.⁶ It creates a low density fractional epidermal and

superficial dermal coagulation under the conductive pins and delivers RF travelling through the reticular dermis, combining a low density ablative effect in the epidermis with sub-necrotic heating in deeper layers of the skin. This fractional RF approach, with relatively low impact epidermal-junctional effect and deep dermal effect, has demonstrated improvement in lines, acne scars, and pigmentation after multiple treatment sessions.^{6,7} The technology sometimes compromises with treatment efficiency in comparison to deep ablative fractional lasers, but due to deeper collagen remodeling, delivers consistent and safe results after a number of non-aggressive treatment sessions. This technology was demonstrated to be particularly good for tissue tightening and acne scar treatment in Caucasian as well as Asian skin.⁷

The objective of this study is to demonstrate the safety and efficacy of the 24 pins coated tip for facial treatments of patients with skin type VI.

METHODS

The goal of this single center clinical study was to evaluate safety and efficacy of a fractional RF applicator (Fractora, In-Mode Ltd., Israel) for the treatment of facial wrinkles, fine lines, acne scars, and laxity on skin type VI.

Thirty-five subjects (25 females and 10 males) between the ages

FIGURE 1. Fractora 24 pin tip.



of 21-63 (mean age, 39.9 years), with skin type VI (according to the Fitzpatrick skin type classification), participated in the study. Subjects signed informed consents that were obtained from participants prior to enrolment in the study.

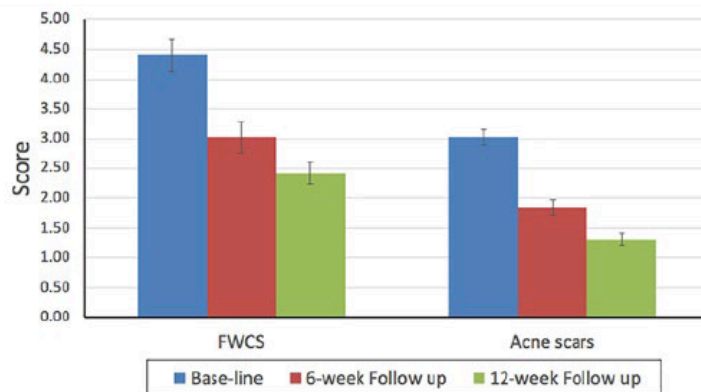
Information on medical history and demographics was gathered at baseline screening visit. The study included subjects with skin type VI who have had skin textural irregularities including acne scarring and lax facial skin.

Exclusion criteria included pacemaker or internal defibrillator, other implanted metallic or electronic device, permanent implant 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, history of or current 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, 4 weeks apart, using the fractional RF device. The tip that was in contact with the skin is composed of an array of 24 RF conducting pins (Figure 1) and each pin is 2500µm in length with insulating coating along 2000µm. Safety and efficacy of the treatment were evaluated at 2 follow-up visits, 6, and 12 weeks after the last treatment.

Safety was evaluated after each treatment and at follow-up sessions. Photographs were taken by Visia (Canfield, USA) before and after each treatment session, and at follow-up time points. Comparative photos before the first treatment session and at the follow-up time points were evaluated for assessment of lesions improvement. Parameters assessed were textural lesions (wrinkles, fine lines, and acne scars), and overall facial skin improvement. Acne scars classification was done using a 5-scores scale, where 0 represents normal condition with no

FIGURE 2. Histogram representing progress of changes in Fitzpatrick Wrinkle Classification Score (FWCS) and acne scars score at 6 weeks and 12 weeks follow-up visit comparing to baseline scores.



scars and 4 represents a severe condition of deep scars. Wrinkles and elastosis were classified using the 3 classes, 9 scores Fitzpatrick Wrinkle Classification Scale (FWCS).⁸ Overall skin improvement was evaluated according to 5-scores scale where 0 represents no change and 4 is an extreme, major change. Patients' satisfaction from the treatment was also evaluated using subjective questionnaire with 4-scores scale, where 0 is not satisfied and 3 is very satisfied.

RESULTS

Thirty-two subjects completed all study visits. One subject withdrew after the first treatment and 2 subjects withdrew after second treatments.

Skin characteristics evaluations demonstrated improvements in follow-up visits after the last Fractora treatment comparing to baseline. FWCS was reduced by 2 scores from an average of 4.41 (Class II: Fine to moderately deep wrinkles and moderate number of wrinkle lines) to an average of 2.21 (Class I: Fine wrinkles in motion) in 12 weeks follow-up.

Acne scars score was reduced from an average of 3 (moderate) to average of 1.3, where 1 is trace and 2 is mild. Figure 2 demonstrates the scores reduction at follow-up visits comparing to baseline.

In addition, there was an increased score of overall skin improvement: average of 1.4 at 6 weeks follow-up visit (in 5 points-scale where 1 is mild, slight change and 2 is moderate change) and an average score of 3.3 at 12 weeks follow-up visit, where 3 represents good, considerable change. Average patient satisfaction was 2.34, where 2 is satisfied and 3 is very satisfied.

Figures 3-7 demonstrate 12 weeks follow-up results using the Fractora coated 24 pins tip to protect the epidermis of patients

FIGURE 3. Acne and PIH treatment. Before (Left) and 12 weeks post 3 treatments with 24 pin coated tip (Right).

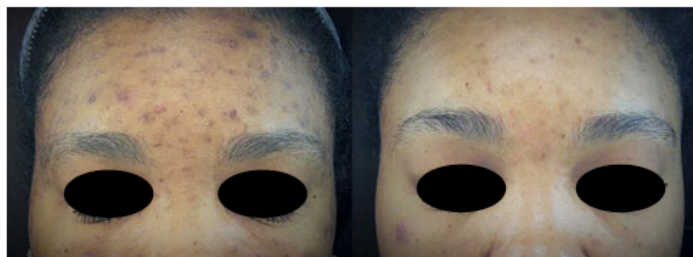


FIGURE 4. Acne scars and PIH treatment. Before (Left) and 12 weeks post 3 treatments with 24 pin coated tip (Right).



FIGURE 5. Pores and skin texture treatment. Before (Left) and 12 weeks post 3 treatments with 24 pin coated tip (Right).



FIGURE 6. Pores and skin texture treatment. Before (Left) and 12 weeks post 3 treatments with 24 pin coated tip (Right).



FIGURE 7. Acne scars treatment. Before (Left) and 12 weeks post 3 treatments with 24 pin coated tip (Right).



device. The treatments utilized tips with 24 coated pins for extra protection of the epidermal layer to maximize the safety aspect of the treatment in such a sensitive skin type.

In a recently published study, histological and long term clinical results from the treatment of active acne and acne related scarring, using the same fractional RF device (Fractura, InMode Ltd., Israel) were demonstrated.^{9,10} Patients were treated with the 24 RF conducting pins tip, while some of the tips used in this study featured the insulating coating to provide additional epidermal protection for dark skin. Coated or non-coated tips were used according to patient Fitzpatrick skin type. The availability of the coated pins tip optimized the suitability of the treatment to dark skin patients with a high level of safety.

In the above-mentioned study, results were followed for long term of 1-2 years and demonstrated that similar fractional RF treatment that was used in the current study was found to have significant advantages in treating simultaneously acne scars and active acne. The advantages were the minimally invasive nature of the procedure, the relatively very low downtime (most patients required 3-4 days of recovery), and safety.^{9,10} No cases of unexpected adverse event, including scarring and pigmentation alteration, were encountered and therefore the treatment was found to be suitable for dark skin types. The availability of the coated pins tip optimized the treatment to dark skin patients with a high level of safety. It was also noted that this treatment is of significant value as adult acne and atrophic scarring may be more prevalent in darker skin types.¹¹

with Fitzpatrick skin type VI. Treatment parameters were 15-30 energy levels determined according to patient tolerance and starting from the lower and increasing gradually in successive treatments, double stack, and one pass at a pulse rate of 1.5pps. Safety assessment conducted after each treatment and at follow-up visits demonstrated high safety profile with no unexpected significant adverse events. Responses such as mild erythema and edema resolved in less than one hour. One case of mild pigmentation around the mouth, one case of acne around the mouth, and one case of itching were all resolved spontaneously with no intervention.

DISCUSSION

The current publication reports overall facial skin texture improvement including improved appearance of wrinkles, acne scars, and pores in patients of skin type VI, using fractional RF

Other publications about fractional RF technologies reported safety and efficacy in the treatment of various indications, such as acne scars, enlarged pores, and periorbital wrinkles in Asian skin.^{12,13} Similar treatment protocols resulted in decreased melanin and increased elasticity supported by biochemical results that indicated increased levels of procollagen type I and III and elastin post treatment.¹² No PIH was recorded and only minor and transient adverse events of erythema and edema were documented in this study, similar to the current study.

In summary, the use of conventional resurfacing procedures is limited in patients with skin-of-color because of concerns about adverse effects, most notably pigmentation alterations. Fractional technologies represent a favorable alternative treatment in darker skin types, as it can yield clinical efficacy in a number of dermatologic conditions with minimal risk of adverse effects.¹⁴ This is due to the fractional nature of the treatment which spares healthy areas and makes the treatment less aggressive.

The development of fractional radiofrequency, especially the use of tips with coated pins, has expanded the advantages and resulting tolerability of the fractional technologies. This is done by preservation of the epidermis that allows for the procedure to be repeated multiple times until satisfactory outcome is achieved. The current study supports the safety and clinical efficacy of the fractional RF facial treatment, resulting in improved skin texture, wrinkles, and acne scars appearance for dark skin type VI patients.

REFERENCES

1. D. Manstein, G. S. Herron, R. K. Sink, et al. Fractional photothermolysis: a new concept for cutaneous re-modeling using microscopic patterns of thermal injury. *Lasers Surg Med.* 2004; 34(5):426-438.
2. N. P. Chan, S. G. Ho, C. K. Yeung, S. Y. Shek and H. H. Chan. Fractional ablative carbon dioxide laser resurfacing for skin rejuvenation and acne scars in Asians. *Lasers Surg Med.* 2010; 42(9):615-623.
3. B. M. Hantash, V. P. Bedi, B. Kapadia, Z. Rahman, K. Jiang, H. Tanner, K. F. Chan and C. B. Zachary. In vivo histological evaluation of a novel ablative fractional resurfacing device. *Lasers Surg Med.* 2007; 39(2):96-107.
4. A. M. Chapas, L. Brightman, S. Sukai, et al. Successful treatment of acneiform scarring with co2 fractional resurfacing. *Lasers Surg Med.* 2008; 40(6):381-386.
5. Sharad J. Combination of microneedling and glycolic acid peels for the treatment of acne scars in dark skin. *J Cosmet Dermatol.* 2011; 10(4):317-323.
6. G. Hruza, A. F. Taub, S. L. Collier, S. R. Mulholland. skin rejuvenation and wrinkle reduction using a fractional radiofrequency system. *J Drugs Dermatol.* 2009; 8(3):259-265.
7. Mulholland RS, Ahn DH, Kreindel M, Paul M. Fractional ablative radio-frequency resurfacing in asian and caucasian skin: a novel method for deep radiofrequency fractional skin rejuvenation. *J Cosmet Dermatol Sci App.* 2012; 2:144-150.
8. Fitzpatrick TB. The validity and practicality of sun-reactive skin types I through VI. *Arch Dermatol.* 1988; 124(6):869-71.
9. Hellman J. (2015) Retrospective study of the use of a fractional radio frequency ablative device in the treatment of acne vulgaris and related acne scars. *J Cosmet Dermatol Sci App.* 2015; 5:311-315.
10. Hellman J. long term follow-up results of a fractional radio frequency ablative treatment of acne vulgaris and related acne scars. *J Cosmet Dermatol Sci App.* 2016; 6:100-104. Published Online June 2016 in SciRes.
11. Perkins, A.C., Cheng, C.E., Hillebrand, G.G., Miyamoto, K. and Kimball, A.B. Comparison of the Epidemiology of Acne Vulgaris among Caucasian, Asian, Continental Indian and African American Women. *JEADV.* 2011; 25:1054-1060.

12. Kim JE, Lim HW et al. Objective evaluation of the clinical efficacy of fractional RF treatment for acne scars and enlarged pores in Asian skin. *Dermatol Surg.* 2014; 40(9):988-995.
13. Seung Jae L, Jung-In K, You Jin Y; Jae Hui N, Won-Serk K. Treatment of periorbital wrinkles with a novel fractional radiofrequency microneedle system in dark-skinned patients. *Dermatol Surg.* 2015; 41 (5):615-622.
14. Cohen BE, Elbuluk N. Microneedling in skin of color: A review of uses and efficacy. *J Am Acad Dermatol.* 2016; 74:348-55.

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