Clinical Evaluation Of The Safety And Efficacy Of FSR Applicator

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Introduction

Skin resurfacing has been used for medical and aesthetic purposes for more than 100 years. Skin resurfacing can be performed using mechanical devices (dermabrasion), chemical peeling compounds, lasers and radio frequency devices.

Full face resurfacing by chemical peels, mechanical dermabrasion or pulsed carbon dioxide (CO2) laser are considered to be very effective treatment options [1]. However, these full face procedures are usually quite painful and involve considerable downtime.

The intrinsic disadvantage of current laser fractional systems is the low volume of dermal heating (narrow laser beam) and the inability to differentiate between epidermal ablation and dermal heating. Fractional lasers must be used at a higher laser power in order to increase volumetric heating in the dermis. This will significantly increase epidermal ablation downtime and possible side effects such as prolonged erythema and post inflammatory hyper pigmentation. Decreasing laser power will provide good epidermal results with little or no dermal effect.

The concept of fractional skin resurfacing using laser devices was developed to address the shortcomings of ablative and non-ablative device modalities [2,3,4]. These systems perform ablation on small microscopic "dots" of skin allowing rapid healing with minimal pain and downtime. Although fractional ablation of the epidermis can be achieved with various types of laser systems, the amount of dermal volume that is heated by these lasers is very limited (5%-7%). Radiofrequency devices have been used for many years by dermatologists for focused or larger surface ablation of skin.

In the current study, we examined the Fractional Skin Resurfacing (applicator of the EndyMed PRO System. The EndyMed PRO System is an cleared computerized system that generates pulses of radio frequency energy which are emitted into the skin, causing a non-ablative deep d heating effect, and resulting in skin tightening, with various handpieces for Facial and periorbital/oral treatments. In addition to the effect of skin tighte RF energy can be used for ablative treatments, for skin resurfacing. The FSR (Fractional Skin Resurfacing) handpiece contains a matrix of 112 tir electrodes, allowing for the first time; simultaneous fractional microablati the epidermis together with volumetric heating of 100% of the dermis. technology provides the capability to differentiate between microablatio dermal heating which appears to be the optimal multilayer treatment to aged and lax skin and atrophic acne scars.

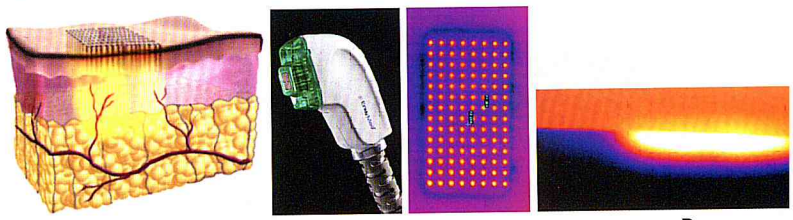

***Figure 1:** A - 3DEEP Fractional RF Skin Resurfacing (FSR) technology all simultaneous fractional ablation of epidermis and deep volumetric non-ab dermal heating. B - FSR handpiece;112 contact points (300 micron) C - Th image of the FSR tip. D – Thermal image of the FSR pulse.*

A post marketing study was conducted in order to evaluate the efficac safety of the FSR applicator of the EndyMed Pro System for skin resur Altogether, 30 subjects participated in the study. 25 patients were treat skin texture defects related to wrinkles, and 5 patients were treated for t defects caused by acne scars. Patients were followed 1 week and 1 monti treatment. In order to evaluate treatment efficacy, pre and post treatment p were introduced to two uninvolved physicians for blinded evaluation.

The following report describes the cumulative results of the 30 patients tha completed the facial wrinkle and acne scar improvement treatments.

Patients And Methods

All 30 patients, (4 male, 26 female), ages 23-71 years (average 51.9 ±14.1), were enrolled in the study after meeting all inclusion/exclusion criteria and providing signed Informed Consent Form. Patients received 1 treatment and 2 follow-up visits - 1 week and 1 month following treatment.

Prior to the FSR treatment - the treated areas was assessed visually as t relevant parameters and photogr in a standardized method using resolution digital photography in to allow comparison and asses of skin texture improvement fol treatment. Photographs were prior to treatment.

Topical anesthesia (Emla, Astra Z was applied 30 min prior to tre initiation. Treatment area was c thoroughly with a wet gauze (to r

lotion and makeup) followed by with 70% alcohol. Skin was dried using a dry gauze. The treatment parameters used were standard parameters. The treatment tip was positioned on the treated area. RF pulse was released. For the second RF pulse, the tip was repositioned next to the previous treated spot and another pulse was emitted. Procedure was repeated until all area intended for treatment was covered.

The use of a moisturizing cream (such as Biafine) was recommended post treatment. Patients were seen for follow-up evaluation 1 week and 1 month after the treatment.

Assessments of clinical improvement and overall improvement in skin texture were assessed and graded by two physicians blinded to the study and the patients. Improvement was considered by pre-treatment photographs (baseline) and photographs taken at 1 month follow-up visit. Evaluation of the clinical improvement was based on a quartile scale of improvement (Table 1).

Table 1: Scale of Clinical Improvement

0	No improvement
1	1-25% Improvement
2	26-50% Improvement
3	51-75% Improvement
4	76-100% Improvement

The safety of the procedure was also evaluated by monitoring the occurrence of potential procedure related side effects. During the treatment, subjects were asked to rate their overall pain level on a three point scale (mild, moderate and severe pains). In addition, treated areas were visually assessed for skin responses, including edema, erythema, hypopigmentation, hyperpigmentation, and textural changes following treatment. It is expected that following skin resurfacing procedure the skin is red for a few hours, and micro crusts are formed two days following treatment. Micro crusts usually disappear 5-7 days following treatment.

Results

All 30 patients completed the course of the treatment protocol. All patients have completed the 1 week and 1 month follow-up.

No unexpected adverse side effects were detected or reported. As expected, patients' skin was red for few hours following treatment, micro crusts were formed one to two days following treatment and resolved within 5-7 days following treatment.

In two patients, the crusts resolved after 10 days. There were no incidences of infections, scarring, hypopigmentation, or any other serious complications.

All patients (100%) were very satisfied from treatment results. The following sets of before and after photographs (Figure 1 - 6) illustrate the significant beneficial effect achieved by this resurfacing treatment.

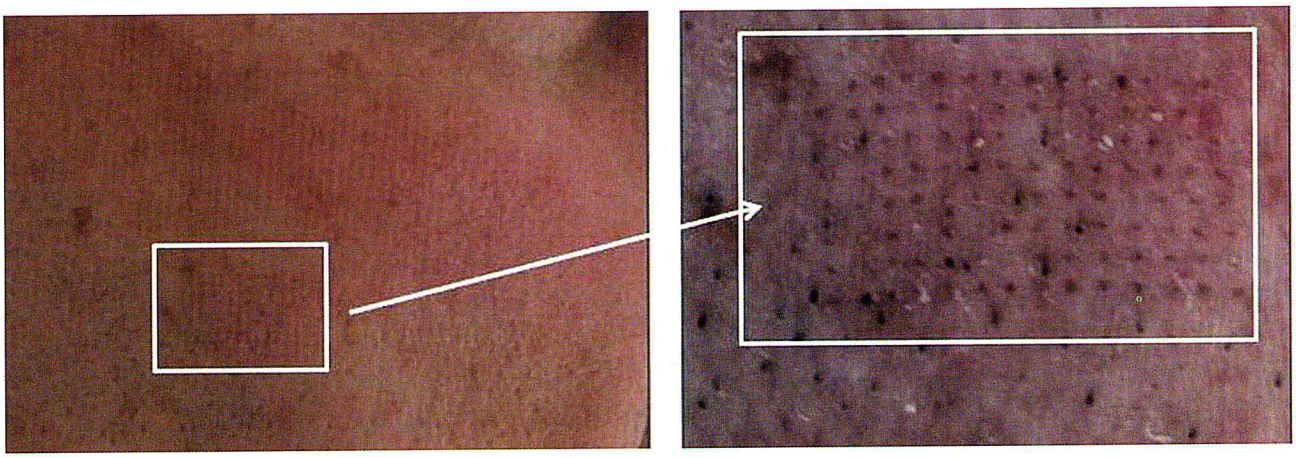

Figure 2: 40 hours after treatment there is an appearance of small, dry 300 micron crusts. These crusts r esolved after 5-7 days.

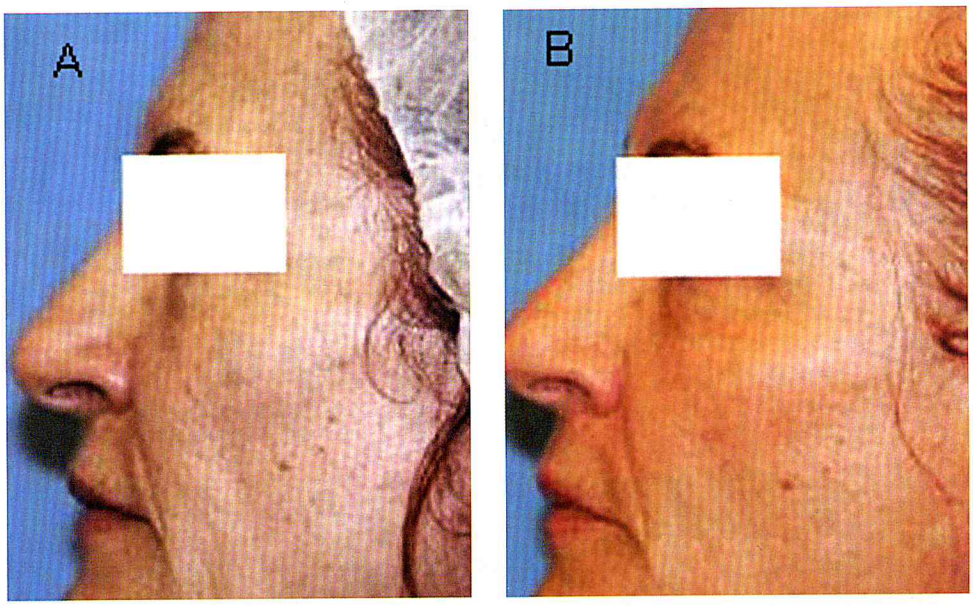

Figure 3: A 61-year old female (A – before treatment; B- at one month follow-up).

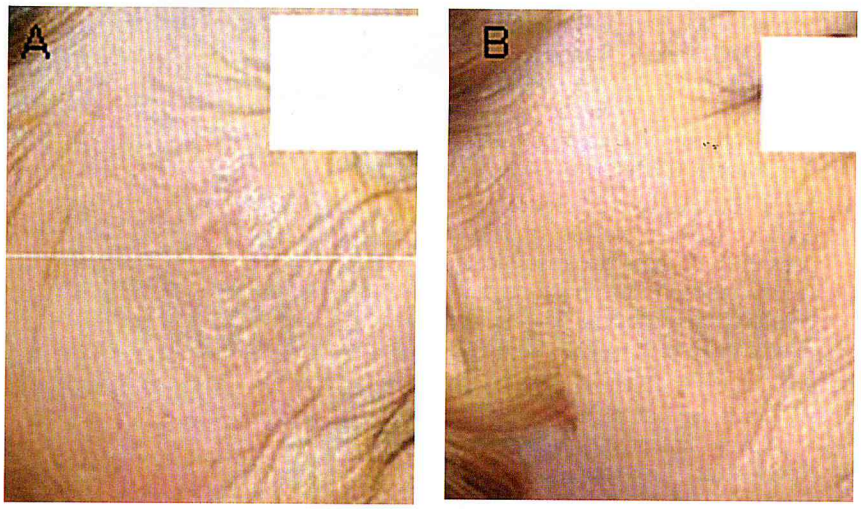

Figure 4: A 70-year old female (A – before treatment; B- at one month follow-up).

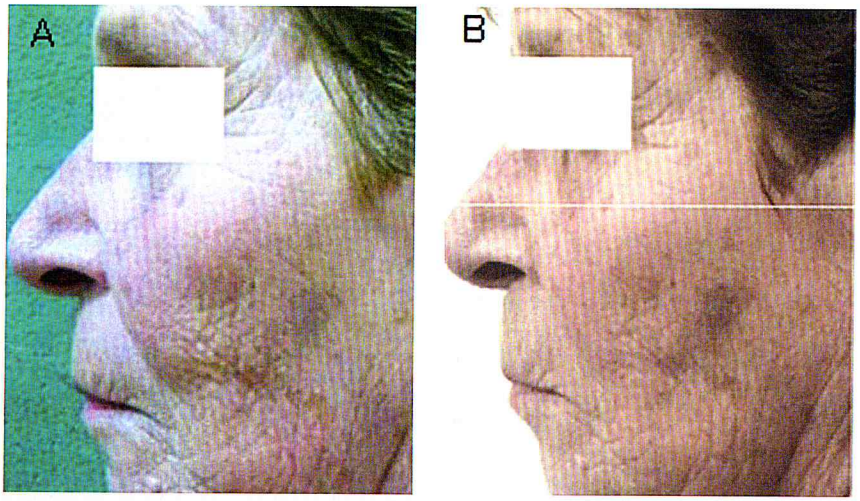

Figure 5: A 71-year old female (A – before treatment; B- at one month follow-up).

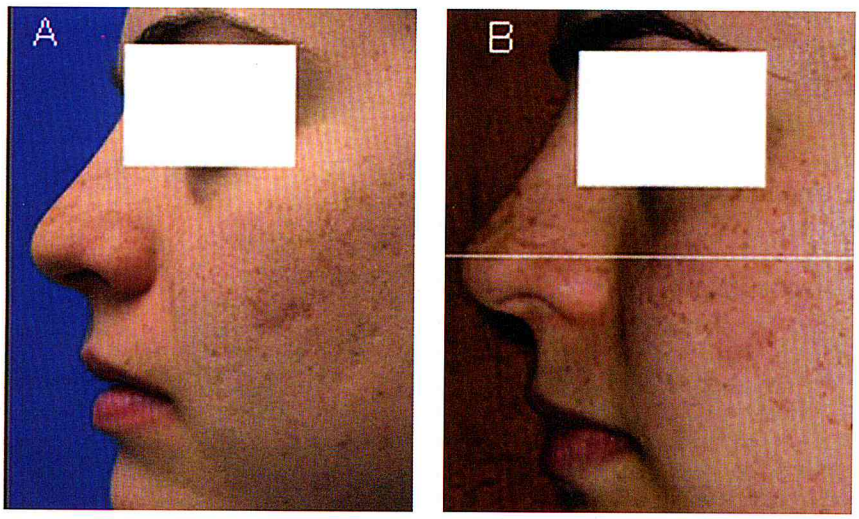

Figure 6: A 23 -year old female (A – before treatment; B- at one month follow-up). Noticeable scar improvement.

Photographic analysis of pre-and post treatment of the digital images was conducted by two blinded Board certified dermatologists according to the generally accepted quartile skin improvement scale [9]. Analysis revealed improvement (according to the quartile scale) in all (100%) patients according to both reviewers. Average clinical improvement at 1 month follow-up was 2.5 (±0.78) according to first reviewer and 1.83 (±0.70) according to the second reviewer. Furthermore, analysis of the frequency of improvement degree reveal that both reviewers found that the degree of improvement is moderate to good (25%-75% improvement) in most of the study participants (83.3% according to first reviewer and 66.7% according to the second reviewer); These results support significant improvement in skin texture as a result of the treatment.

Table 2: Improvement frequency

Characteristics	Reviewer1	Reviewer 2
0 - No improvement	0	0
1- 1-25% mild Improvement	4	10
2 - 26-50% moderate Improvement	8	15
3 - 51-75% good Improvement	14	5
4 - 76-100% excellent Improvement	4	0

Discussion and conclusions

Thirty patients were treated for face wrinkle and acne scar improvement and followed for 3 months following last treatment. In order to evaluate treatment efficacy, pre and post treatment photos were introduced to two uninvolved physicians for blinded evaluation.

Fractional skin resurfacing, according to the treatment parameters investigated in this study, resulted in clinical improvement in skin texture in patients with both wrinkles and acne scars. There were no complications, which is exceptional compared to traditional ablative resurfacing [1, 2, 6, 9].

Fractional resurfacing with radiofrequency results in dry microablation, thus downtime is shorter and the risk for side effects such as

infection is minimal as compared to laser resurfacing methods that result in open wounds. Clinically, the affected areas are erythematous and mildly edematous after treatment, but resolve within few hours. This rapid healing is likely related to the persistence of healthy unaffected tissue that remains between the ablated pulses after ablative fractional resurfacing [3,4].

The data reported in this study demonstrate that this Fractional Skin Resurfacing (FSR) applicator of the EndyMed PRO system offers a safe and effective technique to improve skin texture. Furthermore, this study evaluated the clinical effect after a single session. Neil S. Sadick et al. showed the clinical and Histological effect following a series of up to three Fractional skin resurfacing [8]. Since the clinical recommended protocol include 3 sessions, we anticipate that even better results can be achieved when performing a 3 session course of treatment.

In our study, analysis revealed improvement (according to the quartile scale) in all patients according to both blinded reviewers. Furthermore, analysis of the frequency of improvement degree reveals that both reviewers found that the degree of improvement is moderate to good (25%-75% improvement) in most of the study participants.

The EndyMed PRO FSR technology provides the unique ability to treat epidermis and dermis simultaneously - fractional microablation for skin texture at the epidermal layer - and significant full volume dermal heating for collagen remodeling of aged skin and atrophic acne scars at the dermal layer.

In conclusion, the results of this study clearly indicate that this innovative Fractional Skin Resurfacing (FSR) applicator of the EndyMed PRO system offer an effective, safe and virtually painless face wrinkle and acne scar improvement treatment.

References

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