

Depressed Acne Scars—Effective, Minimal Downtime Treatment with a Novel Smooth Motion Non-Insulated Microneedle Radiofrequency Technology

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Abstract

Background: The microneedle fractional RF handpiece used in our study (Intensif Handpiece, EndyMed Medical, Caesarea, Israel) is a novel handpiece that uses a tip with 25 non-insulated, gold plated microneedle electrodes. The needles are inserted into the skin by a specially designed electronically controlled, smooth motion motor minimizing patient discomfort. RF emission delivered over the whole dermal portion of the needle allows effective coagulation resulting in minimal or no bleeding, together with bulk volumetric heating. **Study Design/Materials and Methods:** The study included 20 patients, treated for depressed acne scars using the Intensif™ Microneedles handpiece (EndyMed PRO Platform System, EndyMed Medical, Caesarea, Israel). The degree of clinical improvement was assessed by the global aesthetic improvement scale (GAIS) and subjects satisfaction by post treatment questionnaires. **Results:** The number of treatments per patient varied between 1 and 6 (average 3.3 treatments per patient). Eleven patients (55%) reported none to minimal pain, six (30%) moderate discomfort and only three (15%) reported significant pain. Objective evaluation of the improvement by a board certified dermatologist showed improvement in 95% of patients. 25% showed excellent improvement, 50% experienced good improvement, and the 20% showed minimal improvement. One patient showed no improvement. **Conclusions:** The presented results show that the tested electronically controlled motorized insertion, non-insulated microneedle treatment technology provides a minimal discomfort, minimal downtime, effective and safe treatment for depressed acne scars.

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Keywords

Microneedles, Radio-Frequency, Acne Scars, RF, Multisource, Fractional Lasers, Non-Insulated

1. Introduction

Acne scars are one of the most difficult disorders to treat in aesthetic dermatology. Depressed acne scars are divided into 3 categories: boxcar, ice pick and rolling scars. The pathogenesis of the scars relates most probably to thickened bands of collagen under the scars causing a retraction of skin surface. Based on the study of Zheng *et al.* that found that depressed scars may reach a depth of 0.7 mm; an effective treatment will have to reach further into the depth to remodel the retracting collagen fibers under the scar [1]. Based on these findings we may assume that the optimal treatment system for atrophic depressed scars will need to have deep volumetric dermal heating for collagen remodeling in the dermis up to at least 2.5 or 3 mm, and the ability to mechanically disrupt the dystrophic scar tissue. For the patient we will need to allow minimal discomfort, minimal downtime and minimal post treatment side effects.

Fractional ablative or non-ablative lasers are used for minimally invasive treatment of depressed. Ong *et al.* published an extensive review on these lasers found in different studies improvement range of 26 - 83 percent for ablative fractional lasers and lower (26% - 50%) for the non-ablative fractional lasers [2].

Although minimally invasive, the treatment of acne scars with fractional lasers, was accompanied by significant downtime and pain; causing prolonged erythema for up to 11.5 days after ablative fractional laser treatment and up to 7.5 days after fractional non-ablative laser treatment. Pain levels were (5.9 - 8.1) for ablative and (3.9 - 5.6) for non-ablative (on the pain scale of 10). Post inflammatory hyperpigmentation (PIH) incidence was also significant; 0% - 93% (for up to 6 months) after ablative fractional laser treatment and 0% - 13% (for up to 7.5 days) after the non-ablative fractional laser treatment.

Radiofrequency (RF) is non-ionizing electromagnetic radiation used in medicine for nearly 100 years. In contrast to most lasers that target specific chromophores, RF is chromophore-independent and has better penetration to the dermis and hypodermis as compared to light based technologies. Clinical treatment systems using radiofrequency energy (RF) were proven in the last decade to be safe and effective for both non-ablative skin tightening of the face and body, and fractional RF skin resurfacing for skin [3]-[5].

The first generation of microneedle RF delivery technology used insulated needles for skin rejuvenation and acne scars with promising results. These microneedles allowed the heating of small volume of tissue near their needle tip while the rest of the needle was insulated. With these needles the energy flows only through the tip of the needle, resulting in a small coagulated sphere-like shape in the dermis. These devices have several disadvantages, including micro-bleeding during the treatment and the need to perform several passes on the skin at different depths to affect the entire the dermis [5] [6].

Cho *et al.* described treatment of atrophic acne scars with insulated microneedle radiofrequency devices [6]. These authors used needles in which the entire needle electrode is nonconductive except the tip, (beginning 0.3 mm from the distal end) inserted to a maximum depth of 2 mm. They reported reduction of large pores in 70% of the patients treated. Skin surface roughness, dermal density, and microscopic and composite images also improved, whereas TEWL and sebum measurement did not change. Eight weeks after two sessions of treatment, the grade of acne scars improved in 22 patients (73.3%), did not change in seven (23.3%), and became aggravated in one (3.3%). The mean duration of visible erythema after treatment was 7.8 ± 2.6 days. Pain persisted for longer than 1 day in 10 patients (33.3%) and for longer than 3 days in five (16.7%). Folliculitis was observed in two patients (6.7%).

The microneedle fractional RF handpiece used in our study (Intensif Handpiece, EndyMed Medical, Caesarea, Israel) is a novel FDA cleared handpiece that uses a sterile treatment tip with 25 non-insulated gold plated microneedle electrodes (max diameter of 300 micron at their base gradually tapered to an extra sharp edge) (Figure 1). Penetration depth is up to 3.5 millimeter with digitally controlled increments of 0.1 mm. Maximal power is 25 Watts with a maximal pulse duration is 200 milliseconds [7]. The needles are inserted into the skin by a specially designed, electronically controlled, smooth motion motor minimizing patient discomfort. When the needles reach the pre-defined insertion depth the RF is emitted selectively heating the dermis while sparing the epidermis. The difference in electrical impedance between the epidermis (high impedance) and the dermis (low



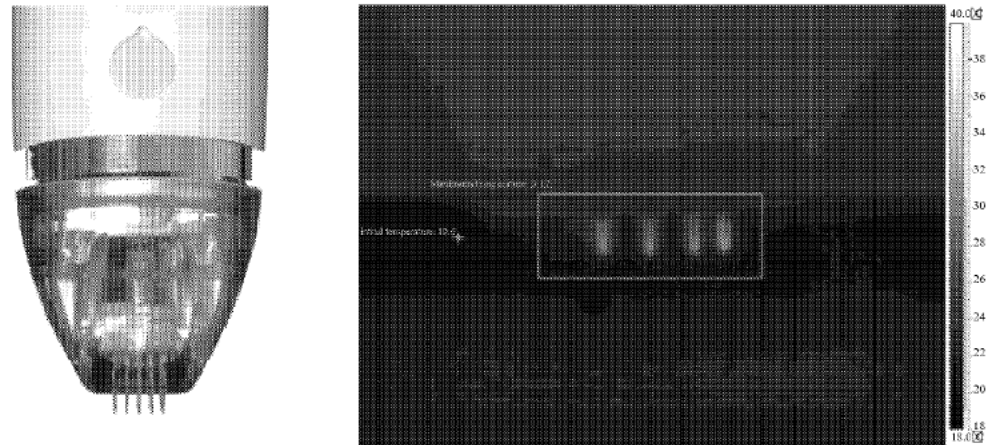


Figure 1. Left: EndyMed's Intensif Handpiece. Right: Thermal image of a treatment of laboratory skin model with impedance similar to dermal impedance (Flir Systems, ThermoCAM SC 640).

impedance) further increase selectivity—enhancing RF flow through the dermis. The RF emission delivered over the whole dermal portion of the needle allows effective coagulation resulting in minimal or no bleeding, combined with deep dermal heating.

2. Study Design/Materials and Methods

The study included 20 patients treated by two board certified dermatologists for depressed acne scars. We used the EndyMed PRO platform system (EndyMed medical, Caesarea, Israel) equipped with the Intensif™ micro-needle RF handpiece. Topical anesthetic cream was applied to the patient skin for 40 minutes before the fractional microneedle RF treatments. The microneedle RF collagen remodeling treatments were performed once a month, (1 to 5 sessions). Patients were photographed by a professional photography assessment system (Foto-finder Systems, Germany and Reveal Imager, Canfield Imaging systems, USA).

The degree of clinical improvement was then given a global aesthetic improvement scale for each patient by the investigator assigning an overall value for reduction in number of scars, reduction in depth of scars and improvement of color uniformity. Excellent improvement (defined as >75% improvement), very good improvement (defined as 51% - 75% improvement), good improvement (defined as 26% - 50% improvement), minimal improvement (defined as 5% - 25% improvement), and no improvement (<5%).

The score was calculated based on blinded comparative analysis of baseline picture and post treatment photographs.

Subjects' satisfaction was assessed by questionnaires that included specific questions about the treatment discomfort and downtime. Subjective assessment of was categorized to excellent, good to very good, moderate to good or none to minimal.

3. Results

Twenty patients, fifteen females and five males were included in the study. Treatment was performed by two different board certified dermatologist. Fitzpatrick's skin type was II-2 patients, III-11 patients, IV-5 patients and V-2 patients. Mean age was 32.6 ± 11.9 years. Number of treatments varied between one and six, with an average of 3.3 treatments per patient.

Eleven patients (55%) reported none to minimal pain, six (30%) moderate discomfort and only 3 (15%) reported significant pain.

When asked about subjective improvement 19 out of 20 patients (95%) of the treated patients experienced some improvement. 25% experienced very good to excellent improvement (defined as >50% improvement) additional 30% experienced good improvement (defined as 26% - 50% improvement) and the rest reported some improvement (up to 25%). Only one patient did not notice any improvement.

Regarding downtime: 80% of patient reported mild erythema for less than 48 hours (50% percent reported an erythema of a few hours; an additional 30% reported erythema of 1 - 2 days). The rest 20% reported erythema of 72 hours. Edema subsided in less than 24 hours for all patients.

Eighty percent of patients didn't have micro crusts or had a minimal number (up to 5). Twenty percent reported moderate number of visible micro crusts that disappeared in 4 - 5 days. Ninety percent of patients were back to normal activities in less than 48 hours. 65% in less than 24 hours, 25% needed 48 hours and 10 percent needed 72 hours.

No adverse events occurred during the treatments.

Seventy percent of patients said they would recommend the treatment to their friends 25% were not sure and only one patient (5%) said he would not recommend the treatment. Improvement in acne scars was noted starting at 4 weeks after the first treatment improving to a maximum at 3 months follow-up.

Objective evaluation of the improvement by a board certified dermatologist showed improvement in 95% of patients. 25% showed excellent improvement (defined as >75% improvement) additional 50% experienced good improvement (defined as 26% - 50% improvement) and the 20% showed minimal improvement. One patient showed no improvement. None of the patients experienced worsening in their skin condition (Figures 2-5).

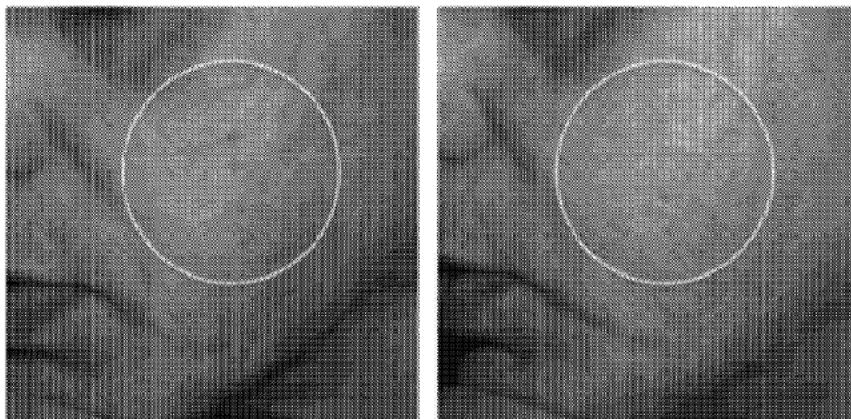


Figure 2. Left: Baseline. Right: One month after three microneedle RF treatments sessions. Significant decrease in the depth of the scars and general texture improvement.

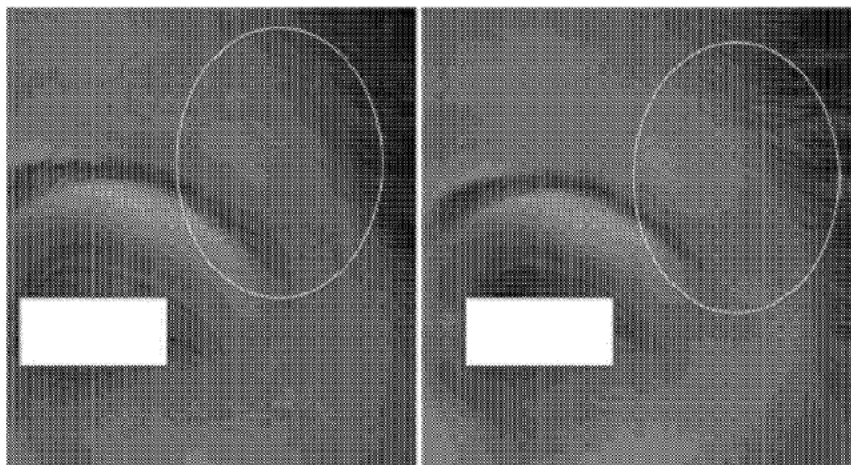


Figure 3. Left: Baseline. Right: One month after three microneedle RF treatments sessions. Significant reduction in the number and depth of the scars, with general texture improvement.

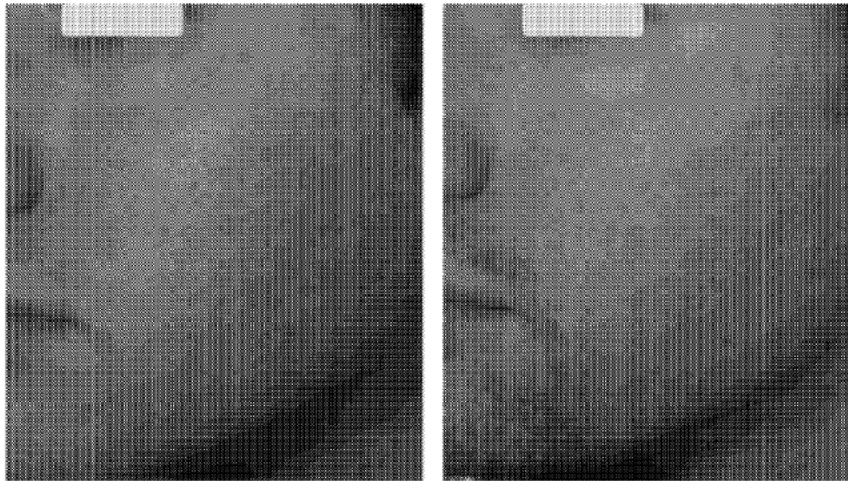


Figure 4. Left: Baseline. Right: One month after two microneedle RF treatments sessions. Significant texture improvement with decrease in the depth and number of atrophic and ice pick scars.

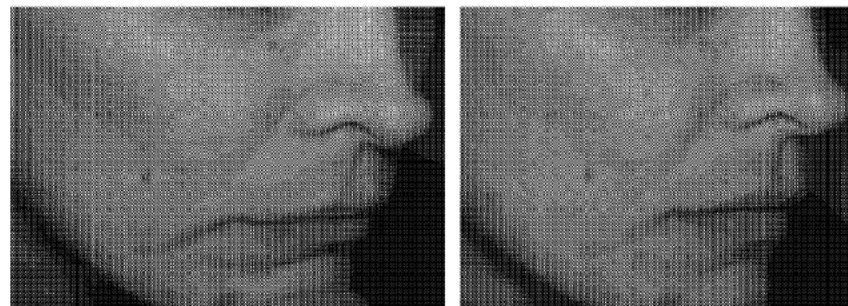


Figure 5. Left: Baseline. Right: One month after two microneedle RF treatments sessions. Decrease in the number and depth of the scars.

4. Discussion

The current study as a few previous studies proves the efficacy and safety of the microneedles radiofrequency technology in the treatment of depressed acne scars. The efficacy seem to be in the same effectiveness range of ablative fractional lasers and somewhat higher than the non-ablative fractional lasers.

This difference can be explained by considerable higher skin penetration of the microneedles (up to 3.5 mm) vs lower penetration of fractional lasers (up to 0.7 mm) and the additional benefit of the mechanical scar disruption.

Based on recent reviews ablative fractional laser are usually associated with longer post treatment erythema and higher percentage of post inflammatory hyperpigmentation as compared to microneedle RF treatment. Pain is also more significant in ablative and non-ablative fractional lasers than in microneedle RF treatments. This fact may be explained by the ability to use topical anesthesia in microneedles RF treatments. (Not possible for some of the fractional laser procedures.)

Microneedle RF handpieces can be differentiated based on two main features. First is the mode of insertion into the skin (Fixed needles inserted manually, needles inserted mechanically using a “spring” and the latest generation using electronically controlled motorized gradual insertion). Second important differentiating feature involves the needle quality basically the sharpness and coating material.

Our study shows that motorized electronically controlled smooth insertion of the needles allows a minimal pain and downtime procedure with minimal unnecessary trauma to the epidermis and no bleeding. Unlike tech-

nologies that use fixed needles with manual insertion, where the user can't control the depth of penetration, the accurate predefined penetration depth enabled by the Intensif system, allows precise treatment for different skin thickness with high safety and efficacy.

Our data show comparable or better clinical results with lower pain level, lower downtime and lower PIH level as compared to fractional ablative or non-ablative lasers [3].

The advantage in efficacy can be explained by considerable higher skin penetration of the microneedles (up to 3.5 mm) vs lower penetration of fractional lasers (up to 0.7 mm) and the mechanical scar disruption effect of the microneedle RF devices.

The lower incidence of PIH may be explained by the difference in physical effects of light and RF. Long term PIH is believed to be caused by damage to the dermo-epidermal junction and dropping of melanin to the dermis. By definition the fractional lasers coagulate or ablate the epidermis with thermal damage to the dermal epidermal junction and upper part of the dermis. We hypothesize that the non-thermal penetration of the epidermis with the smooth motion, extra sharp microneedle is less traumatic to the epidermis and epidermal dermal junction leading to a decreased chance of PIH in microneedle RF treatments.

The reduced pain experience in microneedle RF treatment may be related to sharpness of the needles and the unique smooth needle motorized insertion.

The clinical efficacy of insulated needles is limited by the small volume of heat produced through the small non-insulated part near the tip and significant micro-bleeding through the treatment.

We believe that the use of gold plated non-insulated needles allows multiple clinical advantages over insulated and stainless steel needles. In contrast to the insulated needles that emit RF through a small area near their tip the novel non-insulated gold plated needle emit RF through the whole length allowing heating of 3× the volume. While RF is delivered when the needle is inserted to its maximal penetration and dermal impedance is lower than epidermal impedance the RF will flow through the dermis with no epidermal coagulation.

Gold plating allows better RF conductivity than stainless needles and thus better treatment efficacy. In addition, RF emission through the whole needle provides a coagulation effect eliminating micro-bleeding improving the patient experience.

Fixed microneedle RF treatment handpiece have a few disadvantages. Insertion in the skin is manual and thus more uncontrolled and more traumatic. Fixed length of needles would lead to the use of a few tip per patient which will be more costly to the doctor. This may lead to increased pain and risk of PIH. Digitally controlling the penetration depth of the needles with automatic motorized insertion allows better control of patient experience reducing discomfort and side effects.

5. Conclusion

This recently introduced FDA cleared non-insulated fractional RF treatment system allows controlled heating to a pre-defined depth of the dermis without epidermal coagulation. This eliminates most of the micro crusting, reduces the risk of post-inflammatory hyperpigmentation associated with epidermal injury, and allows return to normal routine after 24 hours or less. A specially designed smooth motion electronically controlled motor assures minimal trauma to the epidermis and significantly decreases discomfort to the patient. The presented results show that microneedle RF technology with electronically controlled smooth insertion motor and non-insulated gold plated needles is a safe and effective treatment option for atrophic acne scars, providing a minimally invasive, minimal discomfort and minimal downtime for all skin types. This study shows high objective and subjective satisfaction rates with minimal downtime or adverse effects.

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Effective Treatment of Atrophic and Icepick Acne Scars Using Deep Non-Ablative Radiofrequency and Multisource Fractional RF Skin Resurfacing

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ABSTRACT

Background and Objectives: Effective treatment for atrophic (depressed) and icepick acne scars requires treatment of both epidermis—for roughness, texture and hyperpigmentation, and the dermis—for collagen remodeling. All first generation radiofrequency systems allow nonablative RF treatment while a few others allow simple bipolar Fractional RF skin resurfacing. The FDA cleared multisource radiofrequency therapy system (EndyMed PRO, EndyMed Ltd., Cesarea, Israel) allows, for the first time, phase controlled multisource RF for both deep (up to 11 mm) non ablative RF and fractional RF skin resurfacing on the same treatment device. **Study Design/Materials and Methods:** Ten subjects with atrophic acne scars were enrolled in the study. Patients were photographed using standardized methods. In each treatment session, each patient received a full face 3DEEP non ablative skin tightening treatment followed by a Fractional skin resurfacing treatment. The treatment sessions were repeated once a month to a total of up to 4 treatments. **Results:** All subjects experienced mild-moderate edema and erythema as an immediate response to treatment. Edema resolved after up to three hours post treatment and erythema lasted up to 2 days. Micro ablative crusts were formed 1 - 2 days post treatments and lasted up to 5 days on facial areas. Patients' photographs—before each treatment session and 1 and 3 months after the last session—were graded according to the accepted Cosmetic Improvement Scale. All patients obtained significant skin improvement. Seventy percent of patients had 50% - 75% improvement one month after the third treatment session while the other thirty percent experienced a 25% - 50%. **Discussion and Conclusions:** The presented results describe for the first time a new treatment system (EndyMed PRO™) that allows both deep non ablative RF delivery and Fractional skin resurfacing on the same treatment platform. This work shows the synergy of combining these two applications for the improvement of acne scars, as well as for some secondary possible pigmentation and vascular improvement.

Keywords: Fractional Radio Frequency; Skin Resurfacing; Acne Scars

1. Introduction

Effective treatment for atrophic depressed acne scars requires treatment of both epidermis—for epidermal roughness, texture and hyperpigmentation and dermis—for collagen remodeling [1-3]. Many treatment modalities can improve color and texture. Nevertheless, building new collagen is dependent on the amount and volume of heat delivered to the deep dermis. The improvement offered by fractional lasers or fractional bipolar RF systems is usually limited, due to the small volume of dermal heat produced by these devices.

A new multisource RF, FDA cleared therapy system (EndyMed PRO, EndyMed Ltd., Cesarea, Israel) allows for the first time phase controlled multisource RF for both deep (up to 11 mm) non ablative RF together with

multisource fractional RF skin resurfacing on the same treatment device.

In the current study, we used a combined protocol that included two complementary treatments in one session—a full face non ablative skin tightening, followed by Fractional Skin Resurfacing (FSR). Both treatments were performed using the EndyMed PRO multisource radiofrequency system. The EndyMed PRO RF System is an FDA cleared computerized system that employs up to six radio frequency generators at the same time, creating few simultaneous electric fields in the same phase, that force the energy to penetrate into the deep dermis, causing a non-ablative deep dermal heating effect that results in painless skin tightening. In another handpiece, the multisource RF is used to form micro ablative fractional skin resurfacing with simultaneous volumetric

heating of the upper dermis (**Figures 1 and 2**).

The non-ablative skin tightening application was applied first, creating a continuous deep volumetric dermal heating for stimulation of collagen remodeling, followed by the FSR (Fractional skin Resurfacing) application that reinforced the volumetric heating on the upper dermis and added micro-ablative resurfacing in up to 10% of the affected area.

2. Methods

Ten subjects with atrophic acne scars were enrolled in the study. Patients were photographed using standardized methods. In each treatment session, each patient received a full face 3DEEP non ablative skin tightening treatment followed, 45 minutes after, by a Fractional Skin Resurfacing treatment. A topical anesthetic (EMLA) was applied after the non ablative treatment to prepare skin for the fractional treatment. The treatment sessions were repeated at a minimum interval of once a month for a total of up to 4 treatments.

Before starting the non ablative procedure the skin was cleaned with 70% alcoholic gauze in order to remove make up or other lotions. The patients had up to 8 minute treatment in each area in which skin surface temperature was maintained at 40 - 42 degrees Celsius. Before the FSR treatment the residual EMLA was removed gently with gauze containing 70% alcohol. During the treatment,

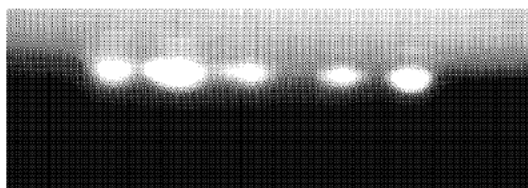


Figure 1. Thermal imaging of the Ablative phase of the Fractional Skin Resurfacing application pulse of EndyMed PRO multi-source RF system (EndyMed Ltd., Cesarea, Israel), showing the creation of the micro-ablative effect (ThermaCAM SC 640).

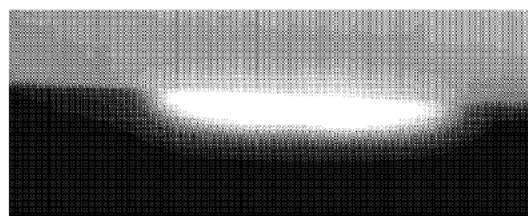


Figure 2. Thermal imaging of the volumetric phase of the Fractional Skin Resurfacing application pulse of EndyMed PRO multi-source RF system (EndyMed Ltd., Cesarea, Israel), showing significant volumetric heating (ThermaCAM SC 640).

the treatment tip was placed on the skin and a short (<1 sec.) RF pulse of energy was delivered. Then, the tip was placed next to the first area and another RF pulse was delivered. This scenario was repeated until the whole treatment area was covered. In each treatment session, the fractional treatment was repeated 1 - 3 times over the whole scar area.

Treated areas were visually assessed for skin responses, including edema, erythema, hypopigmentation, hyperpigmentation, and textural changes following the treatment.

The use of a moisturizing cream (Ortho Dermatologics Topical Emulsion, Biafine) was recommended post treatment.

Patients' photographs were graded according to scales accepted by board certified dermatologists. Dedicated questionnaires were used for both doctor and patients in order to grade different parameters such as efficacy, safety, comfort of treatment, in addition to subjective satisfaction of the patients.

3. Results

The patients, nine women, one man, ages 21 - 70 years (average 37.2), were enrolled in the study after meeting all inclusion/exclusion criteria and providing signed informed consent forms.

All patients completed three to four treatment sessions, except for two patients who had only 2 sessions, due to unrelated personal reasons. Mild to moderate erythema and mild edema were noted following the non ablative Skin Tightening procedure. By the time the Fractional RF procedure started, the erythema was faded. Following the FSR treatment mild to moderate erythema and edema were noted. Erythema lasted up to one day. Micro crusts were formed one to two days following the treatment. These crusts started to peel off 3 - 4 days post treatment and totally resolved within 4 - 5 days following treatment. Post treatment instruction included gentle cleaning of the face during the first days after the treatment, and a four week intense regimen of high potency sunblock. The male patient was advised not to shave for one week. No unexpected adverse effects were detected or reported. There were no incidences of infections, scarring, hyper/hypopigmentation, or any other serious complications.

3.1. Physician Evaluation

70% of the patient showed 51% - 75% improvement in skin texture, roughness and acne scar appearance, while the other 30% of the patients showed 26% - 50% improvement (**Figure 3**). When evaluated 3 months after the last session, all patients showed significant improvement in skin texture and scar appearance (**Figures 4-6**).

Global Aesthetic Skin Improvement Scale (GAIS)

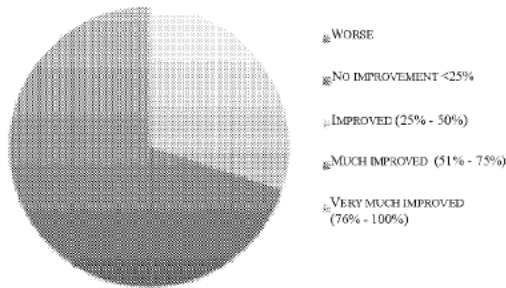


Figure 3. The overall improvement in skin appearance, 3 months after the last session.

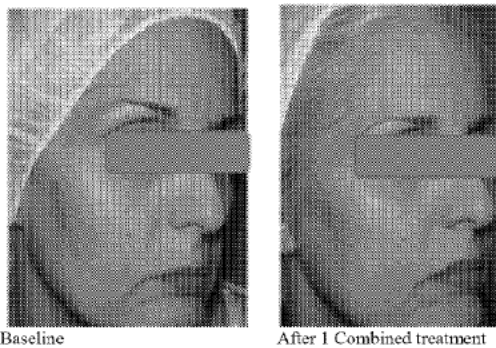


Figure 4. Significant improvement in skin texture and reduction of acne scars appearance after one combined session (Left—Baseline, Right—After one combined session). Parameters; 3 - 4 Watts, 30 - 40 msec. Facial Skin Tightening handpiece and Fractional Skin Resurfacing handpiece of the EndyMed PRO multi-source RF system (EndyMed Ltd., Cesarea, Israel.) Photo: Dr. Monica Elman, Holon, Israel.

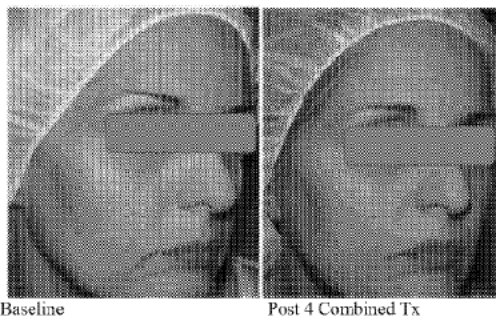


Figure 5. Figure 4 demonstrates further improvement in skin texture and reduction of acne scars appearance after four combined Sessions (Left—Baseline, Right—After four combined sessions). Parameters; 3 - 4 Watts, 30 - 40 msec. Facial Skin Tightening handpiece and Fractional Skin Resurfacing handpiece of the EndyMed PRO multi-source RF system (EndyMed Ltd., Cesarea, Israel.) Photo: Dr. Monica Elman, Holon, Israel.

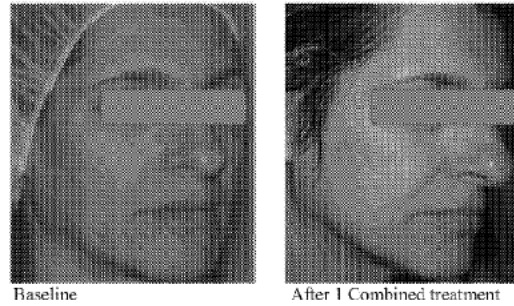


Figure 6. Significant improvement in skin texture and reduction of acne scar appearance after one combined session. Parameters; 3 - 4 Watts, 30 - 40 msec. Facial Skin Tightening handpiece and Fractional Skin Resurfacing handpiece of the EndyMed PRO multi-source RF system (EndyMed Ltd., Cesarea, Israel.) Photo: Dr. Monica Elman, Holon, Israel.

3.2. Reduction of Pigmentation and Small Blood Vessels Congestion

Improvement in skin pigmentation and appearance of capillaries was not in the initial scope of this study. However, patients' photos were taken using a multi-filter camera (Reveal Imager, Canfield Imaging Systems, NJ, USA) that enables filtering brown and red spots.

Applying these filters and evaluation of the baseline photos compared to those of the following treatments revealed interesting data—some of the patients demonstrated a mild to moderate improvement in the amount of red and brown spots, meaning decrease in skin pigmentation and superficial blood vessels (Figures 7 and 8). This result may be attributed to the intense bulk heating caused by the two applications and mainly by the FSR application.

3.3. Patients' Experience

Patients' experience was evaluated using multiple choice questionnaires.

When asked about their subjective opinion about the cosmetic change they experienced, 30% reported 51% - 75% improvement at the end of the last session. When asked the same question 3 months post the last treatment, 50% of the patients reported 51% - 75% improvement (Figure 9).

When asked "Did the treatment meet your expectations?" At the end of the last session, 40% responded "yes" while 60% responded "yes to some extent". When asked the same question one month and 3 months after the end of treatment, 50% answered "yes" (Figure 10).

When asked at the end of three treatments "Would you recommend the treatment to your colleagues and friends?" 80% of patients answered definitely yes and

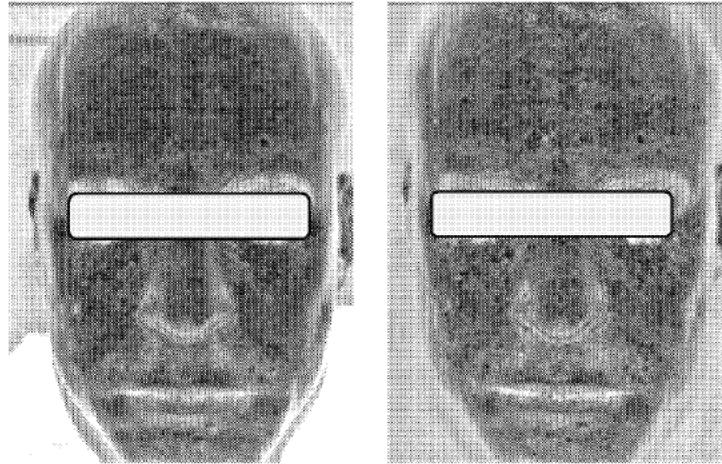


Figure 7. Mild reduction in the level of skin pigmentation. Left—Baseline; Right—Post one combined session.

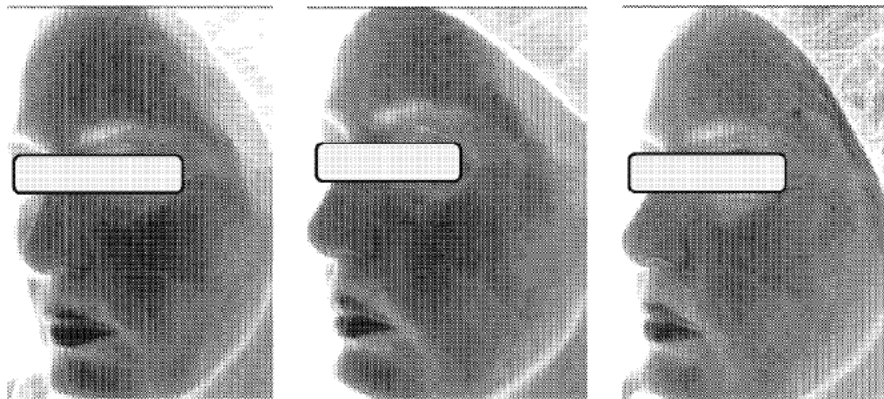


Figure 8. Reduction of redness and capillary congestion. Left—Baseline; Middle—Post two combined sessions; Right—3 months after three combined sessions.

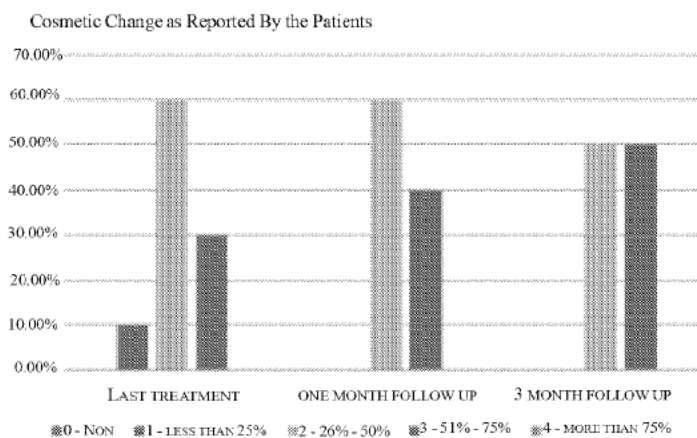


Figure 9. Patients opinion regarding their cosmetic improvement (Y axis = Percent of the patient group).

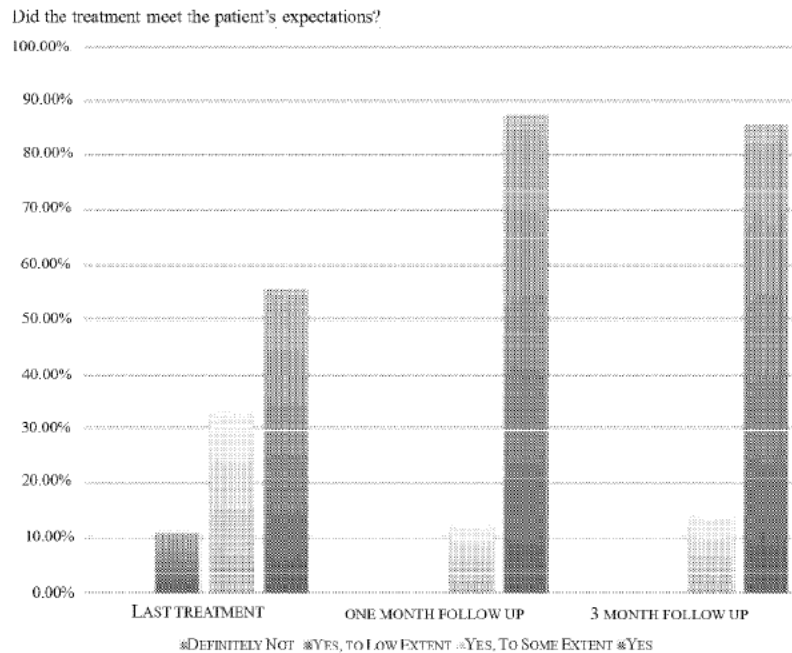


Figure 10. Patients were asked whether the treatment fulfilled their expectations; after completing three treatment sessions, and one and 3 months after the last treatment session (Y axis = percent of the patient group).

20% answered yes. When asked the same question 3 months after the end of treatment all patients (90%) answered definitely yes.

4. Discussion and Conclusions

Multisource radiofrequency (EndyMed PRO) is one of the leading technologies for body and face non ablative skin tightening. In this present report we describe, for the first time, clinical data from a study using a unique combination of Multisource RF Skin Tightening application together with Fractional RF applicator on the same platform. This RF based Multisource Fractional RF applicator enables, together with the non ablative skin tightening, a combination of RF microablation and volumetric deep dermal heating for the simultaneous epidermal and dermal skin rejuvenation effect [4-8].

The intrinsic disadvantage of current fractional laser 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 hyperpigmentation. Decreasing laser power will provide good epidermal results with little or no dermal

effect [8].

Fractional resurfacing using radiofrequency results in dry microablation, thus downtime is shorter and the risk for side effects such as infection are 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 [8-11].

Laboratory thermal studies using EndyMed's Multisource Fractional handpiece on Agar have shown volumetric heating of the dermis up to 2.8 mm, with a concomitant epidermal ablation with a contact diameter of 300 micron and a depth of 100 - 150, which is optimal for fractional epidermal skin resurfacing. Animal studies have shown the formation of micro crusts 1 - 2 days after treatment with full recovery of the epidermis in 5 - 7 days.

Sadick *et al.* have used the EndyMed PRO on thirty patients treating wrinkles on the face and acne scars. They reported clinical improvement in skin texture in patients with both wrinkles and acne scars. They also noted that the incidence of complications was much lower than that seen following traditional ablative laser

resurfacing [12-14].

The treatment was well accepted by the patients with minimal or no pain after the application of a 5% topical anesthetic cream (Emla). There was no need for post therapy treatment and patients were able to return to work with makeup as soon as one hour after therapy. Micro crusts developed 24 - 48 hours after therapy and resolved 4 - 5 days after therapy.

Beneficial epidermal effects were noted starting one week after therapy and included significantly improved brightness of the skin, smoothening of the skin and some secondary decrease in pigmentary changes (post acne and senile lentigines). Four to six weeks after treatment dermal changes were noted including significant improvement in skin texture, reduction of wrinkles and skin laxity.

Based on the above results, we believe the new EndyMed PRO combined treatment which combines non invasive skin tightening followed by multisource Fractional skin resurfacing procedure, provides an exciting new option for effective multilayer skin rejuvenation and treatment of skin laxity with minimal discomfort and downtime. We found that this specific protocol delivers better results than traditional lasers for acne scars and superficial skin imperfections and about the same results for the treatment of facial wrinkles.

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Treatment of Acne Scars of Skin Types II to V by Subablative Fractional Bipolar Radiofrequency and Bipolar Radiofrequency Combined with Diode Laser

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(J Clin Aesthet Dermatol 2011;4(10):18–27)

Abstract

Objective: This study evaluated the safety and efficacy of subablative fractional bipolar radiofrequency and bipolar radio frequency combined with diode laser for the treatment of both superficial and deep acne scars in patients with skin types II to V.

Design: Prospective, single-center study. Subjects received up to five treatments with subablative fractional bipolar radiofrequency and bipolar radiofrequency combined with diode laser. Treatments were directed to at least two facial (forehead, perioral, cheeks) and/or neck areas with acne scars at four-week intervals.

Treatment parameters on each subject were based on skin type and on skin response to test spots on the target area just before treatment.

Setting: Physician office.

Participants: Subjects ($n=20$, aged 40.7 ± 10.5 years [mean $\pm$ SD], skin

types II–V) with acne scars and without acne lesions enrolled in this prospective study. **Measurements:** Results were evaluated just before each treatment and at four and 12 weeks after the final treatment using the Goodman Scar Scale, a quantitative method of evaluating scars that attempts to reduce grading subjectivity, as well as by patient satisfaction. **Results:** Acne scars improved significantly one month after three treatments and improvement persisted for at least 12 weeks after the fifth treatment. Improvement was not affected by skin type. Adverse effects were limited to transient erythema and edema. **Conclusion:** The combination of diode laser and bipolar radiofrequency energy device in addition to fractionated subablative radiofrequency is a safe and statistically significantly effective

combined modality for the treatment of both superficial and deep acne scars in patients with skin types II to V with minimal downtime and no significant side effects.

Introduction

Acne scars have multiple morphologies¹ and often require different technical approaches to achieve an optimal cosmetic outcome, especially in dark-skinned subjects.² Acne scars are commonly classified as ice pick, rolling, or boxcar.¹ Ice pick scars have traditionally been treated by punch excision, subcision, or chemical reconstruction of skin scars (CROSS) technique with 100% trichloroacetic acid³; rolling scars by subcision and/or laser resurfacing; boxcar scars by punch elevation, subcision, and/or laser resurfacing; deep boxcar scars by punch excision; and shallow boxcar scars by laser resurfacing. Combinations of modalities may also be required.⁴

Dermabrasion is very effective in the treatment of scars, but is not widely used due to blood spattering and the need for a high skill level to produce excellent results. Chemical peels, which are most effective against macular scars,⁵ are associated with variable levels of improvement. Biomaterials such as collagen, hyaluronic acid (HA), autologous fat, or other fillers offer transient improvement,^{6,7} but are often used for focal rolling scars. Subdermal minimal surgery has recently been introduced,⁸ which is performed by pneumatically accelerating a carrier fluid jet containing high-mass molecules of HA. These molecules then disperse into the skin under the targeted scar.

For the past 10 years, the mainstays of acne scarring therapy have been nonablative and ablative lasers. Newer fractional technologies

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have advanced the treatment of acne scarring significantly, as they are able to reach the dermal layer yet have a relatively low side-effect profile. These technologies may even be used safely in dark skin.² Laser procedures are effective against boxcar scars and rolling scars.⁵ The ablative devices, such as the CO₂ and erbium-doped yttrium aluminium garnet (Er:YAG) lasers,¹⁰ are effective, but may be associated with long recovery times and side effects including postinflammatory hyperpigmentation. They can, however, be used successfully in dark skin.¹¹

Nonablative devices include the neodymium-doped yttrium aluminium garnet (Nd:YAG) and diode lasers, long-pulsed 1450nm diode, the 1320 and 1064nm Nd:YAG, and 1540nm erbium glass lasers;¹² although careful attention must be paid to parameters in Asian skin types.¹³ Although side effects and recovery times with nonablative lasers are reduced compared to ablative lasers, multiple treatments are required to reach significant efficacy. Examples include the 1550nm fractional erbium-doped laser¹⁴⁻¹⁶ and the 1540nm fractional laser.¹⁷

Recent reports have presented objective evidence of the efficacy of devices that combine ablative with nonablative fractional technology for the treatment of acne scars.¹⁸⁻²² A relatively new modality uses fractionated bipolar radiofrequency (RF) energy, which has been shown to improve mild rhytids, skin texture, smoothing, and tightening.^{24,25} This treatment—sublative rejuvenation (SR)—provides a coagulative (nonablative) effect limited to the mid-dermis in addition to an ablative injury to less than five percent of the epidermis. The advantages of this modality are reduced down time, lack of interaction with melanin, and low

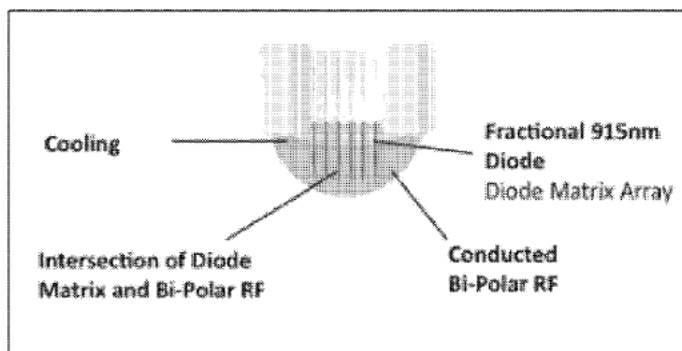


Figure 1. Schematic of Combination Bipolar Matrix Array and Bi-Polar RF (DLRF). The intersection of the two modalities created thermabands at 1.5mm into the dermis causing collagen contraction. Figure courtesy of Syneron Medical Ltd.

side-effect profile. One prior evaluation with similar technology has been published for acne scars.²²

The current article seeks to ascertain the efficacy and safety of SR in addition to a diode laser/bipolar RF (DLRF) energy for the treatment of both superficial and deep acne scars in skin types II to V.

Methods

Subjects. Healthy men and women (n=20, 8 men/12 women, aged 40.7±10.5 years [mean ± SD], skin types II–V) with acne scars successfully enrolled in the study. All female subjects were postmenopausal, surgically sterilized, or used an acceptable form of birth control for at least three months before the study began. All subjects provided signed informed consent. Exclusion criteria were active acne; pregnancy; breastfeeding; active electrical implant; permanent facial implant; injectable filler in area to be treated within nine months of investigation; surgical, chemical, or light-based facial treatments in the past six months; isotretinoin treatment within six

months; immunosuppression; currently tanned or unable to refrain from tanning within the investigation period; or any dermatological, hormonal, or medical condition (or history) or therapy that might compromise a subject's safety or interfere with interpretation of the study results.

Treatment device. Treatment of acne scars consisted of irradiation with a combination of bipolar RF and 915nm diode laser energy (Matrix IR, Syneron Medical Ltd., Yokneam, Israel) (DLRF) followed by sublative bipolar RF energy (Matrix RF, Syneron) (SR). Both applicator handpieces derived energy from a common platform (eLaser, Syneron).

The DLRF device was designed to create a focal coagulation of tissue at approximately 1.5mm skin depth to stimulate collagenesis (Figure 1), thereby elevating the deeper area of the scar.²² The SR energy enters the dermis through ablation caused by rows of electrode pins on the square disposable tip (Figure 2). The nonablative dermal heating is a combination of coagulative damage

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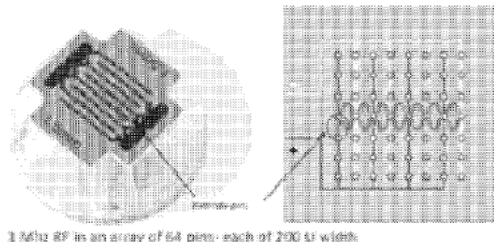
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Sublative RF – The Technology



2 kHz RF in an array of 64 pins - each of 200 μ width.

Figure 2. Sublative Rejuvenation Disposable Tips and Schematic Radiofrequency current flows between the positive and negative mini-electrodes. Control of this current allows varying degrees of tissue impact. In the space of no current flow a healing reservoir is obtained. Image courtesy of Syneron Medical LTD.

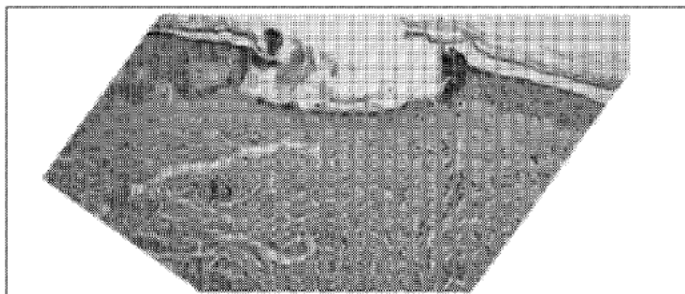


Figure 3. Photomicrograph of skin wound taken immediately after a sublative rejuvenation pulse. Note clear ablation of epidermis and upper dermis with slight coagulation of the upper dermis. Photomicrograph courtesy of Syneron Medical LTD.

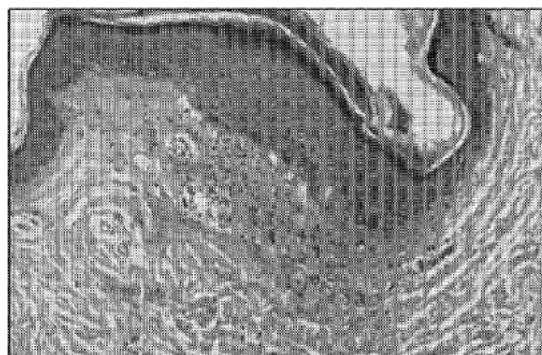


Figure 4. Thirty-six hours after treatment note crust formation and deep dermal coagulation and remodeling. Reprinted with permission from: Hruza G, et al. Skin rejuvenation and wrinkle reduction using a fractional radiofrequency system. *J Drugs Dermatol* 2009;8(3):259–265.

and a subcoagulative heat effect (Figure 3), causing dermal remodeling. DLRF was included in this study because the authors hypothesized that this could be beneficial in treating ice pick scars due to the device design since these types of scars have proven particularly difficult to treat²⁵ and many individuals presenting for treatment of acne scarring have multiple types of scarring (i.e., rolling, ice pick, boxcar).

Study design. In this prospective study, subjects with acne scars received up to five treatments in at least two facial (or neck) areas at four-week intervals. Areas treated included the cheeks, forehead, perioral, and neck. Target areas were washed with mild soap and water before DLRF treatment. After a layer of conductive gel was applied to the target areas, subjects received 3 to 4 lesional passes. Treatment parameters on each subject were based on skin type and skin response to test spots on the target area just before treatment, with clinical endpoints being erythema and edema. DLRF laser fluence ranged from 40 to 85 J/cm² and RF fluence ranged from 50 to 100 J/cm². No anesthetic was used for this portion of the treatment. When DLRF treatment was completed, the conductive gel was removed and the treated areas were allowed to cool at room temperature for 30 minutes, after which topical anesthesia (prilocaine [7%] and lidocaine [7%]) was applied for 30 minutes. The skin was then cleansed with acetone, alcohol, and water; patted dry; and left to air dry for 10 minutes. These areas were then treated with SR with fluence (17–25 J/cm²/pin) determined by skin response to a test spot. Epidermal ablation was five percent in each area treated, with dermal coagulation area

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directly proportional to the energy of the RF (Figure 4).

Post-treatment care consisted of application of petrolatum and sunscreen. Subjects were instructed to avoid exfoliants, to not excoriate healing lesions, to avoid tanning salons and sun, and to use sunscreen (sun protection factor [SPF 30]) during the entire study period.

Evaluation of results. Efficacy and adverse effects were assessed by physical examination at each treatment visit and at the 4- and 12-week follow-up visits. The evaluation was one month after treatment three and immediately before treatment four. Other assessments were made as shown in Table 1. Scars were evaluated at each time point using the scale in Table 2. Differences were evaluated for significance by Friedman's test, the Wilcoxon Signed-Rank test, the Mann-Whitney test, and Pearson's chi square test.

Results

Scar and scar texture scores. Scars. Scar on the cheeks, perioral area, forehead, and neck were assessed at each visit according to the scale in Table 2. Scores of the four anatomical areas were combined for non-parametric statistical analysis. The median scar assessment scores at each visit are shown in Table 3. A graph of the scar scores is presented in Figure 5.

Friedman's test (a nonparametric equivalent to the repeated measures analysis of variance) for the treatment 1 (T1) through T5, four-week follow-up, and 12-week follow-up visit groups showed that the median scar assessments among the seven groups differed significantly ($p < 0.0001$). Friedman's test, however, does not specify which among the six non-baseline groups differs significantly from baseline (T1). Wilcoxon Signed-

TABLE 1. Study protocol

EVALUATION TOOL	VISIT						
	T1	T2	T3	T4	T5	4-WEEK FOLLOWUP	12-WEEK FOLLOWUP
*Photography	x	x	x	x	x	x	x
*Assessment of scars and texture	x	x	x	x	x	x	x
†Comfort during treatment	x	x	x	x	x		
*Subject satisfaction, improvement			x		x	x	x
Adverse events	x	x	x	x	x	x	x

*Before treatment; †After treatment; T=treatment

TABLE 2. Global acne scarring classification

(GRADE) TYPE	NUMBER OF LESIONS 1 (1-10)	NUMBER OF LESIONS 2 (11-30)	NUMBER OF LESIONS 3 (>30)
(A) Mild scarring (1 point each) • Macular erythematous or pigmented • Mildly atrophic dish-like	1 point	2 points	3 points
(B) Moderate scarring (2 point each) • Moderately atrophic dish-like • Punched out with shallow bases small scars (< 5mm) • Shallow but broad atrophic areas	2 points	4 points	6 points
(C) Severe scarring (3 point each) • Punched out with deep but normal bases small scars (< 5mm) • Punched out with deep abnormal bases small scars (< 5mm) • Linear or troughed dermal scarring • Deep broad atrophic areas	3 points	6 points	9 points
(D) Hyperplastic papular scars	2 points	4 points	6 points
(E) Hyperplastic keloidal/hypertrophic scars	Area < 5cm ² 6 points	Area 5-20cm ² 12 points	Area > 20cm ² 18 points

Reproduced with permission from Goodman GJ, Baron JA. Postacne scarring—a quantitative global scarring grading system. *J Cosme Dermatol* 2006;5(1):48-52.

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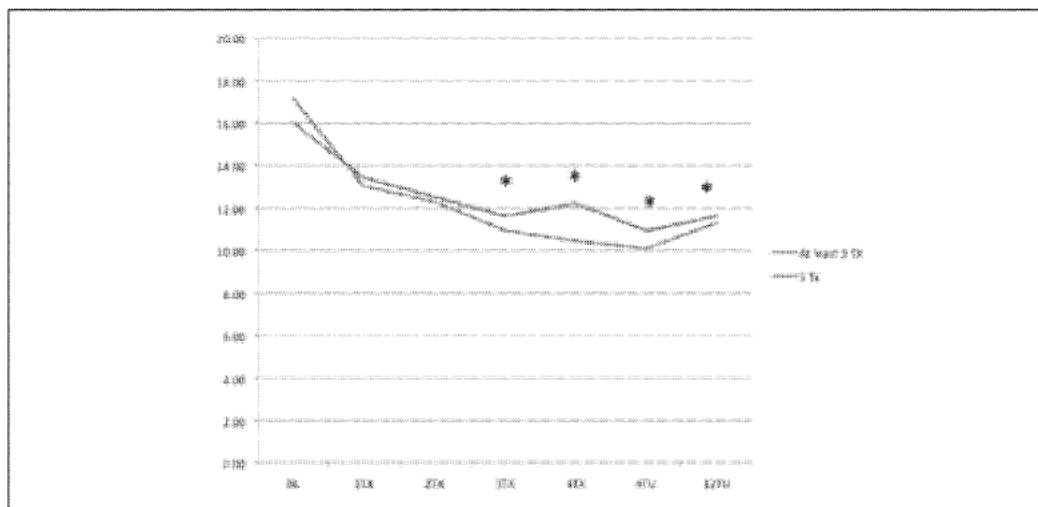


Figure 5. Average Goodmar Scar Score Over Time. Patients with at least three treatments versus patients with five treatments. * = statistical significance.

TABLE 3. Median (IQR) scar scores (cheek, perioral, forehead, neck) at each visit

VISIT	SCAR SCORE	P VALUE*
T1	15.0 (8.3)	
T2	11.0 (6.0)	0.0775 (ns)
T3	11.0 (6.7)	0.0100 (ns)
T4	9.0 (5.7)	0.0002 (s)
T5	9.5 (6.3)	<0.0001 (s)
4-WEEK FOLLOWUP	9.5 (4.6)	<0.0001 (s)
12-WEEK FOLLOWUP	9.0 (6.0)	0.0001 (s)

IQR = interquartile range, a measure of dispersion; T = treatment; s = significant; ns = not significant; *Compared with baseline (T1), Wilcoxon Signed-Rank test

Rank comparisons of each treatment group with baseline (T1) revealed treatment groups in which the median scar assessment score differed

significantly from baseline. The p values are presented in Table 3.

The data show that the median scar scores at the T4, T5, four-week

follow-up, and 12-week follow-up visits were significantly lower than the median scar score at baseline. Since six comparisons with baseline were made, the Bonferroni correction was applied to obtain the appropriate cutoff level. The traditional level ($p=0.05$) was adjusted by dividing 0.05 by six, the number of comparisons with baseline. With the new $p=0.0083$ cutoff level, the median scar scores of only the four previously mentioned groups differed significantly from baseline.

The effect of skin type on improvement in scar assessment scores at 12 weeks compared to baseline was evaluated by the Mann-Whitney test. Data were divided into two categories: Skin types II through III and skin types IV through VI. The analysis showed that the median scores of the two groups did not differ significantly ($p=0.9758$), indicating that the scar assessment scores are not affected by skin type. Early in the

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TABLE 4. Distribution of subjects among rough and regular scar texture groups and comparison with baseline (T1)

TEXTURE	VISIT						
	T1	T2	T3	T4	T5	4-WEEK FOLLOWUP	12-WEEK FOLLOWUP
ROUGH	19	13	12	7	1	2	1
REGULAR	8	14	15	20	23	22	24
P VALUE		p=0.0955(ns)	p=0.0541(ns)	p=0.0011(s)	p=<0.0001(s)	p=<0.0001(s)	p=<0.0001(s)

T=treatment s=significant ns=not significant

study it appeared that people with darker skin types were getting better results than Caucasians (Figure 6), but this difference did not persist after the treatments were completed. Clinical examples of patients after treatment series are presented in Figures 7, 8, and 9.

Scar texture. Pearson's chi square test was used to evaluate scar texture because texture consisted only of two groups—rough and regular. The comparative data are presented in Table 4.

The analyses show that the proportions of scar texture scores at the T4 (1 month after the 3rd treatment), T5, four-week follow-up, and 12-week follow-up visits all differed significantly from baseline (T1). The data indicate that texture improves for more subjects with continued treatment up to T5, in which all but one subject achieved regular texture, and that the effects persist for at least 12 weeks after T5 in nearly all subjects.

Subject grading. Subjects graded acne scars, skin texture, coloration, and

overall improvement at T3, T5, four weeks, and 12 weeks, using the following scale: 0=no improvement, worsening; 1=slight improvement; 2=moderate improvement; 3=good improvement; 4=excellent improvement.

For acne scars, at least moderate improvement was achieved by 50 percent of subjects at T3, 75 percent of subjects at T5, 58 percent of subjects at four weeks, and 63 percent of subjects at 12 weeks. These data suggest a trend toward maximum improvement in acne scars at T5 and persistence of the improvement in most subjects for at least 12 weeks. For skin texture, at least moderate improvement was achieved by 60 percent of subjects at T3, 62 percent of subjects at T5, 68 percent of subjects at four weeks, and 60 percent of subjects at 12 weeks.

For coloration, at least moderate improvement was achieved by 43 percent of subjects at T3, 46 percent of subjects at T5, 58 percent of subjects at four weeks, and 58 percent of subjects at 12 weeks. These data suggest a trend toward maximum

improvement in coloration at four weeks and persistence of this level of improvement in most subjects for at least an additional eight weeks. For overall improvement, at least moderate improvement was achieved by 50 percent of subjects at T3, 69 percent of subjects at T5, 58 percent of subjects at four weeks, and 62 percent of subjects at 12 weeks. These data suggest a trend toward maximum overall improvement at T5 and persistence of the improvement in most subjects for at least 12 weeks.

Subject satisfaction. Subject satisfaction with the treatment and results was evaluated at T3, T5, four weeks, and 12 weeks. Subject responses included "not satisfied," "somewhat satisfied," "satisfied," "very satisfied," or "extremely satisfied." The percentage of responses of "satisfied" or better, however, was 55 percent at T3, 69 percent at T5, 58 percent at four weeks, and 50 percent at 12 weeks, suggesting a trend toward peak satisfaction at T5, which may begin to decline at four and 12 weeks.

Tolerance. Discomfort during

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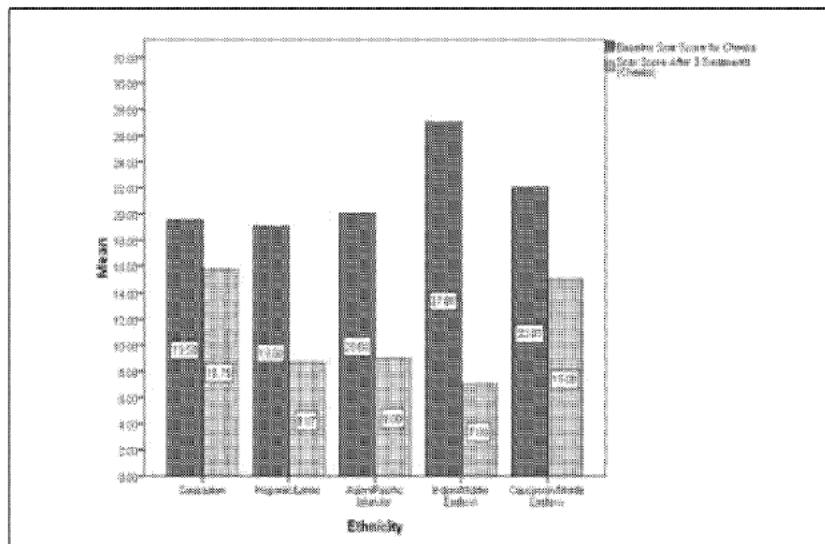


Figure 6. The mean acne scar score for each ethnicity at baseline compared to the mean acne scar score for each ethnicity one month after completing three treatments. The number of patients in each ethnicity group was Caucasian=10 (Hispanic/Latino=Asian/Pacific Islander=3 Indian/Middle Eastern=2 and Caucasian and Middle Eastern (sheels Fitzgeral skin type I)=1).

treatment was evaluated for each modality (DLRF and SR) at each treatment visit using a 5-point scale in which 0=no pain and 4=maximum tolerable pain. Data were evaluated by nonparametric statistics. Median pain scores were usually higher during DLRF treatment than during SR treatment. The median pain scores for DLRF decreased from 2.6 for treatment 1 and to 1.75 for treatment 5. The median scores for SR decreased from 1.55 to 0.75 from treatment 1 to 5.

Side effects and complications.

Crust formation and shedding. The duration of the appearance and shedding of treatment-induced crusts was recorded at each treatment visit. Crusts on average appeared within 1 to 2 days after treatment and were

shed by 3 to 4 days. Subjects were able to apply makeup effectively on Days 2 to 3.

Edema and erythema. Edema was noted in almost all patients and resolved in 1 to 3 days. Erythema was observed in all patients and resolved within 1 to 2 days. Post-inflammatory hyperpigmentation occurred in one patient with skin type IV but resolved after the next treatment without intervention other than reminding the patient to use sunscreen. No ulcerations, scars, infections, or prolonged or delayed evidence of hyper or hypopigmentation was noted in any patient.

Discussion

To the authors' knowledge, this is the first study to evaluate the

combination of diode laser and fractional bipolar RF with subablative fractionated RF for the treatment of acne scars. Rameshet al⁸ treated acne scars of 30 subjects (skin types IV–VI) with a Matrix tunable RF device similar to the RF device used in the present study. All subjects were pretreated with oral antibiotics and the acne scars of eight subjects were subjected to subcision before RF treatment. Subjects received up to four treatments at one-month intervals. Adverse effects included a transient burning sensation, edema, and erythema. Crusting was observed on the treated areas. Improvement ranged from 10 to 50 percent at two months and from 20 to 70 percent at six months. Improvement in this study was based on comparison of

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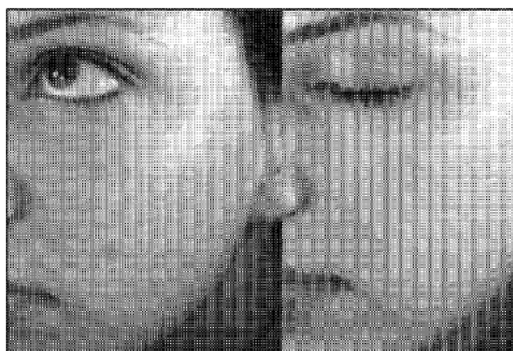


Figure 7. Hispanic study patient before and one month after three treatments of SR and DLR

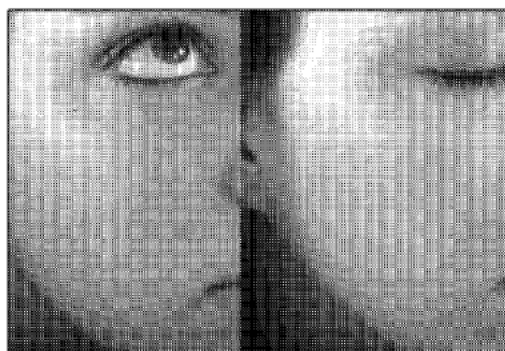


Figure 8. Same patient as Figure 7, opposite cheek view. Hispanic patient before and one month after three treatments

photographs by two independent observers using a visual analog scale. Subcision appeared to enhance outcomes as reported by patients who had undergone subcision versus patients who had not.

Bipolar RF with a diode laser has been used for nonablative treatment of concave skin irregularities such as atrophic acne scars.³⁰ Unlike laser energy, RF energy is not absorbed by melanin, making this modality potentially safer in subjects with dark skin. Sublative rejuvenation technology attempts to blend ablative and nonablative modalities to create a more effective therapy with less downtime. As with all acne scarring treatments, the deepest and most "bound down" scars are the most difficult to treat. These scars have been treated in the past with punch elevation, excision, subcision, or a combination of these modalities. The bipolar RF device with diode laser is designed to remodel these scars without an epidermal wound by creating a coagulative focal point at 1.5mm where the RF and laser meet, stimulating collagen synthesis at the depth of the scar.²⁷

As stated previously, acne scars have been successfully treated with nonablative and ablative fractional lasers. Prior evaluation of nonablative therapies showed modest success.³¹⁻³⁴ The development of the 1550nm Er:YAG laser was an important advance in the treatment of acne scarring by nonablative fractional photothermolysis³⁵ as well as for the treatment of darker skin. However, multiple treatment sessions are necessary to achieve 50- to 75-percent

improvement. Ablative lasers have also been successfully utilized in the hopes of reducing the number of treatments required.³⁶ One study showed that combining nonablative with ablative resurfacing produced a better result with fewer complications than ablative resurfacing alone.¹⁸ Another study³⁷ compared nonablative (fractional erbium glass) with ablative (fractional carbon dioxide) laser. The ablative laser produced better results after one session, but with considerably more

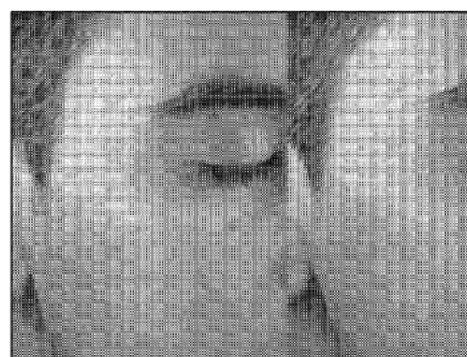


Figure 9. East Indian study patient before and one month after five treatments of SR and DLR

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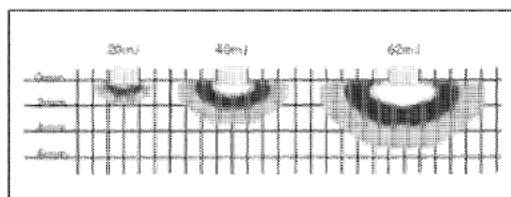


Figure 10. Thermabioheat at different energies. Sublative 64 (.86W/electrode). As the energy is increased, both the depth and diameter of affected tissue increases.

discomfort and downtime.

Additionally, safe and effective treatments for skin of color have become increasingly sought after, leading to usage of other modalities than light in order to avoid the frequent problem of postinflammatory hyperpigmentation. Trying to balance the social downtime, discomfort, efficacy, and safety of energy-based aesthetic treatments has been an important theme over the last 10 years. Sublative rejuvenation is a modality that attempts to answer these aesthetic needs in a different way by utilizing mainly RF and harnessing the novel concept of ablative RF, something that is used frequently in other areas of medicine.

Acne scars are principally dermal. The resurfacing, chemical peels, and diamond fraises of the past aimed to wound the epidermis and the superficial dermis profoundly and thus secondarily promote dermal remodeling. Nonablative erbium glass resurfacing or ablative fractional treatments can penetrate deeply into the dermis making this a more direct method, while promoting faster healing from the reservoir of untreated skin.³² These wounds tend to be straight columns into the dermis, whereas the sublative fractional bipolar RF current creates small epidermal wounds that are much wider in the dermis (Figure 10). The

advantage of this in relation to scarring is that the downtime is limited due to minimizing epidermal injury, yet the scar remodeling is still maximized due to the profound direct impact on the dermis. The DLRF combination has a focal point of about 1.5mm, where the laser and RF energies merge and create a focal coagulation at a deep level effect that is probably most important in the treatment of punched out, ice pick, or troughed scars. The nonablative dermal injuries create collagen remodeling that is delayed, mirroring the delayed results in the subjects of the present study.

The main advantages of the RF modalities are their lack of side effects, especially in darker skin, and the low social downtime. Although there is crusting for a number of days, it is relatively easy to cover with makeup. Even without makeup, the crusting is not significantly disfiguring. The RF modalities require multiple treatments and the treatments require time before results are seen due to the need for collagen regeneration, which takes 1 to 6 months. The platform used for this study was a prototype; the newer generations have energies that are more than twice the energies that were available to us at the time.

Conclusion

The combination of diode laser and bipolar RF energy along with sublative

bipolar RF is a safe and effective modality for the treatment of both superficial and deep acne scars. The encouraging results warrant additional studies to further characterize this modality.

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Evaluation of the Clinical Efficacy of Fractional Radiofrequency Microneedle Treatment in Acne Scars and Large Facial Pores

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Hee Jin Cho, MD,* Chun Wook Park, MD,* Cheol Heon Lee, MD,* and Hye One Kim, MD*

BACKGROUND Fractional technology overcomes the problems of ablative lasers, such as inaccurate depth control and damage to the epidermis. Minimally invasive fractional radiofrequency microneedle devices allow for more-selective heating of the dermis.

OBJECTIVE To evaluate the clinical efficacy of fractional radiofrequency microneedle (FRM) treatment in acne scars and large facial pores.

MATERIALS AND METHODS Thirty patients with acne scars and large facial pores were enrolled. Bipolar radiofrequency energy was delivered to the skin through the electrodes of the FRM device. Skin lesions were evaluated according to grade of acne scars, Investigator Global Assessment of large pores, skin surface roughness, transepidermal water loss (TEWL), dermal density, microscopic and composite image, sebum measurement, and questionnaires regarding patient satisfaction.

RESULTS The grade of acne scars and Investigator Global Assessment of large pores improved in more than 70% of all patients. Skin surface roughness, dermal density, and microscopic and composite images also improved, whereas TEWL and sebum measurement did not change.

CONCLUSION Clinical improvement from FRM treatment appeared to be related to dermal matrix regeneration. FRM treatment may be effective in improving acne scars and facial pores.

The authors have indicated no significant interest with commercial supporters.

Unlike ablative lasers, fractional laser treatment has been shown to be clinically efficient in managing acne scars and other dermatologic diseases with cosmetic problems without causing direct damage to the epidermis.¹ Although conventional fractional treatment has some disadvantages of inaccurate depth control and possible indirect damage to the epidermis, a recently introduced minimally invasive fractional radiofrequency microneedle (FRM) device has been used to overcome such problems by creating radiofrequency thermal zones with minimal epidermal injury.²

After damage to the reticular dermis, long-term dermal remodeling, neoelastogenesis, and neocollagenesis result in dermal thickening.³

Although previous studies on fractional lasers have confirmed their clinical efficacy in acne scars and large facial pores, the efficacy of FRM treatment in such skin conditions has not been fully elucidated.^{1,4}

This study was conducted to evaluate the clinical efficacy of FRM treatment of acne scars.

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Materials and Methods

Patient Selection

This study included 30 patients with mild to moderate facial acne scars and enlarged facial pores. There were 12 men and 18 women aged 16 to 45. Exclusion criteria were concurrent systemic diseases (e.g., hematologic diseases with bleeding tendency or diabetes mellitus and atopic dermatitis affecting wound healing), currently taking anticoagulants or antiplatelet agents, pregnancy, previous history of frequent herpes simplex viral infection of the face, any esthetic procedures on the face within 6 months before the study, any implantable electronic device (e.g., pacemaker), active infection, and previous history of hypersensitivity to anesthetic creams. Only patients who consented to longitudinal follow-up during the study period were enrolled.

The Institutional Review Board of Kangnam Sacred Heart Hospital approved the protocol for the study. Informed consent was obtained from all participants.

Treatment Protocol

One day and 4 weeks after baseline measurements, patients underwent two sessions of radiofrequency treatment using a FRM device (INTRAcel; Jeisys, Seoul, Korea). The device uses bipolar radiofrequency technology to provoke plasma sparks, creating multiple partial thermal injury columns in the deep dermis. Bipolar radiofrequency energy is delivered through 49 microneedle electrodes in an area of 1 cm² and deployed into the deep dermis perpendicular to the skin surface. The entire needle electrode is nonconductive except the tip, beginning 0.3 mm from the distal end, to protect from radiofrequency heating at the insertion site. Radiofrequency energy is emitted to the dermis 0.2 seconds after microneedle insertion. The radiofrequency energy delivery durations differ according to energy levels. The currently available microneedles are 0.5, 0.8, 1.5, or 2.0 mm long. In

this study, only a 1.5-mm needle at a power of 500 W (maximum power 700 W) was used for treatment.

Immediately before treatment, all makeup was removed and the face was cleaned with facial foam cleanser and 70% alcohol. Topical lidocaine-prilocaine cream (EMLA Cream 5%; Korea AstraZeneca, Seoul, Korea) was applied under occlusion to both cheeks for local anesthesia 30 to 60 minutes before treatment. A full-face, double-pass treatment was performed using a FRM device with a depth of 1.5 mm. No epidermal cooling device was used simultaneously.

Clinical and Bioengineering Assessments of Facial Pores, Skin Roughness, Transepidermal Water Loss, Skin Density, and Sebum Quantity

Two dermatologists rated the acne scars as macular, mild, moderate, or severe: macular—erythematous, hyper- or hypopigmented flat marks; mild—mild atrophy or hypertrophy that may not be obvious at social distance of 50 cm or greater; moderate—moderate atrophic or hypertrophic scarring that is obvious at social distance of 50 cm or greater but can still be flattened by manual stretching of the skin; severe—severe atrophic or hypertrophic scarring that is obvious at social distances >50 cm and cannot be flattened by manual stretching of the skin.⁵ Gross photographic images were obtained using an Alpha 700 digital camera (Sony, Tokyo, Japan). The extent of enlarged facial pores was evaluated using the Investigator Global Assessment (IGA; 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, 4 = severe, 5 = very severe) based on photographic documentation. Other bioengineering measurements were made as follows: skin surface roughness using the GFM PRIMOS pico (GFM, Berlin, Germany), transepidermal water loss (TEWL) of two acne lesions and one control site using the Vapometer (Delfin, Kuopio, Finland), dermal density of the right cheek using Dermascan Ultrasound (Cortex Technology, Hadsund,

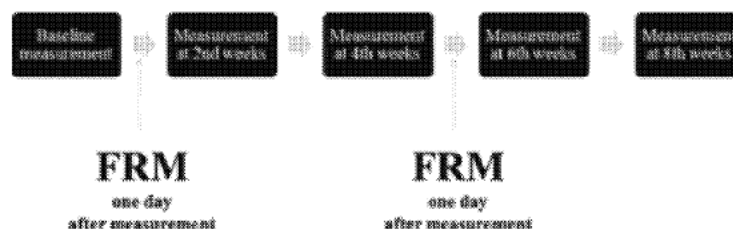


Figure 1. The schedules of skin measurements and fractional radiofrequency microneedle (FRM) treatment in this study.

Denmark), microscopic and composite images of the right cheek (depth of image, 100 μ m; original magnification 9–30) using confocal reflectance microscopy using a Vivascope 1500 (Lucid, Rochester, NY), and sebum measurement at an acne lesion and the control site using a sebumeter (SM 810; Courage + Khazaka electronic GmbH, Köln, Germany). The area of the facial pores in three 1- by 1-mm confocal microscopic images were measured using ImageJ 1.43u (National Institutes of Health, Bethesda, MD). These measurements were taken at baseline and weeks 2, 4, 6, and 8, except for microscopic and composite images, which were obtained only at baseline and weeks 4 and 8 (Figure 1).

At 12 weeks of follow-up, each patient filled out a questionnaire. Patient satisfaction was classified as very satisfied, satisfied, ordinary, dissatisfied, or very dissatisfied. The questionnaire contained questions regarding pain during treatment (severe, moderate, mild, and none) and adverse events associated with the treatment, such as persistent pain, folliculitis, erythema, edema, hyperpigmentation, or hypopigmentation.

All statistical analyses were conducted using SPSS 12.0 for Windows (SPSS Korea, Inc., Seoul, Korea). The results were analyzed using Student t-tests or R-by-C crosstabs. Significance levels for all analyses were set at $p < .05$.

Results

Eight weeks after two sessions of FRM treatment, the grade of acne scars improved in 22 patients

(73.3%), did not change in seven (23.3%), and became aggravated in one (3.3%) (Figure 2). Of these 22 patients, one improved two grades from baseline, and 21 improved one grade. Enlarged pores improved in 21 patients (70%), did not change in seven (23.3%), and became aggravated in two (6.7%) (Figure 3). These results were not significantly different between sexes or between

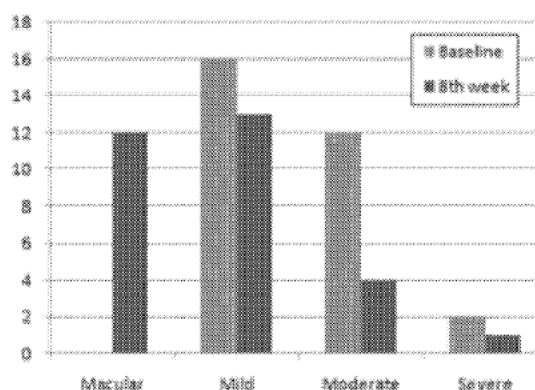


Figure 2. Changes in the grade of acne scars before and after treatment.

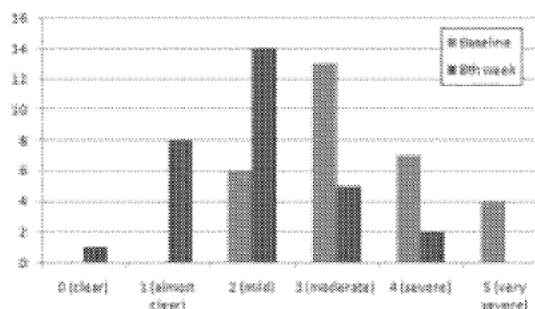


Figure 3. Changes in Investigator Global Assessment on large pores before and after treatment.

age groups. Clinical photographs taken in the eighth week showed improvement in acne scars and large pores (Figure 4).

Skin surfaces roughened slightly 2 and 4 weeks after treatment and softened 8 weeks after treatment (Figure 5A). These images were converted to the roughness parameters arithmetic average height and 10-point height.⁶ Both parameters increased during the procedure and decreased at completion of the procedure, although there were no significant differences ($p > .05$) (Figure 5B).

TEWL was decreased 2 weeks after treatment, but there were no significant differences between the

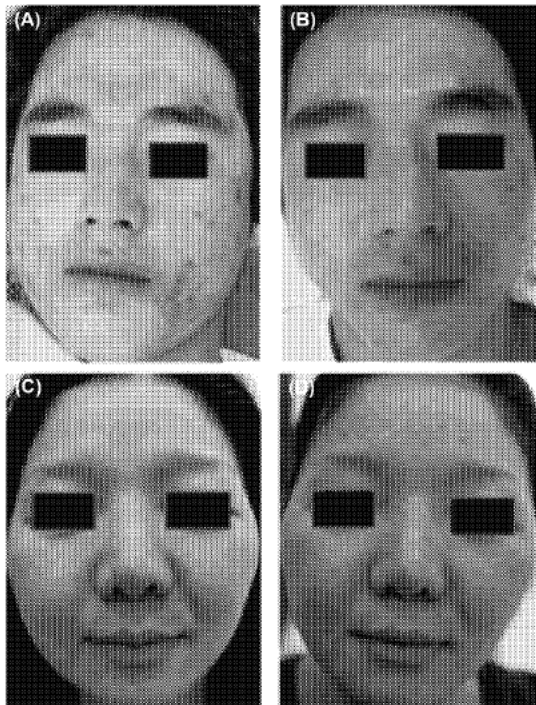


Figure 4. Atrophic acne scars and large facial pores in a 22-year-old man before (A) and 8 weeks after (B) two treatment sessions. The grade of acne scars and Investigator Global Assessment of large pores both changed from severe (4) to mild (2). Mixed atrophic and hypertrophic acne scars and large facial pores in a 32-year-old woman before (C) and 8 weeks after (D) two treatment sessions. The grade of acne scars changed from moderate (3) to mild (2), and Investigator Global Assessment of large pores changed from moderate (3) to almost clear (1).

acne lesions and control sites ($p > .05$). No significant changes in TEWL were noted (Figure 6). Dermal density decreased 2 and 6 weeks after treatment but increased 8 weeks after treatment, without significant differences ($p > .05$) (Figure 7A,B). On microscopic and composite images of the right cheek taken 8 weeks after treatment, enlarged pores became smaller and more even (Figure 8A). Image analysis revealed that the area of facial pores decreased 58.7%, with significant differences ($p < .001$) (Figure 8B). The size of the facial pores decreased in 22 patients (73.3%), did not change in seven (23.3%), and increased in one (3.3%). These results were consistent with IGA in 27 patients (90%) ($p < .001$). The sebum measurements were not significantly different between the acne lesions and the control sites after FRM treatment ($p > .05$). No significant changes in sebum measurements were noted (Figure 9).

Patients' satisfaction at 12 weeks of follow-up was very satisfied in 12 patients (40%), satisfied in 14 (46.7%), ordinary in three (10%), dissatisfied in one (3.3%), and very dissatisfied in none (0%). Pain during the treatment was severe in two patients (6.7%), moderate in four (13.3%), mild in 18 (60%), and none in six (20%). The mean duration of visible erythema after treatment was 7.8 ± 2.6 days. Pain persisted for longer than 1 day in 10 patients (33.3%) and for longer than 3 days in five (16.7%). Folliculitis was observed in two patients (6.7%), but these lesions were mostly mild.

Discussion

Acne scars are one of the most distressing chronic dermatologic conditions and affect patients physically and psychologically because the lesions usually appear on the face.^{7,8} The negatively affect quality of life and can cause psychological problems such as depression and social avoidance.⁹ All efforts have been made to improve scars using chemical peels, intense pulsed light, nonablative and ablative lasers, fractional photothermolysis,

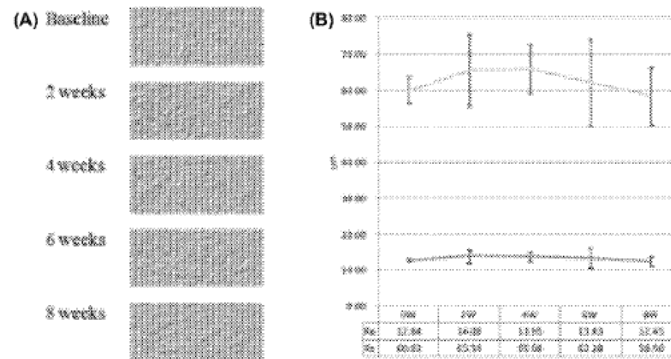


Figure 5. Three-dimensional images of skin surface roughness as assessed using GFM PRIMOS pico (A). Skin surface roughness was slightly roughened 2 to 4 weeks after treatment and softened 8 weeks after treatment. Laser treatment was performed the day after measurements at baseline and at 4 weeks. Ra, arithmetic average height; Rz, 10-point height.

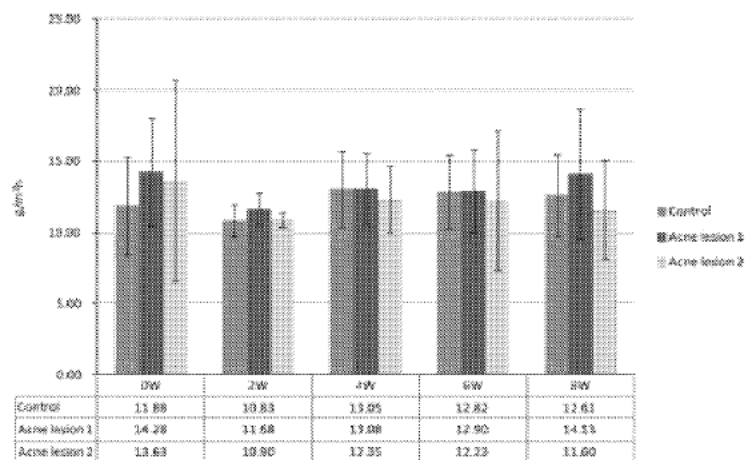


Figure 6. Transepidermal water loss was decreased 2 weeks after treatment, but the differences between the acne lesions and the control sites were not statistically significant. The overall changes in transepidermal water loss during the study was not statistically significant. Laser treatment was performed the day after measurements at baseline and at 4 weeks.

intralesional corticosteroid injection, and surgical removal,¹⁰ but some procedures have poor clinical outcomes, and others have disadvantages including pain during the procedure, long downtime, and a high rate of adverse events.

Enlarged facial pores that, in the past, were regarded as an irreversible aging process rather than a correctable cosmetic problem are now arousing new interest in dermatology with significant advances in dermatologic devices. Previous

studies have shown that pore size is associated with high sebum output level (seborrhea), aging, sex, genetic predisposition, chronic ultraviolet light exposure, and vitamin A deficiency.¹¹ Previous studies have indicated that enlarged pores are attributable to skin aging caused by changes in the dermal matrix.^{12,13} In skin aging, photoaging, one of the most important extrinsic factors, changes dermal thickness and disorients the dermal matrix, including collagen and elastin, by upregulating the matrix metalloproteinases.¹⁴ It

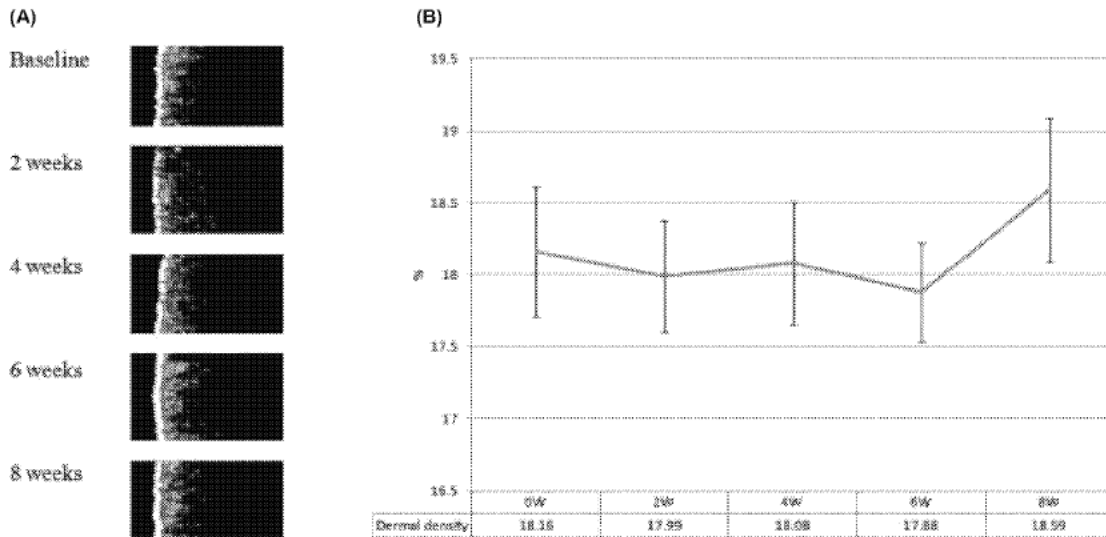


Figure 7. Images of dermal density of the right cheek (A). Dermal density decreased 2 and 6 weeks after the initial treatment, returned to baseline 4 weeks after treatment, and increased 8 weeks after treatment (B). Laser treatment was performed the day after measurements at baseline and at 4 weeks.

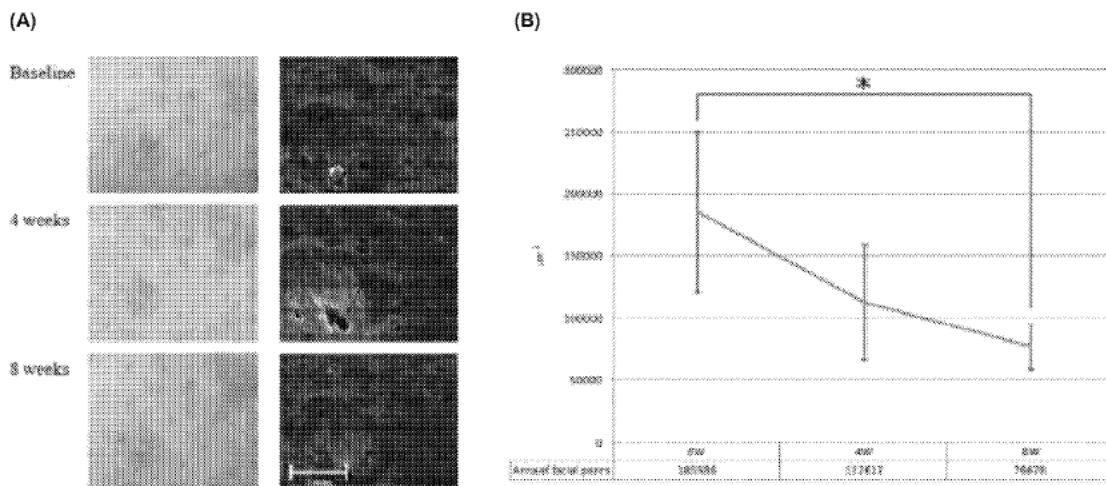


Figure 8. Microscopic and composite image of the right cheek showing changes in large pores (left, microscopic image; right: composite image; depth of image, 100 μ m; magnifying power 9-30) (A). The average total area of the facial pores decreased 58.7% (* $p < .001$) (B). Laser treatment was performed the day after measurements at baseline and at 4 weeks.

has been suggested that large pore size is more significantly associated with increased sebum output level than with sex or age.¹⁵ Excessive sebum excretion has been also accepted as one of the most important etiological factors in acne vulga-

ris, and patients with acne tend to have enlarged facial pores.¹⁶

Several previous studies have demonstrated the good clinical efficacy of fractional lasers in treating

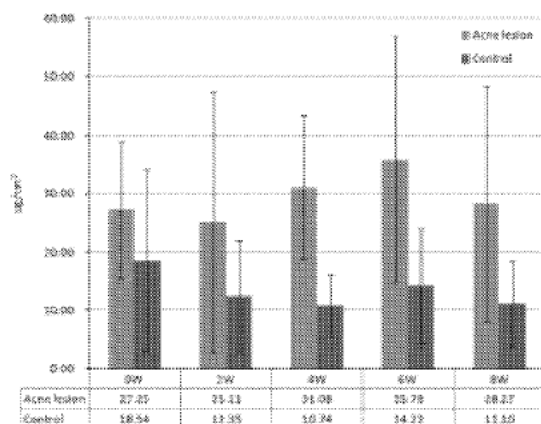


Figure 9. There were no significant differences in the amount of sebum between the acne lesions and the control sites. Laser treatment was performed the day after measurements at baseline and at 4 weeks.

acne scars and large facial pores,^{1,4} but these lasers can cause indirect damage to the epidermis, such as burns, and adjustments of the depth of radiofrequency thermal zones are imprecise. The newly introduced, minimally invasive FRM device is expected to overcome these limitations.^{2,17}

FRM treatment showed good outcomes in improving acne scars and large pores. Physician evaluation (grade of acne scars and IGA of large pores) and patient satisfaction showed overall improvement of more than 70%. There were temporary exacerbations of skin surface roughness and dermal density that had reversed by 8 weeks after treatment. Previous studies on the wound healing process after FRM treatment have shown that radiofrequency thermal zones containing denatured collagen were maintained in the reticular dermis for longer than 28 days after treatment, although new dermal tissue partially replaced the zones, and that various wound healing genes involved in dermal remodeling, such as tropoelastin and procollagen, steadily increased until 28 days after the procedure.³ This result is in accord with ours, which showed immediate regression by coagulation of the dermal matrix, as well as gradual remodeling by ne elastogenesis and neocollagenesis. Dermal density decreased 2

and 6 weeks after the 2-week treatment and increased 4 and 8 weeks after the 4-week treatment. In contrast, there were no significant differences in TEWL between the measurements before and after treatment. Because TEWL is mainly correlated with the skin barrier function of the epidermis, especially the stratum corneum, our results mean that FRM treatment could lead to only marginal changes in epidermal barrier function.¹⁸ Although microscopic and composite images showing minimized facial pores were consistent with IGA, they were in disagreement with sebum measurements showing insignificant changes. This indicates that changes in sebum excretion did not decrease the size of the facial pores. Instead, an increase in the dermal matrix by FRM treatment contributes to dermal thickening, increases the amount of collagen that had previously been decreased by photoaging, and rejuvenates the enlarged pores. It has been suggested that changes in facial pores may be attributed to dermis remodeling rather than a decline in sebum production.⁴

Although the adverse events from FRM treatment were infrequent and only transient, most patients complained of pain during the treatment and even intractable pain in some cases. The pain rarely persisted for several days, but it could influence patient adherence. Detailed description of side effects and adequate local anesthesia before treatment is necessary. The downtime of our treatment device seemed to be shorter than those of previous fractional lasers, even though there have been no comparative studies between the FRM device and other fractional lasers. When the needles are directly inserted into pores, they may increase pore size. Because the proportion of the large pores to all facial pores was small, there was low probability that the microelectrode would enter a large pore. Furthermore, because the treatment promotes dermal matrix regeneration, patients with predominantly hypertrophic acne scars may have a poor response or high complication rates. We did not experience any serious complications. Most of

our patients were satisfied with the treatment outcome.

This study evaluated the efficacy of FRM treatment using various noninvasive bioengineering tools. These recently developed tools are more physiologic than those used in previous studies. Moreover, our method is noninvasive. Although some measurements showed no statistical significance, probably because of small sample size, our FRM treatment improved skin lesions.

In conclusion, the results of this study suggest that FRM treatment could be effective in the treatment of acne scars and large facial pores, without significant adverse events, and may have some advantages in patient safety and a short down time.

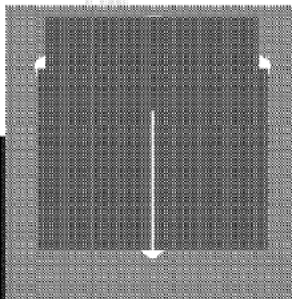
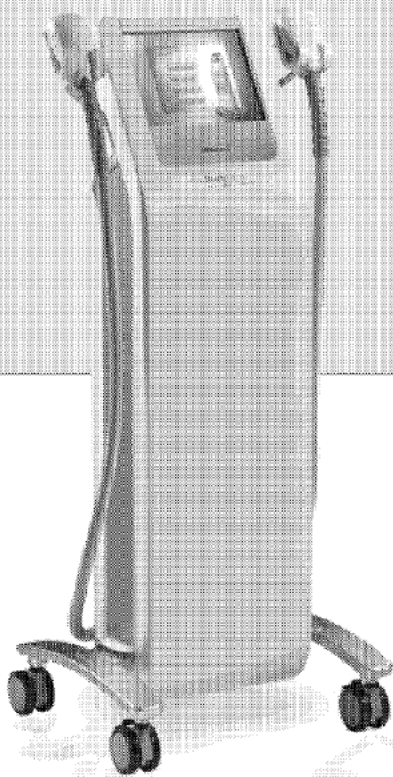
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The 3DEEP Advantage – RF Will Never Be The Same



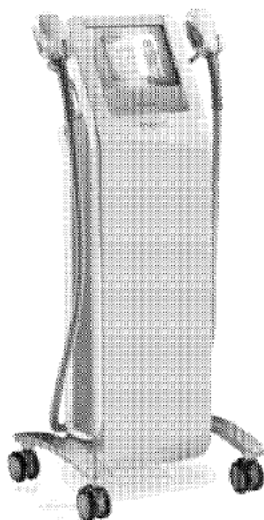
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THE 3DEEP® COMPANY

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EndyMed PRO Advantages

Patient Benefits	Physician Benefits
• Highly effective • Customized treatment parameters • Optimal safety with minimal discomfort and no side effects • Short treatment with minimal downtime • Noticeable immediate improvement • Long term results	• Effective solutions for anti-wrinkles, skin tightening, fractional skin resurfacing and body contouring • Fast, walk-in / walk-out procedure for optimal patient satisfaction • Customized treatment plan with preset default parameters • Suitable for the complete range of skin types • Single platform growth plan • No consumables (for the T&C handpieces) and low priced consumables (for the FSR handpiece) for rapid ROI and profitability



EndyMed PRO Specifications

Handpiece Specifications		
	Skin Tightening / Body Contouring Handpieces	FSR Handpiece
Maximum output power	65 Watts	
Pulse duration		0.1 – 0.6 sec.
Total RF energy		Up to 62mJ/pin
Disposable tip matrix spots		112 matrix spots
Disposable tip spot size		10 x 15 mm
Disposable tip pulses		Up to 300 pulses



System Specifications	
Output frequency	1MHz
Power consumption	220 Watts
Input power	110-120 V, 50-60 Hz, 2A or, 220-240 V, 50-60 Hz, 1A
User interface	LCD color touch screen
Dimensions	115 x 30 x 19 cm; 45 x 12 x 7 in.
Weight	33 kg; 72.5 lb.

EndyMed Medical

EndyMedMedical Ltd., established in 2007, is a medical device company that develops and commercializes energy based aesthetic treatment systems for the professional markets. EndyMed's management, clinical, marketing and R&D teams have extensive experience in the medical aesthetic market. EndyMed's proprietary 3DEEP™ radiofrequency technology is a unique solution for fractional skin resurfacing, wrinkle treatment, skin tightening and body contouring.



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3DEEP® – Technology Anchored in Science

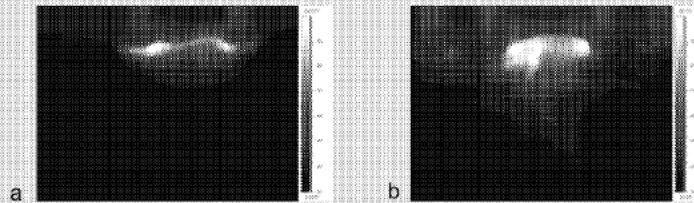
EndyMed's proprietary 3DEEP technology is a multi-source, phase-controlled radio frequency energy source that is state-of-the-art, safe and effective.

3DEEP uses an array of multiple electrodes and a sophisticated algorithm to manage the phase of the energy flowing between sets of electrodes. The repelling forces between adjacent electromagnetic fields drive the energy vertically into the target tissue, reducing significantly the energy flowing along the skin's surface (and any potential side effects) and eliminating the need for cooling.

Compare thermal profiles of 3DEEP RF and bipolar RF

(a) Bipolar thermal image.

(b) 3DEEP thermal image – note the depth of penetration. Identical energy was delivered to the tissue for both 3DEEP and bipolar. A FLIR ThermoCAM SC 640 thermal camera was used.

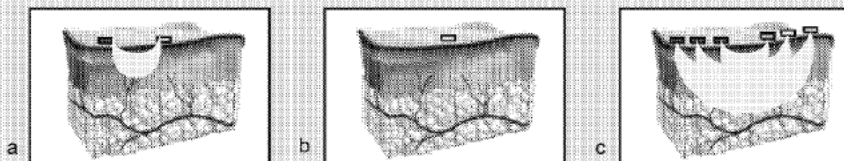


Compare energy penetration depth of 3DEEP RF with bipolar or monopolar RF technologies

a) Bipolar and x-polar RF– relatively superficial and less efficient

b) Monopolar RF– energy flows uncontrolled in the tissue, requiring intense cooling

c) 3DEEP RF focused and contained deep energy flow with no need for cooling

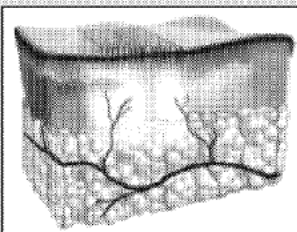


3DEEP Fractional Skin Resurfacing

To treat aging skin, it is necessary to remove the upper layers of the skin (stratum corneum and epidermis) by ablation to reduce skin roughness and hyperpigmentation. Fractional ablation accomplishes this effectively with minimal downtime and rapid recovery.

In addition, for the best long lasting effect, the dermis should be treated with non-ablative deep dermal heating, which leads to collagen remodeling and the reduction of wrinkles and scars.

EndyMed's 3DEEP Fractional Skin Resurfacing simultaneously performs micro-fractional ablation on the epidermal layer and deep dermal volumetric heating in one pulse.

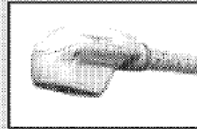


3DEEP Fractional Skin Resurfacing provides a smoother, brighter skin surface (stratum corneum and epidermis) and reduced hyperpigmentation (epidermis). Simultaneously, volumetric deep dermal heating reaches the collagen fibers causing an immediate and long term tightening effect. 3DEEP Fractional Skin Resurfacing effectively treats all skin layers for an optimal result.

EndyMed PRO® – Experience the Difference

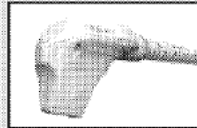
The sleekly designed EndyMed PRO system is multi-application, upgradeable and available with multiple handpieces, customized to different applications and treatment areas. The device includes an easy-to-use, intuitive touchscreen interface and is equipped with a range of safety features.

EndyMedPRO has integrated real time impedance measurements assuring exact energy delivery customized to each patient's skin impedance. Treatment presets, based on clinical experience, provide optimized energy settings by specific treatment area and application.



3DEEP Body Contouring Handpiece

Specially designed for treatment of larger body areas such as abdomen, buttocks and thighs for treating skin laxity, cellulite, body shaping and circumference reduction.



3DEEP Body Tightening Handpiece

Specially designed for skin laxity treatment of smaller body areas such as peri-umbilical, neck, arms and knees.



3DEEP Facial Tightening Handpiece

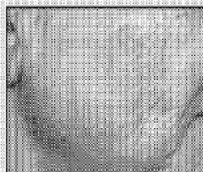
Specially designed for the treatment of wrinkles and lax skin on the face and neck, including forehead, temples, cheeks and under chin areas.



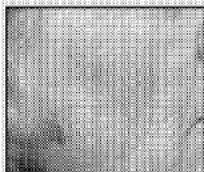
3DEEP Fractional Skin Resurfacing Handpiece

Specially designed for fractional skin resurfacing and treatment of skin roughness, hyperpigmentation, and wrinkles and scars on both facial and body areas.

Visible Results

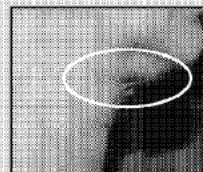


Before treatment

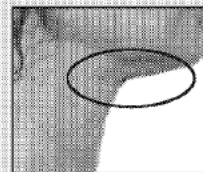


4 months after 1 treatment

1. Full face anti-wrinkle treatment

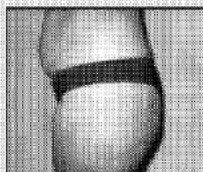


Before treatment

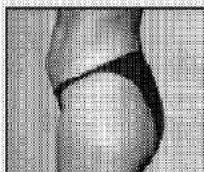


2 months after treatment

2. Skin tightening on the neck

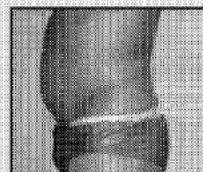


Before treatment

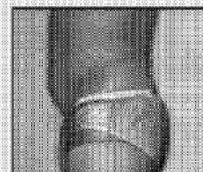


After 4 treatments

3. Thigh contouring and cellulite reduction



Before treatment



After 4 treatments

4. Abdomen contouring (male)

Photos 1: Courtesy of Monica Elman, MD, Holon, Israel

Photos 2: Courtesy of Prof. Daniel Cassuto, Milan, Italy

Photos 3: Courtesy of Tzahi Vider, MD, Medical OR Clinic, Hertzalia, Israel

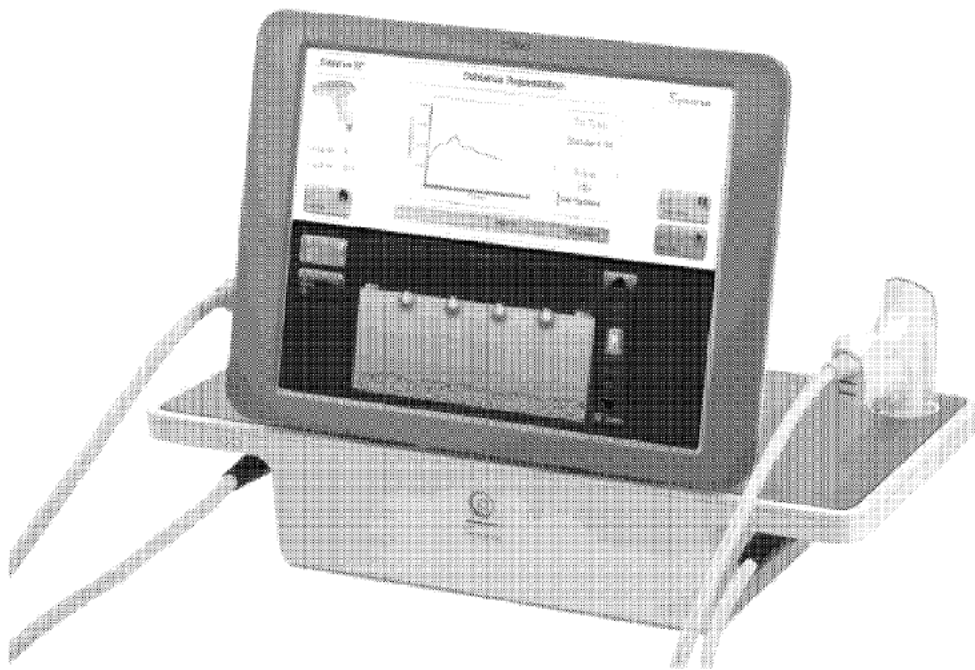
Photos 4: Courtesy of Josefina Royo de la Torre, MD and Javier Moreno Moraga, MD, IML, Madrid, Spain

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eTwo / eMatrix

Sublative Rejuvenation and Wrinkle Treatment System Console User Manual



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Revision Release Date: October 2011

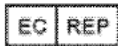


Before using the device, please check local regulations. If any local legislation is violated, use cannot be authorized.

In the United States, federal law restricts prescription medical devices to be sold by or on the order of a physician, or properly licensed practitioner. Syneron makes no representations regarding federal, state, or local laws or regulations that might apply to the use and operation of this device.

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1. BEFORE YOU START

Read this manual to become familiar with all safety requirements and operating procedures before attempting to operate the system.



Caution

Any radiofrequency (RF) device can cause injury if used improperly.

The eTwo/eMatrix system must be serviced only by Syneron Medical Ltd. qualified personnel.



Warning

High voltage is present inside the system. Always be aware of the possible dangers and take proper safeguards as described in this manual.

Conventions Used in this Manual

1. The following conventions in the form of notes, cautions and warnings are used in this manual:



Note

The content of this **Note** offers general information that is important to keep in mind.



Caution

A **Caution** alerts the user to the possibility of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user and/or patient, or damage to the equipment.

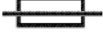


Warning

A **Warning** alerts the user to the possibility of injury, death, or serious adverse reactions associated with the use or misuse of the system.

2. In many places throughout this manual you will see words or phrases in the text which are bolded in a sans-serif typeface, **such as this**. These are words and phrases that you will see on the LCD display of the control panel.
3. System Name: if you have ordered and received a system with **both** Sublative RF and Sublime applicators, the system will be named **eTwo**. If you have ordered and received a system with **only** the Sublative RF applicator, the system will be named **eMatrix**.

Explanation of the Symbols Used in the System

Symbol	Description
	(on system) Attention: Consult Accompanying Document
	(on packages of high-density 144-pin tips) Caution: Use with Low Energy Settings!
	CE Compliance Symbol
	CSA Compliance Symbol
 10.08.2012	Discard Product After Expiration Date
	Product was Sterilized by Ethylene Oxide Process
	Waste of Electrical and Electronic Equipment (WEEE) compliance symbol
	RF Interference may occur in the vicinity of equipment with the following symbol
	Single Use Only
	Fuse
	Type BF Equipment
	Manufacturer
	Authorized Representative in the European Union

2. SAFETY

This chapter describes the safety issues regarding the use and maintenance of the eTwo/eMatrix system, with special emphasis on electrical safety.

Introduction

The system is designed for safe and reliable treatment, when used in accordance with proper operation and maintenance procedures. Only trained practitioners are qualified to operate the system. The user and all other personnel operating or maintaining the system should be familiar with the safety information provided in this chapter. Syneron Medical Ltd. assumes no liability whatsoever for any damage or injury as a result of an application of a product which is not in strict accordance with the instructions provided with the product, or its operation by non-authorized personnel. The primary consideration should be to maximize safety for both treating attendant and the patient.



Warning

Read this chapter to be familiar with all of its safety requirements and operating procedures prior to operating the system.

Any radiofrequency (RF) device can cause injury if used improperly.

High voltage is present inside the system.

Always be aware of the possible dangers and take proper safeguards as described in this manual.

Failure of the RF device could result in an unintended increase of output power.

In the event of adverse effects or injury/illness, immediately contact:

- In North America: **Syneron, Inc.**
- In Europe: **CEpartner4u B.V.**
- Outside North America and Europe: **Syneron Medical Ltd.**

For complete contact information please refer to page 3 of this manual.

Patient Safety

Patient safety is primarily assured by a well-trained staff. A complete medical history of the patient should be completed and patient eligibility assessed, prior to scheduling treatment with the system. Patients should be fully informed of the treatment protocol, the likely results and any risks associated with the treatment.

The patient should wear Syneron-provided protective eyewear during the treatment.

For more detailed information please refer to the Clinical Guides in this manual.

Treating Attendant

Personnel should not operate the system until they have been fully trained in its use.

Cautions

There are no user-serviceable parts inside the system.

ONLY SYNERON-AUTHORIZED PERSONNEL MAY SERVICE THE SYSTEM, ESPECIALLY INSIDE ITS CABINET.

Do not use the system if it has been dropped or if any other type of excessive force has been applied. The system must be examined by Syneron for safe operation after such an occurrence.

Keep the bodies of the applicators clean; pay particular attention to the Sublime applicator tip's output lightguide and electrodes, as well as the RF electrodes of the Sublative RF applicator. Check the integrity of all components.

Do not allow the applicators to come in contact with hard materials that could damage the tips.

Make sure that all treatment personnel are familiar with the system's controls and know how to shut down the system instantly in case of an emergency.

Patients with cochlear implants should not be treated on skin areas within a 1-centimeter (0.4") radius of the implant's location.

Patients with cardiac pacemakers or other active implants should not be treated with the eTwo/eMatrix system; a possible hazard exists because of interference with the action of the pacemaker.

Never use the system to treat on or in proximity to open/healing wounds.

Never use the system in the presence of explosive or flammable gasses (such as flammable anesthetics, oxidizing gasses, etc.). If alcohol is used for cleaning and disinfecting, it must be allowed to dry thoroughly before the system is set to **Ready** mode.

When treating with the Sublime applicator: always use a thin layer of clear coupling gel (recommended by Syneron) that has the appropriate optical transparency and electrical conductivity properties.

Optical Safety

Refer to the **Sublime** applicator user's manual [PB7555(x)] for complete optical safety information concerning the Sublime applicator.

RF Safety

For complete RF safety information concerning the Sublative RF and Sublime applicators, refer to:

Sublative RF applicator user's manual

Sublime applicator user's manual

Electrical Safety Issues

Keep all covers and panels of the system closed. Removing the covers creates a safety hazard.

Always make sure the system is turned off before connecting/disconnecting the applicators to/from the system.

Keep hands away from the applicators during system start-up.

Do not allow contact between the patient and earthed metal components. If this cannot be achieved, use antistatic sheeting to protect the patient.

Never use the system in the presence of explosive or flammable materials.

Do not immerse any part of the system into liquids.



Portable and mobile RF communications equipment can affect medical electrical equipment, interference may occur in the vicinity of the equipment.

The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the device. It is forbidden to connect any third-party equipment to the system without written approval from Syneron Medical.



Warning

To avoid the risk of electric shock, this equipment must be connected only to an electrical supply outlet with protective earth.

Do not touch the tip connectors of the Sublative RF applicator while the system is turned on; this may cause electrical shocks.

Press the trigger to activate the applicator **only** when the applicator's tip is in full contact with the skin.

Fire Hazards

The absorption of energy raises the temperature of the absorbing material. Do not use the system in the presence of explosive or flammable materials.

Keep drapes and towels moist to prevent them from igniting and burning.

If alcohol is used for cleaning and disinfecting, it must be allowed to dry thoroughly before the system is set to **Ready** mode.

System Safety Features

The system incorporates the following safety features. All personnel operating the system should be familiar with these features.

The eTwo/eMatrix operating system is password-protected. Protect the password to avoid unauthorized use of the system. The password may be changed in the **Utilities** menu.

The treatment mode cannot be activated unless an applicator has been connected to the system.

An adjustable audible tone indicates system transition from **Standby** to **Ready** mode when a treatment pulse can be emitted.

During startup, the system performs an internal self-test of its hardware and software.

Hardware is tested while the system is idling (not emitting pulses), to ensure proper operation of its electrical circuitry. When a problem is detected, the system is disabled and an appropriate error message appears on the screen (refer to the **Troubleshooting** chapter).

On-line monitoring of output energy prevents accidental energy emission to the patient.

Equipment Classification

Electric shock protection: Class I, Type BF

Protection against ingress of liquids: Ordinary equipment

Mode of operation: Continuous

Not suitable for use in presence of flammable substance.

The eTwo/eMatrix system and applicators comply with the U.S. Federal Regulations.

The eTwo/eMatrix system is classified as a IIa device defined by the Medical Device Directive (93/42/EEC) for CE marking.

System Nameplate

The system's ID nameplate is located on the bottom panel of the system, and it includes the system's identification, regulatory and electrical requirement information.

Applicator Nameplates

The Sublative RF and Sublime applicator ID nameplate labels are adhered to the umbilical cable of each applicator near the connector, and they include the applicator's identification and electrical output information.

Do not operate the eTwo/eMatrix system before verifying that the following information is printed on the labels of the Sublative RF and/or Sublime applicators:

Verify that the **Sublative RF** applicator's label has this printed on it:

Rated Voltage 275 V_{RMS}

Verify that the **Sublime** applicator's label has this printed on it:

Rated Voltage 300 V_{RMS}



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3. SYSTEM SETUP

The system is designed for operation in a clinical environment and it may be easily transported inside a protective carrying case. The eTwo/eMatrix system is set up by doing the following:

1. Unpack the system.
2. Check the integrity of the system and all components.
3. Connect the Sublative RF and/or Sublime applicators to the system platform.
4. Connect the power cable to the system cable connection port.
5. Plug the system's power cable into an appropriate electrical outlet.
6. Turn the system on.

Equipment List

The following equipment is delivered in the shipping pack:

eTwo system console (if system ordered with Sublative RF **AND** Sublime applicators), or:

eMatrix system console (if system ordered **ONLY** with Sublative RF applicator)

Sublative iD treatment tips (2 x 10-packs)

User manual: eTwo/eMatrix system console

User manual: Sublative RF applicator

User manual: Sublime applicator *

Ultrasound gel (for Sublime treatment), ¼ liter bottle (x1) *

* Delivered only with eTwo system for the Sublime applicator

Electrical Requirements

The eTwo/eMatrix system incorporates a universal power supply module that allows it to be connected to standard electrical outlets anywhere. The system's electrical requirements are:

100 – 240 VAC $\pm$ 10%; 3A; 50/60Hz; Single Phase

The electrical requirements are printed on the system's nameplate, located on the system's bottom panel.



Warning

For continued protection against fire, replace the fuse only with one of the same type and rating.

Proper grounding is essential for safe operation.

Environmental Requirements

Corrosive materials can damage the system's elements; therefore the system should operate in a non-corrosive atmosphere.

Metallic dust can damage electrical equipment.

For optimal operation of the system, maintain room temperature between 15-30°C (59-86°F) and relative humidity of 10-80%.

Due to the ablative nature of the treatment, always work in a well-ventilated room.

Connect the Applicators

**Warning**

Turn the system off and disconnect the power cable before connecting or disconnecting the applicators.

Refer to Figure 3-1:

Connect the Sublative RF applicator to the connector on the **right** side of the system console.

Connect the Sublime applicator to the connector on the **left** side of the system console.

**Note**

To prevent mistakes when connecting the applicators, the system and the applicator umbilical cables have been marked with matching images (see Figure 3-1):

The system's platform above the Sublative RF connector **and** the Sublative RF applicator's umbilical cable are marked with a single, grey-colored circle.

The system's platform above the Sublime connector **and** the Sublime applicator's umbilical cable are marked with a double, grey-colored circle.

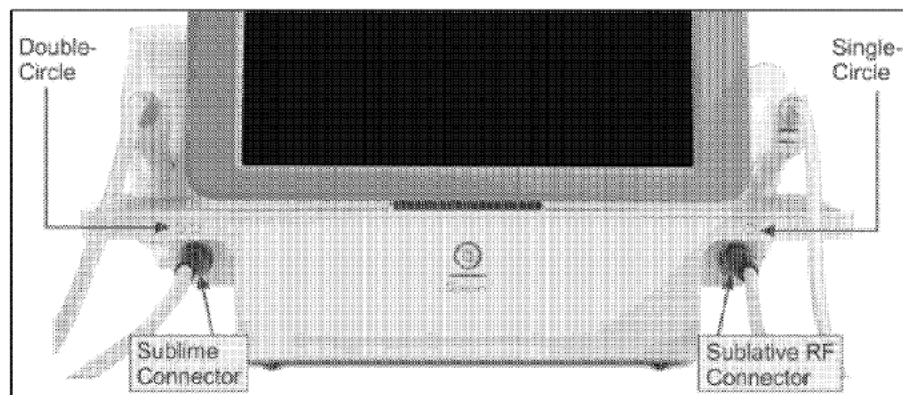


Figure 3-1: Applicator Connection Ports

Both the Sublative RF and Sublime applicators are connected in the same manner. Refer to Figure 3-2:

1. Connect the applicator's cable connector (A) to the system's connection port (B):

Align the white dot on the connector with the white arrow on the connection port.

Another way to properly insert the connector (A) is to align the single- or double-circle on the applicator umbilical cable with the single- or double-circle on printed on the console (see Figure 3-3).

Push the connector in until you feel it 'snap' into place.

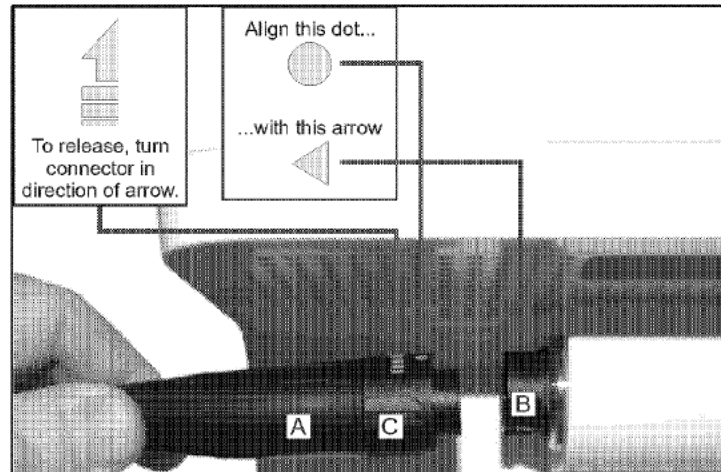


Figure 3-2: Connecting the Applicator

- 2. To disconnect the applicator, turn the black ring (C) counter-clockwise (in the direction of the arrow) until it releases and then pull the connector out.**
- 3. Seat the applicator in its cradle (see Figure 3-3).**

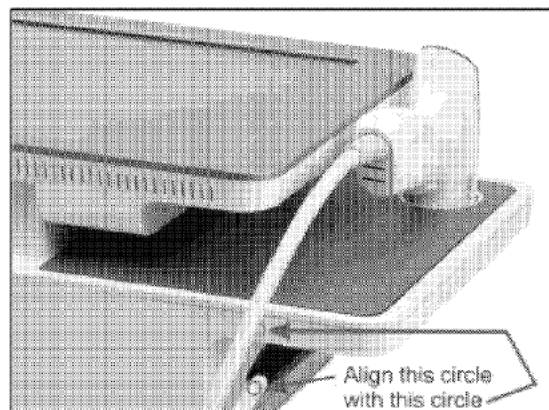


Figure 3-3: Applicator in Cradle

4. OPERATING INSTRUCTIONS



Warning

Ensure that the power cable is connected properly before turning the system on.

Dangerous voltage is present inside the system.

The applicators should always be connected and positioned in their respective cradles during system start-up.

Always turn the system off before connecting/disconnecting the applicators.

Never direct the applicator's tip at anything other than the treatment site.

System Operation

1. Press the system's On/Off switch, shown by the red arrow in Figure 4-1.

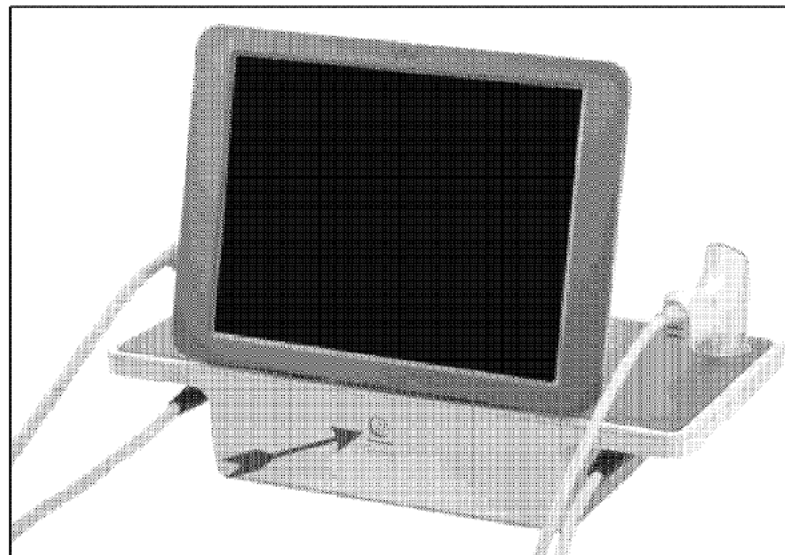


Figure 4-1: On/Off Switch

2. The system starts a self-test of controller memory while displaying a startup animation. When complete, the **Login** screen will be displayed.

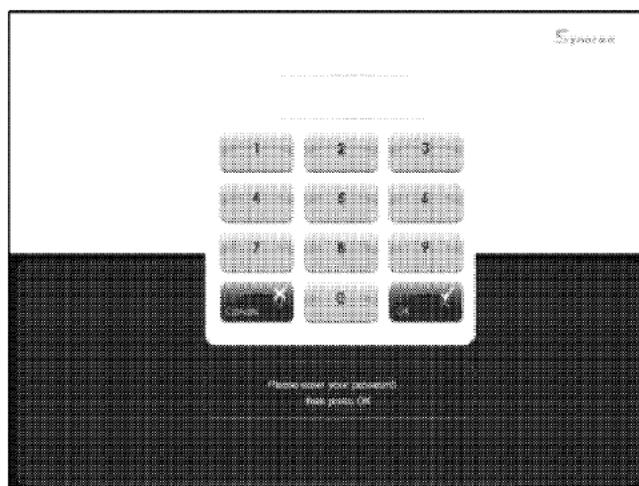


Figure 4-2: Login Screen

3. **First-Time Operation:** press the **OK** button on the touch-screen – no password is required until one is set in the **Utilities** area of the program; the system will display the **Home** screen (see Figure 4-3).



Note

Syneron strongly recommends setting a security password to protect the system from unauthorized use. Password configuration instructions are on page 4-12.

Once the password is configured, it will be required by the **Login** screen (see Figure 4-2) every time the system is turned on.

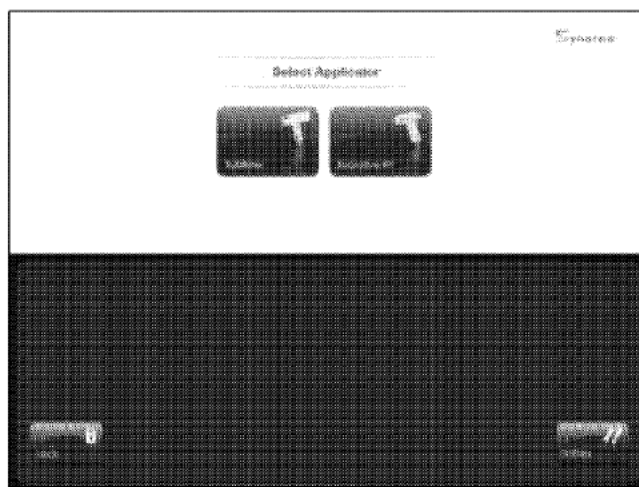


Figure 4-3: Home Screen

4. From this screen you can advance to the following areas of the program by pressing the appropriate button on the screen:



Sublative RF treatment mode



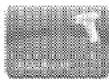
Sublime treatment mode



Utilities screen



5. Pressing the **Lock** button will return the system to the **Login** screen (see Figure 4-2); the system password will have to be keyed in again in order to continue operation.



6. Select the applicator you wish to use for the current treatment by pressing the appropriate button; the button will turn blue as an indicator that this applicator is now active:

If you pressed the **Sublative RF** button, the **Treatment Program Selector** screen will appear (see Figure 4-4).

When the **Sublime** button is pressed, no program selection is required; the system transitions directly into the **Sublime Treatment** screen (see Figure 4-7).



Note

If one or both of the applicators is not connected to the system when it is turned on, the applicator selection button(s) will not appear on the screen, indicating that the mode is disabled.

Sublative RF Treatment Mode

Select a **Treatment Program**: there are three treatment programs to choose from, each offering different levels of ablation and resurfacing to the skin, at different intensities of impact. Select program **A** (Low Impact), **B** (Medium Impact) or **C** (High Impact); the **Treatment** screen will appear (see Figure 4-5).

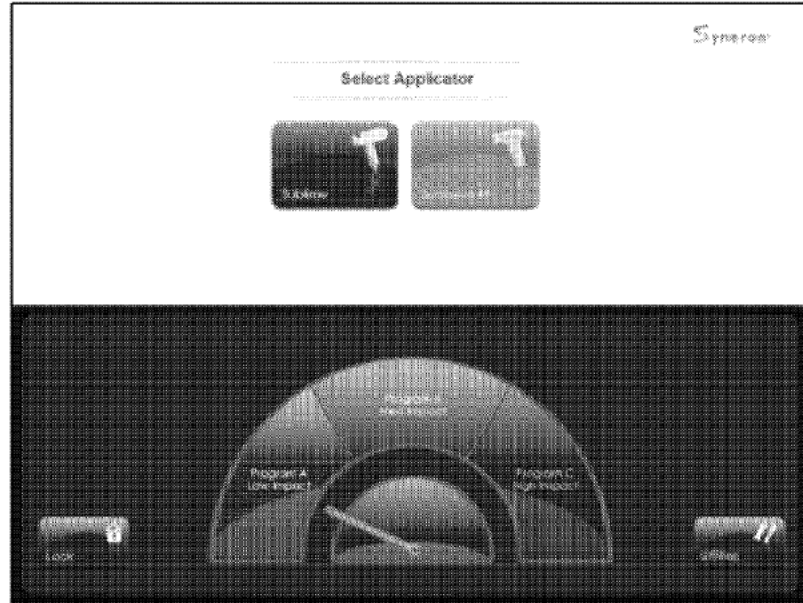


Figure 4-4: Treatment Program Selection Screen

Figure 4-5 presents the main **Sublative RF Treatment** screen. The numbered tags in the illustration correspond to the following numbered explanations and definitions of the screens elements:

1. **Name and Illustration:** nametag and illustration of the currently active applicator.
2. **Description:** this tag describes the function of the currently active applicator.
3. **Standby and Ready Buttons:** press the **Ready** button to set the system to **Ready** mode; RF pulses will be emitted through the applicator tip when the trigger is pressed. Press the **Standby** button to set the system back to **Standby** mode. When the system is in **Ready** mode, pressing any other button will automatically return the system to **Standby** mode.



Note

Wait until the green LED bar on the rear of the applicator illuminates, indicating that the system is charged and ready to emit a pulse.

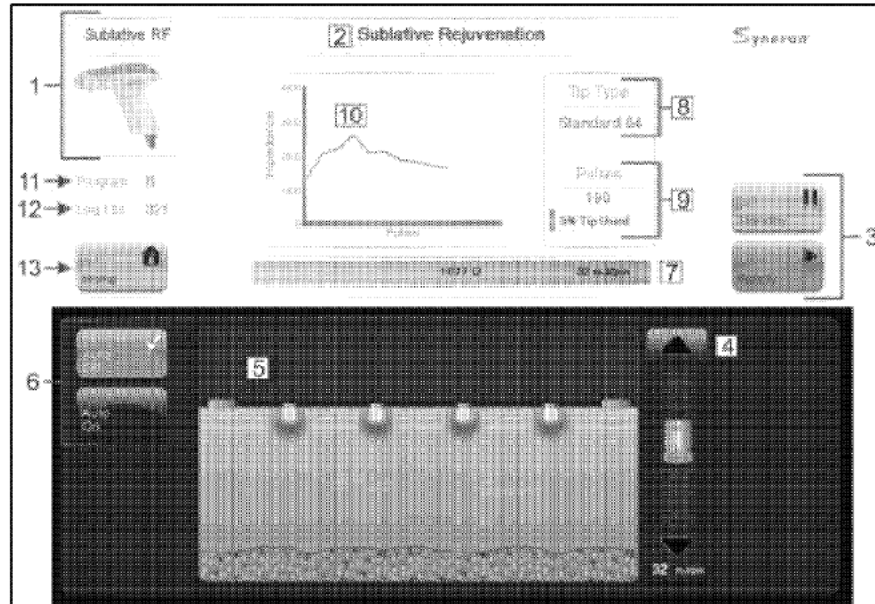


Figure 4-5: Sublative RF Treatment Screen Elements

4. **Requested Energy Selection Bar:** press anywhere inside the bar, or on the ▲ or ▼ buttons to increase or decrease the RF energy (mJ/pin) within program A, B or C.



Note

Pressing the ▲ or ▼ buttons after reaching the extreme end or beginning of the treatment program's energy range will transition the system to the next higher or lower treatment program, as exhibited by the **Program** tag shown by arrow # 11 in Figure 4-5.

5. **Tissue Effect Illustration:** displays effect of the RF energy penetration into the skin. The illustration changes intuitively as the levels of requested RF energy (mJ/pin) are adjusted.
6. **Auto Off** and **Auto On:** toggle the **Auto Repeat** mode that enables continuous pulsing at a fixed repetition rate of 1 pulse per second (Hz) by pressing the **Auto On** button.
7. **Skin Feedback Bar:** after a pulse is emitted, this bar exhibits four indications: the skin's impedance (Ohms), the RF energy delivered (mJ/pin), corrective action (on Orange or Red) and the type of pulse delivered. The pulse type is displayed by the following color bars:

Green Bar – optimal delivery of energy, this pulse is accompanied by a single 'click' sound. This pulse will be counted by the **Pulses** counter.



Orange Bar – non-optimal delivery of energy; accompanied by a corrective action message (**Dry the skin**) and a single 'click' sound. The pulse delivered energy to the treatment spot, yet it may need to be repeated.

This pulse will NOT be counted by the Pulses counter.



If the **Training Sound** mode is turned on (refer to **Utility Screen Elements** starting on page 4-8), a single tone will sound.

Red Bar (High Impedance) – a high impedance red bar means that the pulse was cut before energy was delivered to the treatment site due to debris on the tip or incomplete contact with the skin; this pulse is accompanied by a corrective action message (**Clean Tip/Check Contact**) and a double tone.

This pulse will NOT be counted by the Pulses counter.



Note

If the **Clean Tip/Check Contact** message appears on the skin feedback bar, set the system to **Standby** mode and clean the tip's matrix according to instructions starting on page 5-1.

8. **Tip Type Indicator:** indicates the type of Sublative iD tip currently connected to the applicator: **Standard 64** or **High Density 144**.
9. **Pulses Counter:** when a new tip is connected the bar starts at 0%, and progresses up to 100% as the tip is used until completion.

When a tip reaches the end of its pulse life, a message will be displayed warning that the tip has expired and needs to be replaced. The pulse life indicator will reset to zero when the tip is replaced with a new one.

If no tip is connected to the applicator and you attempt to set the system to **Ready** mode, the system will display a message (**No Tip Detected**) requiring a tip to be connected before proceeding.

10. **Impedance/Pulses Graph:** displays a forward-moving average of the impedance measured by the pulses. Each point in the graph on the Y-axis represents the average impedance of the previous five pulses; the next point of the graph will show the average impedance of the previous five pulses.



Note

During the first four pulses of the treatment session – before a 5-pulse average can be established – each point on the graph represents the measured impedance of only that pulse. The moving average begins at the fifth pulse emitted.

The measured impedance of **each** pulse is displayed on the skin feedback bar (in Ohms).

- 11. Selected Program Indicator:** displays which Sublative RF treatment program was selected for use: **A** (Low Impact), **B** (Medium Impact) or **C** (High Impact).
- 12. Log File:** denotes the name of the currently open system log file. These log files may be downloaded to a flash drive (disk on key) and then emailed to Syneron for troubleshooting purposes. Refer to the **Utilities Screen Elements** section starting on page 4-12.
- 13. Home:** pressing the **Home** button will transition the system to the **Home** screen (see Figure 4-3 on page 4-2).

System Sound Effect Definitions

The following table defines the various sound effects emitted by the eTwo/eMatrix system and to which actions they relate.

If you are reading a PDF copy of this manual, click the speaker icons in the table to hear the sound effect sample for each of the actions.

Description	Definitions	Demonstration
Click	- On-screen parameter changes. - Treatment pulse that generates a <u>Green</u> skin feedback bar or (if Training Sound is turned off) an <u>Orange</u> skin feedback bar (will be accompanied by a Dry the skin message).	
Single Tone	Treatment pulse that generates an <u>Orange</u> skin feedback bar when the Training Sound feature is toggled on. This will be accompanied by a Dry the skin message.	
Double Tone	Treatment pulse that generates a <u>Red</u> skin feedback bar. This will be accompanied by a Clean Tip/Check Contact message.	
Down-Scaled Whistle	Tip cleaning is required; the system will transition to Standby mode. This will be accompanied by a Clean Tip/Check Contact message.	
Bell	Warning! This sound is generated when the system detects an error situation. An appropriate error message is displayed on the screen.	
Down-Scaled Chime	This sound is generated when the system transitions to Standby mode.	
Up-Scaled Chime	This sound is generated when the system transitions to Ready mode.	
Voice Message	The system delivers several instructions or selection indications in the form of a voice message; click the icon to hear a sample.	

Charging and Emitting a Pulse

The eTwo/eMatrix applicators emit a radiofrequency pulse when charged and the applicator's trigger is pressed.

The green RF indication light bar on the applicator illuminates when the applicator is sufficiently charged and ready to emit the pulse (see Figure 4-6).

The indication light bar goes off during pulse discharge, and remains off until the applicator is recharged and ready for the next pulse.

If a pulse was not delivered, or delivery of energy was not optimal, the indication light bar will flash amber light until the applicator is properly charged for the next pulse (green light bar).

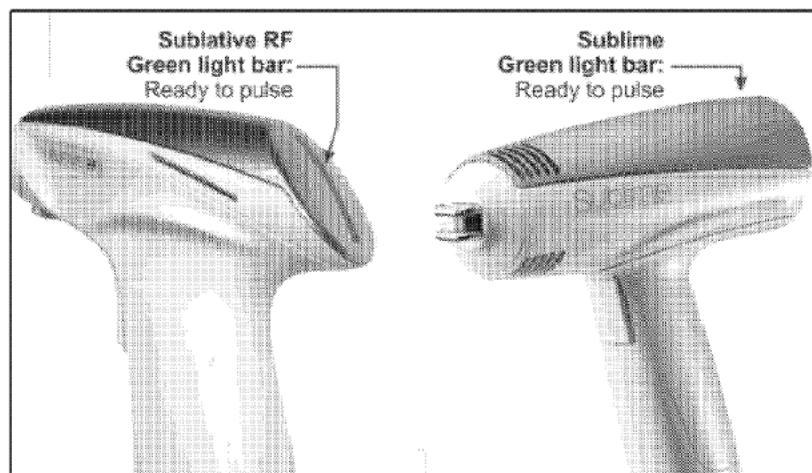


Figure 4-6: Charge Indication Light Bar

Sublime Treatment Mode

Figure 4-7 presents the main **Sublime Treatment** screen. The numbered tags in the illustration correspond to the following numbered explanations and definitions of the screens elements:

1. **Name and Illustration:** nametag and illustration of the currently active applicator.
2. **Description:** this tag describes the function of the currently active applicator.
3. **Standby and Ready Buttons:** press the **Ready** button to set the system to **Ready** mode; light pulses and RF energy will be emitted through the applicator tip when the trigger is pressed. Press the **Standby** button to set the system back to **Standby** mode. When the system is in **Ready** mode, pressing any other button will automatically return the system to **Standby** mode.
4. **Requested RF Energy Selection Bar:** select the desired RF energy to be delivered to the treatment site by pressing anywhere inside the bar, or on the ▲ or ▼ buttons to increase or decrease the RF energy anywhere from a minimum of 40 J/cm³ up to a maximum of 100 J/cm³ in increments of 10 J/cm³.



Note

The optical energy is automatically set without user input.

5. **Tissue Light & RF Effect Illustration:** displays the relative depth penetration into the skin of the light and RF energies. The illustration changes intuitively as the level of applied RF energy is adjusted.
6. Select the desired mode for the level of tip cooling in the Sublime applicator's tip:

Cooling Normal temperature (default selection):	15°C / 59°F
Cooling Strong temperature:	10°C / 50°F
7. **Normal Area** and **Sensitive Area Modes:** determine if the treatment area is to be considered **Normal** or **Sensitive**, and select the appropriate mode:

The **Sensitive Area** mode should be employed when treating bony areas such as the forehead, around the eyes or other bony or thin-skinned areas known to be sensitive. Otherwise use the **Normal Area** mode.

Sensitive Area mode will reduce the selected RF energy level by 30%.
Normal Area will increase the RF energy level back to the selected level.

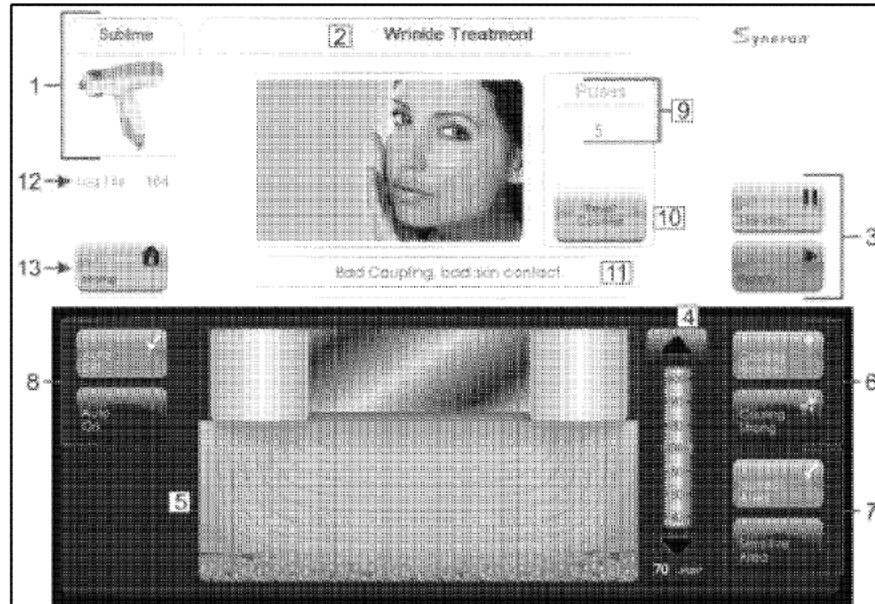


Figure 4-7: Sublime Treatment Screen Elements

8. **Auto Off** and **Auto On**: toggle the **Auto Repeat** mode that enables continuous pulsing at a fixed repetition rate of 1 pulse per second (Hz) by pressing the **Auto On** button.
9. **Pulses**: represents the accumulated number of pulses in the current treatment.
10. **Reset Counter**: press this button to reset the **Pulses** counter back to 0 (zero).
11. **Message Area**: informative, cautionary or error messages generated by the system are displayed in this box.
12. **Log File**: denotes the name of the currently open eTwo/eMatrix system log file. These log files may be downloaded to a flash drive (disk on key) and then emailed to Syneron for troubleshooting purposes. Refer to the **Utilities Screen Elements** section starting on page 4-12.
13. **Home**: pressing the **Home** button will transition the system to the **Home** screen (see Figure 4-3).

Utilities Screen Elements

Figure 4-8 presents the **Utilities** screen. The numbered tags in the illustration correspond to the following numbered explanations and definitions of the screen elements:

System Information Box:

1. **Software Version:** displays the version of the software package currently installed in your eTwo/eMatrix system.
2. **Sublative RF Applicator Pulses:** this open-ended counter displays the accumulated number of pulses emitted by the Sublative RF applicator. This count value will be displayed only when the applicator is connected to the system.
3. **Sublime Applicator Pulses:** this open-ended counter displays the accumulated number of pulses emitted by the Sublime applicator. This count value will be displayed only when the applicator is connected to the system.

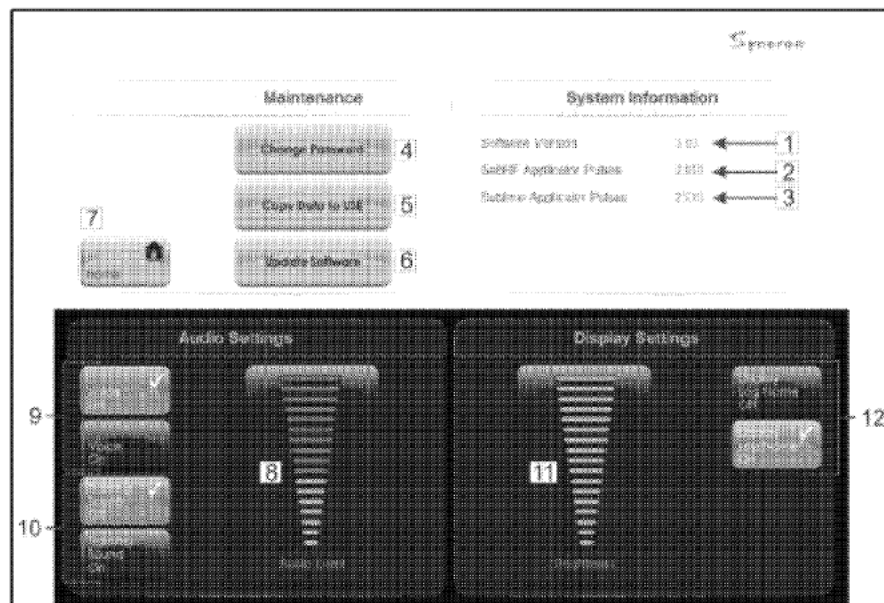


Figure 4-8: Utilities Screen Elements

Maintenance Box:

4. **Change Password:** press this button; a virtual keypad screen (similar to the **Login** screen) will appear. Follow the on-screen instructions above the keypad to change the password:
 - Enter the old (current) password and press **OK** (*).
 - Enter the new password and press **OK** (*).
 - Enter the new password again for confirmation and press **OK** (*).

**Note**

Press the **Cancel (X)** button to exit without changing the password.

5. **Copy Data to USB:** the system's save log files may be downloaded to a flash drive (disk on key) and then emailed to Syneron for troubleshooting purposes:

Press this button; a pop-up window will appear.

Follow the on-screen instructions.

6. **Update Software:** refer to the **Software Update Procedure** section, beginning on page 5-3.
7. **Home:** pressing this button will transition the system to the **Home** screen (see Figure 4-3 on page 4-2).

Audio Settings Box:

8. **Audio Level:** adjust the volume level of the voice messages and action tones emitted by the system.
9. **Voice On/Off:** the system emits messages and instructions in a human voice. This feature may be turned off () or back on () by toggling this button.
10. **Training Sound** (Sublative RF only): when set to **On**, every emitted pulse that generates an **orange** skin feedback bar will also sound this single tone, instead of the normal 'click' sound. This feature may be turned **On** () or back **Off** () by toggling this button.

**Display Settings Box:**

11. **Brightness:** adjust the brightness level of the LCD screen.
12. **Display Log Name:** when active, the name of the log file (*.csv) will be displayed on the **Treatment** screen, directly under the icon of the active applicator. This feature is useful when performing clinical trials with the eTwo/eMatrix system, or for troubleshooting purposes. This feature may be turned on () or back off () by toggling this button.



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5. MAINTENANCE

Cleaning the System

Clean the system at least once a week. Turn the system off and wipe all surfaces with a soft, damp, non-abrasive cloth. Be careful not to spill any liquids on or into the system.

The LCD screen should be cleaned with a dedicated LCD cleaning solution; this can be obtained from any office supply store.

Cleaning the Applicator

Wipe the body of the applicator with alcohol/chloride/acetone-free disinfectant after each treatment session.

Pay special attention to the tip of the Sublime applicator (light guide and electrode rails).

Cleaning the Sublative iD Tip

Ablated debris may accumulate on the tip's pin matrix during treatment.

The system will switch to **Standby** mode and display a message requiring cleaning of the tip at specific intervals, dependent on the energy level used.

The higher the energy level – the more often the system will stop for tip cleaning.

After cleaning the tip as instructed, press **Ready** to continue treatment.

How to Clean the Tip

Clean the tip's matrix with a gauze pad slightly moistened with 70% alcohol.

Use a dry gauze pad to absorb all the alcohol. Make sure the tip is completely dry before beginning to treat again.

When finished, reset the system to **Ready** mode and continue the treatment.



Caution

Ensure clean tips; accumulated debris or non-dry skin may lead to pain!

Discard used Sublative iD tips as bio-hazardous waste.

Fuse Replacement

To replace burnt fuses:

1. Turn off the system and disconnect the power cable from the outlet.
2. Unplug the power cable from the cable's connection port on the service panel.
3. Remove the fuse housing as shown in Figure 5-1.
4. Remove the burnt fuses from the housing and replace them with new ones.
5. Make sure that the fuses fit snugly within the fuse housing.
6. Insert the fuse housing into its receptacle and push it in until it snaps into place.
7. Connect the power cable to the system and to the power outlet.
8. Turn on the system and verify that it is functioning properly.



Caution

Make sure that the type and rating of the new and the replaced fuses match.

Always replace both fuses at the same time.

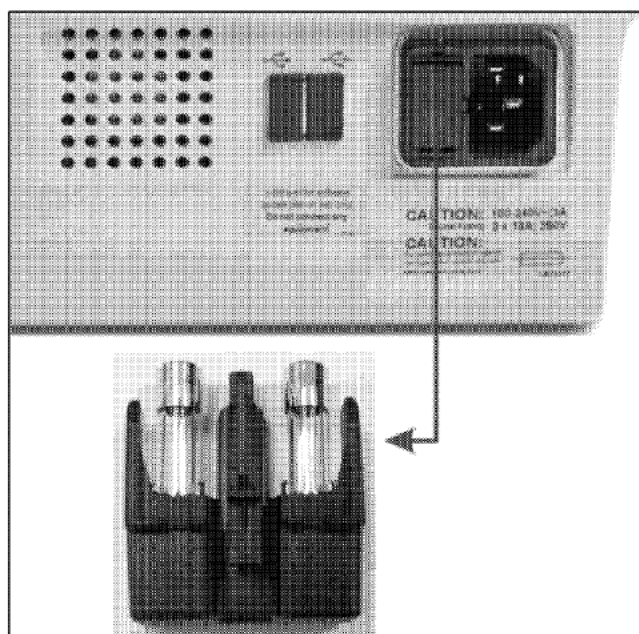


Figure 5-1: Fuses Replacement

Software Update Procedure

The **Software Update** feature in the **Utilities** screen (see Figure 4-8) allows you to easily update the eTwo/eMatrix system's software application package after receiving a new version from Syneron.

The new software package will be delivered to you by one of the following methods:

A USB flash drive (disk on key) with loaded software will be mailed to you, or:

The software package will be emailed to you; unzip the package directly onto your own blank disk on key.

To update the software, access the **Utilities** screen and press the **Update Software** button; a pop-up window will appear with complete instructions on how to install the new software. Follow the on-screen instructions until the installation is complete.



Caution

It is very important that during the update process the system does not lose power, or be interrupted in any way.

System Integrity

Inspect the eTwo/eMatrix system on a regular basis and at least once a month for damage to the applicators, umbilical cables and system base. If any evidence of broken, cut or otherwise damaged parts are detected, contact the Syneron Service Center to correct this. Using the system when it is damaged may cause unexpected results.



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6. TROUBLESHOOTING

The eTwo/eMatrix system is equipped with a self-testing software routine that continuously monitors system operation. If a system malfunction is detected, an error message will appear on the LCD screen.

The following troubleshooting tables do not attempt to list all possible system failures. Any fault not listed should be referred to Syneron's Service Center.

Sublative iD Tip Related Messages

Table 6-1 provides a list of Sublative iD tip related pop-up messages that will appear on the LCD screen during the normal course of patient treatment; follow the actions required by the pop-up message and resume normal operation. If the corrective action does not clear the pop-up message, restart the system and try again. If the problem persists, contact Syneron's Service Center.

Table 6-1: Sublative iD Tip Related Messages

Message	Required Action
New Tip Detected	The system has detected that a new tip is connected to the applicator during transition to Ready mode; press OK , observe Tip Type display at the top-right corner of the treatment screen, and proceed with normal operation.
No Tip Detected	During transition to Ready mode the system has detected that <u>no tip</u> is connected to the applicator; ensure that a valid tip is connected, press OK and proceed with normal operation.
Used Tip Detected	During transition to Ready mode the system has detected that you have connected an expired tip to the applicator; discard the expired tip, connect a new tip, press OK and proceed with normal operation.
Please clean tip and press Ready to continue	This message will pop up during treatment after specific intervals or events; clean the tip per instructions, resume Ready mode and proceed with normal operation.
Tip Is Disconnected	This message will pop up if the tip is inadvertently disconnected during operation; reconnect the tip, press Cancel and proceed with normal operation. If the problem persists replace the tip with a new one.
Tip has expired	This message will pop up when the connected tip reaches the end of its pulse life; discard the used tip, connect a new tip, press Cancel and proceed with normal operation.
Incorrect tip connected. Replace with correct tip type.	The system has detected that an old-style tip is connected to the applicator. The old tips are no longer supported by the system; discard all old-style tips from your stock and use only the new tips.

Sublime Related Messages

Table 6-2 provides a list of Sublime applicator related pop-up messages that may appear on the LCD screen during the normal course of patient treatment; follow the actions required by the pop-up message and resume normal operation. If the corrective action does not clear the pop-up message, restart the system and try again. If the problem persists, contact Syneron's Service Center.

Table 6-2: Sublime Related Messages

Message	Required Action
Bad coupling, bad skin contact	The system has detected that light/RF energy transfer to the skin is less than optimal, probably because there is not full contact or not enough coupling gel applied to the treatment area. Ensure full contact or apply more coupling gel to the treatment area and proceed with normal operation.
Applicator is cooling down	The internal temperature of the Sublime applicator has risen above its design limit and the system has disabled operation until it cools down; wait several minutes and proceed with normal operation.
Replace Sublime IR lamp	The system has detected that the Sublime IR lamp is not functioning correctly and must be replaced. Contact your local Syneron representative.

System Warning Messages

Table 6-3 provides the list of system warning messages that may appear on the LCD screen during operation. A system warning will disable further use of the system until the problem is resolved. If the corrective action does not resolve the problem, contact Syneron's Service Center.

Table 6-3: System Warning Messages

System Warning Message	Probable Cause	Corrective Action
Sublative RF applicator disconnected	The applicator has been disconnected while the system is in Standby or Ready mode.	Connect the applicator to the system and proceed with normal operation.
Sublime applicator disconnected		
Preventive maintenance of Sublime applicator required	The Sublime applicator will require service in the near future.	Contact Syneron Service Center to schedule service.
Preventive maintenance of Sublime applicator required prior to use	The Sublime applicator requires service before it can be used.	Contact Syneron Service Center to schedule immediate service.
Incorrect Sublative RF applicator connected	The wrong Sublative RF applicator is connected to the system.	Connect and use only the Sublative RF delivered with this system [FG7054(x)]

System Error Messages and Malfunctions

Table 6-4 provides the list of system error messages that may appear on the LCD screen during operation. A system error will disable further use of the system until the problem is resolved. If the corrective action does not resolve the problem, contact Syneron's Service Center.

Table 6-4: System Error Messages

System Error Message	Probable Cause	Corrective Action
No Applicators connected	Applicators are not connected properly or are disconnected.	Turn the system off, check applicator connection and turn system on.
Missing Start-Up Values	Software malfunction.	Restart the system. If problem persists, contact Syneron Service Center.
Temperature Fault	Cooling system malfunction.	Turn the system off, allow to cool for several minutes and restart. If problem persists, contact Syneron Service Center.
Missing Calibration Data	Software malfunction.	Restart the system. If problem persists, contact Syneron Service Center.

Symptoms without Messages

Table 6-5 lists several possible symptoms indicating malfunctions that do not appear on the LCD panel. If the corrective action listed in the table does not solve the problem, contact Syneron Service Center.

Table 6-5: System Malfunctions Troubleshooting Guide

Symptom	Probable Cause	Corrective Action
System does not start.	Power cable disconnected.	Check power cable Plug cable into wall
	Blown fuse(s).	Replace fuses (refer to Maintenance section)
No display on the LCD.	LCD malfunction.	Call Syneron Service.
Sublative iD tip ceases to function.	Tip disconnected. System is restarted. System was shut down as a result of a power failure.	Replace the tip with a new one.
No light emitted from the Sublime applicator's IR lamp.	IR lamp malfunction.	Check for IR lamp operation by pressing the trigger in Ready mode with the tip pressed against the skin; call Syneron Service if not functioning.



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CX-2590C.75

7. SYSTEM SPECIFICATIONS

Sublative RF Output Parameters

Total RF energy:	Up to 62 milliJoules per pin (mJ/pin)
Programs' RF energy:	
Program A:	10 – 30 mJ/pin, in 5 mJ increments
Program B:	32 – 48 mJ/pin, in 4 mJ increments
Program C:	50 – 62 mJ/pin, in 3 mJ increments
Power range:	20 – 75 W (Impedance: 200 – 2,500 Ohms)
Max. Voltage output (applicator electrodes):	275 V _{RMS} (without load)
Electrodes:	Two active and bi-polar applicator electrodes (no neutral electrode)

Sublative RF Power Characteristics

IEC 60601-2-2:2006 Cl. 6.8.3 bb-1: Output Power versus Load impedance at Half and Full Output Control

The power curve of the Sublative RF applicator with 144-pins tip is shown in Figure 7-1 below (Half and Full output control diagrams are identical).

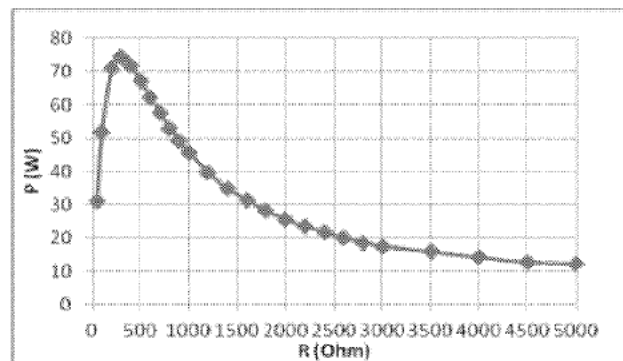


Figure 7-1: Power versus Load Impedance, Sublative RF 144-Pins

IEC 60601-2-2:2006 Cl. 6.8.3 bb-2: Output Power versus Output Control at a Specified Load

Output power of the Sublative RF applicator with 144-pins tip at 500Ω (as a typical load) is 70W for the whole range of output control.

IEC 60601-2-2:2006 Cl. 6.8.3 cc: Peak Output Voltage versus Output Control

Peak output voltage of the Sublative RF applicator with 144-pins tip is 275V for the whole range of output control.

Sublative iD Treatment Tips

Sublative iD Standard tip:	64 electrode pins
Tip footprint:	12 x 12 mm
Sublative iD High Density tip:	144 electrode pins
Tip footprint:	12 x 12 mm

Sublime Output Parameters

RF energy density:	40 – 100 J/cm ³
Optical fluence:	6 W/cm ² ± 20%
Wavelength:	700 – 2000 nm
Power range:	70 – 200 W (Impedance: 50 – 500 Ohms)
Pulse repetition rate:	1 Hz
Tip footprint:	8 x 12 mm
Max. Voltage output (applicator electrodes):	300 V _{RMS} (without load)
Electrodes:	Two active and bi-polar applicator electrodes (no neutral electrode)

Sublime Power Characteristics

IEC 60601-2-2:2006 Cl. 6.8.3 bb-1: Output Power versus Load Impedance at Half and Full Output Control

The Power curve of the Sublime applicator is shown in Figure 7-2 below (Half and Full output control diagrams are identical).

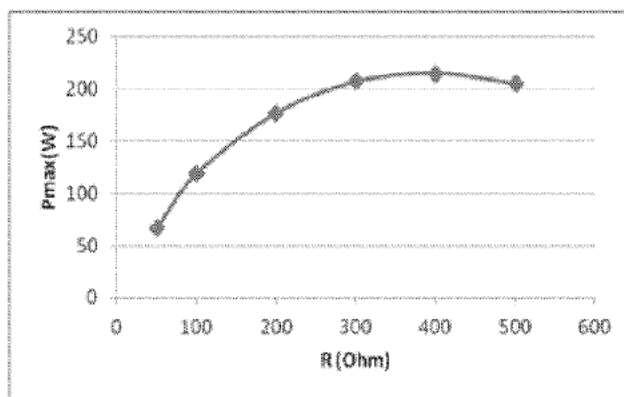


Figure 7-2: Sublime Power versus Load Impedance

IEC 60601-2-2:2006 Cl. 6.8.3 bb-2: Output Power versus Output Control at a Specified Load

Output power of the Sublime applicator at 200 Ω (a typical tissue load) is 175W for the whole range of output control.

IEC 60601-2-2:2006 Cl. 6.8.3 cc: Peak Output Voltage versus Output Control

Peak output voltage of the Sublime applicator is 300V for the whole range of output control.

Electrical Requirements

100 – 240 VAC $\pm$ 10%; 3A; 50/60Hz; Single Phase

Environmental Requirements**Treatment Room**

Temperature:	15 – 30 C [59 – 86 F];
Relative humidity:	10% – 80%
Air pressure range:	700 – 1060 hPa [0.70 – 1.06 Bars]

Storage/Transportation

Temperature:	10 – 55 C [50 – 131 F];
Relative humidity:	10% – 80%
Air pressure range:	700 – 1060 hPa [0.70 – 1.06 Bars]

System Display

High-resolution color, 15" LCD screen with touch-screen technology

System Dimensions

Closed system [W x D x H]:	53 x 30 x 23 cm / 21.8 x 11.8 x 9.1"
Open system [W x D x H]:	53 x 30 x 40 cm / 21.8 x 11.8 x 15.7"
Sublative RF applicator [W x H]:	15 x 16 cm / 5.9 x 6.3"
Sublime applicator [W x H]:	20 x 20 cm / 7.8 x 7.8"
Applicator umbilical cable:	190 cm / 74.8"

System Weight

eTwo/eMatrix system:	8.5 kg. / 18.7 lbs.
Sublative RF applicator:	0.5 kg. / 1.1 lbs.
Sublime applicator:	1.0 kg. / 2.2 lbs.

Jeisys

ABOUT JEISYS

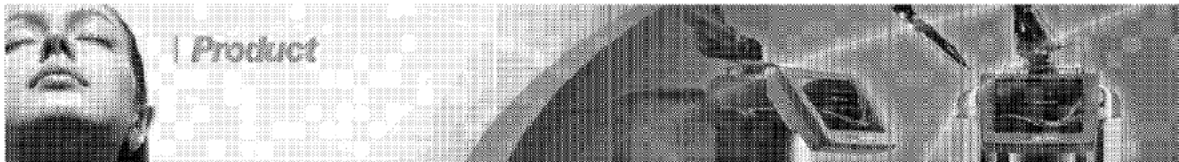
PRODUCT

NEWS&MEDIA

SUPPORT

CONTACT US

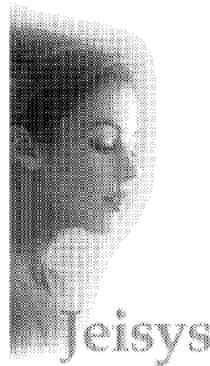
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INTRAcel

INTRAcel™

Fractional RF Microneedling



Jeisys

Intracel

Specification

Treatment

1. Intracel



The INTRAcel ElectroSurgical unit is a device that uses Fractional RF Micro needles to achieve electrocoagulation and hemostasis. INTRAcel gives selective heating in the dermis using microneedles of bipolar and monopolar RF in a minimally invasive way. The electrical energy as like RF is converted to heat in tissue as the tissue resists the flow of current from microneedles. For the safety of device operation, there are an emergency switch and a key switch so that the operator can control by touch screen based on window O/S program.

Patented FRM(Fractional RF Microneedle) Technology™

- FRM Technology™ is a unique technique to treat the target area by the fast penetration of a specially designed compound numbers of insulated microneedles without a destruction of epidermis. Then, it makes column for healing and simultaneously emitting a high-tensioned RF pulse on the target tissue inside the skin.

http://www.jeisy.com/?page_id=22#4

Product

- + INTRAcel
- + SmoothCool
- + Edge ONE
- + PlasmaLipo
- + TGI-BEAM K
- + MxLax
- + Collec
- + IntraGen
- + ULTRAce!

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1/2

ABM-ITC1356-0000782

CX-2590C.80

Ex. 2048-0080

2. Specification

Overall Dimensions	350 mm (W) x 405 mm (D) x 1,080 mm (H)
	350 mm (W) x 405 mm (D) x 1,380 mm (H) (Including hand-piece stand)
Weight	63 Kg
LCD	Active screen size : 12.1 inch
	Pixel format : 800*600
	Outline dimension : 128(H)*218(V)*12(D) mm
Hand-piece	Color depth : 262,144 color
	Bipolar, Monopolar, SRR
Chiller	350(W)*216(D)*225(H)
Caster	Coolant capacity: 1.3liters, COMP. : 1/8PS
	4EA (φ100mm)

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Family Sites

Jeisys Family Sites ▼

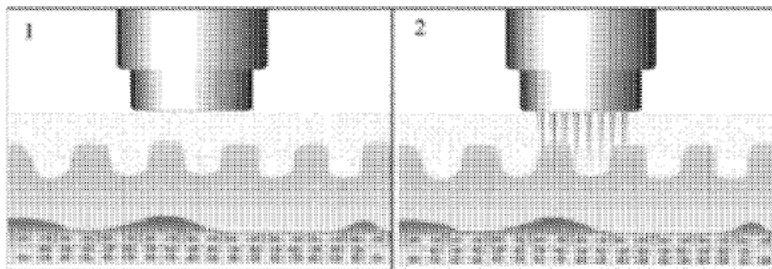
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INTRAcel

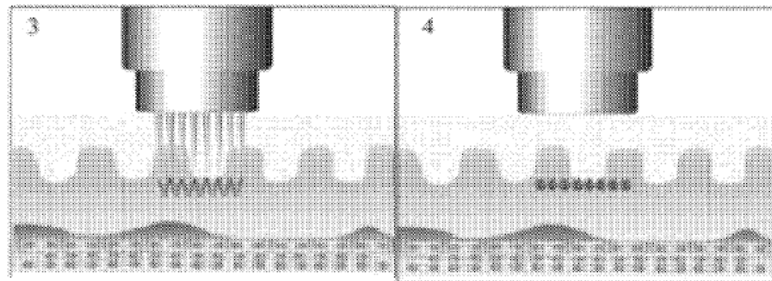
Fractional RF Microneedle™

HOW INTRAcel WORKS



The Handpiece is placed on the skin.

The RF Microneedles penetrate the skin.



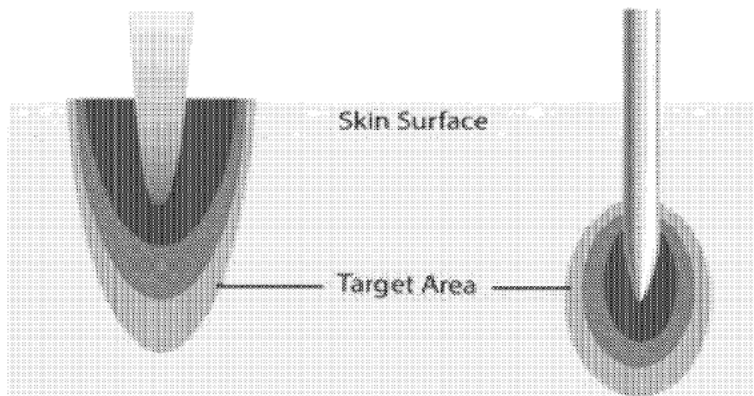
Bi-polar RF energy is applied to the target area.

The RF Microneedles retract and the regeneration process begins.

Tissue Damage - Fractional Laser vs INTRAcel

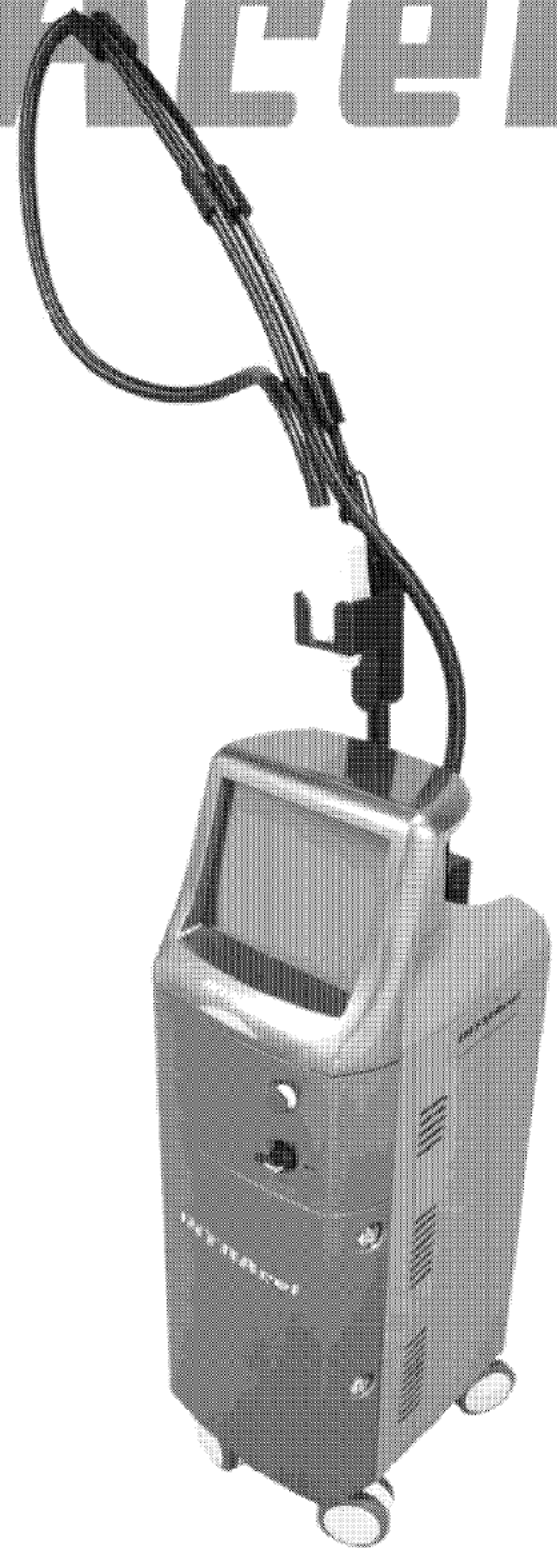
Fractional Laser

INTRAcel



- 100 C - Vapourization
- 60-80 C - Necrosis and Coagulation
- 40-60 C Protein Denaturation
- <40 C Ineffective Energy

The INTRAcel RF Microneedles are able to apply the energy directly to the target area. Fractional Lasers require high energy levels to attempt to reach the target area causing significant surface damage to the skin as well as pigment changes and creating longer recovery time after treatment.

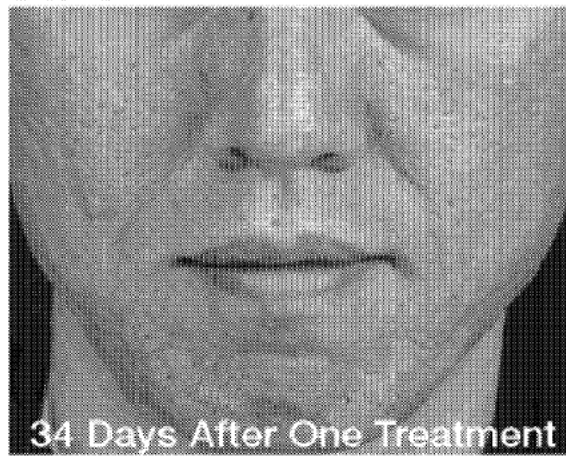
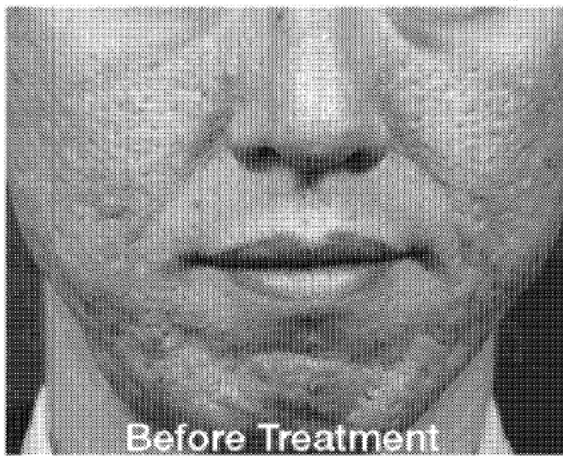


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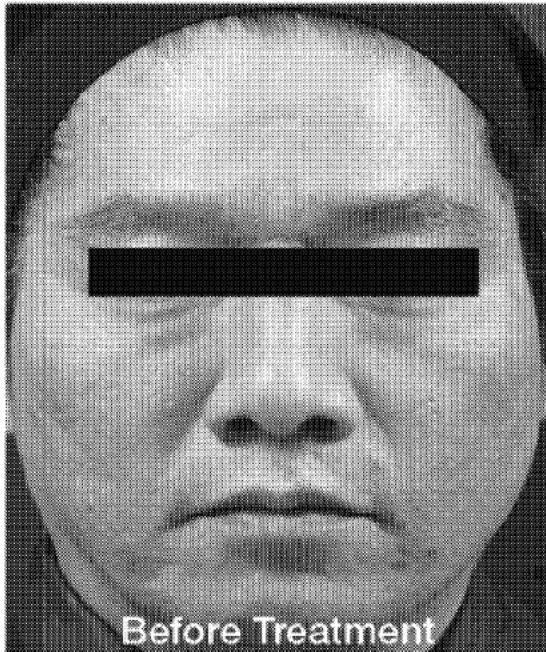
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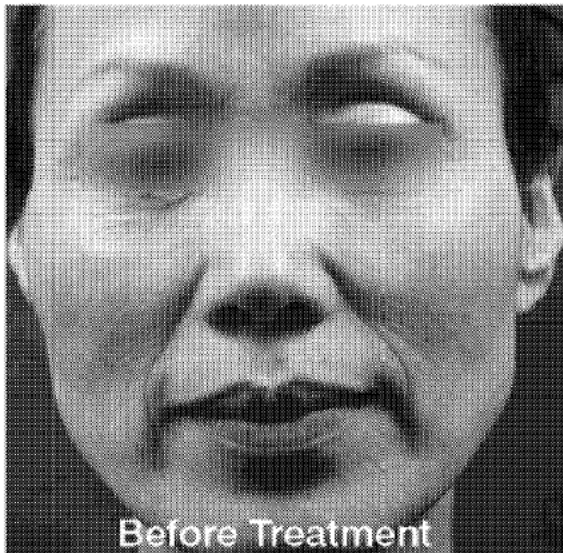
Acne Scars



Skin Tightening



Wrinkle Reduction



ABM-ITC1356-0000785

CX-2590C.83