

NOVEL MULTI-SOURCE PHASE-CONTROLLED RADIOFREQUENCY TECHNOLOGY FOR NON-ABLATIVE AND MICRO-ABLATIVE TREATMENT OF WRINKLES, LAX SKIN AND ACNE SCARS

Monica Elman MD ¹ and Yoram Harth MD ²

1: *Dermatology Laser Aesthetic Surgery Clinic, 11 Tarzav Street, Beth Ha'rofeem Holon, Israel*

2: *Medical Or Clinic, 8 Aba Even Ave, Herzlyya Pituach, Israel*

The basic properties of lasers and pulsed light sources limit their ability to deliver high energy to the dermis and subcutaneous tissues without excessive damage to the epidermis. Radiofrequency was shown to penetrate deeper than optical light sources independent of skin color. The early RF-based devices used single source bipolar RF, which is safe but limited in use due to the superficial flow of energy between the two bipolar electrodes. Another type of single source RF employs a single electrode (monopolar) in which the RF energy flows from one electrode on the surface of the skin through the entire body to a plate under the body. Although more effective than bipolar, this devices require intense active cooling of the skin and may be associated with considerable pain and other systemic and local safety concerns. Latest generation of RF technology developed by EndyMed Medical Ltd. (Caesarea, Israel) utilizes simultaneously six or more phase controlled RF generators (3DEEP technology). The multiple electrical fields created by the multiple sources "repel" or "attract" each other, leading to the precise 3 dimensional delivery of RF energy to the dermal and sub-dermal targets minimizing the energy flow through the epidermis without the need for active cooling. Confocal microscopy of the skin has shown that 6 treatment sessions of Multisource RF technology improve skin structure features. The skin after treatment had longer and narrower dermal papilla and denser and finer collagen fiber typical to younger skin as compared to pre treatment skin. Ultrasound of the skin showed after 6 treatment sessions reduction of 10 percent in the thickness of the subcutaneous fat layer. Non ablative facial clinical studies showed a significant reduction of wrinkles after treatment further reduced at 3 months follow-up. Body treatment studies showed a circumference reduction of 2.9 cm immediately after 6 treatments, and 2 cm at 12 months after the end of treatment, proving long term collagen remodeling effect. Clinical studies of the multisource fractional RF application have shown significant effects on wrinkles reduction and deep atrophic acne scars after 1-3 treatment sessions.

Background:

Patient demand for a non-invasive and long-lasting treatment to reduce wrinkles has grown dramatically over the past decade as new treatments and technologies have been introduced. A major cause of skin wrinkles, skin laxity and cellulite is the reduction in the quantity and quality of collagen fibers in the dermis and hypodermis. It is well documented that one of the

effects of dermal heating is an immediate change in collagen structure followed by a longer term stimulation of neocollagenesis starting at 4-6 weeks after therapy.¹⁾ These changes can help reduce the appearance of wrinkles and lax and improve contours on both the face and body.

Lasers and pulsed light technologies are very effective in the treatment of colored skin lesions such as lentiginos and vascular lesions and in hair removal. Nevertheless, due to the limited penetration of optical energy into tissue, lasers and light are less useful for

Addressee for Correspondence:

Monica Elman MD
Dermatology Laser Aesthetic Surgery Clinic
11 Tarzav Street, Beth Ha'rofeem Holon, Israel
E-mail: elman1@bezeqint.net

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the non-ablative deep heating of the dermis and subcutaneous tissue required for skin tightening, body contouring and atrophic acne scar therapy.

Radio frequency energy heats tissue through the induction of rotational movement in water molecules. This type of movement produces heat and, similarly to laser or light, this heat triggers the production of new collagen. In contrast to optical energy, RF energy penetrates easily into the skin and heats the target tissue, independent of skin type (Fitzpatrick skin types I-VI). The early RF-based devices developed by various manufacturers used single source bipolar RF, which has shown some benefits, but has been limited by the superficial flow of energy between the two bipolar electrodes.⁵⁾ Other devices using monopolar (or unipolar) RF employ a single electrode which results in the RF energy flowing uncontrolled through the entire body, beyond the target area. Since monopolar RF energy is typically delivered at higher power to enable it to penetrate to the treatment site from the single electrode, the use of this type of RF device requires intense active cooling of the skin and is frequently associated with pain and other systemic and local safety concerns.

EndyMed Medical Ltd. (Caesarea, Israel) has developed a new, proprietary RF delivery technology, using, for the first time, multi-source, phase controlled RF. This 3DEEP™ RF technology overcomes most of the drawbacks of the other RF devices developed for aesthetic medicine use by implementing an array of RF sources and controlling the phase of the current flowing between the electrodes using a sophisticated software algorithm. Since adjacent electrodes possess identical polarities, no current is created between these electrodes on the skin's surface and the energy is driven deeper into the skin. These multiple deep electrical fields created repel each other, leading to the precise delivery of RF energy to the dermal and sub-dermal targets. **(Fig. 1)**

The EndyMed 3DEEP technology provides the ability to deliver constant power customized in real-time to the individual patient's skin impedance, thereby improving the predictability of results.¹⁰⁾ Unique contact motion and temperature sensors integrated into the device's handpieces allow optimal safety. EndyMed's 3DEEP technology can be used for two main categories of indications: non-ablative treatment for wrinkles, skin tightening and contouring of the face and body, and for micro-ablative fractional treatment for skin resurfacing and acne scarring.

Non-ablative treatments for wrinkles, skin tightening, and contouring of the body and face

Skin tightening and body contouring may be achieved through surgery. Non-invasive vacuum and massage-based body contouring treatments offer only partial and short-term benefits as the improvement is only temporary. Newer systems use infrared dermal heating for the induction of immediate and longer term effects on collagen structure through the stimulation of neocollagenesis.^{2,3)} Although the combination of massage with heating via infrared (IR) or bi-polar radio frequency in some devices enhances the results of the vacuum and massage systems, the heat penetration into the deep dermal and sub-dermal layers is not sufficient for longer term effective collagen tightening and remodeling.⁴⁾

Royo de la torre et. published recently a study⁹⁾ in which 33 patients were treated for skin laxity on the body using the EndyMed PRO. They found Mean reduction in the contour of the treatment area after the first six sessions was -2.9 ± 1.6 cm, which stabilized after 12 months at -1.9 ± 2.0 cm. There were no significant differences in the variation of the contour of the control area (-0.5 ± 0.6 cm after 6 sessions and -0.5 ± 0.5 cm at the 12-month visit). They also determined by confocal microscopy that increase in papilla height of $9.5 \pm 8.8 \mu$ at six months, $12.9 \pm 4 \mu$ at nine months, which increased gradually to $13.3 \pm 8.7 \mu$ at the 12-month visit (28.79%, 39.20% and 40.30%, respectively). We examined the effect of multi-source phase-controlled radiofrequency (EndyMed PRO, EndyMed Medical, Caesarea, Israel) on lax skin. The study that was done for body contouring included 30 treatment sites on 23 healthy volunteers at two study sites. The treatment protocol included four weekly and two bi-weekly (n=6) treatments on different body areas. Results were evaluated by standardized photography and by circumference measurements at the treatment area, and were compared to changes in body weight, as a control to prove that circumference changes were not a result of weight loss. Significant improvement **(Fig. 2)** could be observed in skin laxity, the appearance of stretch marks and the appearance of cellulite. Circumference changes up to 4.3 cm were measured, the average circumference reduction in the abdomen area was 2.3 cm (decrease in weight of 0.03 kg.), while in the thighs the average circumference reduction was 2.52 cm (increase of weight of 0.16 kg).⁵⁾

Micro-ablative fractional treatment for skin resurfacing and acne scarring

Skin resurfacing has been used for medical and aesthetic purposes for more than 100 years. Ablating the skin removes the upper layer allowing the natural mechanism of renewal to form a new layer of healthier and better-looking skin. Skin resurfacing can be performed using mechanical devices (dermabrasion), chemical peeling compounds, lasers and radiofrequency devices. The concept of fractional skin resurfacing using laser devices was developed to address the shortcomings of ablative and non-ablative devices. These fractional skin resurfacing systems perform ablation on small microscopic "dots" of skin allowing rapid healing with minimal pain and much less downtime.

In a study done early this year, we examined the Fractional Skin Resurfacing (FSR) handpiece of the EndyMed PRO system, which uses a variation of the proprietary 3DEEP radiofrequency technology mentioned earlier in this article. The FSR handpiece contains a matrix of 112 tiny RF electrodes, which allows simultaneous fractional microablation of the epidermis, together with volumetric heating of 100% of the targeted dermis. **(Fig. 3)** The technology provides the capability of differentiating between microablation and dermal heating which appears to be the optimal multi-layer treatment needed to affect aging skin and atrophic acne scars.

Thirty patients (26 female, 4 male, ages 23-71 years) were enrolled in the study, 25 for wrinkle treatment and 5 patients for acne scar treatment, after meeting all

the inclusion/exclusion criteria and signing informed consent forms. Treatment was preceded by the application of topical anesthesia (Emla, Astra Zeneca) for 30 minutes prior to treatment initiation, following which the skin was thoroughly cleaned and wiped with 70% alcohol. Patients received one treatment and 2 follow-up visits, at one week and one month after treatment. Photographic analysis of pre-and post treatment of the digital images was conducted by two blinded board certified dermatologists according to the generally accepted quartile skin improvement scale.⁷⁾ Analysis revealed improvement in all (100%) of patients according to both reviewers. **(Fig. 4, 5)** Analysis of the frequency of improvement degree revealed that both reviewers found that the degree of improvement was moderate to good (25-75% improvement in most of the study participants (83.8% according to the first reviewer and 66.7% according to the second reviewer).⁸⁾

No adverse side effects were reported for any of the patients in the three studies detailed above. Patients were satisfied with the treatments for each study respectively.

Conclusions:

The EndyMed PRO device, using 3DEEP RF technology, offers a new and very effective way to deliver energy deep into the cutaneous and subcutaneous tissue with minimal to no pain. Clinical results yielded significant efficacy in the reduction of wrinkles, contouring of the face and body, and fractional skin resurfacing for wrinkles and scars.

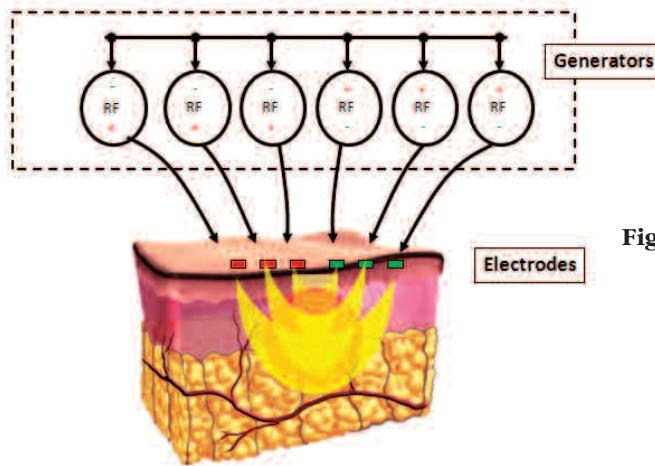


Fig. 1: The EndyMed PRO non-ablative 3DEEP handpieces use multiple phase controlled RF generators allowing deep penetration of thermal energy with minimal surface heating, without pain or need for active epidermal cooling.

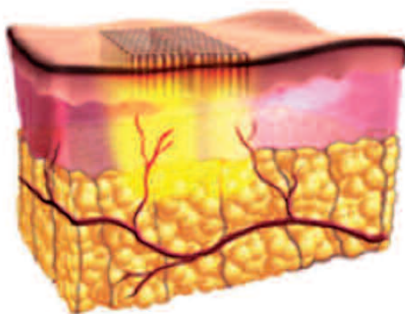


A



B

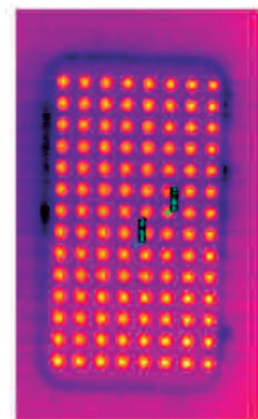
Fig. 2: A. Baseline. B. Six months after 6 EndyMed PRO treatment sessions on ablative showing significant skin tightening and circumference reduction.



A



B



C

Fig. 3: A. The EndyMed PRO microablative fractional RF handpiece uses multiple phase controlled RF generators for simultaneous fractional microablation and non-ablative deep dermal heating of up to 2.9 mm. B. Hand piece C. Thermal imaging of the treatment tip showing 112 contact points, diameter 300 micron each.



Fig. 4: A. Baseline showing multiple pitted and atrophic acne scars. B. One month after 3 treatment with EndyMed PRO fractional RF skin resurfacing showing a significant reduction of diameter and depth of the acne scars.



Fig. 5: A. Baseline showing Multiple lentigines on the decolte area. B. One month after 1 treatment with EndyMed PRO fractional RF skin resurfacing showing a significant reduction of hyperpigmentation and improvement of skin texture.

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