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Painless, safe, and efficacious noninvasive skin tightening, body contouring, and cellulite reduction using multisource 3DEEP radiofrequency

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Summary

In the last decade, Radiofrequency (RF) energy has proven to be safe and highly efficacious for face and neck skin tightening, body contouring, and cellulite reduction. In contrast to first-generation Monopolar/Bipolar and "X -Polar" RF systems which use one RF generator connected to one or more skin electrodes, multisource radiofrequency devices use six independent RF generators allowing efficient dermal heating to 52–55 °C, with no pain or risk of other side effects. In this review, the basic science and clinical results of body contouring and cellulite treatment using multisource radiofrequency system (Endymed PRO, Endymed, Cesarea, Israel) will be discussed and analyzed.

Keywords: radiofrequency, skin tightening, multisource, body contouring, 3DEEP

Introduction

Body skin laxity and cellulite affect more than 90% of women. Onset of skin laxity occurs at the age of 35–40 years, while cellulite may be manifested in women as young as 18–20 years. The impact of these problems on the patient's self-esteem can become important enough to affect quality of life in psychological and in sociocultural terms.[1,2]

Basic science shows that both skin laxity and the skin condition called cellulite are related to loss in quantity and function of dermal collagen fibers. Skin laxity is frequent in younger people after weight loss or pregnancy and in older age due to diminished collagen production and function. Histological studies of lax skin show diminished biosynthesis of collagen and elastin and abnormalities of the extracellular environment with an increase in the concentration of hyaluronic acid.[3] Some authors have hypothesized that lengthening and weakening of dermal collagen and elastic fibers accompanied by fat protrusion cause cellulite.[4,5]

Massage in different forms was shown to reduce body circumference and cellulite for the short term. A significant progress in the treatment of lax skin was the understanding that an increase in temperature as small as 5 degrees Celsius can trigger the release of heat-shock proteins (HSPs). The increased level of heat-shock proteins starts a healing cascade.[6,7] Radiofrequency, in particular, was shown to induce the release of HSP-47, a protein that is found in the endoplasmic reticulum and seems to be necessary for proper production of three-dimensional collagen type I molecules by tissue fibroblasts.[8]

Increasing the dermal temperature from 52 °C to 55 °C will trigger the fibroblasts to destruct old dysfunctional collagen, building new collagen fibers, in a process called collagen remodeling.[9–13] The delivery of

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heat to the dermis and hypodermis can be achieved by a few different technologies mainly infrared light and radiofrequency (RF). As optical energy in the infrared range is limited in its ability to penetrate into the deep dermis and hypodermis without excessive heat on the surface, research efforts in the last few years were targeted toward radiofrequency energy.

Current RF systems use two basic mechanisms of heating. In the Monopolar (or Unipolar) RF devices, a single electrode emits energy onto the skin. The current is dispersed in the tissue and is either flowing toward a receiving pad attached to the patient or is grounded through the body to the treatment table (no pad). To achieve enough heat at the desired target depth, high energies are needed. An intense epidermal cooling is usually needed to prevent epidermal damage leading to the need of more power and back again. In the bipolar or "X-polar" configuration, the current produced by a single RF generator flows between two electrodes. Although maximal penetration is considered to be equal to half the distance between the electrodes, most of the thermal effect is concentrated very superficially along the shortest path between the 2 electrodes, leaving the deep dermis unaffected.

The 3DEEP multisource RF technology overcomes these problems using up to six independent phase-controlled RF generators connected to an array of electrodes (4–112 depending on the application). For skin tightening and body contouring, the three generators on the left will be configured to "plus" and the three on the right to be "minus". As the three electrodes on the left are in the same phase, the RF energy from the two extreme electrodes on the left will not able to flow on the surface to the positive electrodes on the right and will have to penetrate deeper into the tissue (Fig. 1). This unique, Multisource RF treatment platform allows the use of five different hand pieces including nonablative skin tightening for face, body, and periorbital, fractional RF skin resurfacing and fractional microneedle RF (Fig. 2).

It is known that tissue impedance depends on its physiological properties where, for example, gender and body area have to be considered. To normalize the power emitted by the system for tissue impedance, the system performs frequent intermittent measurements of skin impedance and automatically corrects system output to achieve a constant energy delivery independent of skin impedance. Real-time impedance measurement and constant energy mechanisms in the tested system are believed to provide higher results treatment predictability.[21]

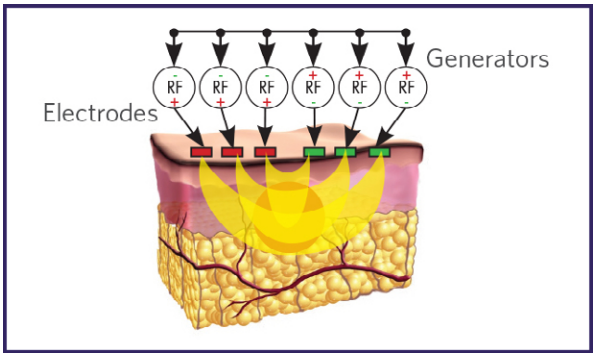

Figure 1 Typical multisource RF configuration uses six independent phase-controlled RF generators. For skin tightening and body contouring, the three generators on the left will be configured to "plus" and the three on the right to be "minus".

Basic science research

Laboratory studies using four phase-controlled sources of RF (multisource RF technology) on an *ex vivo* duck skin have demonstrated a selective heat flow through the dermis and the fibrotic tissue surrounding the subcutaneous fat lobules (Fig. 3).

The selective heating through the areas of lower electrical impedance may be the mechanism for peri lobular collagen tightening with subsequent reduction in body circumference and cellulite. Using confocal microscopy, on patient skin before and after six treatments, Royo *et al.*[14] observed an increase in papilla height (28.79% at 3 months after end of treatment and 40.30% 9 months after the end of treatment). These changes reflect a significant improvement in the quality of the dermal–epidermal junction and are consistent with the results of other clinical studies based on conventional histology. They noted in addition an increased depth of the collagen refringence band (9.7 ± 5.0 [9.7%] at 3 months and 6.3 ± 8.6 [5.18%] at 9 months) a clear evidence to long-term collagen remodeling.[9,15–18]

Clinical studies

Elman *et al.*[19] the multisource RF system (Endymed PRO, Endymed Medical Ltd., Cesarea, Israel) for the treatment of 30 patients (29 female, one male) with body lax skin and cellulite. Treatment areas included abdomen (20 patients), thighs (eight patients), flanks (one patient), and arms (two patients). Some patients were treated for more than one area. Treatment protocol included six sessions: four weekly treatments and two additional treatment sessions at 2 weeks inter-

Figure 2 Lt. multisource RF, body contouring hand piece, showing an array of six phase-controlled electrodes with built-in skin surface temperature measurement, motion sensor, and real-time impedance measurement Rt. The Multisource RF treatment platform allows the use of five different hand pieces including nonablative skin tightening for face, body, periorbital areas, fractional RF skin resurfacing and fractional microneedle RF.

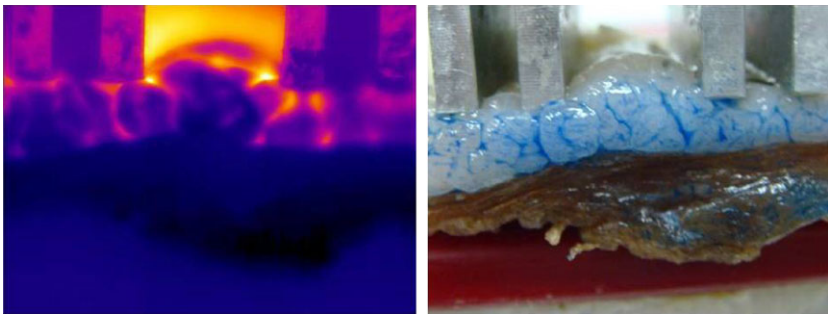

Figure 3 Lt. four phase-controlled sources of RF (multisource RF technology) used on *ex vivo* duck tissue demonstrating a selective heat flow through the dermis and the fibrous tissue surrounding the subcutaneous fat lobules. Rt. Tissue stained with Aniline Blue reveals a match between collagen fibers network (stained in blue) and the heating pattern on the left side.

val (total 8 weeks). The treatment area was divided into squares of 10 × 10 cm. Each treatment was started using system presets for the specific area (30W for abdomen and thighs, 25W for flanks, 20W for arms). A thin layer of clear ultrasound gel was spread over the treatment area. Each area was treated in a circular motion for 4 min (Fig. 4).

No adverse events were recorded. All patients had transient erythema in the treatment area, which resolved within 10–15 min. All patients reported the treatment as comfortable (no pain). The average circumference reduction in the abdomen area was 2.3 cm with an average insignificant weight fluctuation (increase of 0.19 kg). The average circumference reduction in the thighs was 2.2 cm with insignificant weight fluctuation (increase of 0.54 kg).

Royo *et al.*[14] used the same multisource RF system for the treatment of 33 patients (three men and 30 women) with cellulite, skin laxity, or both. Mean age was 44.2 ± 13.6 years. The distribution of the anatomical areas treated was as follows: abdomen, 10 areas (30.3%); buttocks and hips, eight areas (24.24%); and internal aspect of the arms and thighs, 15 areas (45.45%). All the patients received six sessions: the first four every 2 weeks and the last 2 every 3 weeks. In addition, all patients received one maintenance session at 3, 6, and 9 months after the initial sessions (Fig. 5).

Mean reduction of treatment area circumference after the first six sessions was –2.9 cm, which stabilized after 9 months at –1.9 cm. There were no significant differences in the variation of the contour of the control area (–0.5 ± 0.6 cm after six sessions and –0.5 ± 0.5 cm at the 9-month visit). Adipose tissue thickness, as measured by ultrasound from the skin surface, decreased by a mean of –0.6 cm after the initial six sessions and –0.6 cm at 9 months.

Figure 4 Before treatment (Lt.) and 3 months after 12 multisource RF treatments (Rt.) showing significant skin tightening and body contouring. Photographs courtesy of Dr. Isabelle Rousseaux, Board Certified Dermatologist, Loos, France.

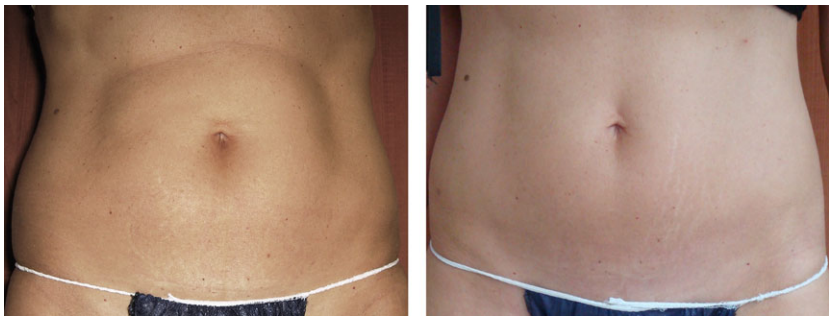

Figure 5 Before treatment (Lt.) and 3 months after 6 Multisource RF treatments (Rt.) showing significant skin tightening and body contouring. Photographs courtesy of Dr. Yoram Harth, Board Certified Dermatologist, FAAD, Herzlya, Israel.

Both the attending physician and an external observer found the degree of clinical improvement in cellulite to be 1.2 degrees after six sessions, and this essentially remained stable during the maintenance sessions (1.2 degrees at 9 months). The external observer's evaluation was similar (1.1 after six sessions and 1.1 at the 9-month visit). The clinician and external reviewer evaluation of laxity after six sessions was 3.5 and 3.2 degrees (improved-much improved); at 9 months this was 3.2 and 2.9. The degree of patient satisfaction was initially 3.4 ± 0.8 degrees of 5, and 3.1 ± 0.9 at 9 months. The mean degree of pain reported by the patients was low, 1.1 on a scale of 1–10. Erythema of varying durations (0.1–3 h) and a local increase in temperature were observed, with no side effects (Figs 6 and 7).

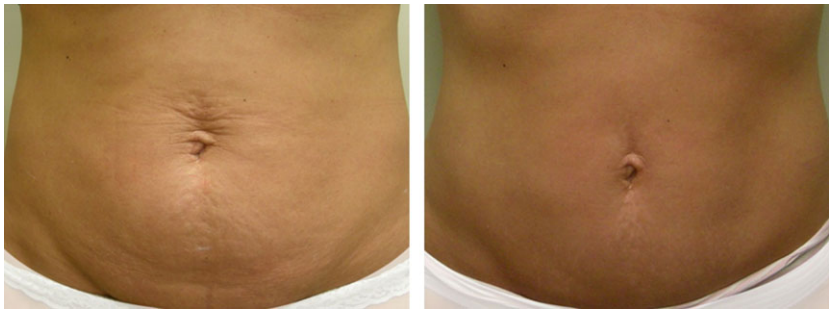

Figure 6 Before treatment (Lt.) and 3 months after six multisource RF treatments (Rt.) showing significant skin tightening and body contouring. Photographs courtesy of Dr. Sharon Kshettry, Edina, Minnesota, United States.

Figure 7 Before treatment (Lt.) and 3 months after eight multisource RF treatments (Rt.) showing significant reduction in the appearance of cellulite. Photographs courtesy of Dr. Fiona Wright, Plano, Texas, United States.

Conclusions

The novel phase-controlled multisource RF system described in this review was shown to be effective for skin tightening, improvement of skin laxity, cellulite, and circumference reduction in the face and neck, abdomen, arms and thighs area.[19–21] All patients monitored for circumference changes have shown reduction in the circumference of the treated area, which was unrelated to weight changes. The FDA cleared, multisource RF (3DEEP®) technology implemented in the Endymed PRO system has proven to be efficient while providing pain free, totally safe treatment for the specified indications. This system provides a platform allowing the full spectrum of available RF technologies including in addition to the nonablative skin tightening hand pieces, a fractional skin resurfacing hand pieces, and the novel microneedles RF treatment hand piece. The unique safety features implemented in the design of the system assure both exact energy delivery customized in real time to individual patient's skin impedance assuring high predictability of the results, with significant efficacy and safety.

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