

Minimally Invasive Radiofrequency

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Abstract

Minimally invasive radiofrequency is most commonly applied in a fractional manner (fractional radiofrequency, or FRF). The approach relies on introduction of a set of fine needle electrodes into the skin, which are then activated to deliver energy. Its role is similar to that of fractional lasers, namely to induce neocollagenesis by thermal effects within the dermis. The fractional thermal injury of deep dermal collagen induces a vigorous wound healing process with dermal remodeling and the generation of new collagen, elastin and hyaluronic acid. The major benefit of minimally invasive FRF is that, depending on the needle configuration and insulation, energy can be deposited directly within the dermis with no thermal effects to the epidermis. Side effects are minimal and typically include transient erythema lasting approximately 2 days. It is a viable nonsurgical therapeutic option for the improvement of numerous cosmetic indications including skin rejuvenation, facial skin laxity, rhytides, acne scars, large pores, and photoaged skin.

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Laser light and radiofrequency (RF) energy sources have succeeded in effectively treating the typical signs of skin aging. Nonsurgical devices have become very popular in the treatment of rhytides and skin laxity as patients prefer to achieve aesthetic improvement of these cosmetic indications with minimal side effects and downtime.

A novel ‘minimally invasive RF’ approach employing a bipolar microneedle electrode system was recently introduced and its thermal effects on human skin *in vivo* were characterized in some studies.

To improve the efficacy and predictability of nonsurgical treatments, a minimally invasive bipolar RF system was developed with real-time tissue temperature feedback that delivers fractional RF (FRF) thermal pulses to the reticular dermis. This system safely creates thermal injury zones in a fractional manner within the reticular dermis without damage to the dermal-epidermal junction, epidermis or subcutaneous tissue.

Adnexal structures such as hair follicles, and sweat and sebaceous glands are spared during FRF treatment. Histological evidence of neocollagenesis and neoelastogenesis following treatment suggests the replacement of dermal volume.

The currently marketed devices can be categorized into various platforms. These will be described below.

ePrime Platform

The e-Prime system was the first to be reported. It is based on the work of Hantash et al. [1]. The system uses a handpiece with detachable cartridges equipped with multiple pairs of needles. The 32-gauge needles penetrate the skin at a 25° angle. The procedure, which is performed under local anesthesia, utilizes RF to produce thermal heating to stimulate neocollagenesis and neoelastogenesis. Hantash et al. [1] first reported a 35-watt bipolar RF device then called (Renesis, Primaeva Medical Inc., Fremont, Calif., USA), configured with 5 microneedle pairs of 30-gauge electrodes. The device is currently marketed as ePrime or Evolastin.

In this first human pilot study, 15 adult patients undergoing elective surgical facelift or abdominoplasty were evaluated. All patients were treated with local anesthesia except for one patient who underwent general anesthesia just prior to treatment. Tissue impedance, power and temperature were measured. Histological examination revealed neocollagenesis, elastin replacement, and heat shock protein response. Results showed that a minimally invasive bipolar microneedle RF device can create thermal zones within the reticular dermis, and that lesion size can be controlled by treatment pulse and lesion temperature.

Alexiades-Armenakas et al. [4] recently performed a study using a minimally invasive bipolar FRF system (ePrime™, Syneron Medical Ltd., Yokneam, Israel). This prospective, open-label, multicenter clinical trial enrolled 100 patients with mild to severe facial and neck rhytides who received a single treatment with the device. Treatment parameters were target temperature, treatment duration and number of insertions. Results showed that 96% of patients demonstrated improvement of rhytides at the 3-month follow-up (after a single treatment), which improved to 100% at the 6-month follow-up. The data indicate that a substantial improvement can be achieved by 3 months after treatment, with continued improvement to at least 6 months.

In another clinical study conducted by Alexiades-Armenakas et al. [5], 15 patients with facial skin laxity received FRF treatments with Miratone™ system (Primaeva Medical Inc., Pleasanton, Calif., USA), a minimally invasive bipolar FRF device. Baseline and follow-up digital photographs of the 15 patients were randomly mixed with 6 sets of baseline and follow-up images of patients who underwent surgical facelift with equivalent baseline facial laxity grades, and all images were compared and graded by 5 independent blinded evaluators. The side effects of patients who underwent



Fig. 1. Evolastin (ePrime) cartridge.



Fig. 2. Fractora tip.

FRF treatment included transient erythema, mild edema and mild to moderate purpura that resolved within 5–10 days. Results showed that the patients who underwent a surgical facelift had a 49% improvement in skin laxity over baseline, compared with 16% of patients treated with FRF. Minimally invasive FRF had an effect in skin laxity without adverse effects and complications of surgical procedure, suggesting that the minimally invasive FRF treatment could provide an important nonsurgical treatment option for the treatment of facial skin laxity [5].

The use of minimally invasive microneedle electrode pairs and bipolar energy has several advantages. It is a very direct method to control the precise location within the skin where energy is delivered, and allows tissue characteristics to be measured. When the microelectrodes were intentionally deployed subcutaneously into the adipose tissue, the impedance was significantly higher than the reticular dermis. When elec-

trodes were deployed in the papillary dermis, impedance was lower than the reticular dermis. A direct benefit of the minimally invasive approach is the ability to obtain real-time feedback of treatment effects through the use of temperature sensors at the distal end of the microelectrode.

As this treatment is a minimally invasive procedure, local anesthesia proved sufficient to achieve patient comfort. Manufacturers of noninvasive monopolar or bipolar RF devices recommend against infiltration with local anesthetics as they may alter energy deposition and heating patterns. The use of local anesthetics provides an advantage in pain management [1].

Fractora Platform

The Fractora (Invasix, Yokeam, Israel) FRF resurfacing system utilizes a reusable handpiece, into which a Fractora disposable tip is inserted. Each tip consists of a variable density and variable-length sharp array of needles, all of which are positively charged needle electrodes. On the sides of each Fractora tip are flat, negatively charged electrodes which receive the RF energy from the positively charged needle electrodes. RF energy is generated in the console (Inmode or Bodytite, Invasix, Yokeam, Israel), that then travels down the electrical cord into the reusable Fractora handpiece. The RF energy from the needle-electrode creates an ablative crater, surrounded by a circular ring of nonablative, but irreversible, coagulative thermal injury and finally a wide, broad, deep zone of nonablative RF thermal stimulation as the current flows from the tip of the positively charged pin to the negatively charged side electrodes.

There are a variety of Fractora which can be categorized by tip density, with a high-density or low-density epidermal impact, or by depth of the needle and hence ablative injury and RF penetration, from 600 to 3,000 μm . Based on numerous abdominoplasty histologies, the ablative depth and clinical wound healing profiles have been well documented, and the clinical protocols are based upon these biological/histological studies, and then multicenter empirical skin trials [6].

(a) Nonablative tip. High-density, shallow dermal depth impact tip: for almost a purely nonablative effect and very little epidermal impact. This tip has a 60-pin array, and the ablative craters are 150–300 μm in depth.

(b) 60-pin, 600- μm -depth tip. Moderate epidermal impact, with a density array with 5–8% epidermal coverage (without overlap). Mid-dermal vertical impact tip: 60 pins for moderate density and a 600- μm -depth impact (mid-papillary dermal effect).

(c) 126-pin, 600- μm -depth tip. Higher epidermal impact with 10–16% coverage (without overlap) and a mid-dermal depth impact of 600 μm .

(d) 24-pin, uncoated 3,000- μm -depth tip. Lower density, lower epidermal impact (less than 4% coverage without overlap), but transdermal 3,000- μm -length needles for a very deep dermal impact.

(e) 24-pin, silicon-coated, 3,000- μ m-depth tip. This tip, also called the BiFrax tip (for Bifractional, horizontal and vertical fractional injury) is designed for selective deep thermal ablation, but with no epidermal-thermal impact (because of the proximal silicone coating) and thus has worked well for treating lighter skin patients who want a 'lift' effect or tightening, with minimal superficial effects.

The Fractora can be deployed in the same fashion as fractional CO₂, or fractional erbium laser resurfacing in skin types I, II and III. The treatment technique is similar with all tips; specifically, one can deliver a pulse every second to 2.5 pulses per second. Overlap is approximately 30–50%, with care taken not to overlap one negative electrode on top of another, or there will be too much superficial positive current flowing up to the negative electrode in that area, and there will be a strip of epidermal lysis. With 30–50% overlap, the aesthetic physician or technician moves across the entire treatment area.

With RF energy fluences between 10 and 25 mJ per pin, the clinical ablative effect is much like that seen with infrared fractional microthermal zone injuries. These lower-fluence Fractora treatments can be performed with simple topical anesthesia without nerve blockade or diffuse hypodermal infiltration. A Zimmer cyro air chiller device is highly recommended for all ablative treatments, laser or RF.

At all energy levels with the Fractora, when treating the face, there is an RF-mediated stimulation of the facial nerve, as RF travels half the distance between the positive pin electrodes and the negative side electrodes, which will stimulate the facial nerve and result in contraction of some of the facial muscles. Although at moderate energies patients do not find this contraction painful, they should be warned as it is an unusual sensation that they will not have experienced with lasers. With higher energies, the facial contractions can be stronger, and using your contralateral hand to flatten the skin and facial muscles will greatly minimize their contractile movement. In general, with high fluence (those over 40 mJ/pin) I will use hypodermal infiltration with double-strength Klein solution, with or without V1, V2 and V3 nerve blocks to ensure a comfortable treatment. With this hypodermal 'wetting' anesthesia, high-energy Fractora patients are comfortable at all energy levels. This hypodermal 'wetting' is very simple to perform, is not as distensive as tumescent lipo-infiltration (and, by the way, I must also perform this type of anesthesia for fractional CO₂ resurfacing, at higher settings).

With Fractora FRF energies between 25 and 40 mJ per pin, the ablative effect is like a mild, low-fluence CO₂ or more aggressive erbium treatment. At these energies, topical anesthesia, a Zimmer air cooler and possibly nerve blocks will be required to make the treatments comfortable. Between 40 and 62 mJ per pin, these high-fluence ablative energies are very similar in pain and discomfort to a strong fractional CO₂ treatment, and topical anesthetic alone is not recommended. A Zimmer cooler and nerve blocks, with or without hypodermal dilute anesthetic 'wetting' infiltration is required. There are various protocols that can be used with the Fractora FRF resurfacing. With mild energies, a treatment can be performed every week to 3 weeks, and a series of 3–6

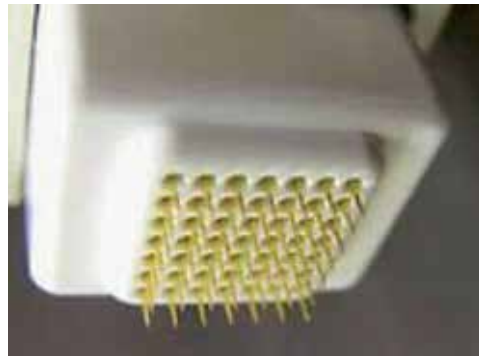


Fig. 3. INTRAcel tip.

treatments is required to achieve results similar to those seen with multiple low-level fractional CO₂, erbium, or infrared fractionals. However, the FRF resurfacing device can also be used in high-fluence, single-treatment protocols. High-fluence, single treatment protocols would deploy the clinical tip most relevant to the pathology presented by the patient.

INTRAcel Platform

Cho et al. [7] recently performed a clinical study using a minimally invasive FRF microneedle device (INTRAcel, Jeisys, Seoul, South Korea) in 30 patients with acne scars and large facial pores. This bipolar RF technology delivers its RF energy through 49-microneedle electrodes in an area of 1 cm², which are deployed into the deep dermis perpendicular to the skin surface, creating multiple partial thermal injury columns in the target area. The entire needle electrode is nonconductive except for the tip (beginning at 0.3 mm from the distal end), thereby protecting from RF heating and thermal tissue damage at the insertion site. The currently available microneedles are 0.5, 0.8, 1.5, or 2.0 mm long, and the RF energy delivery durations differ according to set energy levels. In this study, only a 1.5-mm needle at 500-watt power (maximum power 700 W) was employed. Prior to treatment, all makeup was removed, the face was cleaned with a facial foam cleanser and 70% alcohol, and a topical lidocaine-prilocaine anesthetic cream was applied under occlusion to both cheeks for 30–60 min. A full-face, double-pass treatment was then performed without the simultaneous use of an epidermal cooling device. Results were very positive, with physician evaluation and patient satisfaction showing an overall improvement in acne scars and large pores in more than 70% of all patients. The investigators concluded that clinical improvement appeared to be related to dermal matrix regeneration, and that the FRF microneedle treatment may be effective in improving acne scars and facial pores [7].



Fig. 4. Scarlet RF tip.

Scarlet Platform

The Scarlet™ (Viol Co., South Korea) adopted noninsulated microneedle electrodes. This device utilizes disposable single-use treatment tips consisting of 5 noninsulated microneedle electrode pairs per 10 mm² area, with the exposed electrode extending from 0.5 to 3 mm below the surface of the skin. Having an outer diameter of 0.3 mm each, these bipolar electrode pins form a closed circuit through the irradiated skin, delivering 2 MHz of conducted RF current to the skin. It appears the needles were designed to be noninsulated to reduce bleeding and to broaden the electric treatment field in the dermis. Seo et al. [3] found the microneedle FRF device to be a safe and effective treatment for skin rejuvenation in Asian patients. The microneedle RF treatment combined with a stem cell-conditioned medium showed a synergistic effect for skin rejuvenation.

In another study, Seo et al. [8] used a microneedle FRF device (Scarlet, Viol Co.) in 25 female patients, evaluating its safety and efficacy for the treatment of skin rejuvenation. In this study, patients received a total of 3 FRF treatments spaced 4 weeks apart. Adverse events were minimal and limited to mild pain and transient erythema during and after the procedures. In general, the incidence of side effects is lower with FRF compared to other modalities such as nonablative fractionated lasers. The authors concluded that microneedle fractional bipolar RF treatment is effective for the treatment of photoaged Asian faces with darker skin types, and has little risk of postinflammatory hyperpigmentation. The main limitations of this study were the small number of patients and lack of long-term follow-up after the final treatment [8].

Conclusion

The results of the above-mentioned studies suggest that ‘minimally invasive FRF treatment’ is a viable nonsurgical therapeutic option. The fractional thermal injury of deep dermal collagen induces a vigorous wound healing process with dermal remodeling and the generation of new collagen, elastin and hyaluronic acid. All studies rec-

ommend the application of local anesthesia prior to treatment. Side effects are minimal and typically include transient erythema lasting approximately 2 days. Following treatment, patients should avoid makeup for 24 h, and minimize sun exposure for approximately 14 days. These studies suggest that minimally invasive FRF treatment may provide an important nonsurgical alternative for the improvement of facial skin laxity, rhytides and acne scars.

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