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Treatment of Skin Laxity Using Multisource, Phase-Controlled Radiofrequency

Yohei Tanaka

Additional information is available at the end of the chapter

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Abstract

Regardless of age, sex and skin type, skin tightening is a common procedure requested by patients seeking cosmetic treatments to improve facial contours and skin laxity. Radiofrequency has been proven to penetrate deeper than optical light sources independent of skin color and to be beneficial for skin tightening. I previously reported on the efficacy of multisource phase-controlled radiofrequency treatment and noninsulated microneedle radiofrequency applicator with fractionated pulse mode. The evaluation process was both subjective and objective; I evaluated objectively using three-dimensional color schematic representation with quantitative volume measurements. These three-dimensional results showed significant improvement after the treatments. The post-treatment volume was drastically reduced as compared to the pretreatment volume. Most of the patients reported satisfaction with the improvement of skin laxity. The advantages of these multisource phase-controlled radiofrequency treatments are their long-lasting high efficacy of tightening effects, and the reduction of discomfort and side effects. These characteristics facilitate repeated treatments as well as provide safe and effective treatment of skin tightening.

Keywords: skin tightening, skin laxity, multisource phase-controlled radiofrequency, noninsulated needles, noninvasive fractional radiofrequency, quantitative volume measurement, three-dimensional imaging, wrinkles

1. Introduction

Demand for a noninvasive, effective, and long-lasting treatment to improve laxity has grown dramatically over the past decades as new esthetic technologies have been introduced. Although invasive procedures such as facelifts can achieve skin tightening quickly, they do not rejuvenate the skin and subcutaneous tissues and are accompanied with prolonged downtime and potential adverse effects. Ablative procedures such as traditional skin resurfacing with CO₂ laser devices

are also effective for skin tightening, however they are associated with extended recovery time, bleeding, oozing, and risk of post-treatment hyper- or hypopigmentation [1, 2]. In addition, laser treatments can be very problematic for treating darker skin types or sensitive Asian skin.

A major cause of wrinkles and laxity is the reduction in the quantity and quality of collagen fibers in the dermis and hypodermis [3]. Therefore, various devices have been introduced to stimulate collagen production. I previously reported that near-infrared can penetrate deep into human tissue, achieve skin tightening and muscle thinning, and nonthermally induce various responses in the skin and subcutaneous tissues [4–11]. In addition, I previously reported that near-infrared or radiofrequency (RF) treatments stimulate collagen and elastin production while safely and effectively promoting long-lasting skin tightening results that decrease wrinkles and laxity [12, 13].

RF treatments for skin tightening are common, as they heat the dermis and subcutaneous tissues, thereby stimulating dermal collagen remodeling. It is well documented that dermal heating induces an immediate change in collagen structure followed by a long-term stimulation of neocollagenesis [14]. These thermal effects can improve wrinkle appearance, skin laxity and contour of both face and body.

RF has been shown to overcome several disadvantages inherited in optical light-based treatments by offering enhanced tissue penetration that is independent of skin color, and beneficial skin tightening effects. The working principle of RF devices is to heat the dermis and subcutaneous tissues [15], and to induce both collagen remodeling and skin tightening. RF techniques have been proven to be safe and effective for both nonablative skin tightening and fractional RF skin resurfacing [16–18].

The thermal effects of different RF technologies such as monopolar and bipolar RF have been proven to be beneficial in skin tightening. Nevertheless, these effects were frequently partial or unpredictable because of the uncontrolled nature of monopolar or unipolar RF and the superficial nature of energy flow for bipolar, tripolar or multipolar configurations. These first-generation RF systems lack adaptation of delivered power to address the differences in individual skin impedances. Therefore, I have been using a multisource phase-controlled system, which allows continuous real-time measurement of skin impedance and delivers constant adjusted energy to the patient skin, independent of changes in its impedance.

In fractional laser or skin resurfacing treatments, thermally ablated or coagulated microscopic zones from the epidermis to the dermis are spaced in a grid over the skin surface with the nonablated zones in the undamaged surrounding tissue serving as a reservoir of cells that accelerate and promote rapid healing [19]. Same principle is implemented with microneedling, as a healthy tissue reservoir assists to reduce downtime.

The first generation of microneedle RF delivery technology used insulated needles to provide skin rejuvenation and treat acne scars. With insulated RF microneedles, the energy flows only through the tip of the needle, resulting in a small, coagulated sphere-like shape in the dermis. However, insulated RF microneedles can have several disadvantages, including: (i) microbleeding during treatment; (ii) the need for several passes at different lengths to affect the entire depth of the dermis [15, 18, 20]; (iii) ineffective for skin laxity.

Therefore, in my studies I have been using a tapered, noninsulated microneedle radio-frequency (NIMNRF) applicator with novel fractionated pulse mode. This device achieves cylindrical micro zones of coagulation in the papillary and reticular dermis with minimal damage to the epidermis. The needles are inserted into the skin by a specially designed smooth motion motor that is electronically controlled to minimize patient discomfort. Furthermore, RF emission delivered throughout the whole dermal portion of the needle allows for effective coagulation, resulting in minimal or no bleeding, together with bulk volumetric heating.

RF technology is now considered to be one of the standard options for esthetic treatments, and as such I would like to provide clinical evidence of skin tightening using multisource phase-controlled RF treatment in this chapter. Many previous studies have reported the efficacy of various types of esthetic devices, but these studies have not included sufficient objective evaluations. Conventional evaluations using before and after treatment photographs have been widely used, but they do not provide accurate objective assessment [12, 13, 21]. For quantitative volume measurements, I have used a 3-dimensional photographic system to objectively evaluate the amount of post-treatment volume change in my clinical research.

2. Radiofrequency (RF)

RF is a part of the electromagnetic spectrum. RF can induce thermal effects in the deep tissue, whereas nonablative intense pulse light only reaches the superficial dermis, which is not clinically sufficient to treat laxity (**Figure 1**).

RF has been traditionally used for tissue heating in the field of surgery, especially as a method of coagulation for hemostasis. Tissue heating for skin tightening is achieved through tissue resistance to RF conductivity current (Joule's law). A major cause of wrinkles, laxity and cellulite is the reduction in the quantity and quality of collagen in the dermis and hypodermis. A loss of normal elastic fiber function is a common age-associated feature of both photoaging and intrinsic aging processes. The accelerated aging and sagging of the skin seen in several

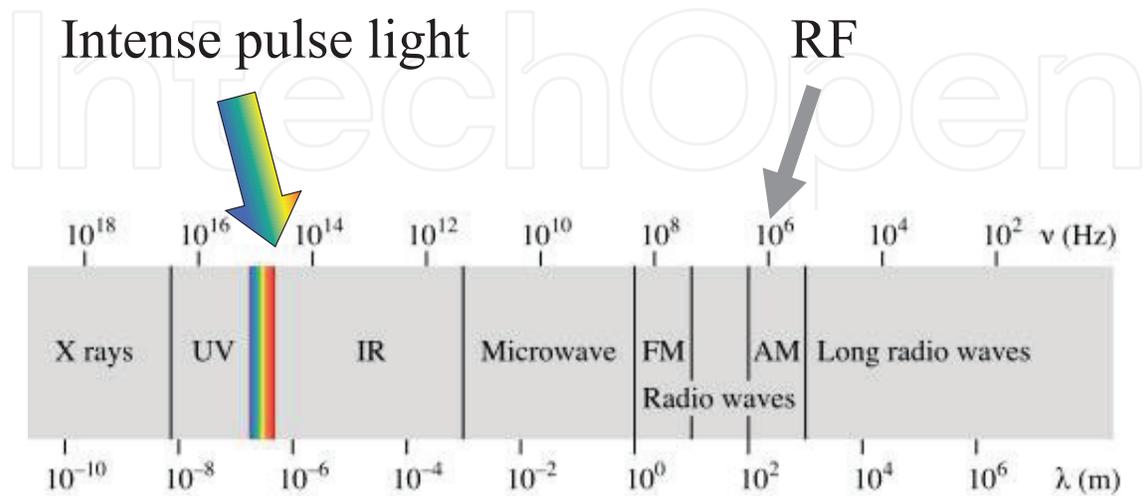


Figure 1. The electromagnetic spectrum covers a wide range of energy radiation types.

hereditary disorders involves collagen or elastin deficiency. RF is considered to be safe and very effective procedure to stimulate production of water-binding proteins, such as collagen and elastin. The effects induced by RF treatment are independent of skin color.

2.1. Monopolar RF

Monopolar RF was the first nonablative RF technology shown to be effective for skin tightening. Although deep penetration could be more effective, the treatment by use of monopolar RF is painful. Due to the uncontrolled RF flow, the treatment is less safe and requires high energy of RF and intense cooling to protect the epidermis (**Figure 2**). Finally, because the device has a disposable tip, cost effectiveness is another important concern.

2.2. Bipolar and multipolar RF

Bipolar and multipolar devices have one RF generator, which connects to two or more electrodes. Because the RF energy delivery is superficial, following the shortest path between the electrodes, the treatment is relatively safe. However, with these devices, RF energy does not penetrate to the required depth and therefore is less efficient for skin tightening (**Figure 3**). Bipolar RF devices require active cooling of electrodes to prevent epidermal burns, whereas multipolar RF devices does not need cooling because the energy is split between two or more

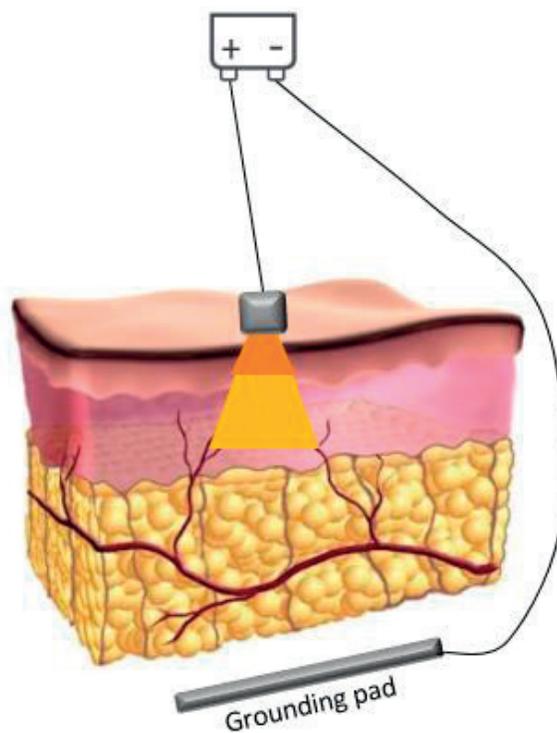


Figure 2. Monopolar RF technologies. One RF generator controls one electrode. Penetration is deeper than bipolar, since there is a flow of energy through the body to the grounding pad. Monopolar RF energy delivery results in high temperature near the electrode, requiring intense epidermal cooling, and uncontrolled energy spreading toward the grounding pad. Monopolar RF may be painful since higher power is required to “push” the RF from the single electrode into the skin.

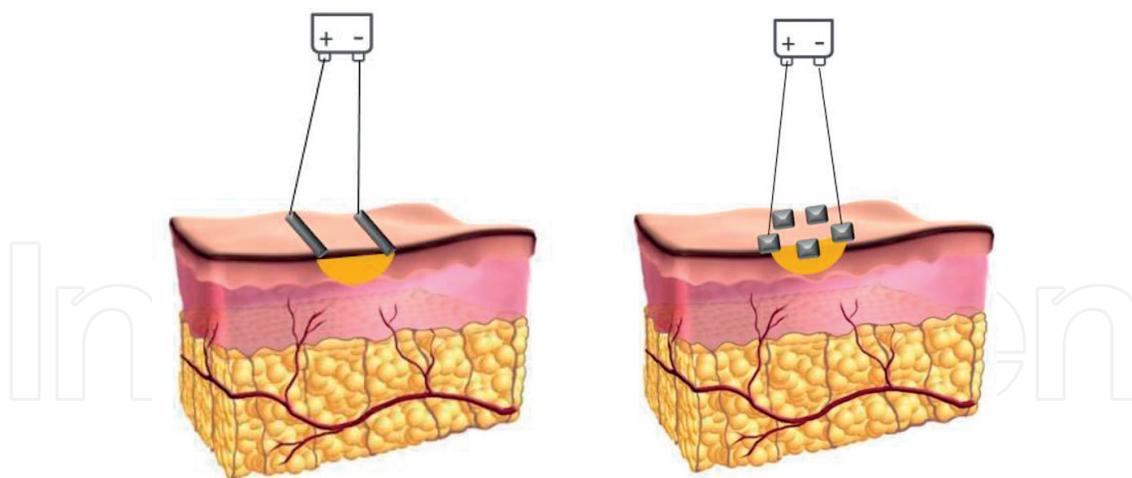


Figure 3. Bipolar RF technologies (left). One RF generator controls two electrodes. There is only superficial penetration since the energy flows along the shortest path, between the two electrodes. It requires active cooling of electrodes to prevent epidermal burns. “Multi-polar” RF Technologies (right). One RF generator controls 3–5 electrodes. There is only superficial penetration since the energy flows along the shortest path, between the 3–5 electrodes (similar to bipolar RF). No cooling is needed because the energy is split between two or more receiving electrodes.

receiving electrodes. Moreover, at any given moment during treatment only a single path is made between two electrodes.

2.3. Multisource phase-controlled RF

The effects induced by monopolar, bipolar, and multipolar RF devices have been frequently partial or unpredictable because of the uncontrolled nature of monopolar or unipolar RF and the superficial nature of energy flow for bipolar, tripolar or multipolar configurations. These first-generation RF systems lack adaptation of delivered power to differences in individual skin impedance.

Due to this lack of efficacy in these traditional RF technologies, I have been using a multisource phase-controlled RF system, which allows continuous real-time measurement of skin impedance and delivers constant energy to the patient skin independent of changes in its impedance. The RF device I have been using is an EndyMed PRO™ 3DEEP treatment platform (EndyMed Medical, Caesarea, Israel), a phase-controlled, multisource RF system that emits at 1 MHz at 1–65 W. This RF device has a unique way to deliver energy to the deep dermis and hypodermis while minimizing epidermal heating. It has six phase-controlled RF generators, allowing a complex 3D interaction between the electromagnetic fields produced in the tissue. The inner electrodes current acts as a potential barrier, which forces the next set of electrode current to penetrate deep below, and so on, creating a 3DEEP energy complex. In addition, due to the repulsion of electrical fields with the same polarity, no current is created between these electrodes on the skin surface, allowing minimal epidermal flow (**Figures 4 and 5**).

I typically perform treatments using approximately 33 W output, which is low enough that the sensation of excessive heat would not be felt. If the patient reports a strong sensation of heat, treatment movement can be performed slightly faster and/or the handpiece head can be

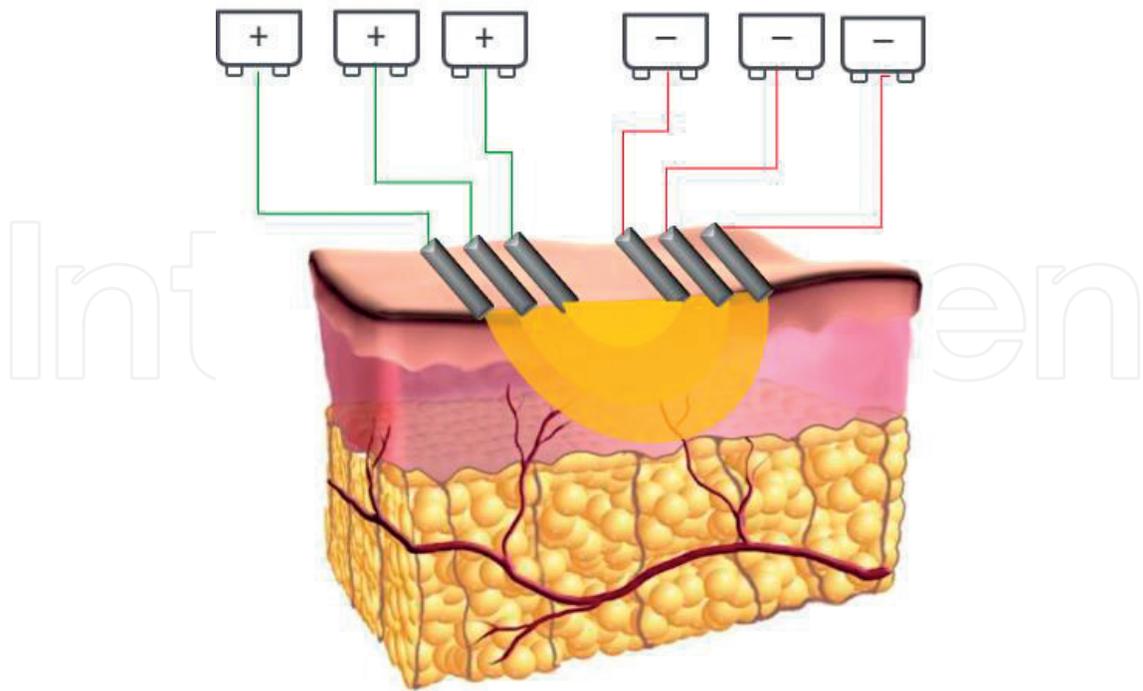


Figure 4. Multisource phase-controlled, RF system. This system can deliver RF energy to deep layers of the skin. Focused & contained deep energy flow. Minimal surface energy flow eliminates the need for intense cooling. Totally safe & painless. Personalized parameters based on multiple unique automatic skin sensing feedback mechanisms.

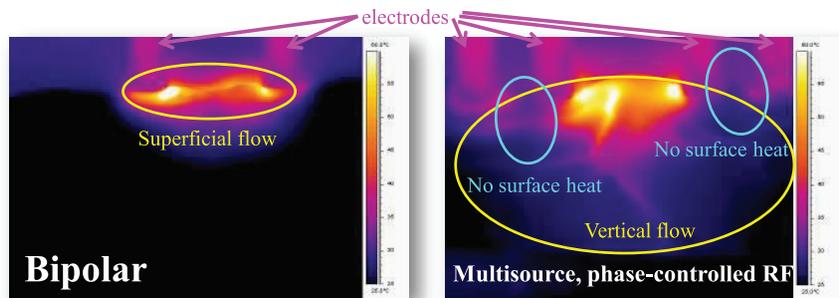


Figure 5. Comparison of bipolar vs. multisource phase-controlled RF system. With bipolar device (300 W, 1 s), superficial flow of energy, penetrates only to 1.5 mm depth. Multisource phase-controlled RF system (4 electrode, 2 × 150 W, 1 s) shows vertical flow of energy, penetrates to 6 mm depth. Absolutely no surface heat between the external electrodes. The surface flow is only between the two middle electrodes.

moved slightly away from the point of heat sensation. No topical anesthetics or oral analgesics are needed before, during, or after the treatment, and skin cooling is not required.

2.4. Noninsulated microneedle RF

I have been using the tapered noninsulated microneedle radiofrequency (NIMNRF) applicator operating with a novel fractionated pulse mode (Intensif Handpiece, EndyMed Medical,

Caesarea, Israel) for tightening and acne scar treatments (**Figures 6 and 7**) [22–25]. The system platform (1MHz) incorporates six independent phase controlled RF generators that allow the RF microneedles to induce skin remodeling through controlled dermal coagulation. The needle penetration depth is up to 3.5 mm in digitally controlled increments of 0.1 mm. The power is adjustable from 0 to 25 W with increments of 1 W. The pulse duration can be changed in 30 ms increments (maximal pulse duration is 200 ms) [15].

Thermography during a laboratory model simulation taken by a thermal camera (FLIR SC640, FLIR, Boston, MA, USA) using a laboratory skin model with an impedance that is similar to that of the human dermis. The penetration depth is 2.5 mm. The temperatures shown in this figure are relatively low because this is a laboratory model simulation wherein low power RF was used to obtain qualitative imaging. In vivo temperatures would be higher than those of a laboratory model simulation, as demonstrated by histology and coagulative effects on capillaries. Patients undergoing Intensif treatment received from 500 to 1000 pulses with the following parameters: pulse duration 80–110 ms, power 10–14 W and 1.5–2.5 mm penetration depth.

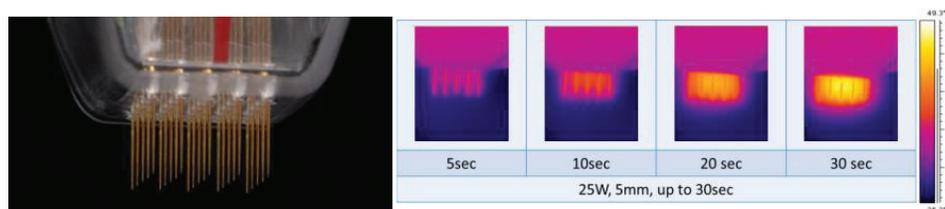


Figure 6. FDA-cleared, very sharply tapered noninsulated gold plated microneedle RF applicator operating with a novel fractionated pulse mode (above). Sterilized treatment tip with 25 microneedles (300 micron diameter at the base that gradually tapers to an especially sharp edge. Microneedles are inserted into the skin by a specially designed smooth motion motor that is electronically controlled to minimize patient discomfort (below).

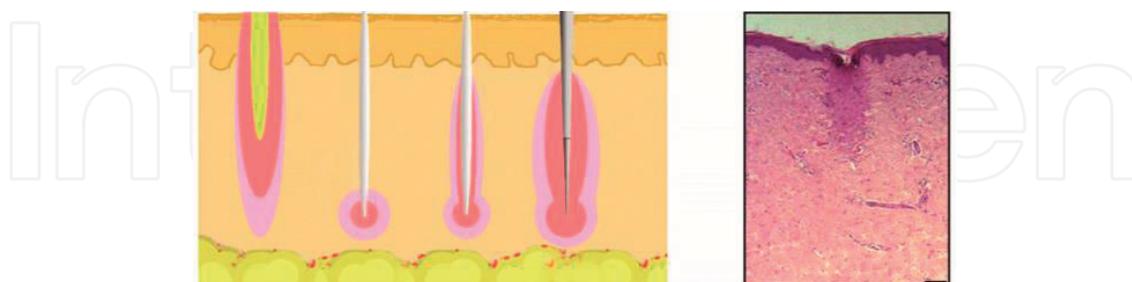


Figure 7. A heat schematic of fractional lasers and microneedles. Images from left to right show fractional lasers, insulated needles, noninsulated needles, and very sharply tapered noninsulated gold plated microneedles. (left). RF emission delivered over the whole dermal portion of the needle allows effective coagulation resulting in minimal or no bleeding, together with bulk volumetric heating. Histology of in vivo pig skin (right). This biopsy was taken immediately after treatment. The protocol was approved by the institutional ethics committee. H & E staining show dermal coagulation that matches the needle penetration depth. The parameters are 15 W, 140 ms, 2.5 mm. Scale bar = 500 μ m. Cited from **Figure 7** (Ref. [22]).

3. Clinical results after RF treatments

3.1. Clinical study results after multisource phase-controlled RF treatments: “Objective Assessment of Skin Tightening Using Multisource, Phase-Controlled Radiofrequency in Asians”

Twenty Japanese patients (18 females and 2 males) aged 26–69 years (mean age, 42.4 ± 9.92 years) with Fitzpatrick skin type III to V were enrolled.

None of the subjects had a history of any type of skin disease or any cosmetic procedures affecting the treatment areas within the last 3 years. No topical pretreatment was used, and the post-treatment skin care regimen consisted of a gentle cleanser and sunblock. All patients gave written informed consent for participation in the study after reading the experimental protocol and being advised about the risks of treatments.

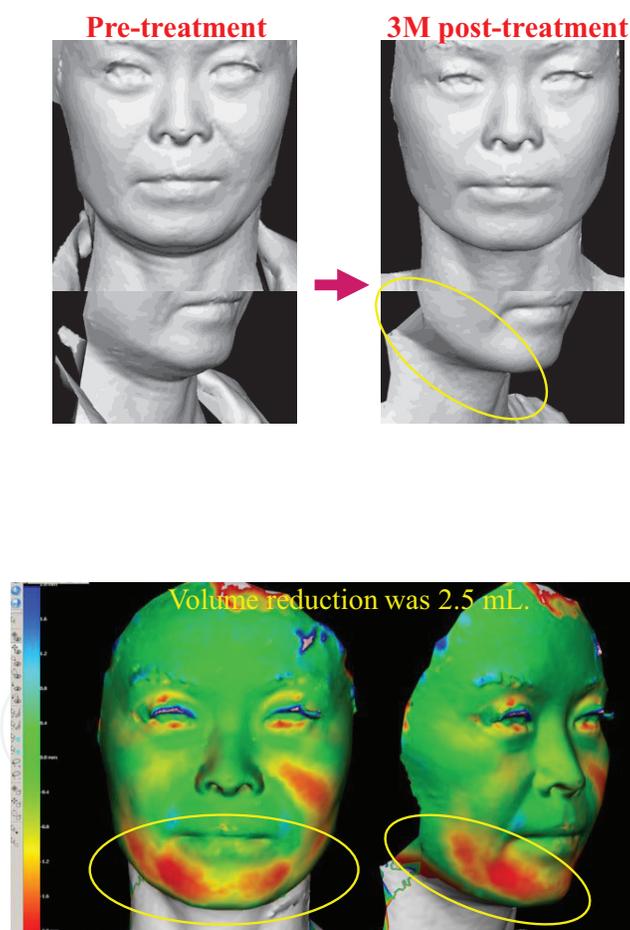


Figure 8. Representative photographs of tightening effects treated with multisource phase-controlled RF treatments. Pretreatment (above, left), a 44-year-old Japanese woman exhibited skin laxity in cheek, mental portion, and neck, and wrinkles such as nasolabial fold. Cheek and neck were treated. Three treatments at 33 W. Three months post-treatment (above, right), significant improvements were noted in both skin laxity and wrinkles. Three-dimensional color schematic representation shows the varying degrees of tightening achieved in colors yellow to red (below). Green areas remain unchanged. These images indicate significant improvement of appearance, skin laxity, and wrinkles after multisource phase-controlled RF treatments.

3.1.1. Evaluation by gray scale images and 3-dimensional imaging with quantitative volume measurements

Objective assessments, evaluated by gray scale images and 3-dimensional color schematic representation with quantitative volume measurements, showed significant improvement after the multisource phase-controlled RF treatment (Figures 8-10).

3.1.2. Histological assessments

Human skin specimens from the face (3–5 from each patient) were obtained for microscopic investigation. Biopsies were taken pretreatment as a control and at 2 month after the final treatment. The specimens were fixed in 20% neutral buffered formalin, processed for paraffin embedding and serially sectioned along the sagittal plane (3–4 μm thickness). Tissue sections were stained by Victoria Blue staining (Figure 11). Elastin densities stained by Victoria Blue

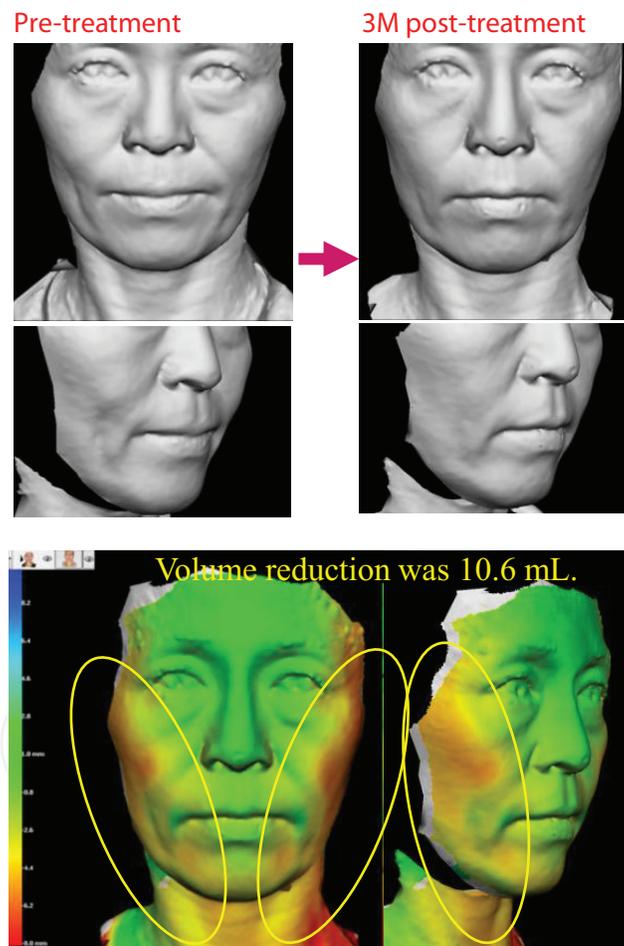


Figure 9. Representative photographs of tightening effects treated with multisource phase-controlled RF treatment. Pretreatment (above, left), a 50-year-old Japanese woman exhibited skin laxity in cheek, mental portion, and neck, and wrinkles such as nasolabial fold. Cheek and neck were treated. Three treatments at 33 W. Three months post-treatment (above, right), significant improvements were noted in both skin laxity and wrinkles. Three-dimensional color schematic representation shows the varying degrees of tightening achieved in colors yellow to red (below). Green areas remain unchanged. These images indicate significant improvement of appearance, skin laxity, and wrinkles after multisource phase-controlled RF treatments.



Figure 10. Representative photographs of tightening effects treated with multisource phase-controlled RF treatment. Pretreatment (left), a 43-year-old Japanese woman exhibited skin laxity in cheek, mental portion, and neck, and wrinkles such as nasolabial fold. Cheek and neck were treated. Three treatments at 33 W only to patient's left cheek. Three months post-treatment (right), significant improvements were noted in both skin laxity and wrinkles. Three-dimensional color schematic representation shows the varying degrees of tightening achieved in colors yellow to red (below). These images indicate significant improvement of appearance, skin laxity, and wrinkles after multisource phase-controlled RF treatments.

staining in the dermis were calculated after an optimized color threshold was applied to each image to distinguish between the stained areas and background. Images were scanned and quantified in five representative fields per section, and subsequently averaged to obtain a final score (**Figure 12**). The sections were photographed under an Olympus BX50 microscope (Olympus, Tokyo, Japan). The digital photographs were processed using Adobe Photoshop (Adobe, San Jose, CA, USA).

Cited from **Figure 4**. (Ref. [13]).

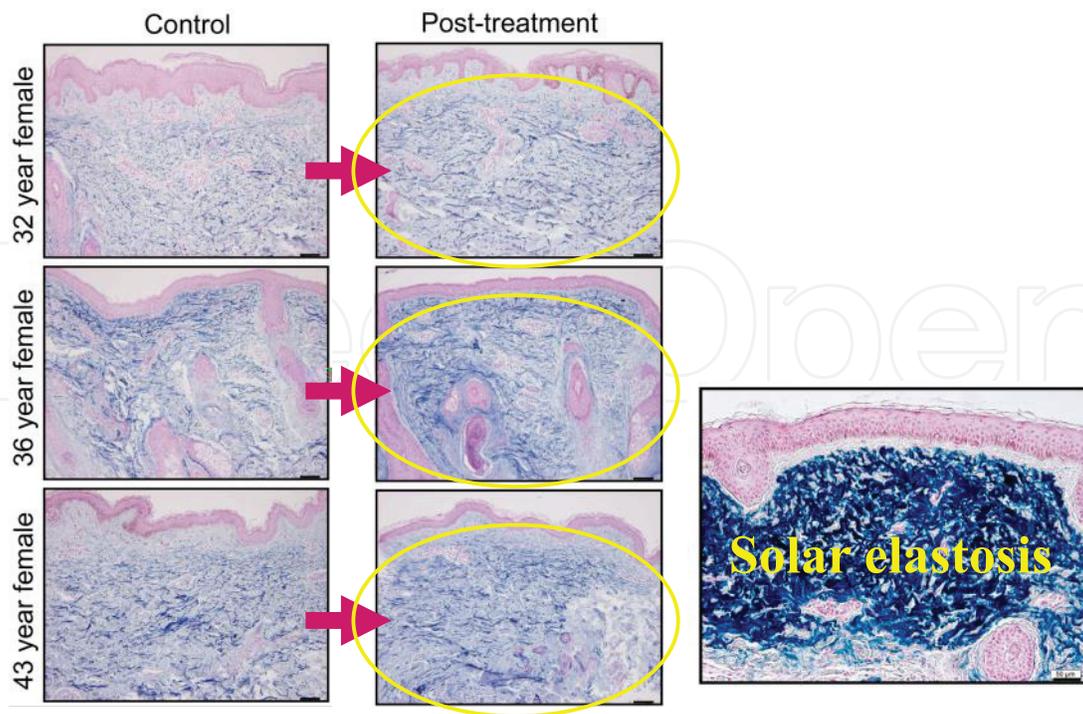


Figure 11. A representative histology of Japanese patients' cheek skin evaluated by Victoria blue staining. The amount of elastin stained in blue significantly increased post-treatment compared with control. Scale bars = 100 μm . Histological studies showed that the amount of elastin was significantly increased after the multisource phase-controlled RF treatment compared with controls in all five Japanese patients. Induced elastin appeared to be relatively fine and delicate, compared with irregular elastic fibers, such as solar elastosis.

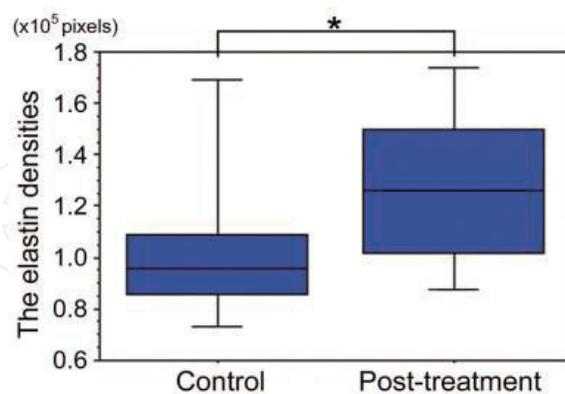


Figure 12. Mean densities of elastin in the dermis. Skin biopsies were taken from five Japanese female patients who had visited the Clinica Tanaka Anti-Aging Center to remove some pigmented nevi (more than one pigmented nevus on both control and treated side of the cheek) and achieve skin rejuvenation on their faces. The densities of elastin were significantly increased compared with controls ($p = 0.0013$). Data represents the means \pm SD. Significant differences compared with control are indicated ($*p < .05$).

3.2. Clinical study results after RF microneedle treatments: “Long-term Nasal and Perioral Tightening by a Single Fractional Noninsulated Microneedle Radiofrequency Treatment”

Fifteen Asian patients (14 females and 1 male) aged 31–66 years (mean age, 43.4 ± 9.0 years) with Fitzpatrick skin type III-V were enrolled. All of the patients had visited the Clinica Tanaka Anti-Aging Center to achieve full facial skin tightening. None of the patients had a history of any type of skin disease or cosmetic procedure that affected the treatment areas. Topical anesthetic cream was applied to the patient’s skin for 60 min before the treatment. The post-treatment skin care regimen consisted of a gentle cleanser and sunblock. Patients did not use any specific skin care products and had no specific diet. Patients who exhibited weight loss during the study period were excluded from volumetric measurement analyses because changes in diet and/or exercise may affect volumetric changes. After reading the experimental protocol and being advised of the treatment risks, all patients gave written informed consent for participation.

3.2.1. Evaluation by gray scale images and 3-dimensional imaging with quantitative volume measurements

Objective assessments evaluated with a superimposed 3-D color schematic representation showed long-lasting and significant volumetric reduction after the treatment. Representative 2-D color, and superimposed 3-D color images and volumetric reductions are shown in **Figures 13-16**.

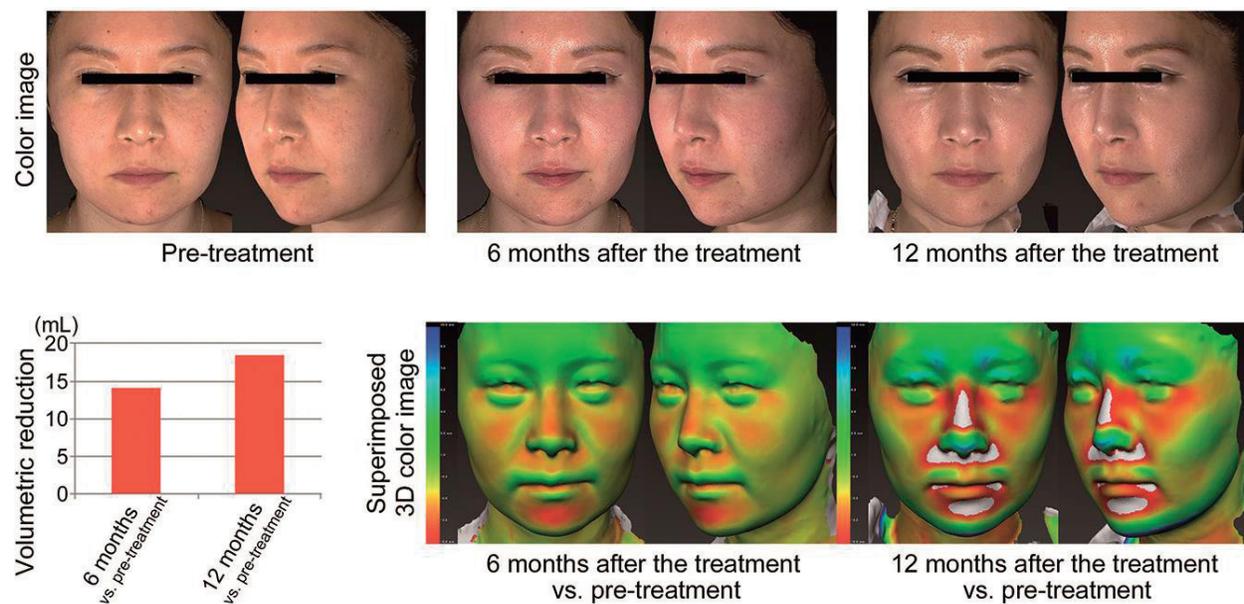


Figure 13. A 31-year-old female. Cheek mode: Pulse width; 110 ms, 14 W, 2.5 mm, 200 shots + Periorbital mode: 80 m, 10 W, 1.5 mm, 100 shots. Images from left to right show the appearance pretreatment to 12 months after the treatment. Improvement of skin texture and dilated skin pores was observed after treatment with time (above). Volumetric reduction (ml) at 6 and 12 months follow up point relative to the pretreatment volume (below, left). Superimposed 3-D color images that show the volumetric change distribution 6 and 12 months after the treatment compared to pretreatment (below, right). The varying degrees of tightening are artificially colored and range from yellow to red (red, -5 mm change). Green areas indicated no changes to the face, and gray areas indicate changes over -5 mm. Significant volumetric reduction in the nasal and perioral areas was observed. Cited from **Figure 1** (Ref. [25]).

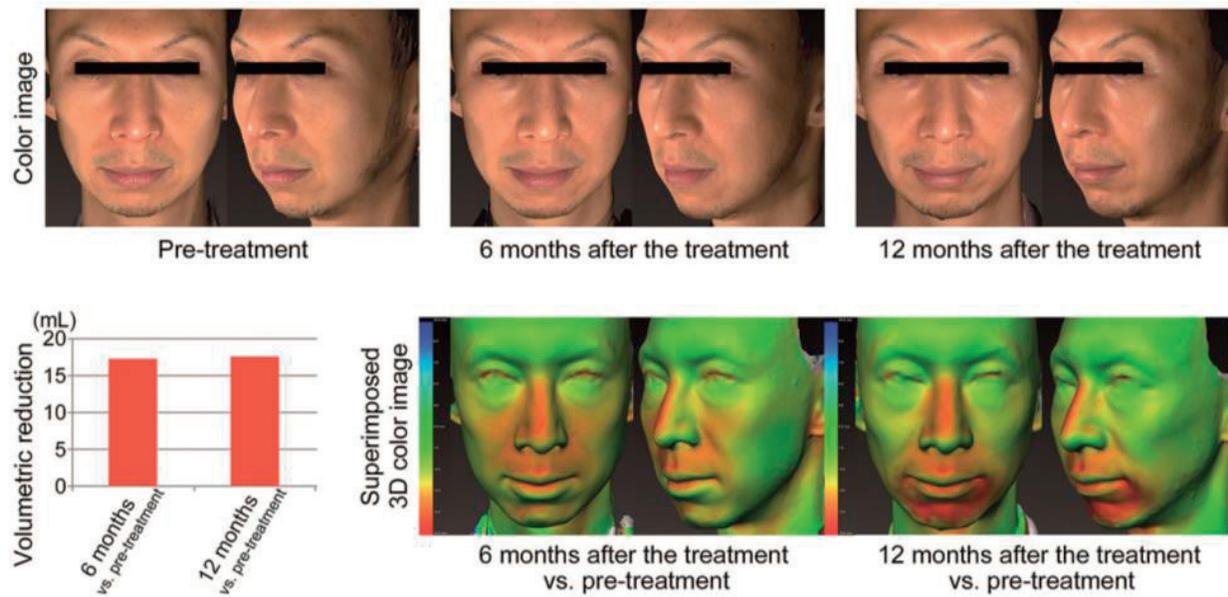


Figure 14. A 40-year-old male. Cheek mode: Pulse width; 110 ms, 14 W, 2.5 mm, 300 shots + Periorbital mode: 80 ms, 10 W, 1.5 mm, 200 shots. Images from left to right show the appearance pretreatment to 12 months after the treatment. Improvement of skin texture and dilated skin pores was observed after treatment with time (above). Volumetric reduction (ml) at 6 and 12 months follow up point relative to the pretreatment volume (below, left). Superimposed 3-D color images that show the volumetric change distribution 6 and 12 months after the treatment compared to pretreatment (below, right). The varying degrees of tightening are artificially colored and range from yellow to red (red, -5 mm change). Green areas indicated no changes to the face, and gray areas indicate changes over -5 mm. Significant volumetric reduction in the nasal and perioral areas was observed. Cited from **Figure 2** (Ref. [25]).

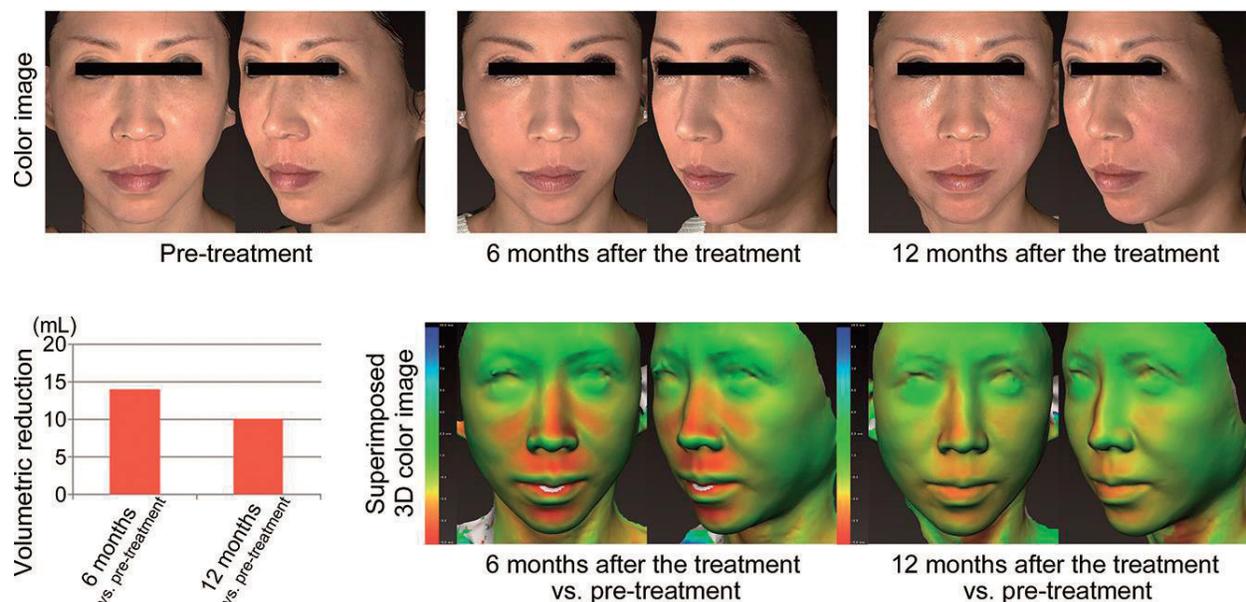


Figure 15. A 47-year-old male. Cheek mode: Pulse width; 110 ms, 14 W, 2.5 mm, 300 shots + Periorbital mode: 80 ms, 10 W, 1.5 mm, 200 shots. Images from left to right show the appearance pretreatment to 12 months after the treatment. Improvement of skin texture and dilated skin pores was observed after treatment with time (above). Volumetric reduction (ml) at 6 and 12 months follow up point relative to the pretreatment volume (below, left). Superimposed 3-D color images that show the volumetric change distribution 6 and 12 months after the treatment compared to pretreatment (below, right). The varying degrees of tightening are artificially colored and range from yellow to red (red, -5 mm change). Green areas indicated no changes to the face, and gray areas indicate changes over -5 mm. Significant volumetric reduction in the nasal and perioral areas was observed. Cited from **Figure 3** (Ref. [25]).

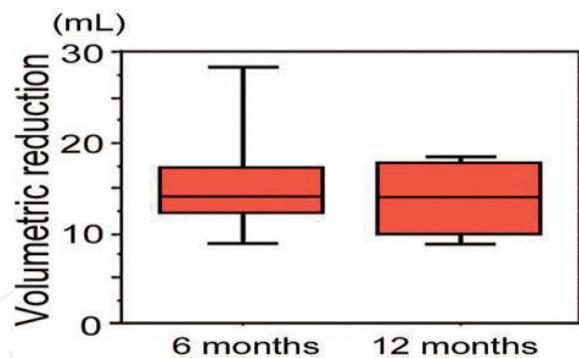


Figure 16. Median volumetric reductions at 6 and 12 months post-treatment were 14.1 and 13.8 ml, respectively. Significant volumetric reductions were observed at 6 and 12 months post-treatment compared with pretreatment ($p = 0.0033$). In contrast, statistical significance was not observed between 6 and 12 months post-treatment ($p = 0.3281$). Post-treatment volumes were significantly reduced compared with pretreatment volumes in all patients. The tightening effects appeared to be stable from 6 to 12 months post-treatment. Cited from **Figure 5** (Ref. [25]).

4. Discussion

4.1. Multisource phase-controlled RF treatments

Objective assessments of skin laxity showed significant improvements, and most patients were satisfied with the results after multisource phase-controlled radiofrequency RF treatments. The advantages of the multisource RF treatments are the reduction in discomfort and side effects. The results indicate that multisource phase-controlled radiofrequency RF treatments provide safe and effective long-term stimulation of elastin, which is beneficial for skin rejuvenation by improving skin laxity and wrinkles.

A multisource phase-controlled radiofrequency RF treatments system was used in this study, which allows continuous real-time measurement of skin impedance and the delivery of constant energy to the patient skin, independent of changes in its impedance. By using this multisource phase-controlled radiofrequency RF system, less thermal damage of the dermis and subcutaneous tissues occurred compared to monopolar or unipolar RF treatments. Multisource phase-controlled radiofrequency RF technology is based on the fact that due to the use of six RF generators, the energy flow on the skin surface is minimal, since all the energy is directed to the depth of the tissue. This is achieved by repulsion between electrical field of the same polarity on each side of the handpiece electrodes [14]. Since multisource phase-controlled radiofrequency RF handpiece delivers energy in constant circulatory motion, the effect will be an average lower temperature on the epidermis ($<42^{\circ}\text{C}$) and higher temperature in the lower skin layers, without the need for cooling. This technology allows the system to keep epidermal temperature below 42°C while reaching up to 57°C in the depth of the tissue [14].

Furthermore, most of the patients did not report feeling pain during the treatment, even though it was performed without anesthesia and contact cooling. A 33 W output was used, which was low enough so that the sensation of heat was not felt. According to peer-reviewed papers, even higher energies used with EndyMed systems were well tolerated by patients without any adverse events.

Side effects, such as epidermal burns, adipose tissue atrophy, and contraction, were not observed, and the patients felt comfortable during multisource phase-controlled radiofrequency RF treatment.

4.2. RF microneedle treatments

The results obtained by RF microneedle treatments appear to be significant even though patients were only treated once. This significant efficacy can be explained by three specific features of the tested RF microneedle device. First, this procedure produced deeper skin penetration of the microneedles (up to 3.5 mm) relative to fractional lasers that usually have a penetration of no more than 1.6 mm. Electronically controlled penetration allows exact monitoring of the penetration depth, which can be customized for different treatment areas. Second, the gold plated noninsulated needles have a smooth insertion that provides a significant advantage over first generation insulated and stainless steel needles. The clinical efficacy of insulated needles is limited due to the small volume of heat produced by RF emission only at the noninsulated area near the tip and significant micro-bleeding induced by the treatment. In contrast, the noninsulated gold plated needles used here emit RF throughout the whole length, thus allowing heating of three times the volume [26]. After the needle is inserted to its maximal depth, due to the lower impedance in the dermis relative to the epidermis, the RF will flow through the dermis with no epidermal coagulation and thus there is no need for needle insulation.

Third, smooth insertion of the needle by an electronically controlled motor that was used in the system tested here resulted in minimal patient pain and downtime while also minimizing trauma to the epidermis and bleeding. Other technologies that use fixed needles, which are inserted by hand or by a spring mechanism, are frequently more damaging to the epidermis and may increase the incidence of post-treatment hyperpigmentation [26].

Most of the patients in this study reported no severe pain during the treatment, even though it was performed without oral or intravenous anesthesia and contact cooling. This reduction in reported pain seen for the fractional RF microneedle treatment may be related to the sharpness of the needles and the unique motorized needle insertion.

Post-treatment complications include burning sensation and mild erythema, but these were minor and lasted less than 5 hours. Furthermore, PIH, epidermal burns and scar formation were not observed.

Nonthermal epidermis penetration performed with a tapered microneedle inserted by smooth motion is less traumatic to the epidermis and epidermal-dermal junction, and in turn decreases the likelihood of extended post-treatment erythema and PIH as compared to ablative and nonablative lasers or other manual or fixed microneedle RF systems. In addition, RF emission through the length of the needle provides for shorter treatment times and a coagulation effect that eliminate micro-bleeding and improve the patient experience [22–26]. Digital control of the needle penetration depth with automatic motorized insertion improves the patient experience by reducing discomfort and side effects [22–26].

5. Conclusions

Significant improvements in skin laxity were observed through objective and histological assessments after receiving EndyMed 3DEEP RF treatments. The results indicate that these RF treatments provide safe and effective stimulation of elastin, which is beneficial for skin rejuvenation by improving skin laxity and rhytids. The advantages of EndyMed RF treatments are long-lasting high efficacy with minimal downtime or side effects. Furthermore, EndyMed RF treatments are convenient for patients and require almost no downtime. Because of these advantages, it will be easily accepted by even socially active individuals regardless of age or sex.

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