Multisource, Phase-controlled Radiofrequency for Treatment of Skin Laxity

Correlation Between Clinical and *In-vivo* Confocal Microscopy Results and Real-Time Thermal Changes

JOSEFINA ROYO de la TORRE, MD; JAVIER MORENO-MORAGA, MD; ESTEFANIA MUÑOZ; PALOMA CORNEJO NAVARRO, MD
Instituto Médico Laser, Madrid, Spain

ABSTRACT

Objective: The objective of this study was to analyze the correlation between degrees of clinical improvement and microscopic changes detected using confocal microscopy at the temperature gradients reached in patients treated for skin laxity with a phase-controlled, multisource radiofrequency system. **Design and setting:** Patients with skin laxity in the abdominal area were treated in six sessions with radiofrequency (the first 4 sessions were held at 2-week intervals and the 2 remaining sessions at 3-week intervals). Patients attended monitoring at 6, 9, and 12 months. **Participants:** 33 patients (all women). **Measurements:** The authors recorded the following: variations in weight, measurements of the contour of the treated area and control area, evaluation of clinical improvement by the clinician and by the patient, images taken using an infrared camera, temperature (before, immediately after, and 20 minutes after the procedure), and confocal microscopy images (before treatment and at 6, 9, and 12 months). The degree of clinical improvement was contrasted by two external observers (clinicians). The procedure was performed using a new phase-controlled, multipolar radiofrequency system. **Results:** The results reveal a greater degree of clinical improvement in patients with surface temperature increases greater than 11.5ºC at the end of the procedure and remaining greater than 4.5ºC 20 minutes later. These changes induced by radiofrequency were contrasted with the structural improvements observed at the dermal-epidermal junction using confocal microscopy. Changes are more intense and are statistically correlated with patients who show a greater degree of improvement and have higher temperature gradients at the end of the procedure and 20 minutes later. **Conclusion:** Monitoring and the use of parameters to evaluate end-point values in skin quality treatment by multisource, phased-controlled radiofrequency can help optimize aesthetic outcome.
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Skin laxity is an aesthetic problem that occurs between the ages of 35 and 40 years, although it generally starts to become visible from age 40 onward. Problems with skin laxity and quality also start to appear in younger people as a consequence of pregnancy or sudden weight loss. 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] The demand for treatment of skin laxity is growing as the conventions of beauty become increasingly demanding.

Laxity is a skin disorder that occurs with natural or accelerated aging and is structurally linked to diminished collagen production. The number and vitality of fibroblasts decrease, and both the dermis and the fibrous septa undergo partial loss of their natural ability to replace themselves. The morphological changes that appear are a consequence of diminished biosynthesis of collagen and elastin and abnormalities of the extracellular environment with a decrease in the concentration of hyaluronic acid.[3] It occurs early on the inner arms and legs and on the abdominal area. Skin laxity is associated with lack of

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ADDRESS CORRESPONDENCE TO: Josefina Royo, MD, Pº Martínez Campos 33(28010), Madrid, Spain; E-mail: consulta@iml.es

physical exercise, rigorous dieting, and other causes and it often appears in combination with cellulite. Cellulite is an inflammation of the subcutaneous adipose tissue and has several causes. It occurs mainly on the legs, buttocks, hips, breasts, arms, and neck.[4] Depending on the pathogenic mechanism, it is classed as dermopanniculosis deformans, adiposis edematosa, or gynoid lipodystrophy.[5–9] The fibrous structure of the interlobular septa that divide female subcutaneous cell tissue into compartments is arranged perpendicular to the skin surface. This structure enables fat lobules in each septum to move toward the skin surface, which is the only structure that contains them. Some authors consider that cellulite visible to the naked eye is caused by lengthening and weakening of connective tissue fibers accompanied by fat protrusion.[10–11]

Radiofrequency is useful in treating skin laxity. Heat-induced behavior of connective tissue and the degree of contraction achieved depend on factors such as the highest temperature reached (peak temperature), duration of exposure to radiofrequency, and the mechanical stress applied to tissue during the heating process. The thermal properties of tissue can also vary depending on skin quality, age, pH, electrolyte concentration, orientation and concentration of collagen fibers, and levels of tissue hydration. Treatment involves increasing tissue temperature to between 55ºC and 62ºC so that local vasodilatation is triggered and new collagen is formed.[12–16]

The authors have clinical experience with different radiofrequency systems (monopolar and bipolar), either alone or in combination with vacuum and infrared systems that have been analyzed in several published clinical trials.[15–19] Their results have varied, ranging from excellent on occasion to very poor or ineffective. In this study, the authors used a phase-controlled, multisource radiofrequency system (EndyMed PRO™, EndyMed Medical, Caesarea, Israel). This system allows the user to confine the emission of energy to a depth of up to 11mm and makes it possible to apply concentrated heat to the papillary dermis, reticular dermis, and fascia superficialis. The authors also searched for clinical references and performed a histological verification of the efficacy of the treatment in order to improve the results. They analyzed subjective and objective levels of improvement and their relationship with temperature modifications as well as the histological changes observed with confocal laser scanning microscopy (CLSM).

This clinical study was carried out according to the ethical principles of the declaration of Helsinki and the guidelines for Good Clinical Practice. The authors had no affiliation with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the manuscript.

MATERIALS AND METHODS

Subjects. The study population comprised 33 healthy patients (all women) with skin laxity on the abdominal area and a mean (±SD) age of 44.2±13.6 years.

Inclusion criteria. All patients had skin laxity on the abdominal area. They also had to be older than 25 years, give their informed consent, and agree to undergo a complete clinical follow up.

Exclusion criteria. Patients were excluded for the following reasons: presence of a pacemaker, metallic implants in the treatment area, medication regimen that alters the cutaneous response (e.g., retinoic acid), invasive intervention in the treatment area during the previous six months, noninvasive intervention in the treatment area (e.g., depilation or other medical-aesthetic procedures) during the previous six months, weight loss (dieting), suspicious cutaneous lesions, history of keloids or hypertrophic scarring, pregnancy or breastfeeding, epilepsy or severe migraines, infection, pain or abscess in the treatment area, presence of tattoos or body piercing in the treatment area, autoimmune disorders or diabetes, eczema or dermatitis in the treatment area, anticoagulant therapy, or clinician-based exclusion criteria.

Treatment protocol. All of the patients received six sessions; the first four treatments were performed every two weeks and the last two treatments every three weeks. At all sessions, the authors recorded the following data: weight, measurement of the contour of the area to be treated at a preset height measurement, and measurement of the untreated control area. The different levels at which the abdominal circumference is measured can lead to errors in data recording. Therefore, in each case, the authors recorded the height (distance from the floor) at which the abdominal circumference and control area were first measured, to ensure that they were always taken from the same point.

The authors also recorded the evaluation of the degree of skin laxity by the clinician and by an external assessor, thermographic images and temperature of the treated area (before, immediately after, and 20 minutes after treatment), total energy used for each square of skin treated, CLSM images (before the first session), and side effects. A photograph of the area also was taken. Similarly, patients were asked to subjectively evaluate the degree of improvement from the second session onward. Patients were asked to evaluate the degree of pain according to a visual analog scale. All sessions were held and data recorded in a room with a stable temperature of 24ºC.

Patients returned at 6, 9, and 12 months after the sessions to record weight, measure the contour of the area to be treated at a preset height, measure the untreated control area, and evaluate the degree of skin laxity by the clinician and an external assessor. CLSM images and photographs of the treated area were taken. Patients were asked to evaluate the degree of improvement (Tables 1 and 2).

Devices. The radiofrequency device used was an EndyMed PRO™, a phase-controlled, multisource radiofrequency system that emits at 1MHz at 1 to 65 watts. The confocal laser scanner microscope used was the VivaScope 1500 (Lucid Inc., Rochester, New York). The infrared camera used was the Flir i7 (FLIR Systems), and the infrared thermometer used was the CEM DT-880B.

Technique. All abdominal areas were drawn and divided into 100cm^2 rectangles or squares. The average number of squares/rectangles in each area was five. The squares/rectangles were drawn with a 20-percent overlap to avoid untreated areas (cold spots) and to ensure that the whole area was heated. Sufficient sweeps were made to complete the pretherapeutic (preheating) stage in which the surface temperature must reach 40 to 42ºC.[14–19]

Once the pretherapeutic temperature was reached, each session involved 8 X 30-second sweeps, with breaks of two seconds between each sweep. In order to prevent hot spots, the sweeps were made following the same protocol in all the squares/rectangles, at all the sessions, and for all the patients:

First sweep—circular movement from inside to outside the square/rectangle;
Second sweep—circular movement from outside to inside the square/rectangle;
Third sweep—horizontal movement starting the square/rectangle at the top;
Fourth sweep—vertical movement from left to right in each square/rectangle;
Fifth sweep—circular movement from inside to outside the square/rectangle;
Sixth sweep—circular movement from outside to inside square/rectangle;
Seventh sweep—horizontal movement starting the square/rectangle at the bottom;
Eighth sweep—vertical movement from right to left in each square/rectangle.

Contact between the skin and the handpiece was improved by applying a fine layer of tepid ultrasound gel (30ºC). During the first session, preheating emission power was optimized by recording the maximum power tolerated by the patient continuously over the 100cm^2 area for 120 seconds (4 uninterrupted sweeps) starting from a base power of 45W. The value obtained was recorded as a reference for subsequent sessions. Once 40 to 42ºC was reached, the therapeutic phase began.

Attempting to avoid interrupting sweeps was essential as sweeps intervals greater than 5 seconds decreased the surface temperature by 2 to 3ºC. When necessary, power was reduced in steps of 2W and more warm contact gel (30ºC) was added to prevent the grid from cooling. The operation was repeated in the neighboring grids until the area was completely treated.

During all sessions, images were recorded using an infrared camera to ensure that the whole area was evenly heated. In each square, temperature was measured before the start of the pretherapy phase (T0), immediately after the sweeps were completed (TF), and after 20 minutes (T20).

Thermographic images were captured using a Flir i7 infrared camera prepared for capture perpendicular to the skin surface. This thermal imaging camera has a meter that measures the distance between the camera and the surface to be photographed. All the images were captured at a distance of 25cm. The maximum temperature was recorded on the image captured. The images captured were stored on the follow-up form for each patient. The maximum temperature values for each image were included in the statistical analysis.

Results. Mean tolerated power was 40±7W. Mean variation in weight during treatment was –0.7±1.7kg after six sessions and –0.6±1.7 at the 12-month checkup. Mean reduction in the contour of the treatment area after the first six sessions was –2.9±1.6cm, which stabilized after 12 months at –1.9±2.0cm. There were no significant differences in the variation of the contour of the control area (–0.5±0.6cm after 6 sessions and –0.5±0.5cm at the 12-month visit) (Table1).

Both the attending physician and an external observer evaluated the degree of clinical improvement in laxity according to the following scale (0=worse; 1=no clinical change; 2=minor change; 3=visible change; 4=obvious change; 5=significant change). The patient made an objective evaluation using a similar scale—the Global Aesthetic Improvement Scale (0=dissatisfaction, worse; 1=no satisfaction, no clinical change; 2=low satisfaction, minor change; 3=somewhat satisfied, visible change; 4=satisfied, obvious change; 5=highly satisfied, significant change) (Table 1).

The clinician's evaluation of laxity after six sessions was initially 3.5±1.0 degrees (improved–much improved); at 12 months, this was 3.2±0.6. The external observer recorded values that were a few tenths below those of the attending physician (3.2±0.8 after 6 sessions and 2.9±0.8 at 12 months). The degree of efficacy and patient satisfaction was initially 3.4±0.8 degrees out of 5, and 3.1±0.9 at 12 months (Table 1, Figures 1 and 2).

The mean measurements taken using CLSM were as follows:

1. **Minimum epidermal thickness (E^{min}).** This is determined by the tip of the uppermost papillae. E^{min} would be defined as the maximum depth at which only the cellular structure of the epidermis contributes to the signal. Reduction in minimal epidermal thickness was –5.2±8.0µ at six months; –7.1±9.4 at nine months with –6.0±11.9µ at the 12-month visit (–10.72%, –14.63%, and –12.37%, respectively).
2. **Maximum epidermal thickness (E^{max}).** This is defined by the valley of the papillae. The different optical properties of the cellular structure in the epidermis and fibrous structure in the dermis cause a change in the slopes in the reflected intensity profile of images. The onset of this change in a slope at E^{max} corresponds to the depth at which a cellular structure is no longer observed in the image stack upon going from the surface to deeper positions. Increase in maximum epidermal thickness was 4.6±9.5µ at six months, 6.1±11.9µ at nine months with an increase to 7.6±11.1µ at the 12-month checkup (5.54%, 7.34% and 9.16%, respectively).
3. **Dermo-epidermal junction.** Determination of E^{max}-E^{min} makes it possible to calculate the thickness of the dermo-epidermal junction (papillary height). Increase in papilla height of 9.5±8.8µ at six months, 12.9±4µ at

TABLE 1. Variations in weight and contour measurements

RESULTS	FIRST 6 SESSIONS	6 MONTHS CONTROL	9 MONTHS CONTROL	12 MONTHS CONTROL
Visual improvement laxity (clinician)[1]	3.5±1.0	2.9±0.7	3.0±0.5	3.2±0.6
Visual improvement laxity (external evaluator)[1]	3.2±0.8	2.6±1.3	2.7±0.5	2.9±0.8
Efficacy and patient satisfaction[2]	3.4±0.8	3.1±0.9	3±0.7	3.1±0.9
Reduction in minimum epidermal thickness, µ	—	-5.2±8.0 (-10.72%)	-7.1±9.4 (-14.63%)	-6.0±1.9 (-12.37%)
Increase in maximum epidermal thickness, µ	—	4.6±9.5 (+5.54%)	6.1±11.9 (+7.34%)	7.6±11.1 (+9.16%)
Increase in papillary height, µ	—	9.5±8.8 (+28.90%)	12.9±9.4 (+39.20%)	13.3±8.7 (+40.30%)
Increase in depth of refringence change area, µ	—	9.7±5.0 (+7.98%)	8.2±8.9 (+6.74%)	6.3±8.6 (+5.19%)
Final variation: weight (kg)	-0.7±1.7	-0.6±2.0	-0.8±2.0	-0.6±1.7
Final variation: treatment area (cm)	2.9±1.6	2.6±1.2	2.3±1.6	1.9±2
Final variation: control area (cm)	0.5±0.6	0.7±0.6	0.5±0.6	0.5±0.5

[1] 0 = Worse; 1 = No clinical change; 2 = Minor change; 3 = Visible change; 4 = Obvious change; 5 = Significant change
[2] 0 = Dissatisfaction (worse);1 = No satisfaction (no clinical change); 2 = Low satisfaction (minor change); 3 = Somewhat satisfied (visible change); 4 = Satisfied, obvious change; 5 = Highly satisfied (significant change)

nine months, which increased gradually to 13.3±8.7µ at the 12-month visit (28.79%, 39.20% and 40.30%, respectively).

4. Upper dermis. At a certain depth, a reflecting layer of fibrous structure in the upper dermis (UD) is observed in the stacks. The location of this reflecting layer was defined as $UD^{min} + UD^{max}/2$, where UD^{min} is the location of the onset of this layer and UD^{max} the location of its maximum intensity. The refringence band (UD) of the reticular dermal collagen was located deeper: +9.7±5.0µ at six months, +8.2±8.9µ at nine months, and this fell partially to +6.3±8.6µ at the 12-month visit (+7.98%, +6.74%, and +5.19%, respectively) (Table 1 and Figure 3).

The mean degree of pain reported by the patients was low—1.1 on a scale of 1 to 10 (Table 2). There were no side effects. The mean increase in temperature (ºC) of each grid was as follows: first session, 11.7±2 immediately after the procedure and 3.8±1 after 20 minutes; second session, 11.5±2 and 3.5±1; third session, 11.2±1.1 and 3.6±1.5; fourth session, 11.5±1.5 and 3.7±1.9; fifth session, 11.8±1.1 and 3.8±1.5; last session, 11.6±1.5 and 3.7±1.9 (Table 2).

Statistical analysis. Qualitative variables were divided into categories and quantitative variables into intervals. Age was separated in intervals by grouping the same number of patients per group starting with patients under 25 years of age and increasing to 66 years of age. Once the variables were divided, the authors calculated the mean of each category or interval in order to have a representative value for each of them and to compare them with each other by observing how they behaved with the remaining variables. The authors correlated clinician evaluation and external observer variation (improvement in laxity), patient satisfaction (efficacy/patient satisfaction), CLSM values (maximum epidermal thickness, minimum epidermal thickness, papillary height, and change in the refringence area), and temperatures. Temperatures of the session were evaluated as follows: increase in temperature immediately after the session ($\Delta T_1 = T_0 - T_F$) and increase after 20 minutes ($\Delta T_2 = T_0 - T_{20}$). The most significant statistical results were as follows:

Age. Younger age was positively correlated with good results (Pearson P: p=0.586, α=0.003).

Increase in final temperature (ΔT_1). The clinical

Figure 1. Before and after pictures (sixth session). Contour measurement change = -5.5cm; weight change = -2.9kg

Figure 2. Before and after pictures (sixth session). Contour measurement change = -2.5cm; weight change = -0.9kg

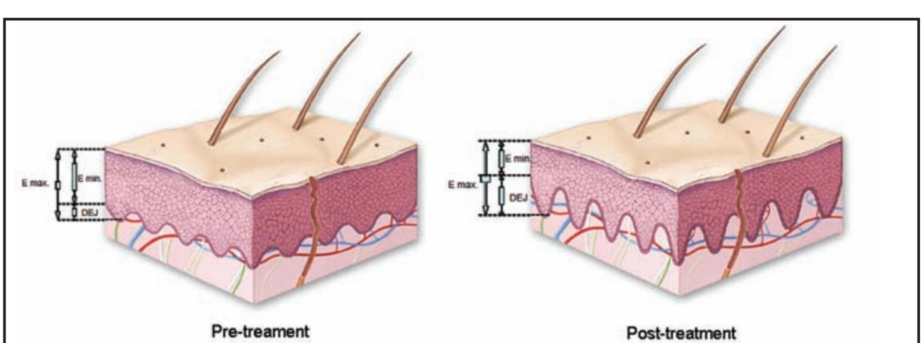

Figure 3. Changes observed with confocal laser scanning microscopy (scaled drawing)

results clearly showed a greater degree of improvement in laxity when the final temperature was higher. Increases in final temperature (ΔT_1) greater than 11.5ºC were positively correlated with a greater degree of improvement (p=0.677, α=0.000).

Increase in temperature at 20 minutes (ΔT_2). The evaluation from patient, clinician, and external observers were better at higher temperatures after 20 minutes. Increases in temperature at 20 minutes (ΔT_2) >4.5ºC (p=0.802, α=0.002) are associated with the best results. The values for the two temperature variables (ΔT_1 and ΔT_2) were positively correlated (p=0.773, α=0.003).

Changes with CLSM. The association between the degree of clinical improvement and histological improvement observed with CLSM was considerable (p=-0.860, α=0.005). The presence of more intense morphological changes, as measured using CLSM, was strongly correlated with increases in final temperature (ΔT_1) greater than 11.5ºC (p=0.812, α=0.002) and with increases in temperature at 20 minutes (ΔT_2) >4.5ºC (p=0.723, α=0.009).

DISCUSSION

Radiofrequency is a widely accepted treatment for skin laxity, thanks to the increased tissue temperature and the subsequent reparative reaction it generates.[19–24] Temperature gradients generated by radiofrequency vary from patient to patient, as does the gradient necessary to induce the repair response and its intensity.

The target of this clinical study was to attempt to find a statistically significant association between tissue response and final skin temperatures. We found that increases over baseline greater than 11.5ºC (ΔT_1) and increases at 20 minutes (ΔT_2) greater than 4.5ºC were associated with better results.

In the authors' experience, it is not always easy to reach these gradients. In fact, the sudden heat that is sometimes observed produces

TABLE 2. Local increases in temperature; grade of pain

CLINICAL DATA (SESSIONS)	SESSION 1	SESSION 2	SESSION 3	SESSION 4	SESSION 5	SESSION 6
Local increases in temperature (ºC) (average per session) Immediately after the procedure(ΔT_1)	11.7±1.2	11.5±1.2	11.2±1.1	11.5±1.5	11.8±1.1	11.6±1.5
Local increases in temperature (ºC) (average per session) 20 minutes after the procedure (ΔT_1)	3.8±1.0	3.5±1.1	3.6±1.5	3.7±1.9	3.8±1.5	3.7±1.9
Grade of pain (scale 0–10) (average per session)	1.3	1.2	1	1	1.1	1

a burning sensation (heat peaks) that reduces the patient's tolerance and makes it necessary to stop the procedure; this results in a sharp fall in skin temperature (2–3ºC in 5 seconds). The design of the handpiece and its large contact area make it much easier to prevent heat peaks and therefore improve the patient's tolerance. The three pairs of electrodes generate electrical fields with equal polarity as a result of the system's synchronized phased energy emission. As "like" poles repel, currents can run in deeper planes[25] using bipolar radiofrequency. Very little current flows on the skin surface, which may also be a reason for the patient's better pain tolerance. Progressive, better-distributed heating facilitates a larger number of sweeps and greater tissue heating. Overlapping of heat in neighboring areas allows all the tissue treated to function as a relative heat reservoir, with the result that neighboring grids require fewer sweeps for preheating.

Clinical improvement in laxity is difficult to measure[25]; therefore, a correlation was attempted to be established through objective histological changes using real-time CSLM. This works by detecting the photon refraction that occurs in illuminated live tissue with an 834nm diode laser. The lateral measurement resolution of the system used is 0.5 to 1µ and the optical thickness of 2 to 5µ can be compared to that of conventional histology.[26] Contrast of confocal images is obtained by the different refraction indices of the organelles and other structures of pigmented epithelia.[27–29] Current technology enables us to obtain images up to a depth of 250 to 350µ, including the epidermis, papillary dermis, and the most superficial part of the reticular dermis.[26]

The Vivascope 1000 generates and measures images parallel to the skin surface. The software included enables the system to run in high definition, both for capture and for analysis of images. Images are captured in parallel to the surface of the skin in very adjusted axial steps (2µ in depth), that is, every image is scanned at depths that increase every 2µ, with the result that 100 images represents a depth of 200µ. The system takes 20 seconds to carry out this analysis.

The images are stored for subsequent analysis. In order to ensure that the images were captured at the same point, the area was marked and the location photographed; the same area was marked for each subsequent image capture. Ten captures were made at each point to avoid variability. The values in the table are average values.

The system is equipped with a mechanical positioner (Physik Instrumente 50) installed on the mount of the camera lens. The pressure generated by the camera-positioning arm on the skin is always the same; therefore, the thickness of the skin is not altered by the pressure.

Given the limits of depth, the authors defined four parameters to measure the potential morphological changes in the dermal-epidermal junction: ΔE^{min} (minimum epidermal thickness), ΔE^{max} (maximum epidermal thickness), Δ DEJ thickness (papillary height), and Δ UD (depth of the reticular collagen refringence band).[30,31]

Minimum epidermal thickness ΔE^{min}—measurement of epidermal thickness taken from the skin surface (stratum corneum) to the point where the first peaks of the dermal papillae become visible. The distance between the surface and the dermal crest increases with age: 50±8µ in patients over 65 years of age compared with 47±5µ in patients under 25 years of age.

Maximum epidermal thickness ΔE^{max}—measurement of epidermal thickness taken from the skin surface (stratum corneum) to the depth at which a cellular is no longer observed (epidermal thickness up to the dermal valley). Maximum epidermal thickness decreases with age: 75±7µ in patients over 65 years of age compared with 89±8µ in patients under 25 years of age.

Δ DEJ thickness (papillary height). The determination of E^{max}–E^{min} makes it possible to calculate the thickness of the dermo-epidermal junction (papillary height). An increase in the thickness of the dermo-epidermal junction is one of the main differences between young skin and mature skin: 25±8µ in patients over 65 years of age compared with 41±8µ in patients under 25 years of age. Mature skin undergoes flattening of the dermo-epidermal junction as a result of flattening of the papillae. Depending on image depth, the confluence of papillae can be observed in skin affected by elastosis.

Depth of the reticular collagen refringence band. At a certain depth (110–140µ), a reflecting layer of fibrous structure in the upper dermis is observed in the stacks. The location of this reflecting layer (UD) is lower in mature skin: 107±8µ in patients over 65 years of age compared with 136±10µ in those under 25 years of age.

The increase in the depth of the refringence band after treatment is also a sign of dermal structural improvement.

Furthermore, in thin skin, the morphology of dermal collagen can be observed accurately up to 200µ. Young collagen is arranged in the form of fine even mesh with structures and is made up of narrower diameter fibers than older collagen, which is arranged irregularly and in the form of clusters (elastosis). A reduction in the larger diameter of collagen fibers represents a structural improvement in dermal collagen.[30–32]

We observed histological changes that reflect structural improvement in the dermis; the most significant absolute values of change, as observed by CLSM, were for the increase in papillary height (28.90% at 6 months and 40.30% at 12 months). This is a considerable improvement in the quality of the dermo-epidermal junction and is consistent with the results of other clinical studies based on conventional histology. The increased depth of the collagen refringence band (9.7±5.0 [9.7%] at 6 months and 6.3±8.6 [5.19%] at 12 months) points to the existence of long-term collagen remodeling.[31–34] Despite the high degrees of temperature obtained in several patients, there were no side effects.

While it is difficult to quantify the peak temperature increase that can lead to improved skin quality in an individual patient, the relationship between the highest degrees of clinical improvement, histological changes, and $\Delta T_1 > 11.5$ºC and $\Delta T_2 > 4.5$ºC seem to indicate that some temperature gradients induce a more favorable tissue response.

CONCLUSION

Radiofrequency skin treatments, in this study, show a statistically significant association between better results at increases in end temperature $\Delta T_1 > 11.5$ºC and increases in temperature at 20 minutes $\Delta T_2 > 4.5$ºC. These gradients are in turn significantly associated with higher indices of structural improvement, as seen using CLSM.

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Objective Assessment of Skin Tightening Using Multisource, Phase-Controlled Radiofrequency in Asians*

Yohei Tanaka[1,2,3]

[1]Clinica Tanaka Plastic, Reconstructive Surgery and Anti-aging Center, Matsumoto, Japan; [2]Department of Dermatology, Tokyo Women's Medical University, Tokyo, Japan; [3]Department of Applied Life Sciences, Niigata University of Pharmacy and Applied Life Sciences, Niigata, Japan.
Email: info@clinicatanaka.jp

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ABSTRACT

Background: Radiofrequency has been proven to penetrate deeper than optical light sources independent of skin color allowing a safer treatment for the Asian skin type. Many studies have indicated the efficacy of various types of devices, but have not included a sufficient objective evaluation. Multisource radiofrequency uses multiple phase controlled radiofrequency generators with real time impedance control, allowing painless, deeper dermal heating with better adaptation to differences in individual skin impedance. In this study we used three-dimensional imaging for the objective evaluation of facial skin tightening by multisource phase-controlled radiofrequency. **Methods:** Twenty Japanese patients were treated with a multisource phase-controlled radiofrequency device. Three-dimensional imaging was performed with a Canfield Scientific Vectra camera and software, and quantitative volume measurements were taken to evaluate the change in the post-treatment volume. The patients then provided subjective assessments. **Results:** Objective assessments of the treated cheek volume evaluated by a three-dimensional color schematic representation with quantitative volume measurements showed significant improvement three months after the final treatment. The mean volume reduction at the last post-treatment visit was 3.878 ± 2.86 mL. The post-treatment volume was significantly reduced compared to the pretreatment volume in all of the volunteers (P = 0.0007). Ninety-five percent of volunteers reported satisfaction with the improvement of skin laxity, and ninety percent of volunteers reported satisfaction with the improvement of wrinkles, such as the nasolabial folds. **Conclusions:** The advantages of these multisource phase-controlled radiofrequency treatments are its high efficacy for skin tightening associated with minimal level of discomfort, minimal side effects, and low cost. Taken together, these characteristics facilitate the ability to give repeated treatments as a stand alone treatment or adjunct to surgery. This study provides for the first time a qualitative and quantitative volumetric assessment, proving the ability of the technology to reduce the volume through non invasive skin tightening.

Keywords: Objective Evaluation; Quantitative Volume Measurement; Skin Laxity; Three-Dimensional Imaging; Wrinkles

1. Introduction

Demand for a non-invasive and long-lasting treatment to reduce wrinkles and laxity has grown dramatically over the past few decades as new aesthetic technologies have been introduced into practice. A major cause of wrinkles, laxity and cellulite is the reduction in the quantity and quality of collagen in the dermis and hypodermis [1].

We previously reported that near-infrared can penetrate deep into human tissue, achieve skin tightening [2-4] and muscle thinning [5,6], and non-thermally induce various responses in the skin and subcutaneous tissues [7-12].

Radiofrequency (RF) devices have also been widely used for skin tightening and are thought to heat the dermis and subcutaneous tissues, thereby stimulating dermal collagen remodeling. It is well documented that one of the effects of dermal heating is an immediate change in collagen structure, followed by a long-term stimulation of neocollagenesis starting at 4-6 weeks after treatment [13]. These thermal effects can help reduce the appearance of wrinkles and laxity and improve contours on both the face and body.

The thermal effects of monopolar and bipolar RF have been proven to be beneficial in skin tightening. Never-

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theless, these effects are often partial or unpredictable because of the uncontrolled nature and possible pain produced during monopolar or unipolar RF treatments and the superficial nature of energy flow for bipolar or tripolar configurations. In addition these first-generation RF therapy systems delivered frequently unpredictable results, possibly due to the large differences in individual skin impedance [14].

In our clinic, a novel multisource phase-controlled system is used. In Multisource RF systems, first introduced in 2009, six independent RF generators produce the RF. Each of this generators is phase controlled, allowing a complex 3 dimensional interaction between the electromagnetic fields produced in the tissue. Since adjacent electrodes, on each side of the handpiece, posses identical polarities, no current is created between these electrodes on the skin's surface and most of the energy is driven deeper into the skin with minimal epidermal flow (**Figures 1** and **2**).

In addition to the new RF delivery technology, the tested system allows for continuous real-time measurement of skin impedance and delivers constant energy to the patient skin independent of changes in its impedance. Several studies have shown the efficacy of multisource RF in both skin tightening and fractional RF skin resurfacing but these studies did not include an objective evaluation of the post treatment volumetric tissue changes [1,14-17]. Conventional evaluations using photographs have been widely used, but they do not provide an accurate objective assessment. Therefore, in this study, a 3-dimensional (3D) photographic system was used to evaluate the amount of post-treatment volume change.

The aim was to quantifiably assess and provide definitive clinical evidence of skin tightening using multisource phase-controlled RF treatment not only subjectively, but also objectively.

2. Materials and Methods

2.1. Japanese Volunteers

Twenty Japanese volunteers (18 females and 2 males) aged 26 to 69 years (mean age, 42.4 ± 9.92 years) with

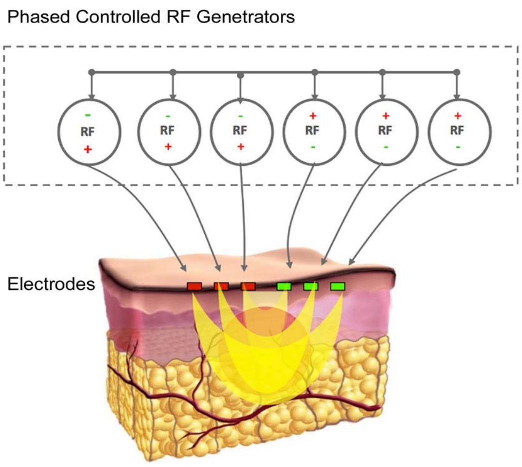


Figure 1. Configuration of six phase controlled RF sources as implemented in the Endymed Pro multisource technology. Multisource RF technology is based on the fact that flow of energy on the surface is minimal, while all energy is directed to the depth of the tissue. This is achieved by repulsion between electrical field of the same polarity on each side of the handpiece.

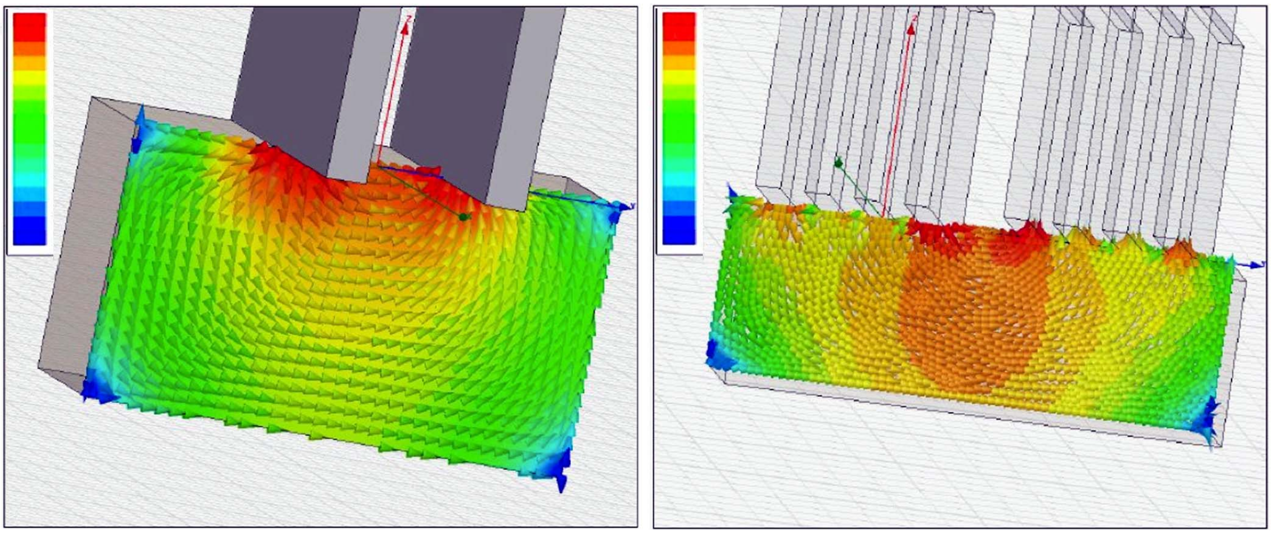


Figure 2. Qualitative electromagnetic field simulation of the tissue effects of simple biolpar RF (left) and mutiple phase controlled RF generators (right). Since the multisource RF handpiece delivers energy in constant circulatory motion the effect will be an average lower temperature on the epidermis (<43 deg) and higher temperature in the lower skin layers, without the need for cooling. This technology allows the system to keep epidermal temperature bellow 43 deg while reaching up to 57 deg in the depth of the tissue.

Fitzpatrick skin type 3 to 5 were enrolled in this study.

The volunteers did not have a history of any type of skin disease or cosmetic procedure affecting the treatment areas within the last 3 years. Volunteers did not have any specific diet. No volunteers exhibited weight loss during the study periods. No topical pre-treatment medication was used, and the post-treatment skin care regimen consisted of a gentle cleanser and sunblock. All volunteers gave written informed consent for participation in the study after reading the experimental protocol and being advised about the risks of treatments.

2.2. RF Treatment

The RF device used in this study was the FDA cleared, EndyMed PRO™, (Endymed Medical, Cesarea, Israel). This system uses multiple phase-controlled RF generators, emitting RF at 1 MHz frequency, 1 to 65 watts. Twenty Japanese volunteers were treated on both cheeks. Three treatment sessions with a 1-week interval between treatments were performed.

Volunteers were treated at a 33 W output, which allowed a painless procedure. If the volunteer reported a strong sensation of heat, the handpiece was rotated slightly faster and/or the treatment head was moved slightly away from the point of heat sensation. No topical anesthetics or oral analgesics were administered before, during, or after the treatment. In addition, no skin cooling was required.

2.3. Objective Assessments

Digital photographs and 3D imaging with quantitative volume measurements were conducted as objective assessments with a Canfield Scientific Vectra camera and software (Canfield Scientific Inc., Fairfield, New Jersey). This system is designed to accurately capture the surface shape and also 2D color information of the human body. The capture sequence of Vectra was set to less than 3 ms in order to capture the shape accurately even if the subject was not perfectly still.

A 3D color schematic representation indicates the volume changes between pretreatment and post-treatment images in the face, and shows the varying degrees of tightening achieved in colors ranging from yellow to red. Green areas indicated no changes to the face.

In this study, volume change was observed as volume reduction in the cheek, and recorded in milliliters. Care was taken to ensure similar non-smiling facial tone in both pretreatment and post-treatment photographs.

2.4. Subjective Volunteer Assessments

Subjective volunteer assessments were performed using questionnaires in which the volunteers were asked to give their degree of satisfaction in terms of skin laxity and wrinkles based on a 5-point scale ranging from 0 to 4 (0 = worse; 1 = little satisfaction or not satisfied; 2 = fairly satisfied; 3 = satisfied; and 4 = very satisfied). Questionnaires were given 3 months after the final treatment.

2.5. Statistical Analyses

The differences were examined for statistical significance using the Wilcoxon signed rank test. A $P < 0.05$ was set as a cut-off for statistical significance. Data are represented as means ± standard deviation (SD).

3. Results

Objective assessments evaluated by 3D color schematic representation with quantitative volume measurements showed significant improvement after the treatment (**Figures 3-5**).

The mean volume reduction measured at the last post-treatment visit was 3.878 ± 2.86 mL. The post-treatment volume significantly reduce compared with pretreatment volume ($P = 0.0007$). Ninety-five percent of volunteers reported satisfaction with the improvement of skin laxity, and ninety percent of volunteers reported satisfaction with the improvement of wrinkles, such as the nasolabial folds (**Figure 6**).

Subjective volunteer assessments were performed using questionnaires (below). The volunteers were asked to give their degree of satisfaction in terms of skin laxity,

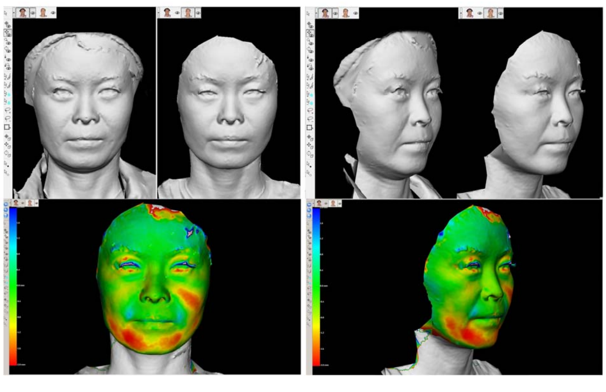


Figure 3. Representative photographs of tightening effects treated with a multisource phase-controlled RF treatment. Pretreatment (Above, left), a 44-year-old Japanese woman exhibited skin laxity in cheek, mental portion, and neck, and wrinkles such as nasolabial fold. Post-treatment (Above, right), 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 the treatments.

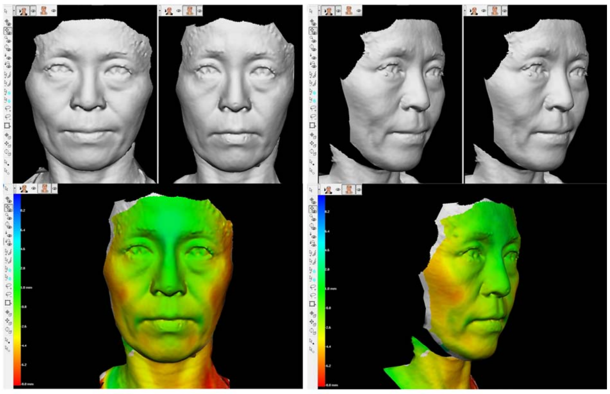


Figure 4. Representative photographs of tightening effects treated with the RF device. Pretreatment (*Above, left*), a 50-year-old Japanese woman exhibited skin laxity in cheek, mental portion, and neck, and nasolabial fold. Post-treatment (Above, right), significant improvements were noted in both skin laxity and wrinkles. Three-dimensional color schematic representation shows significant improvement of appearance, skin laxity, and wrinkles after the treatments.

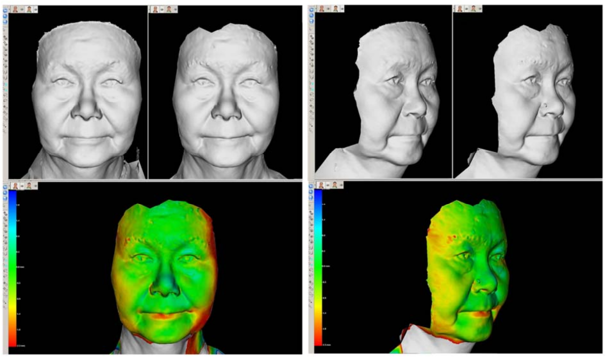
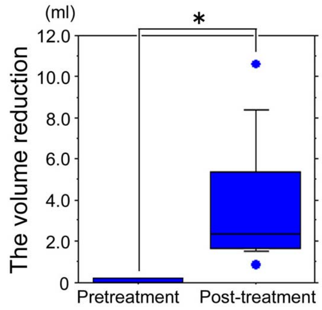


Figure 5. Representative photographs of tightening effects treated with the RF device. Pretreatment (Above, left), a 69-year-old Japanese woman exhibited skin laxity in cheek, mental portion, neck, and nasolabial fold. Post-treatment (Above, right), significant improvements were noted in both skin laxity and wrinkles. Three-dimensional color schematic representation shows significant improvement of appearance, skin laxity, and wrinkles after the treatments.

and wrinkles. Subjective volunteer assessments are shown as follows: very satisfied (blue), satisfied (light blue), fairly satisfied (green), and not satisfied (red). Questionnaires were given 3 months after the final treatment. Ninety-five percent, and 90% of volunteers were satisfied with the improvements in skin laxity, and wrinkles, respectively.

The mean degrees of satisfaction in terms of skin laxity and wrinkles based on a 5-point scale from 0 to 4 were 3.45 ± 0.887 and 3.15 ± 1.040, respectively. There was a very good correlation between the volume reduction in the cheeks and patient satisfaction.

Volunteers did not report pain during the RF treatment, even though it was performed without anaesthesia and



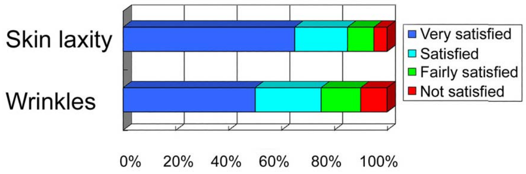


Figure 6. The volume reduction measured by compared the volume at their first pretreatment visit and the last post-treatment visit. The post-treatment volume was significantly reduced compared with pretreatment volume in all the volunteers (P = 0.0007) (above). Data represent the means ± SD. Significant differences are indicated (*: P < 0.05).

contact cooling. Side effects, such as epidermal burns, adipose tissue atrophy, and contraction, were not observed, and the volunteers felt comfortable throughout the study.

4. Discussion

Regardless of skin type, skin laxity is one of the most common complaints among aging patients. Although invasive or ablative procedures, such as face-lifts or laser resurfacing, are affective in skin tightening, the downtime and potential adverse effects are not well accepted [18]. Noninvasive skin tightening procedures can be particularly applicable to skin of color, such as Asians, because such procedures are skin-type independent [18]. Furthermore, the aging process of the skin of Asians differs from that of Caucasians, with mid-face aging, such as sagging of the malar fat pads, being a common manifestation [19]. Therefore, skin tightening is an important aspect in the management of skin aging in patients of color [18].

Whereas nonablative intense pulse light skin rejuvenation heats up the superficial dermis, deep tissue heating that involves radiofrequency or near-infrared sources aims to induce thermal injury in the deep tissue [20].

The aim of deep tissue heating is to stimulate new collagen formation, which can achieve skin tightening. Due to its better tissue penetration, RF treatment is capable of volumetric heating of the mid to deep dermis as well as selective heating of the fibrous septa strands and fascia layer [21]. Specifically, RF energy heats hydrodermal collagen, promoting both collagen remodeling and skin tightening [22]. Clinically, these effects promote dermal and hypodermal collagen production and the tightening of these deep subcutaneous structures [15,21]. RF devices have been used in thermal delivery systems to provide the beneficial effects of heat while avoiding some of the downfalls of more standard lasers [23].

RF has been shown to penetrate deeper than optical light sources independent of skin color, and is beneficial for skin tightening. We previously described the tightening effects of near-infrared objectively and histologically, and reported that near-infrared can penetrate deep into human tissue to achieve skin tightening [2-4] and muscle thinning [5,6], as well as non-thermally induce various responses in the skin and subcutaneous tissues [7-12].

In this study, we evaluated the efficacy of multisource phase-controlled RF treatment both subjectively and objectively.

One of the major issues in all skin tightening clinical studies is the lack of an accepted standard regarding the accurate assessment of the degree of skin tightening [18]. Many studies have suggested efficacy of various types of aesthetic devices, but these studies have not included a sufficient objective evaluation. Conventional evaluations using photographs have been widely used, but do not provide accurate objective assessment. In this study, a 3D photographic system was used to evaluate the amount of post-treatment volume change quantitatively. A 3D imaging approach with quantitative volume measurements (Canfield Scientific Vectra camera and software system) is an effective visual communication tool for skin tightening. Standardized lighting and optically guided object positioning are essential for appropriate pre- and post-treatment evaluation. Photographs are taken from two directions and a 3D quantitative analysis is systemically performed. Thus, 3D quantitative analysis can evaluate and present the effectiveness and duration of the results objectively as well as show patients results that are not demonstrable with standard, 2D photography.

Although the volume measurement was performed three months after the final treatment, the post-treatment volume was significantly reduced compared to the pre-treatment volume in all of the volunteers. Since the effects of this RF treatment are clinically observed for at least several months after the treatment, further studies of volume measurements with a longer follow-up time are needed. Most of the volunteers were satisfied with the improvements in skin laxity and wrinkles, even though the results of the volume measurements were not significant in some volunteers.

Monopolar RF is the first nonablative RF technology shown to be effective for skin tightening [24,25]. The original monopolar RF protocols, using single-pass, high fluence regimen, were associated with a greater degree of discomfort and complications, including tissue irregularity and burns [24]. A multipass, low fluence regimen has been developed with the aim of reducing the discomfort of patients and the risk of adverse effects. Avoiding inadvertent overlap of volumetric areas and the use of lower energies with multiple passes may improve efficacy and minimize the risk of unintended thermal injury [26]. However, the low predictability of monopolar RF treatments and the discomfort that is associated with this procedure is still substantial despite the use of low fluence and multiple passes. Finally, because the device has a disposable tip that can only be used for a single treatment session, the cost effectiveness of this procedure is another important concern.

In bipolar RF one generator is connected to two electrodes on the surface of the skin. In this case the energy delivery will be usually superficial following the shortest way between the electrodes. Other systems with single source of RF connected to 3 or more electrodes (tripolar, multipolar) will provide results similar to bipolar. Both first generation monopolar and bipolar systems are associated with low predictability of treatment results possibly due to large variation of skin impedance causing large variation in the energy delivered into the skin layers.

In this study, a novel multisource phase-controlled system was used, which allows for enhanced energy penetration to lower dermis and hypodermis minimizing epidermal heating. To enhance predictability of energy delivery the system employs a continuous real-time measurement of skin impedance allowing delivery of constant energy to the patient skin independent of changes in its impedance. A 33 W output was used. Treating each 10 cm × 10 cm skin area for 30 seconds allows a painless procedure without the need for cooling or anaesthesia. A significant improvement was observed after three rounds of treatment at this output. Each round of treatment consists of six passes. However, more rounds of treatments or a higher output may enhance the effects. Only a few volunteers were unsatisfied with their individual results, and were mainly patients with thicker skin. Therefore, additional rounds of treatment or a higher output may be needed for these patients.

Side effects, such as epidermal burns, adipose tissue atrophy, and contraction, were not observed, and the volunteers felt comfortable throughout the study. Further studies are necessary to determine if a higher output, increased frequency of treatments, or longer periods of treatment may be even more effective in skin tightening.

It should be noted that this was a preliminary study based on a fairly small number of volunteers. We cannot exclude the possibility that intrinstic and extrinstic factors in everyday life may affect the changes demonstrated in this study. Therefore further studies in this area are warranted in a larger numbers of patients and with longer post-treatment periods to evaluate variations in treatment parameters and correlations with patients' environmental factors.

5. Conclusions

This study examined of first time in Asian population the volumetric changes and subjective effects after treatment with multisource radiofrequency. We found significant improvements in skin laxity through 3 dimensional objective assessments of facial volume. The statistically significant volume reduction measured in treated areas, 3 months after the end of treatment sessions proves a long-lasting skin tightening effect probably to collagen remodeling. Efficacy of the treatment was associated with high predictability of the results with remarkably high subjective patient satisfaction rate.

In our view, this study highlights the advantage multisource RF treatment for higher efficacy, reduced discomfort as well as low cost non invasive skin tightening. Our data show that phase-controlled, multisource RF irradiation provides safe and effective treatment of facial skin laxity and for wrinkle reduction in Asian patients.

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

Yoram Harth, MD[1,2]

[1]Medical OR Center, Herzlya, Israel
[2]EndyMed Medical, Cesarea, Israel

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

Correspondence: Yoram Harth, O.R. Medical Center, 8 Aba Even Avenue, Herzlya, Israel. E-mail: yhart@netvision.net.il

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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]

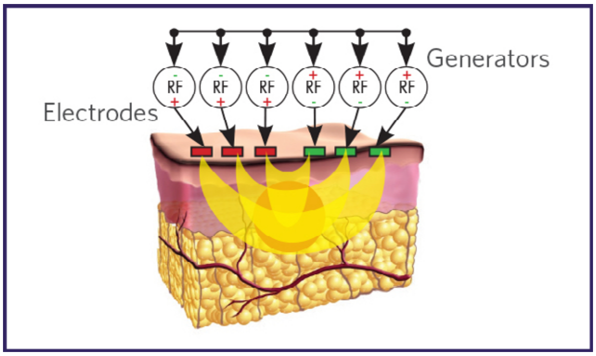

Figure 1 Typical multisource RF configuration uses six independent phase-controlled RF generators. For skin tightening and body contouring, the three generators on the left will be configured to "plus" and the three on the right to be "minus".

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.

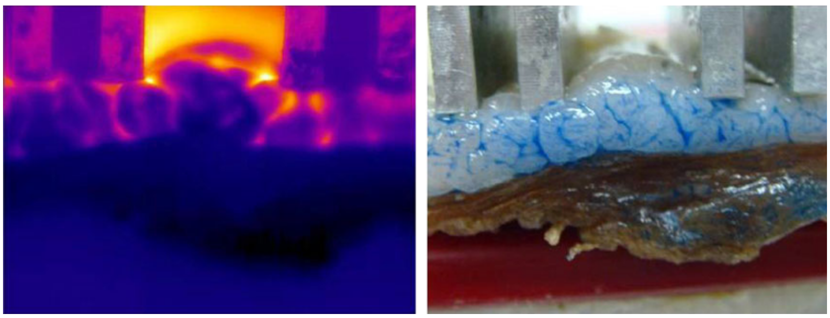

Figure 3 Lt. four phase-controlled sources of RF (multisource RF technology) used on *ex vivo* duck tissue demonstrating a selective heat flow through the dermis and the fibrous tissue surrounding the subcutaneous fat lobules. Rt. Tissue stained with Aniline Blue reveals a match between collagen fibers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

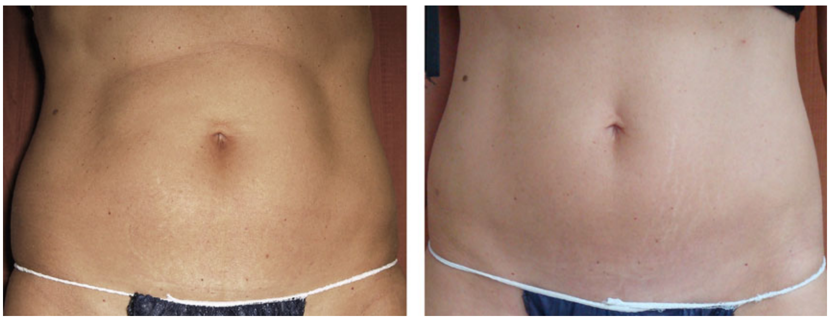

Figure 5 Before treatment (Lt.) and 3 months after 6 Multisource RF treatments (Rt.) showing significant skin tightening and body contouring. Photographs courtesy of Dr. Yoram Harth, Board Certified Dermatologist, FAAD, Herzlya, Israel.

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).

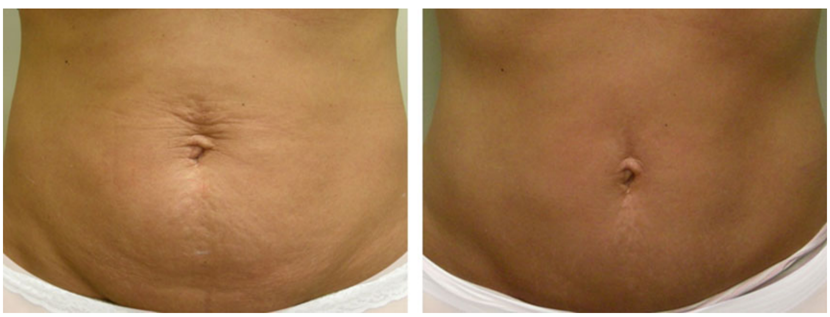

Figure 6 Before treatment (Lt.) and 3 months after six multisource RF treatments (Rt.) showing significant skin tightening and body contouring. Photographs courtesy of Dr. Sharon Kshettry, Edina, Minnesota, United States.

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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Chapter 9

Treatment of Skin Laxity Using Multisource, Phase-Controlled Radiofrequency

Yohei Tanaka

Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.71749

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 CO_2 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 radiofrequency (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

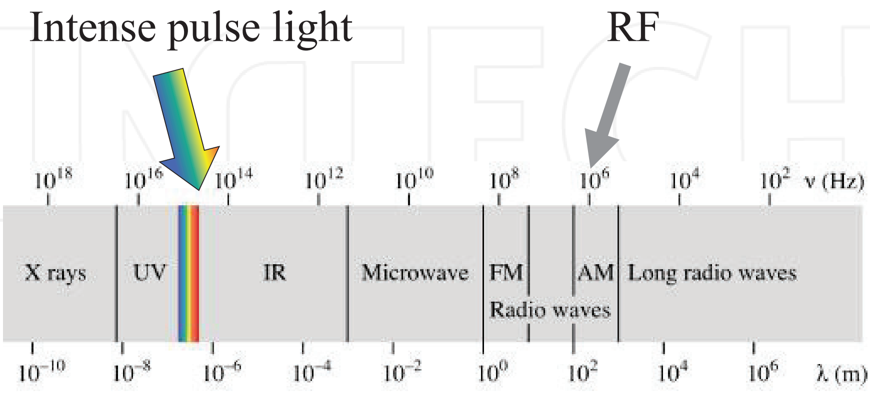

Figure 1. The electromagnetic spectrum covers a wide range of energy radiation types.

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

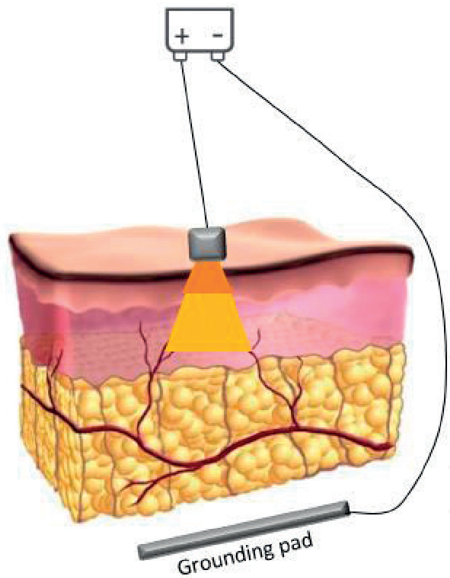

Figure 2. Monopolar RF technologies. One RF generator controls one electrode. Penetration is deeper than bipolar, since there is a flow of energy through the body to the grounding pad. Monopolar RF energy delivery results in high temperature near the electrode, requiring intense epidermal cooling, and 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.

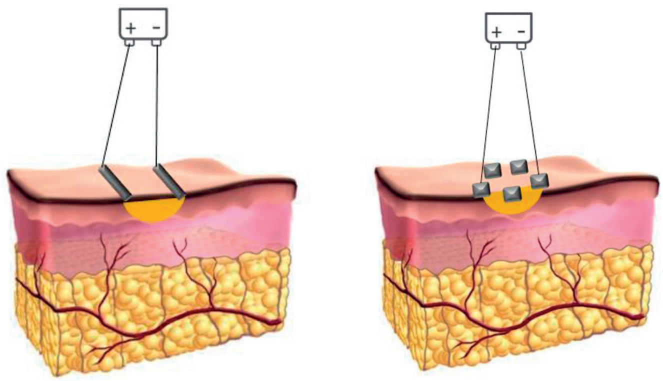

Figure 3. Bipolar RF technologies (left). One RF generator controls two electrodes. There is only superficial penetration since the energy flows along the shortest path, between the two electrodes. It requires active cooling of electrodes to prevent epidermal burns. "Multi-polar" RF Technologies (right). 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

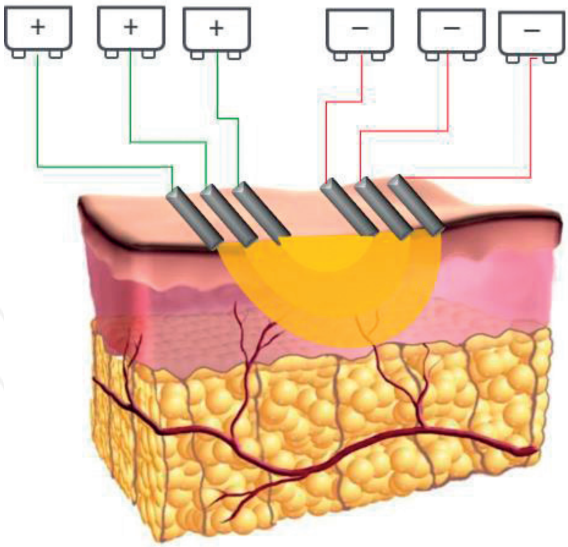

Figure 4. Multisource phase-controlled, RF system. This system can deliver RF energy to deep layers of the skin. Focused & contained deep energy flow. Minimal surface energy flow eliminates the need for intense cooling. Totally safe & painless. Personalized parameters based on multiple unique automatic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

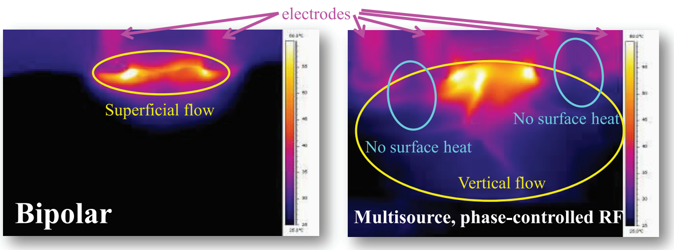

Figure 5. Comparison of bipolar vs. multisource phase-controlled RF system. With bipolar device (300 W, 1 s), superficial flow of energy, penetrates only to 1.5 mm depth. Multisource phase-controlled RF system (4 electrode, 2 × 150 W, 1 s) shows vertical flow of energy, penetrates to 6 mm depth. Absolutely 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,

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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.

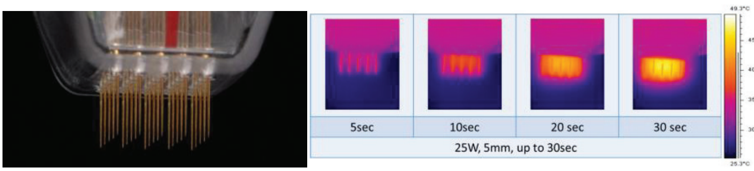

Figure 6. FDA-cleared, very sharply tapered noninsulated gold plated microneedle RF applicator operating with a novel fractionated pulse mode (above). Sterilized treatment tip with 25 microneedles (300 micron diameter at the base that gradually tapers to an especially sharp edge. Microneedles are inserted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

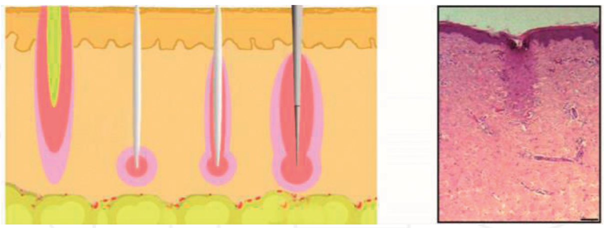

Figure 7. A heat schematic of fractional lasers and microneedles. Images from left to right show fractional lasers, insulated needles, noninsulated needles, and very sharply tapered noninsulated gold plated microneedles. (left). RF emission delivered over the whole dermal portion of the needle allows 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 μm. 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.

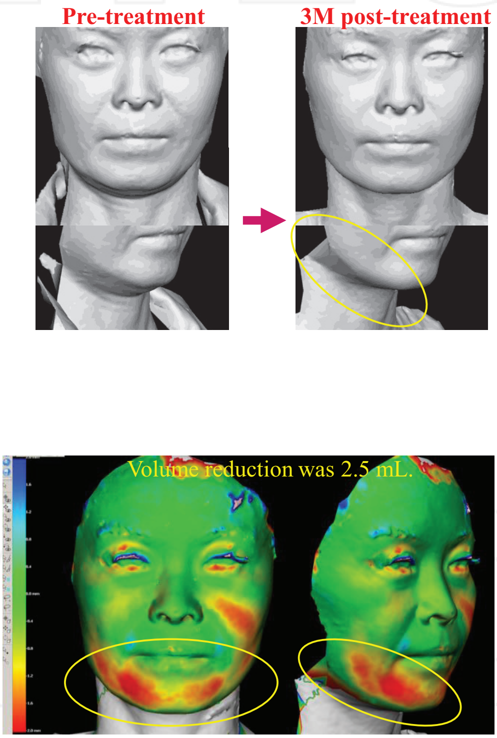

Figure 8. Representative photographs of tightening effects treated with multisource phase-controlled RF treatments. Pretreatment (above, left), a 44-year-old Japanese woman exhibited skin laxity in cheek, mental portion, and neck, and wrinkles such as nasolabial fold. Cheek and neck were treated. Three 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.

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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

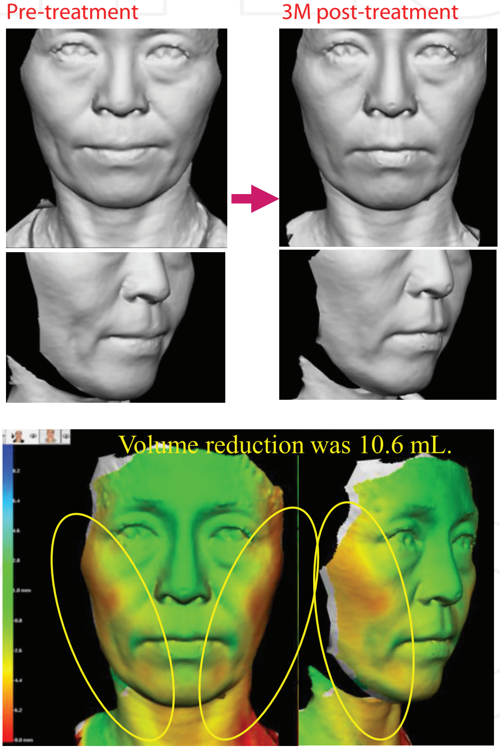
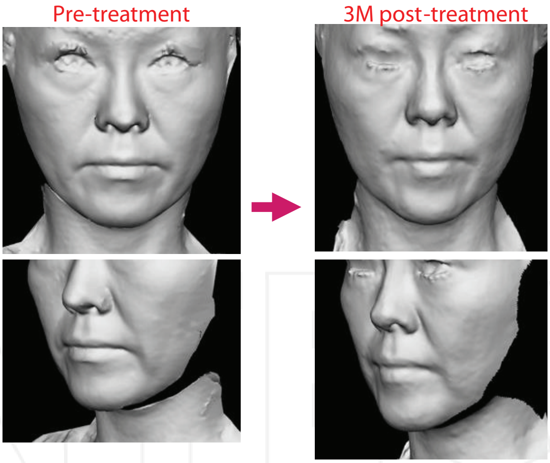


Figure 9. Representative photographs of tightening effects treated with multisource phase-controlled RF treatment. Pretreatment (above, left), a 50-year-old Japanese woman exhibited skin laxity in cheek, mental portion, and neck, and wrinkles such as nasolabial fold. Cheek and neck were treated. Three 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.



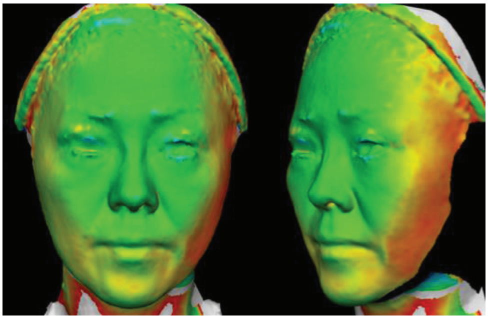


Figure 10. Representative photographs of tightening effects treated with multisource phase-controlled RF treatment. Pretreatment (left), a 43-year-old Japanese woman exhibited skin laxity in cheek, mental portion, and neck, and wrinkles such as nasolabial fold. Cheek and neck were treated. Three treatments 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]).

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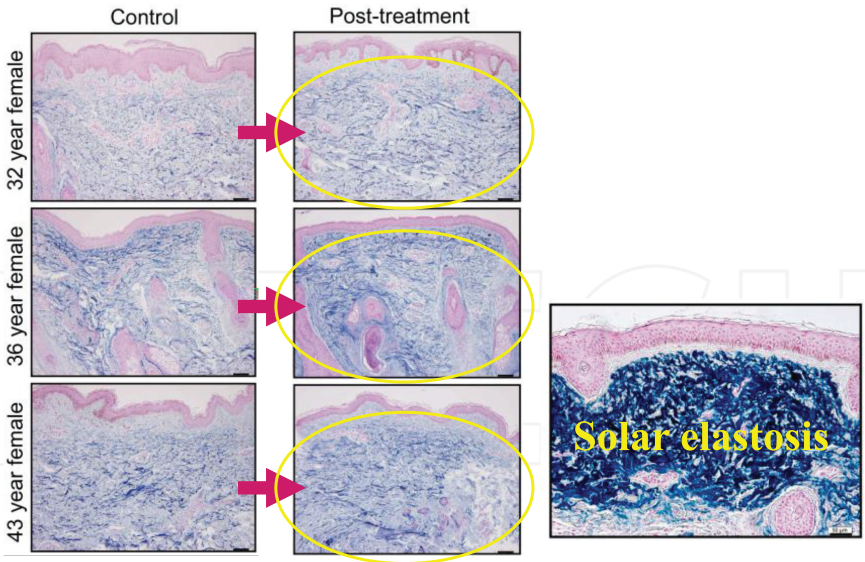

Figure 11. A representative histology of Japanese patients' cheek skin evaluated by Victoria blue staining. The amount of elastin stained in blue significantly increased post-treatment compared with control. Scale bars = 100 μm. Histological studies showed that the amount of elastin was significantly 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.

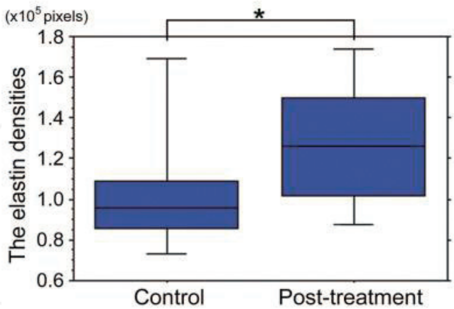

Figure 12. Mean densities of elastin in the dermis. Skin biopsies were taken from five Japanese female patients who had visited the Clinica Tanaka Anti-Aging Center to remove some pigmented nevi (more than one pigmented nevus on both control and treated side of the cheek) and achieve skin rejuvenation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

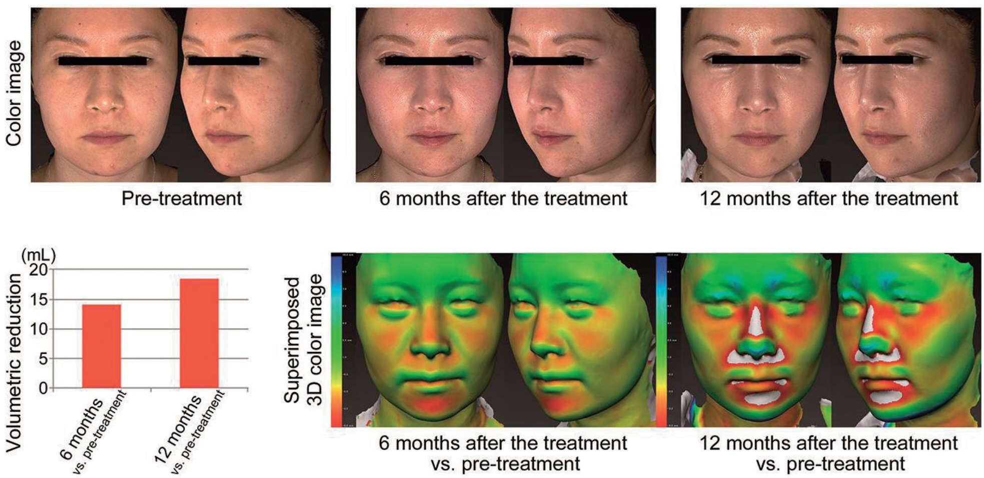

Figure 13. A 31-year-old female. Cheek mode: Pulse width; 110 ms, 14 W, 2.5 mm, 200 shots + Periorbital mode: 80 m, 10 W, 1.5 mm, 100 shots. Images from left to right show the appearance pretreatment to 12 months after the treatment. Improvement of skin texture and dilated skin pores was observed after 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]).

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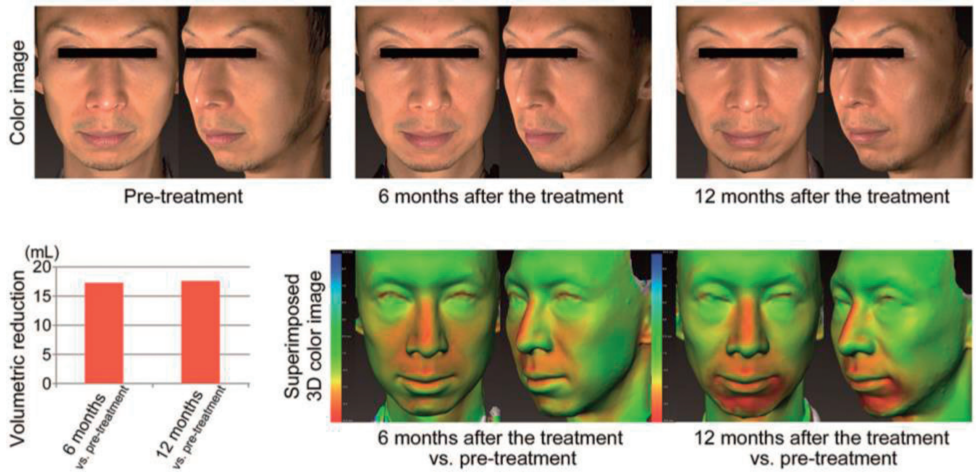

Figure 14. A 40-year-old male. Cheek mode: Pulse width; 110 ms, 14 W, 2.5 mm, 300 shots + Periorbital mode: 80 ms, 10 W, 1.5 mm, 200 shots. Images from left to right show the appearance pretreatment to 12 months after the treatment. Improvement of skin texture and dilated skin pores was observed after 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]).

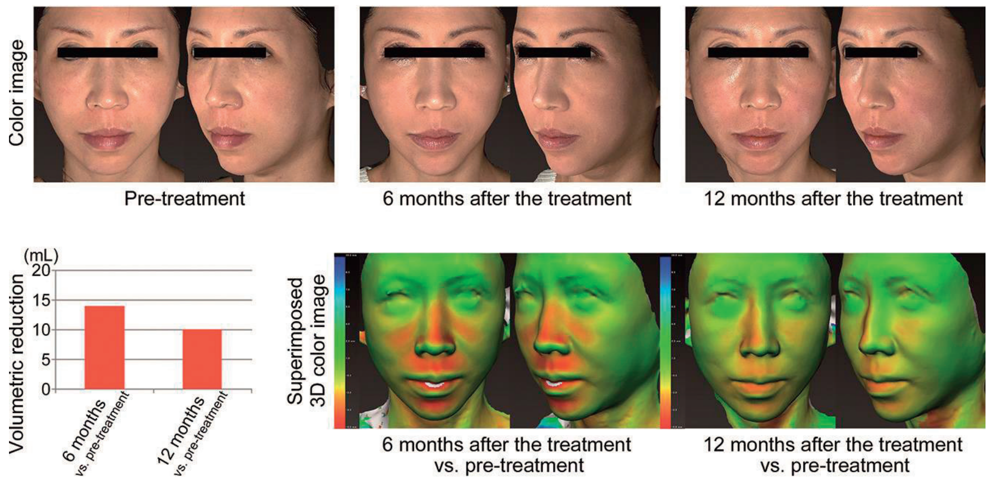

Figure 15. A 47-year-old male. Cheek mode: Pulse width; 110 ms, 14 W, 2.5 mm, 300 shots + Periorbital mode: 80 ms, 10 W, 1.5 mm, 200 shots. Images from left to right show the appearance pretreatment to 12 months after the treatment. Improvement of skin texture and dilated skin pores was observed after 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]).

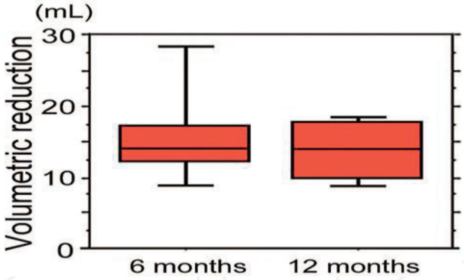

Figure 16. Median volumetric reductions at 6 and 12 months post-treatment were 14.1 and 13.8 ml, respectively. Significant volumetric reductions were observed at 6 and 12 months post-treatment compared with pretreatment ($p = 0.0033$). In contrast, statistical significance was not observed between 6 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°C) and higher temperature in the lower skin layers, without the need for cooling. This technology allows the system to keep epidermal temperature bellow 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.

Author details

Yohei Tanaka

Address all correspondence to: info@clinicatanaka.jp

Clinica Tanaka Plastic and Reconstructive Surgery and Anti-aging Center, Nagano, Japan

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