Long-Term Three-Dimensional Volumetric Assessment of Skin Tightening Using a Sharply Tapered Non-Insulated Microneedle Radiofrequency Applicator With Novel Fractionated Pulse Mode in Asians

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Background and Objective: Non-insulated microneedle radiofrequency (NIMNRF) is a novel method that allows non-thermal penetration of the epidermis followed by radiofrequency (RF) coagulation at selected depths of the dermis that are surrounded by a zone of non-coagulative volumetric heating. The objective of this study was to investigate subjectively and objectively the efficacy of a single fractional NIMNRF treatment.

Study Design/Materials and Methods: Twenty Japanese patients underwent full face skin tightening using a sharply tapered NIMNRF applicator with a novel fractionated pulse mode. The system platform (1MHZ) incorporated six independent phase controlled RF generators coupled to RF microneedles that induced skin remodeling via controlled dermal coagulation. Patients received from 500 to 1000 pulses that were 80–110 milliseconds in duration at a power of 10–14 W, and a 1.5–2.5 mm penetration depth. Topical anesthetic cream was applied before the treatment. Monthly three-dimensional (3-D) volumetric assessments were performed for 6 months after treatment. Patients rated their satisfaction using a 5-point scale.

Results: During the study patients showed significant skin tightening on the lower two-thirds of the face. Objective assessments with superimposed 3-D color images showed significant median volumetric reduction of 12.1 ml at 6 months post-treatment. Ninety percent of the patients were either “satisfied” or “very satisfied” with the treatment results. The treatments were well tolerated with minimal discomfort. Complications included a slight burning sensation and mild erythema that were minor and transitory; both resolved within 5 hours. Side effects such as post-inflammatory hyperpigmentation, epidermal burns, and scar formation were not observed.

Conclusion: The advantages of this NIMNRF treatment for skin tightening are its long-lasting high efficacy as shown through 3-D volumetric assessments. Moreover, NIMNRF produced minimal complications and downtime as well as few side effects. This non-invasive novel fractional NIMNRF approach provides safe and effective treatment of skin tightening in Asian patients. Lasers Surg. Med. © 2015 Wiley Periodicals, Inc.

Key words: facial contours; non-insulated needles; non-invasive fractional radiofrequency; rejuvenation; skin laxity; skin remodeling; volumetric measurement

INTRODUCTION

Regardless of age and skin type, skin tightening is a common procedure requested by Asian patients seeking cosmetic procedures to improve facial contours and skin laxity. The aging process of Caucasians differs from Asians, who tend to experience mid-face aging effects such as malar fat pad sagging. Therefore, skin tightening is an important aspect of managing skin aging in patients of color.

Demand for non-invasive treatments to tighten skin has grown dramatically over the past few decades as new aesthetic technologies have been introduced. A major cause of wrinkles and laxity is a reduction in the quantity and quality of collagen in the dermis and hypodermis [1]. We 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 lessen wrinkles and laxity [2–11].

Although invasive or ablative procedures such as face-lifts and laser resurfacing are effective for skin tightening, they are accompanied by downtime and potential adverse effects. Traditional skin resurfacing with CO2 laser devices is highly effective at producing tissue coagulation, but is associated with prolonged recovery time, bleeding, oozing, and risk of post-treatment hyper- or hypopigmentation [12,13]. In

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addition, these lasers can be very problematic for treating
darker skin types or sensitive Asian skin.

RF has been shown to overcome some disadvantages of
optical light-based treatment by offering enhanced tissue
penetration that is independent of skin color and beneficial
skin tightening effects. RF devices are thought to heat the
dermis and subcutaneous tissues [14] to induce both
collagen remodeling and skin tightening. Over the last
decade, RF devices have been proven to be safe and
effective for both non-ablative skin tightening and
fractional RF skin resurfacing [1,15,16].

In fractional laser or RF skin resurfacing treatments,
thermally ablated or coagulated microscopic zones of the
epidermis and dermis are spaced in a grid over the skin
surface with the non-ablated zones in the uninjured
surrounding tissue serving as a reservoir of cells that
accelerate and promote rapid healing [17].

The first generation of microneedle RF delivery technol-
yogy used insulated needles for skin rejuvenation
and treating acne scars. With RF microneedles, the energy
flows only through the tip of the needle, resulting in a
small, coagulated sphere-like shape in the dermis.
However, these devices can have several disadvantages,
including: (i) micro-bleeding during treatment; (ii) the need
for several passes at different depths to affect the entire
the dermis [1,14,18]; and (iii) ineffective skin tightening.

In this study, a very sharply tapered non-insulated
microneedle radiofrequency (NIMNRF) applicator with
novel fractionated pulse mode was used. 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 electroni-
cally controlled to minimize patient discomfort. Further-
more, 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.

One major issue in clinical studies of skin tightening
is the lack of an accepted standard for accurately assessing
the degree of skin tightening [19]. Conventional evalua-
tions using 2-dimensional (2-D) photographs have been
widely used, but do not provide an accurate objective
assessment. Through experience I have found that
3-dimensional (3-D) assessments are simple and very
useful to obtain an objective volumetric evaluation. In
both our present and prior studies, a superimposed 3-D
color schematic representation was used to evaluate and
present the effectiveness of the results objectively as well
as show patient results that cannot be demonstrated with
standard, 2-D photographs [7,9–11].

Although tightening effects induced by various devices
have been described in many previous studies, continual
volumetric evaluation has not been assessed in detail.
I hypothesized that a single fractional NIMNRF treatment
safely and effectively provides long-lasting skin tightening
effects. To test this hypothesis, I evaluated the efficacy of
the fractional NIMNRF treatment using objective 3-D
volumetric measurements.

MATERIALS AND METHODS

Japanese Patients

Twenty Japanese patients (19 females and 1 male) aged
31–80 years (mean age, 45.5 ± 12.5 years) with Fitzpatrick
skin type III–V were enrolled in this study. 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
minutes before the treatment. The post-treatment skin
care regimen consisted of a gentle cleanser and sunblock.
Patients did not use any specific skin care product, and had
no specific diet. Patients who exhibited weight loss during
the study period were excluded from the 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 in the study.

NIMNRF Treatment

The very sharply tapered NIMNRF applicator operating
with a novel fractionated pulse mode used in this study
(Intensif Handpiece, EndyMed Medical, Caesarea, Israel) is a
novel FDA-cleared handpiece that uses a sterile treatment
Fig. 1. Sterilized treatment tip with 25 tapered, very sharp, gold
plated microneedles (300 micron diameter at the base that
gradually tapers to an especially sharp edge) used in this study.

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gradually tapers to an especially sharp edge) used in this study.
(max diameter of 300 micron at the base that gradually tapers to a very sharp edge) (Fig. 1). 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 was up to 3.5 mm in digitally controlled increments of 0.1 mm. The power was adjustable from 0 to 25 W with increments of 1 W. The pulse duration could be changed in 30 ms increments (maximal pulse duration was 200 ms) [14].

The cheek area was treated with a pulse duration of 110 ms, 14 W, and 2.5 mm penetration depth. Skin on the neck was treated with a pulse duration of 80 ms, 12 W, and 1.5 mm penetration depth. Other areas such as the forehead and nasal, peri-orbital, peri-oral, and mandibular areas were treated with a pulse duration of 80 ms, 10 W, and 1.5 mm penetration depth. The patients received between 500 and 1,000 pulses.

Especially sharp and tapered gold plated needles and a unique step motor enabled the needles to smoothly penetrate the skin and thereby reduce discomfort. The difference in electrical impedance between the epidermis (high impedance) and the dermis (low impedance) further increases selectivity- enhancing RF flow through the dermis. One pulse takes approximately 10 seconds and the RF emission delivered over the whole dermal portion of the needle allows effective coagulation that result in minimal or no bleeding, combined with deep dermal heating (Fig. 2).

The treatment was performed without oral, intravenous anesthesia and contact cooling. All patients were treated by the same physician.

Objective Assessments

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

A superimposed 3-D color schematic representation indicates the volumetric changes in the face between pre-treatment and at every month after treatment (up to 6 months after the treatment), and shows the varying degrees of tightening in colors that range from yellow to red. Green areas indicated no changes to the face. The volumetric changes were measured in milliliters based on pre- and post-treatment images of the treated areas.

Care was taken to ensure a similar neutral, non-smiling expression in both pre- and post-treatment photographs.

Subjective Assessments

Patients completed questionnaires at 6 months after the treatment and were asked to rate their satisfaction with the results and tolerability of the treatments based on a 5-point scale from 0 to 4 (0 = worse; 1 = little satisfaction or not satisfied; 2 = fairly satisfied; 3 = satisfied; and 4 = very satisfied).

Statistical Analysis

The median change in volume was examined for statistical significance using the Wilcoxon signed rank test. A \( P < 0.05 \) was set as a cutoff for statistical significance. The median change and its variability were also illustrated in a box plot graph.

RESULTS

Objective assessments evaluated with a superimposed 3-D color schematic representation showed long-lasting and significant volumetric reduction after the treatment in all patients. Representative 2-D color, gray scale, super-imposed 3-D color images and volumetric reductions are shown in Figures 3–5. Significant tightening effects on the lower two-thirds of the face, as well as the cheeks, nasal and peri-oral areas that were induced by one fractional NIMNRF treatment lasted for 6 months without a severe
edematous stage. The effects could be somewhat unstable for 2 or 3 months after the treatment, and were stable from 4 months after the treatment.

Objective assessments of superimposed 3-D color images showed statistically significant median volumetric reduction of 12.1 ml at 6 months posttreatment (Fig. 6).

Six months after the treatment, ninety percent of the patients were either “satisfied” or “very satisfied” with the treatment results as based on a 5-point scale of 0–4 (average score: 3.53 ± 0.84). Similarly, the 80% of the patients reported being either “satisfied” or “very satisfied” with the tolerability of the treatment (average score: 3.32 ± 0.95, Fig. 6). Furthermore, there was a very good correlation between the amount of volumetric reduction and patient satisfaction. Overall, treatments were well tolerated and patients experienced minimal discomfort. Most patients did not report feeling severe pain during the treatment, even though it was performed without oral or intravenous anesthesia and contact cooling. Complications were minor and transitory, with effects such as a slight burning sensation or mild erythema resolving within 5 hours. Side effects such as post-inflammatory hyperpigmentation (PIH), epidermal burns, and scar formation were not observed throughout the study.

DISCUSSION

To the best of our knowledge, this is the first work that used the 3-D objectives to examine long-term skin tightening effects of microneedle RF on Asian patients.
The present study demonstrated that one fractional NIMNRF treatment is a safe and effective method to provide patients with long-lasting skin tightening as evidenced by significant volumetric reduction. Significant tightening effects in cheek, nasal and peri-oral areas induced by one fractional NIMNRF treatment could be seen in superimposed 3-D color schematic representations that were compiled every month after the treatment, and, with the exception of the forehead area, the tightening effects lasted up to 6 months. Although conventional evaluations using 2-D color and gray scale photographs could not show significant tightening effects, most patients reported a subjective tightening.

3-D volumetric assessment also showed that the effects could be somewhat unstable for 2 or 3 months after the treatment, but were clear and stable after the fourth month. These phenomena may be explained by the transient edematous, inflammation phase that occurs in the first 3 months before the initiation of a proliferative and maturation phase that results in the stable tightening effects seen during months 4–6.

The results appeared to be significant even though only one treatment was performed. This significant efficacy can be explained by three specific features of the tested device (Fig. 7). 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 0.7 mm. Electronically controlled penetration allows more exact monitoring of the penetration depth, which can be customized for different treatment areas. Second, the tested gold plated non-insulated needles have a smooth insertion that presents a significant advantage over first generation insulated and stainless steel needles. The clinical efficacy of insulated needles is limited by the

Fig. 4. A: A 40-year-old Japanese male. Images from left to right show the appearance before treatment to 6 months post-treatment. Panels from top to bottom show 2-D color, gray scale, and superimposed 3-D color images. Significant improvements in skin laxity were observed in the gray scale image and 3-D color schematic representation of the treated side. B: Volumetric reduction (mL) at each follow up point relative to the pretreatment volume.
small volume of heat produced by the emission of RF only at the small non-insulated area near the tip and significant micro-bleeding induced by the treatment. In contrast, the non-insulated gold plated needles used here emit RF throughout the whole length, thus allowing heating of three times the volume [20]. 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 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 that 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 [20].

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 NIMNRF treatment may be related to the sharpness of the needles and the unique motorized needle insertion.

Post-treatment complications included a 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.

The current study shows the long-term skin tightening effect of a single treatment session using a novel micro-needle RF system for Asian patients. Non-thermal penetration of the epidermis with a very tapered micro-needle that is inserted with a 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

Fig. 5. A: A 46-year-old Japanese female. Images from left to right show the appearance before treatment to 6 months post-treatment. Panels from top to bottom show 2-D color, gray scale, and superimposed 3-D color images. Significant improvements in skin laxity were observed in the grayscale image and 3-D color schematic representation of the treated side. B: Volumetric reduction (ml) at each follow up point relative to the pretreatment volume.
non-ablative lasers or other manual or fixed microneedle RF systems. In addition, RF emission through the length of the needle provides a shorter treatment time and a coagulation effect that eliminate micro-bleeding and improve the patient experience [20]. Digital control of the needle penetration depth with automatic motorized insertion improves the patient experience by reducing discomfort and side effects [20].

Although a significant improvement in skin tightness was observed after just one treatment at the tested power output, further studies are needed to determine if a higher power output or increased treatment frequency 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 patients. Moreover, we cannot exclude the possibility that lifestyle habits, such as food, alcohol and salt intake, as well as solar UV and NIR exposure may affect the changes observed in this study.

In conclusion, the advantages of this fractional NIMNRF skin tightening system are its long-lasting high efficacy that is shown through 3-D volumetric measurements. The fractional NIMNRF treatment allows controlled heating to a pre-defined dermal depth without epidermal coagulation. This fine control eliminates most of the micro-crusting that can occur with other RF-based treatments, reduces the risk of PIH associated with epidermal injury, and allows the patient to return to a normal routine within 5 hours. This study showed high objective and subjective patient satisfaction rates with minimal downtime or side effects. Thus, fractional NIMNRF technology that uses an electronically controlled motor for the smooth insertion of non-insulated gold plated needles is a safe and effective treatment to produce skin tightening in patients of color.

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