

Background: The skin tightening effects induced by non-insulated microneedle radiofrequency have proved long-lasting. Our previous three-dimensional volumetric assessment showed significant facial tightening for up to six months. However, nasal and peri-oral tightening effects lasted longer. The objective of this study was to investigate the distribution of the long-term volumetric reduction in facial area induced by a single fractional non-insulated microneedle radiofrequency treatment. **Methods:** Fifteen Asian patients underwent full facial skin tightening using a sharply tapered non-insulated microneedle radiofrequency applicator with a novel fractionated pulse mode. Three-dimensional volumetric assessments were performed at six and 12 months post-treatment. Patients rated their satisfaction using a 5-point scale at each follow up. **Results:** Objective assessments with superimposed three-dimensional color images showed significant volumetric reduction in the nasal and peri-oral areas at 12 months post-treatment in all patients. Median volumetric reductions at six and 12 months post-treatment were 13.1 and 12.3ml, respectively. All of the patients were satisfied with their results 12 months post-treatment. Side effects were not observed.

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Long-term Nasal and Peri-oral Tightening by a Single Fractional Noninsulated Microneedle Radiofrequency Treatment

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A SINGLE FRACTIONAL noninsulated microneedle radiofrequency (NIMNRF) treatment has been shown to induce long-lasting skin tightening effects.¹ Significant volumetric reduction of the lower two-thirds of the face up to six months has been shown through three-dimensional (3D) volumetric assessment.¹

Regardless of age and skin type, cosmetic patients often request skin tightening of the lower two-thirds of the face to improve facial contours and skin laxity. Although lifting procedures, such as face-lift and thread lift, are effective for treatment of skin laxity, they cannot improve skin texture or achieve skin rejuvenation. In addition, scar formation may occur after a face-lift, and visible threads or an unnatural look can be problematic after thread lifts.

A major cause of wrinkles and skin laxity is a reduction in the quantity and quality of collagen in the dermis and hypodermis.² We previously reported that near-infrared or radiofrequency (RF) treatments stimulated collagen and elastin production while safely and

effectively promoting long-lasting skin tightening results that treat laxity.³⁻⁹

Although various devices, such as intense pulsed light and laser therapies, have been introduced for skin rejuvenation, these superficial procedures appear to be insufficient for tightening skin on the lower two-thirds of the face.

Furthermore, nasal and peri-oral skin laxities are commonly found with age. Therefore, nasal and peri-oral tightening are an important aspect of facial rejuvenation.

NIMNRF treatment was able to provide long-lasting high-efficacy skin tightening of the lower two-thirds of the face.^{1,9} This device formed cylindrical micro-zones of coagulation in the papillary and reticular dermis with minimal damage to the epidermis. Furthermore, RF emission delivered over the whole dermal portion of the needle allowed effective coagulation resulting in minimal or no bleeding, as well as bulk volumetric heating.¹ These advantages are also useful for nasal and peri-oral tightening.

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Conclusions: This single fractional NIMNRF treatment provided long-lasting nasal and peri-oral tightening as shown via 3D volumetric assessment. Moreover, NIMNRF produced minimal complications, downtime, and few side effects. This approach provides safe and effective treatment of skin tightening.

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Table 1. Patient characteristics, volumetric reduction results, and satisfaction score

No.	Gender	Age	Volume reduction at 6 months (mL)	Volume reduction at 12 months (mL)	Satisfaction score at 6 months	Satisfaction score at 12 months
1	Female	31	14.1	18.4	4	4
2	Female	32	13.9	8.6	2	3
3	Female	34	17.6	15.3	4	4
4	Female	37	17.5	13.8	2	3
5	Male	40	17.3	17.6	4	4
6	Female	40	8.7	10.5	4	4
7	Female	40	10.9	12.2	3	4
8	Female	44	12.3	16.8	4	4
9	Female	44	9.4	10.6	3	4
10	Female	45	10.7	9.6	3	3
11	Female	47	14.1	10.1	4	4
12	Female	48	12.1	10	4	4
13	Female	50	27.9	17.9	4	4
14	Female	53	11.9	18.5	4	4
15	Female	66	9.0	12.3	4	4

Three-dimensional assessments are simple and very useful for obtaining objective volumetric evaluations. A superimposed 3D color schematic representation can be used to objectively evaluate and present the effectiveness of the treatment as well as show results that cannot be demonstrated with standard two-dimensional (2D) photographs.^{1,4,6–8}

Although long-lasting skin tightening effects without scarring on the lower two-thirds of the face were observed for up to six months after a single NIMNRF treatment, nasal and peri-oral tightening effects appear to last longer. Moreover, though

tightening effects induced by various devices have been described previously, continual and precise evaluation of the distribution of volumetric changes has not been assessed in detail.

Therefore, the current study evaluated the distribution of the volumetric reduction induced by the single fractional NIMNRF treatment using objective 3D volumetric measurements.

METHODS

Asian patients. Fifteen Asian patients (14 women and 1 man) aged 31 to 66 years (mean age, 43.4±9.0

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 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 in the study.

NIMNRF Treatment. The sharply tapered NIMNRF applicator operating with a fractionated pulse mode used in this study (Intensif Handpiece, EndyMed Medical, Caesarea, Israel) is a novel FDA-cleared handpiece that uses a sterile treatment tip with 25 noninsulated gold plated microneedle electrodes (maximum diameter of 300 micron at the base that gradually tapers to a sharp edge). 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 3.5mm

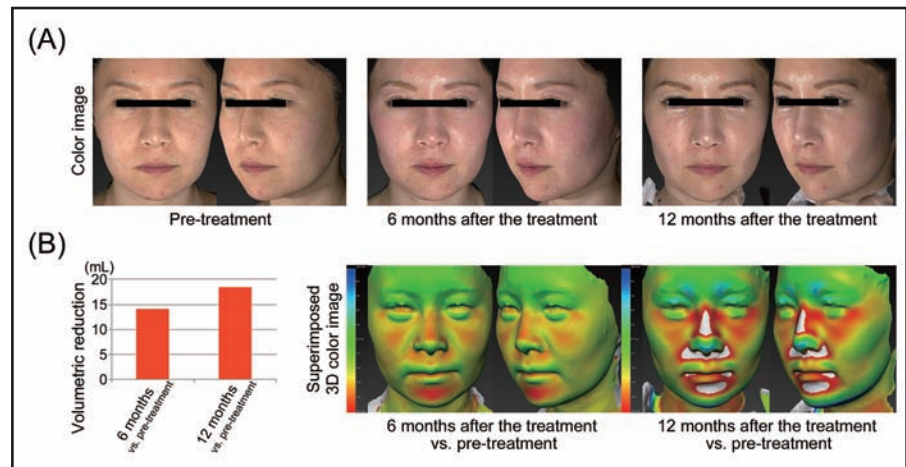


Figure 1. A: Pictured here is a 31-year-old woman (Patient No.1 from Table 1). Images from left to right show the appearance pre-treatment to 12 months after the treatment. Improvement of skin texture and dilated skin pores was observed after treatment with time; B: (Left) Volumetric reduction (mL) at six and 12 months follow up point relative to the pre-treatment volume. (Right) Superimposed 3D color images that show the volumetric change distribution 6 and 12 months after the treatment compared to pre-treatment. 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 peri-oral areas was observed.

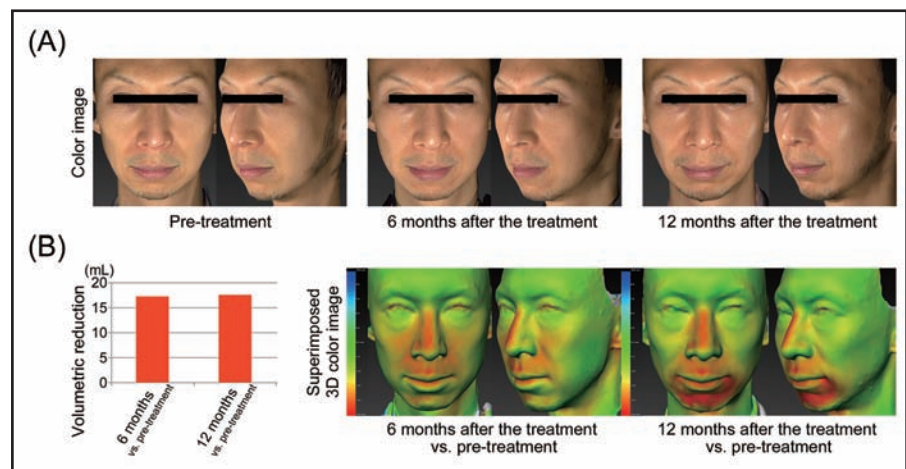


Figure 2. A: Pictured here is a 40-year-old man (Patient No.5 from Table 1). Images from left to right show the appearance pre-treatment to 12 months after the treatment. Improvement of skin texture and dilated skin pores was observed; B: (Left) Volumetric reduction (mL) at 6 and 12 months follow-up point relative to the pretreatment volume. (Right) Superimposed 3D color images that show the volumetric change distribution 6 and 12 months after the treatment compared to pre-treatment. Significant volumetric reduction in the nasal and peri-oral areas was observed.

in digitally controlled increments of 0.1mm. The power was adjustable from 0 to 25W with increments of 1W. The pulse duration could be changed in 30ms increments

(maximal pulse duration was 200ms).¹⁰

The cheek area was treated with a pulse duration of 110ms at 14W and 2.5mm penetration depth. Skin on

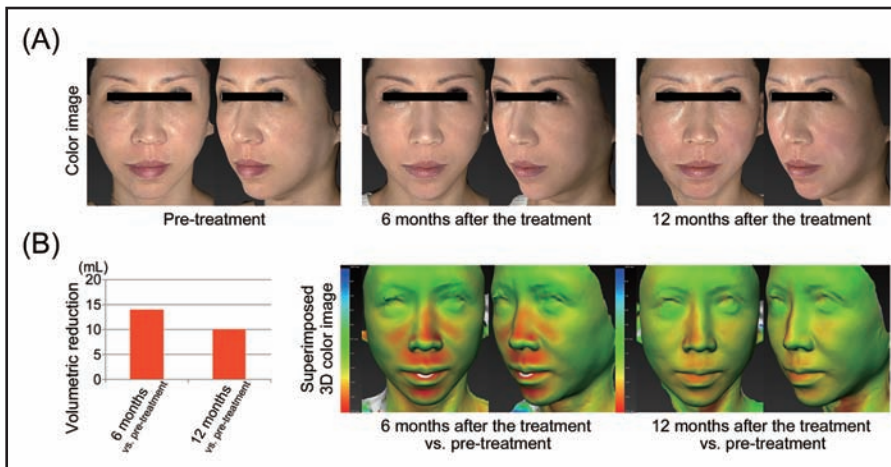


Figure 3. A: Pictured here is a 47-year-old woman (Patient No.11 from Table 1). Images from left to right show the appearance pre-treatment to 12 months after the treatment. Improvement of skin texture and dilated skin pores was observed; B: (Left) Volumetric reduction (mL) at 6 and 12 months follow-up point relative to the pretreatment volume. (Right) Superimposed 3D color images that show the volumetric change distribution 6 and 12 months after the treatment compared to pre-treatment. Significant volumetric reduction in the nasal and peri-oral areas was observed.

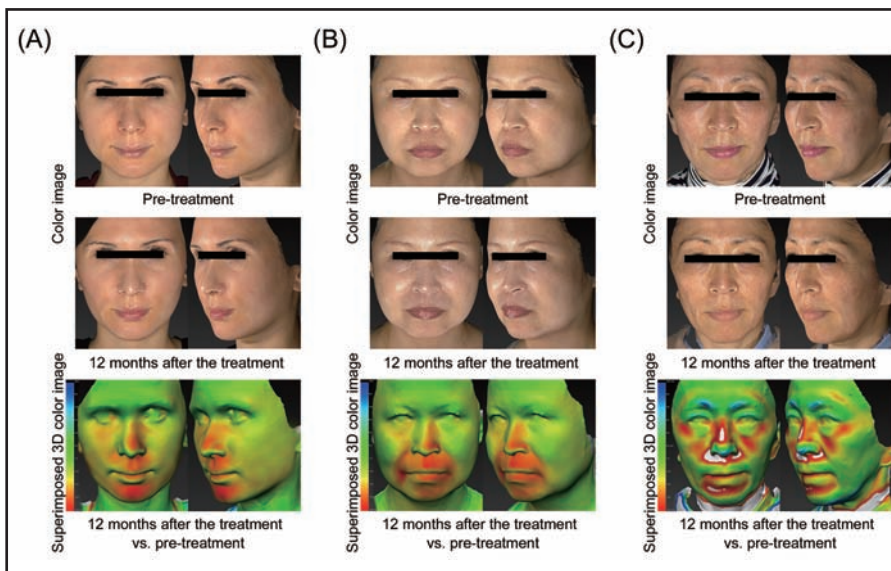


Figure 4. A: Pictured here is a 34-year-old woman (Patient No.3 from Table 1); B: Here is a 50-year-old woman (Patient No.13 from Table 1); C: And here is a 53-year-old woman (Patient No.14 from Table 1). Images from top to bottom show the appearance pre-treatment, and 12 months after the treatment, and superimposed 3D color images that show the volumetric change distribution 12 months after the treatment compared to pre-treatment. Improvement of skin texture and dilated skin pores was observed in the color images. Significant volumetric reduction in the nasal and peri-oral areas was observed in the superimposed 3D color images.

the neck was treated with a pulse duration of 80ms at 12W and 1.5mm penetration depth. Other areas such as the forehead and nasal,

peri-orbital, peri-oral, and mandibular areas were treated with a pulse duration of 80ms, 10W, and 1.5mm penetration depth. All

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 dermis (low impedance) further increased selectivity enhancing RF flow through the dermis. The NIMNRF treatment was performed without oral or intravenous anesthesia or contact cooling. All patients were treated by the same physician.

Objective assessments. Digital photographs and 3D imaging were used as objective assessments and acquired with a Canfield Scientific Vectra Handy 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 image capture sequence of the camera was set to less than 3ms in order to accurately capture facial shapes even if the subject was not perfectly still. The superimposed 3D color schematic representations were used to indicate the volumetric changes in the face between pre-treatment and post-treatment, and shows the varying degrees of tightening in colors that range from yellow to red (red, -5mm change). Green areas indicated no changes to the face, and gray areas observed in nasal and peri-oral areas indicated changes of more than 5mm. The volumetric changes were measured in milliliters based on pre- and post-treatment images of the treated areas. Three-dimensional volumetric

assessments were performed up to 12 months after the treatment. Care was taken to ensure a similar neutral, non-smiling expression in both pre- and post-treatment photographs.

Subjective assessments. Patients completed questionnaires at six and 12 months after treatment and were asked to rate their satisfaction with the results 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* value below 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

The characteristics of the 15 Asian patients enrolled in the current study are illustrated in Table 1. Objective assessments evaluated with the superimposed 3D color schematic representation showed long-lasting and significant volumetric reduction in all patients with one fractional NIMNRF treatment. Representative 2D color images, superimposed 3D color images, and volumetric reductions are shown in Figures 1 through 4.

Significant tightening effects on the lower two-thirds of the face, as well as the cheeks, nasal and perioral areas, lasted for 12 months in all patients. Although the skin of the nasal dorsum was tightened in all patients, volumetric reduction on the nasal tip was not observed in any

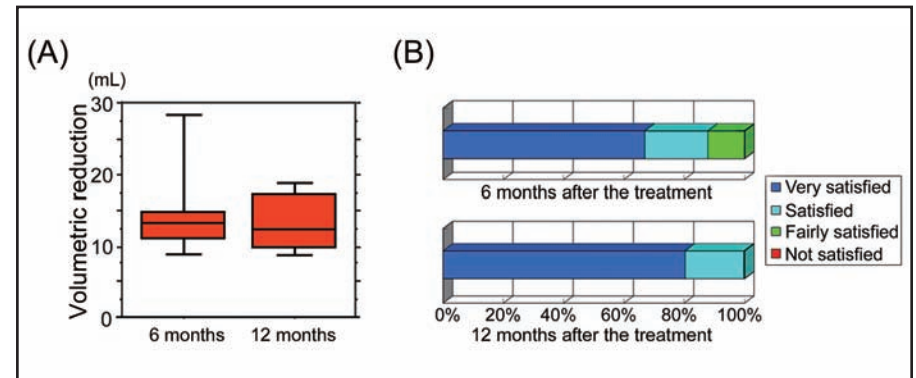


Figure 5. A: This graph illustrates the median volumetric reduction (mL) at 6 and 12 months post-treatment. The box illustrates the interquartile range (IQR) extending from the 25th percentile to the 75th percentile with a line placed at the median (50th percentile). The bottom and top end whiskers show the minimum and maximum data points, respectively; B: This illustrates subjective satisfaction with the results at 6 and 12 months post-treatment [“very satisfied” (blue), “satisfied” (light blue), “fairly satisfied” (green), and “not satisfied” (red)].

patient throughout the study. Furthermore, volumetric reduction on the lower half of the cheek and peri-orbital area was not observed in most patients. The median volumetric reductions at six and 12 months post-treatment were 13.1 and 12.3mL, respectively (Figure 5). Significant volumetric reductions were observed at six and 12 months post-treatment compared with pre-treatment ($p=0.0007$). In contrast, statistical significance was not observed between six and 12 months post-treatment ($p=0.9096$). The tightening effects were stable from 6 to 12 months post-treatment in all patients.

Most patients reported subjective tightening effects and improvement of skin texture and dilated skin pores. Over 80 percent of the patients were either “satisfied” or “very satisfied” with treatment results based on the 5-point assessment scale of 0 to 4 (average score: 3.53 ± 0.74) at six months post-treatment (Figure 5). Similarly, all of the patients reported being

either “satisfied” or “very satisfied” with the treatment results (average score: 3.80 ± 0.41) at 12 months post-treatment (Figure 5). Overall, treatment was 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 or contact cooling. Complications were minor and transitory, with side effects (i.e., slight burning sensation, mild erythema) resolving within five hours. Post-inflammatory hyperpigmentation (PIH), epidermal burns, and scar formation side effects were not observed throughout the study.

DISCUSSION

The present study demonstrated that fractional NIMNRF treatment is a safe and effective method by which to provide patients with long-lasting skin tightening as evidenced by significant volumetric reduction in this study the author’s previous

study. Significant tightening effects in the cheek, nasal, and peri-oral areas induced by one fractional NIMNRF treatment could be seen in superimposed 3D color schematic representations up to six months in all patients. Significant volumetric reduction and improvement of skin texture and dilated skin pores in the nasal, and peri-oral areas was also observed at 12 months post-treatment.

Interestingly, although nasal and peri-oral skin was tightened, volumetric reduction was not observed on the nasal tip in all patients throughout the study. In the aging nose, the nasal tip can droop secondary to atrophy of underlying bone to produce a relatively prominent dorsal hump.^{11–13} NIMNRF treatment may enable nonsurgical enhancement of the nasal tip projection and shape rejuvenation due to the skin tightening effect on the nasal dorsum and improvement of dilated skin pores.

Although conventional evaluations using 2D color photographs could not show significant tightening effects, 3D volumetric assessment showed precise evaluation of the distribution of volumetric change and most patients reported subjective tightening effects and improvement of skin texture and dilated skin pores.

Significant volumetric reductions were observed at six and 12 months post-treatment compared with pre-treatment, but statistical significance was not observed between six and 12 months post-treatment. These results demonstrate that the

tightening effects induced by NIMNRF are long-lasting. However, this single NIMNRF treatment appeared to be insufficient for tightening and rejuvenation of the lower half of the cheek and treatment of baggy eyelids. Volumetric reduction was observed herein at 12 months rather than six months post-treatment in some patients, suggesting that the transient edematous inflammation phase after NIMNRF treatment might last longer.

Most of the patients in the current study were satisfied with their results, and the treatment was well-tolerated with minimal discomfort even though it was performed without oral or intravenous anesthesia and contact cooling. Although a significant improvement in nasal and peri-oral 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 for tightening and rejuvenation of the lower half of the cheek and treatment of baggy eyelids. Furthermore, this NIMNRF treatment may also offer an alternative method for enhancement of nasal tip projection and nasal rejuvenation as well as skin tightening when several treatments are performed.

Limitations. 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 diet, alcohol, and salt intake, as well as solar ultraviolet

and near-infrared exposure, may affect the changes observed in the current study.

CONCLUSION

The major advantage of this single fractional NIMNRF nasal and peri-oral skin tightening system is its long-lasting high efficacy. This technique produced minimal complications and downtime and few side effects. Overall, this noninvasive fractional NIMNRF approach provides safe, long-lasting, and effective treatment of nasal and peri-oral skin tightening.

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