Radiofrequency Microneedling for Skin Tightening of the Lower Face, Jawline, and Neck Region

Lynhda Nguyen, MD,* Marco Blessmann, MD,† Stefan W. Schneider, MD,‡ and Katharina Herberger, MD*

BACKGROUND Radiofrequency microneedling (RFMN) treatment is the latest generation of fractional skin rejuvenation methods.

OBJECTIVE To evaluate the efficacy, safety, tolerability and patient satisfaction of RFMN treatment for skin rejuvenation of the lower face and neck area.

MATERIALS AND METHODS A prospective, intraindividual, controlled study. Subjects were treated with a fractional insulated RFMN system with 1 to 3 sessions at intervals of 4 to 12 weeks. Follow-up visits were scheduled on Day 90 and 180 posttreatment. Outcome was assessed by volume analysis of standardized 3-dimensional imaging, and validated clinical scales were rated by the physician, a blinded investigator, and patients.

RESULTS Thirty patients (mean age 55.5 years, Fitzpatrick skin type I–IV) were included. Mean submental volume difference was -4.72 cm^3 (± 10.07 cm^3; range -26.65 cm^3 to $+16.01$ cm^3). Physician, blinded investigator, and subjects rated the clinical outcome as highly improved. Mean pain intensity was 5.61/10 on Numeric Rating Scale. Beside slight swelling and redness, no relevant downtime has been observed.

CONCLUSION Fractional RFMN treatment is a safe and effective technique for rejuvenation of the lower face, jawline, and neck region. Sufficient pain management should be provided. Data indicated low to no downtime and high patient satisfaction.

The aging of the lower face, jawline, and neck area is characterized by the formation of wrinkles and fine lines as well as a loss of a defined jawline. Aging is a complex process in which different anatomical layers and tissues undergo specific changes. Aesthetic procedures should ideally address the different layers to achieve a natural clinical outcome. Although surgical face-lifts remain one of the most effective methods for facial rejuvenation, many patients seek for minimally invasive alternatives due to associated recovery time, morbidity rate as well as direct and indirect financial implications. Given the widespread interest to improve the aging face and neck region, various minimally invasive laser and energy-based devices have been quickly established as essential features in medical and aesthetic medicine. Chemical peels and lasers have shown to be efficient but are associated to a long downtime and multiple short- and long-term adverse events. Especially patients with Fitzpatrick skin type III to VI are often concerned of post-inflammatory hypopigmentation and hyperpigmentation.[1]

First described by Manstein and Anderson, fractional treatment methods have revolutionized the field of laser medicine.[2] Fractional radiofrequency microneedling (RFMN) is one of the latest generations of fractional techniques for treating the aging skin. Coagulation zones are generated by applying high-frequency and frequency-modulated energy through insulated or noninsulated microneedle electrodes into the dermis. Subsequent wound healing leads to neoangiogenesis and stimulation of collagen and elastin remodeling.[3,4] Previous clinical studies on treating acne scars using RFMN demonstrated to be effective in dermal volumizing.[5,6]

Despite the promising approach of RFMN treatment, no prospective clinical trials have been conducted, yet that investigated the efficacy of RFMN treatment with insulated microneedles for rejuvenation. The aim of the present study was to evaluate the efficacy, safety, tolerability, and patient satisfaction of RFMN treatment with insulated microneedles in patients with photoaged skin laxity and wrinkles of the lower face, jawline, and neck region.

*From the *Laser Department, Department for Dermatology and Venereology, University Medical-Center Hamburg-Eppendorf, Hamburg, Germany; Departments for †Plastic, Reconstructive and Aesthetic Surgery, and ‡Dermatology and Venereology, University Medical-Center Hamburg-Eppendorf, Hamburg, Germany*

The authors have indicated no significant interest with commercial supporters.

The radiofrequency microneedling system Genius was provided by Lutronic Medical Systems. K. Herberger has received lecture fees from Lutronic Medical Systems.

Address correspondence and reprint requests to: Lynhda Nguyen, Laser Department, Department for Dermatology and Venereology, University Medical-Center Hamburg-Eppendorf, Martinistrasse 52, 20246 Hamburg, Germany, or e-mail: l.nguyen@uke.de

http://dx.doi.org/10.1097/DSS.0000000000003607

Methods and Materials

Study Design

This study was designed as a prospective, intraindividual controlled, single-center clinical trial. It was approved by the local ethics committee (PV7392) and conducted in accordance with the Declaration of Helsinki. Patients from the dermatologic Laser Department at the University Medical-Center Hamburg-Eppendorf were recruited. Inclusion criteria were male or female subjects from the age of 35 years with

presence of skin laxity, wrinkles, and fine lines. Exclusion criteria were history of surgical procedures in the head and neck region in the last 6 months, history of resurfacing procedures in the last 2 months, history of injectables in the last 4 weeks as well as tendency to excessive scarring and significant scarring and lesions of the region of interest. Patients with body weight change greater than 5% of baseline measurement at the final control visit accounted for exclusion from volume assessment. After informed consent, 1 to 3 treatment sessions at intervals of 4 to 12 weeks were delivered. Subjects were scheduled for follow-up visits at Day 90 and 180 after final treatment session.

Treatment Protocol

Before each treatment session, subjects received topical anesthesia (23% lidocaine, 3.5% tetracaine, and 3.5% tetracaine-HCl) under occlusion for at least 40 minutes. Provided there were no contraindications, oral analgesic (ibuprofen 800 mg or metamizole 36° [500 mg/mL]) was administered pretreatment. Anesthetic ointment was thoroughly cleansed from each indicated area. The region was disinfected with Octenisept® solution (Schülke & Mayr GmbH, Norderstedt, Germany) and then dried with sterile compresses. Subjects received an RFMN treatment (Genius; Lutronic Medical Systems, Hamburg, Germany) of the lower face, jawline, and neck region. Treatment parameters were selected according to the anatomical location. Three passes were made per region, each with 50% to 70% overlap, starting with the longest needle setting (see parameters in Table 1). In case of severe pain, energy was reduced by 2 to 4 mJ/pin. In this instance, more pulses were used to reach the minimum total energy of 1000 J. A handpiece with an array of 7×7 insulated microneedles (needle tip G49D) was used. Three consecutive passes in alternating horizontal and vertical directions were delivered. Throughout treatment, forced cooled air (Cryo6; Zimmer AestheticDevision) was continuously employed.

Standardized Photographic Documentation

Photographs were taken using a 3-dimensional imaging system (Vectra^{H2}; Canfield Scientific Inc., Bielefeld, Germany). A monotone white background and a single ring flash were used. Outer light sources were shielded. For standardization, 2 orientation planes were set using a laser spirit level (PLL 1 P, Bosch, Stuttgart, Germany). For the frontal plane, the bipupillar line was set, which connects the pupils and runs parallel to the surface of the earth. In addition, the Frankfurt line was used, which passes through the superior margin of the external auditory meatus and the inferior margin of the orbit and runs parallel to the floor. Patients were photographed with closed mouth and relaxed facial expression and were advised to remove decorative cosmetics.

Volume Measurement

Intraindividual volume differences between baseline (Day 0) and last follow-up visit (Day 180 posttreatment) were performed using the Vectra Analysis Module software (VAM, Vectra^{H2}; Canfield Scientific Inc.). Measurements of this software have been shown to have an accuracy of 5 to 20 μm.[7] Submental area was defined using the mentum, mandibular angle, sternocleidomastoids, and laryngeal prominence as anatomical reference points[8] (Figure 1). Volume difference was calculated using the automated analysis algorithm by the VAM software.

Clinical Outcome Assessments

Validated assessment scales were applied by patients, physician, and a blinded, independent investigator based on photographs of baseline and scheduled follow-up visits. Global Aesthetic Improvement Scale (GAIS) was determined, which is a 5-point rating scale ranging from 0 (very much improved) to 4 (worse). Melomental folds were evaluated using a 5-point severity scale (0 = no visible folds to 4 = extremely long and deep folds).[9] For the jawline and neck region, a validated 0 to 4 scale was obtained (0 = no sagging to 4 = very severe sagging).[10,11] For the analysis, difference of the ratings between baseline and follow-up visits were determined.

Safety and Tolerability Assessment

Patients indicated their pain intensity during and 15 minutes after each session using the Numeric Rating Scale (NRS) ranging from 0 (no pain) to 10 (unbearable pain). Any adverse events including erythema, edema, dyspigmentation, and scar formation were documented and treated accordingly.

TABLE 1. Treatment Protocol

Pass	Neck	Jawline/Submental	Lower Face
1st pass	1.8 mm 34 mJ/pin	2.3 mm 50 mJ/pin	1.5 mm 34 mJ/pin
2nd pass	1.5 mm 30 mJ/pin	1.9 mm 50 mJ/pin	1.2 mm 26 mJ/pin
3rd pass	1.0 mm 26 mJ/pin	1.5 mm 40 mJ/pin	1.0 mm 18 mJ/pin

Total energy of 1,000 to 1,400 Joules for the lower face, jawline, and neck region was targeted with an overlap of 50% to 70% per pass. In cases of high pain intensity, energy was decreased by 2 to 4 mJ/pin.

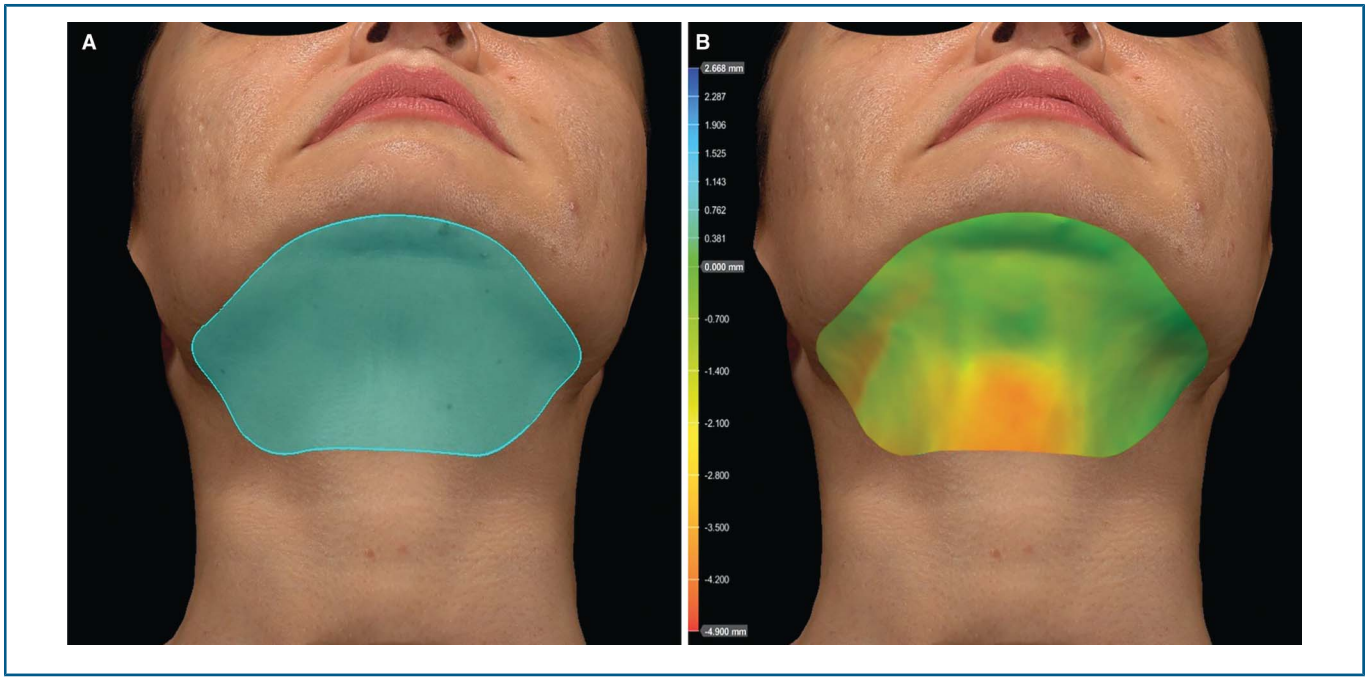

Figure 1. Volume measurement of submental region. (A) Selected submental area. (B) Color-coded volume difference on Day 180 posttreatment to baseline.

Patient Satisfaction Assessment

On Day 180 posttreatment, patients assessed their satisfaction using a 5-point scale: 0 = unsatisfied to 4 = very satisfied. Additionally, they were asked whether they would recommend the treatment or not.

Statistical Analysis

Statistical evaluation was performed using Microsoft Excel (Version 16.56; Microsoft Cooperation, Redmond, USA) and MATLAB software (Version 9.11; The Mathworks Inc.). If not stated otherwise, the paired *t*-test was applied to compare the mean values of each individual. The unpaired *t*-test was used to determine the difference in mean between groups. *p*-values $<.05$ were considered significant. Descriptive data were presented as mean values ± standard errors of the mean (SEM) and ranges.

Results

Baseline Characteristics

Among 30 patients who initially enrolled, 29 completed the entire trial. One patient was excluded due to jawline augmentation. During the period of the trial, 2 patients reported ±5% weight changes. All patients were female with a mean age of 55.9 ± 8.7 years. Mean body mass index (BMI) was 22.63 ± 3.18 kg/m^2. Mean number of pulses performed for each patient was 1,103.6 (±501.6; range 455–2,737). Subject demographics are represented in Table 2.

Efficacy

Evaluation of 3-dimensional photographs revealed significant changes to baseline. One patient was excluded from analysis due to inconsistent head and neck positioning between baseline and follow-up images. Two patients who reported body weight change of ±5% to baseline were excluded from volumetric analysis. Thus, 3-dimensional images of 26 patients were evaluated. Mean submental volume difference was −4.72 cm^3 (±10.07 cm^3; range −26.65 cm^3 to +16.01 cm^3).

Subdivision into group with moderate-to-severe skin laxity −10.08 cm^3 (±7.6 cm^3, range −26.65 cm^3 to +8.05 cm^3; n = 16) and group with minimal skin laxity +3.6 cm^3 (±7.6 cm^3; range −7.98 cm^3 to +16.01 cm^3; n = 10) revealed a highly significant difference between them ($p < .0001$).

A correlation to the number of treatment sessions could be observed: After 1 session, mean volume difference was −3.63 cm^3 (±10.3 cm^3; range −26.65 cm^3 to +12.87 cm^3). After 2 sessions, patients experienced a mean submental volume loss of −6.81 cm^3 (±8.75 cm^3; range −16.83 cm^3 to +8.59 cm^3). Patients who undergone 3 sessions were measured to have a mean volume difference of −8.65 cm^3 (±4.63 cm^3; range −13.98 cm^3 to −5.67 cm^3). However, due to small sample size, no statistical significance could be determined.

Figures 2–4 show representative patients at baseline and 180 days after last treatment session.

Assessments for efficacy are demonstrated in Table 3. At Day 90 posttreatment, overall appearance as well as the melomental region, jawline, and neck area improved as determined by the patients, the physician, and blinded investigator. Interestingly, appearance was rated even higher on Day 180 posttreatment.

Adverse Events

All patients experienced posttreatment transient mild-to-moderate edema and erythema. Patients reported a mean pain NRS score of 5.61 (±1.91). After 15 minutes, pain

TABLE 2. Subject Demographics	
Sex (female/male)	29/0
Mean age [yr] (range)	55.9 ± 8.7 (38–75)
Fitzpatrick skin type (*n*)	I (2); II (20); III (6); IV (1)
Glogau scale type (*n*)	I (0); II (9); III (19); IV (1)

degree decreased to 0.7 (±1.16). During the course of study, no serious or persistent adverse events could be observed. Four cases of perioral dermatitis with pustules and itchiness were documented, which regressed spontaneously after 3 to 4 days. One of them further experienced temporary hematoma at the orbital rim.

Patient Satisfaction

Most patients were very (65%) or mainly (95%) satisfied. Five percent indicated moderate satisfaction. All patients would recommend the treatment.

Discussion

This present study is the first prospective, intraindividual controlled clinical trial that examined the efficacy, safety, tolerability, and patient satisfaction during and after RFMN treatment with insulated needles using subjective assessments as well as objective, 3-dimensional analysis.

During the course of study, submental volume decreased substantially. Especially patients with moderate-to-severe submental skin laxity benefited from RFMN compared with patients with minimal submental skin sagging. Both physician and independent blinded investigator reviewed the clinical outcome as significantly improved compared with baseline. Interestingly, assessment scales were rated higher on Day 180 posttreatment than on Day 90 posttreatment, implicating a continuing collagen and elastin remodeling. Effect latency should be the subject of patient education to ensure patient satisfaction. Furthermore, this

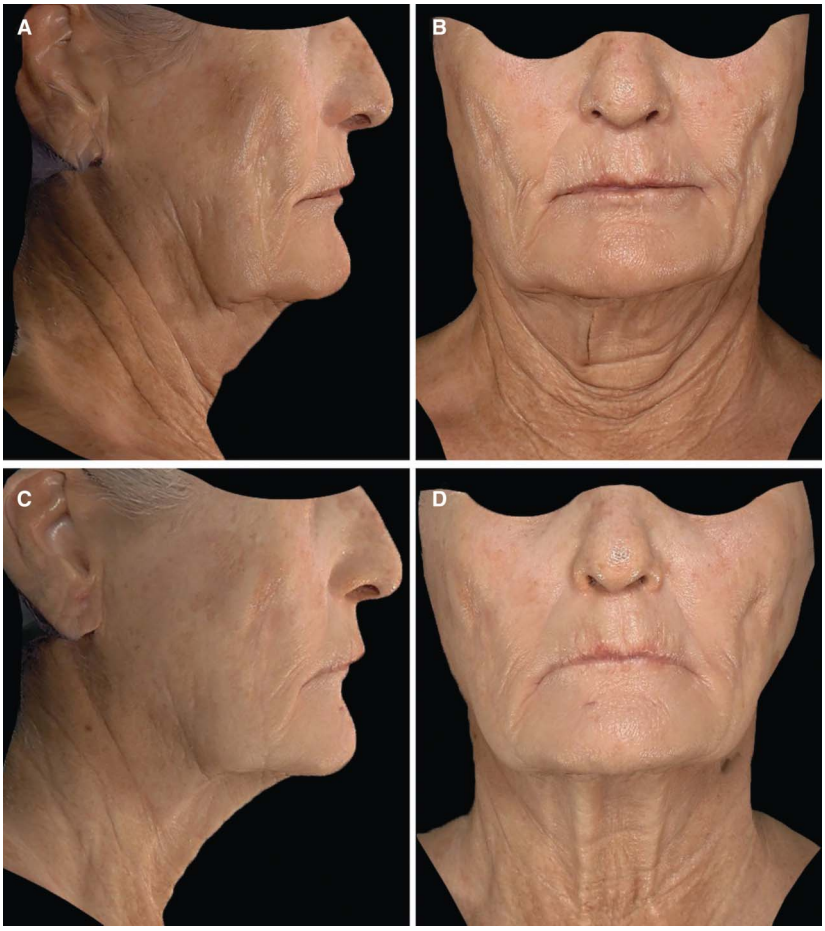

Figure 2. Substantial improvement of skin texture and wrinkles as well as lifting of the lower face could be observed of a 74-year-old patient. Appearance (A and B) before and (C and D) 180 days after 2 radiofrequency microneedling treatment sessions.

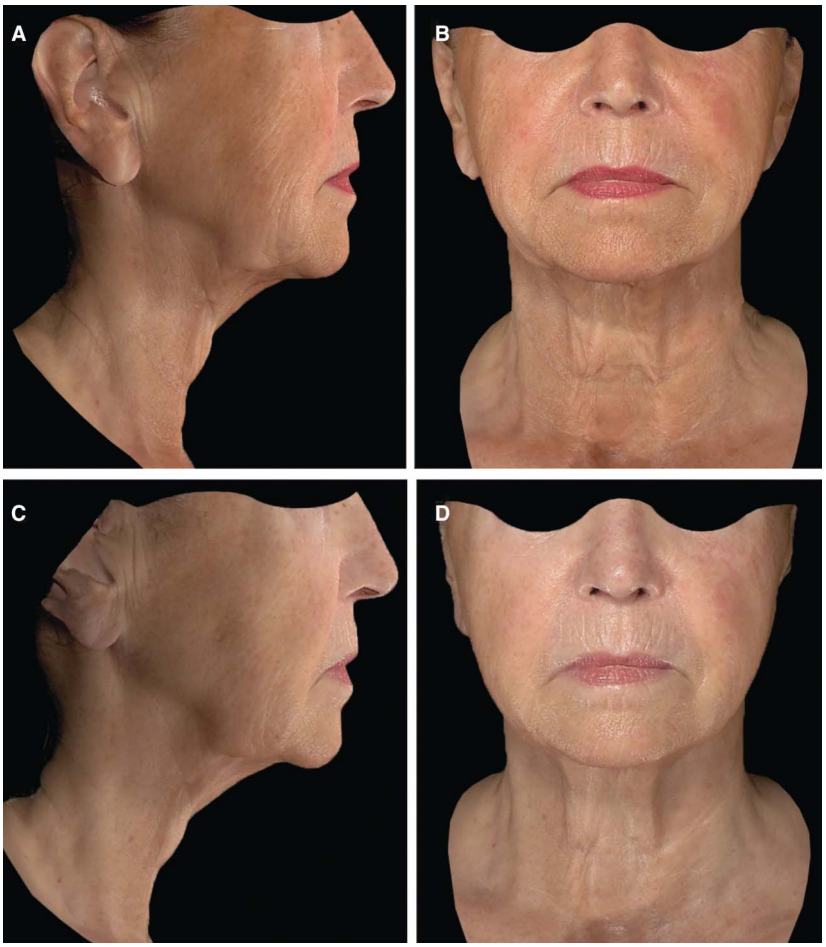

Figure 3. Seventy-five-year-old woman (A and B) before and (C and D) 180 days after last radiofrequency microneedling treatment session. Patient received 2 sessions. Significant skin tightening and contour improvement of the jawline could be determined.

observation suggests that treatment intervals of at least 2 to 3 months possibly should be chosen to allow induced dermal fiber synthesis to progress efficiently. Currently, the ideal treatment interval remains unclear due to lack of data. The study results indicated that efficiency decreases with number of treatment sessions. However, due to small sample size, further investigations are preferred. The authors hypothesize that a specific amount of total energy per surface area should be applied to the region of interest to provide high efficacy.

Mild-to-moderate erythema and swelling were reported immediately after treatment. During the period of trial, except for 4 cases with perioral eczema and 1 case of hematoma, no severe or longtime adverse events could be observed, especially no post-inflammatory dysopigmentation or scar formation. Compared with other minimally invasive skin tightening techniques, such as CO_2 laser resurfacing, RFMN showed a good safety profile. Despite topical anesthetic before treatment and constant air cooling as well as systemic analgesics, degree of pain was rated moderate to high. The high incidence of pain is a limitation of treatment and should be considered in treatment planning. For treatment, the authors extended the exposure time of anesthetic ointment to at least 60 minutes, removed the gel shortly before treating each region, and reduced the number of regions treated in one session. Even though these measures were not the subject of the study and thus not investigated in a structured manner, a better pain profile was shown. Overall, patients rated high satisfaction.

In recent years, the number of minimally invasive skin rejuvenation procedures has increased by leaps with respect to invasive procedures, reflecting people's desire to slow down aging processes in a gentle way and thus achieve natural clinical results.[12] So far, only few trials on the efficacy of RFMN treatment have been conducted, mostly focusing on atrophic acne scars.[5,6,13] To date, there are limited data on RFMN treatment for facial wrinkle reduction and skin tightening of the lower face, mostly using noninsulated microneedles.[14–17] Overall, these trials reported high efficacy as well as minimal complications and low downtime of noninsulated RFMN systems. Most of the previous studies based their evaluation on clinical ratings and subjective patient assessments, whereas in this study, volume changes were additionally calculated using computer-aided, 3-dimensional image analysis.

The degree of treatment effects varied significantly throughout the patients. One factor was the presence of moderate-to-severe skin laxity in the submental region,

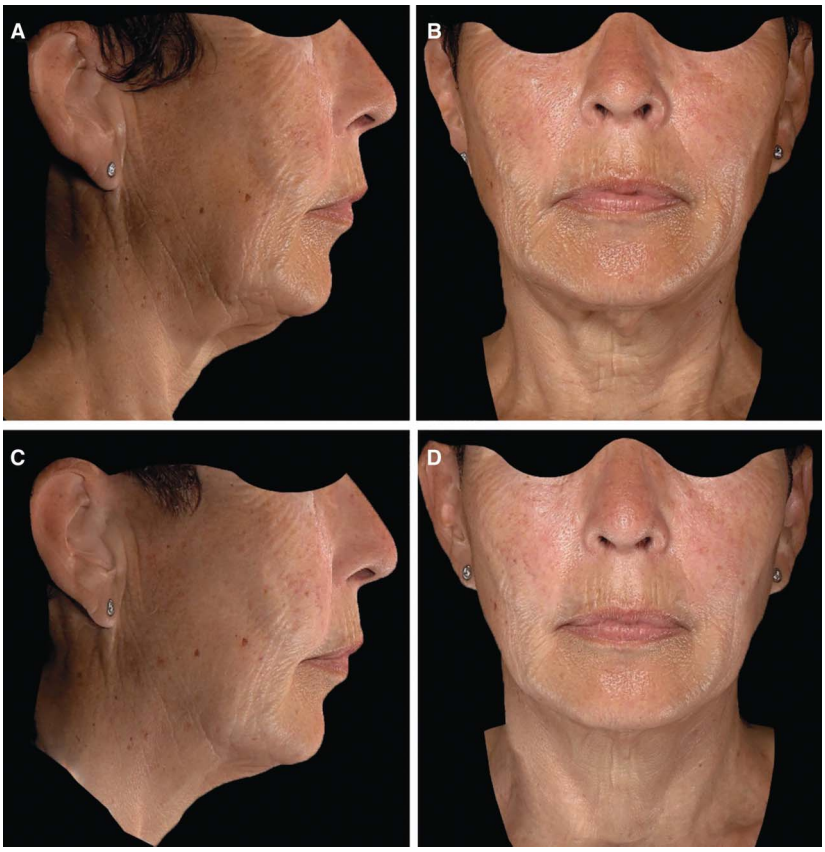

Figure 4. Sixty-three-year-old woman (A and B) before and (C and D) 180 days after last radiofrequency microneedling treatment session. Patient received 2 sessions. Significant skin tightening and smoothening of skin texture could be observed.

which acted beneficial for treatment response. However, due to the relatively small number of cases, no predictors of good response could be surely identified. The authors excluded patients with high body weight change from volume calculation who may have a disproportionately large effect. Obtained photo-numeric assessments provided significant clinical effects although, retrospectively, more sensitive outcome assessment scales would have been preferable. The authors observed a lower rating of outcome in those patients who were assessed in the

TABLE 3. Assessment of Clinical Outcome Rated by the Patients, Physician, and the Independent Investigator

	Day 90 Posttreatment	Day 180 Posttreatment	*p*
Global Aesthetic Improvement Scale (GAIS)			
Patient	2.13 (±0.64)	2.54 (±0.52)	<.05
Physician	2.62 (±0.51)	2.63 (±0.76)	.379
Blinded investigator	2.00 (±0.53)	2.32 (±0.75)	<.05
Melomental region			
Physician	0.36 (±0.67)	0.79 (±0.7)	<.05
Blinded investigator	0.29 (±0.47)	0.45 (±0.51)	.1
Jawline			
Physician	0.45 (±0.52)	0.71 (±0.85)	.19
Blinded investigator	0.35 (±0.61)	0.75 (±0.55)	<.05
Neck region			
Physician	0.5 (±0.53)	0.53 (±0.87)	.255
Blinded investigator	0.69 (±0.79)	0.65 (±0.67)	.225

Differences between baseline (Day 0) and Day 90 as well as baseline (Day 0) and Day 180 posttreatment were calculated. *p*-value between rating on Day 90 posttreatment and Day 180 posttreatment was determined.

summertime. This may be due to the fact that tanned skin may provide a more prominent appearance of skin texture and wrinkles and thus give the illusion of overall lower aesthetic improvement.

In this trial, the authors used an insulated RFMN system that delivers high-intensity focused radiofrequency energy in a fractional pattern into the dermis. By using insulated microneedles, thermal energy is only conducted through the tip of the needles. Although lasers deliver energy to chromophores through selective photothermolysis, the heat produced by the RFMN device originates from electron movement and conductivity of the targeted tissue. Thus, the treatment is independent from skin type or color, and it is possible to bring a large amount of energy into the dermis, although the epidermis remains protected from heat.[18]

This study has to be seen in light of some limitations. First, most of the enrolled patients had a similar Fitzpatrick skin type and ethnicity. Furthermore, the authors could not exclude the influence of patients' lifestyle habits like diet, stress, and UV exposure. A limitation of the study can be seen in the susceptibility of the volume measurement, where small changes in posture can lead to measurement inaccuracies. Through structured photographic documentation with the aid of adjusting the head positioning using a laser spirit level, the authors have compensated this issue. Although significant improvement was observed, further studies are necessary to pursue optimal number of sessions and treatment parameters.

The authors conclude by 3-dimensional analysis, blinded outcome evaluation, and patients' assessment that RFMN treatment is an effective and safe method for wrinkle reduction and skin tightening of the lower face, jawline, and neck region. It provided low to no downtime, minimal side effects and high satisfaction of patients. Focused thermal energy in the dermis forms coagulation zones resulting in wound healing and collagen and elastin remodeling. Thus, pain intensity during treatment was observed to be high with need for local cooling, analgesics, and a proper exposure time of anesthetic gel at least 60 minutes before treatment as well as limitation of treatment time due to smaller areas. Radiofrequency microneedling treatment could be proposed to be an effective combination or in some cases an alternative to the conventional surgical lifting of the face and neck and a viable option for patients with skin of color who are frequently concerned about post-inflammatory dyspigmentation and longer social downtime.

Conclusion

Fractional radiofrequency microneedling treatment is a safe and effective method for skin rejuvenation of the lower face, jawline and neck region. A sufficient pain management should be provided. By stimulating collagen and elastin remodeling through thermal energy, a significant improvement of skin texture, wrinkles, and skin laxity is afforded.

References

1. Metelitsa AI, Alster TS. Fractionated laser skin resurfacing treatment complications: a review. *Dermatol Surg* 2010;36:299–306.
2. Manstein D, Herron GS, Sink RK, Tanner H, et al. Fractional photothermolysis: a new concept for cutaneous remodeling using microscopic patterns of thermal injury. *Lasers Surg Med* 2004;34:426–38.
3. el-Domyati M, el-Ammawi TS, Medhat W, Moawad O, et al. Radiofrequency facial rejuvenation: evidence-based effect. *J Am Acad Dermatol* 2011;64:524–35.
4. Meyer PF, de Oliveira P, Silva FKBA, da Costa ACS, et al. Radiofrequency treatment induces fibroblast growth factor 2 expression and subsequently promotes neocollagenesis and neoangiogenesis in the skin tissue. *Lasers Med Sci* 2017;32:1727–36.
5. Emam AAM, Nada HA, Atwa MA, Tawfik NZ. Split-face comparative study of fractional Er:YAG laser versus microneedling radiofrequency in treatment of atrophic acne scars, using optical coherence tomography for assessment. *J Cosmet Dermatol* 2022;21:227–36.
6. Kwon HH, Park HY, Choi SC, Bae Y, et al. Combined fractional treatment of acne scars involving non-ablative 1, 550-nm erbium-glass laser and micro-needling radiofrequency: a 16-week prospective, randomized split-face study. *Acta Derm Venereol* 2017;97:947–51.
7. Meier JD, Glasgold RA, Glasgold MJ. 3D photography in the objective analysis of volume augmentation including fat augmentation and dermal fillers. *Facial Plast Surg Clin North Am* 2011;19:725–35, ix.
8. Bernstein EF, Bloom JD. Safety and efficacy of bilateral submental cryolipolysis with quantified 3-dimensional imaging of fat reduction and skin tightening. *JAMA Facial Plast Surg* 2017;19:350–7.
9. Carruthers A, Carruthers J, Hardas B, Kaur M, et al. A validated grading scale for marionette lines. *Dermatol Surg* 2008;34(Suppl 2): S167–72.
10. Narins RS, Carruthers J, Flynn TC, Geister TL, et al. Validated assessment scales for the lower face. *Dermatol Surg* 2012;38:333–42.
11. Sattler G, Carruthers A, Carruthers J, Flynn TC, et al. Validated assessment scale for neck volume. *Dermatol Surg* 2012;38:343–50.
12. Heidekrueger PI, Juran S, Ehrl D, Aung T, et al. Global aesthetic surgery statistics: a closer look. *J Plast Surg Hand Surg* 2017;51: 270–4.
13. Vejjabhinanta V, Wanitphakdeedecha R, Limtanyakul P, Manuskiatti W. The efficacy in treatment of facial atrophic acne scars in Asians with a fractional radiofrequency microneedle system. *J Eur Acad Dermatol Venereol* 2014;28:1219–25.
14. Park MY, Hwang S, Chun SI, Kim SM, et al. A prospective, split-face, comparative study of combined treatment with fractional microneedle radiofrequency and nonablative 1927-nm fractional thulium fiber laser for wrinkle treatment. *Dermatol Surg* 2021;47:e101–5.
15. Kauvar ANB, Gershonowitz A. Clinical and histologic evaluation of a fractional radiofrequency treatment of wrinkles and skin texture with novel 1-mm long ultra-thin electrode pins. *Lasers Surg Med* 2022;54: 54–61.
16. Tanaka Y. 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. *Lasers Surg Med* 2015;47:626–33.
17. Clementoni MT, Munavalli GS. Fractional high intensity focused radiofrequency in the treatment of mild to moderate laxity of the lower face and neck: a pilot study. *Lasers Surg Med* 2016;48:461–70.
18. Weiner SF. Radiofrequency microneedling: overview of technology, advantages, differences in devices, studies, and indications. *Facial Plast Surg Clin North Am* 2019;27:291–303.