Efficacy of Micro-needling Radiofrequency in the Treatment of Submental Laxity

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Abstract

Neck skin aging including the submental area is becoming more apparent given its contrast to facial skin in the era of facial rejuvenation therapy. A micro-needling radiofrequency (RF) provides skin resurfacing and subdermal collagen remodeling. Coated tip which was wrapt by an insulator at the proximal end can protect the superficial skin from heat, thus the energy runs through deep skin. This technique is used for treating various cosmetic problems such as skin laxity, wrinkles, acne scars, facial telangiectasia, and hyperpigmentation The objective of the study was to evaluate the efficacy of the radiofrequency micro-needling device to treat submental laxity compared between pretreatment and posttreatment. Twenty-three participants aged over 20 years (average age of 53 ± 13.3 SD, age range 25-66 years old) who had submental skin laxity scale grade II-V were treated with micro-needling radiofrequency on both sides of the submental area. The study was done 2 times at a-month intervals. The fractional 24-coated pins tip which has a 3 mm depth was used on the submental area. The RF energy level is 15 millijoules in all participants. Two blinded dermatologists evaluated the photographs of pretreatment and post-treatment. Antera 3D analysis was used to determine the change in skin wrinkles, pores, and textures. Participants' satisfaction scores and side effects were noted. Twenty-three participants completed all the treatment sessions. The subjective and objective evaluation showed the submental skin laxity improvement after the second session from baseline. All participants had transient erythema immediately after the treatment. Prolonged hyperpigmentation but self-resolution was noted in one participant and another participant had itching for 1 week. micro-needling RF device is one of choice for skin tightening due to its safety, clinical effectiveness, and satisfaction for the participants.

Keywords: *micro-needling radiofrequency, radiofrequency, submental laxity*

1. Introduction

Skin aging is one of the important aesthetic problems. Neck skin aging including the submental area, an underrecognized field in the past decade, is becoming more apparent given its contrast to facial skin in the era of facial rejuvenation therapy. Ptosis of submental skin is a visible and unpleasing characteristic of skin aging. Age-related alteration of the skin's mechanical properties and the gravitational force have major roles in this phenomenon. Several treatment modalities for neck skin rejuvenation, including submental area, have many choices depending on the problems such as skin laxity, fat accumulation, loss of bony prominence, or other aesthetic problems (Fisher, Varani, & Voorhees, 2008).

Radiofrequency (RF) is used for many cosmetic purposes such as skin tightening, wrinkles, acne scars, facial telangiectasia, and hyperpigmentation (Dayan, Burns, Rohrich, & Theodorou, 2020). The mechanism of action of RF is to induce thermal micro-coagulation zones by using radio wave wavelengths to thus stimulate collagen remodeling in the dermis. Many studies mention the positive outcomes of the efficacy of RF in the treatment of skin wrinkles and laxity (Alexiades-Armenakas, 2013).

There were many studies on the use of radiofrequency for rejuvenating skin, treating face and neck skin laxity, and reducing skin wrinkles, acne vulgaris, and atrophic acne scars. Recently, a study on using RF for submental laxity was conducted. Turer, James and DiBernardo (2021) enrolled 72 subjects with mild to moderate skin laxity in the submental area. All subjects received one treatment at baseline with an average subdermal temperature of 63°C. At Day 90, 72.1% of subjects achieved at least a 20-mm2 lift of the submental area. All Cutometer-measured skin elasticity values showed significant improvement within 180 days. It is

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concluded that the treatment with temperature-controlled monopolar radiofrequency alone is a safe and effective treatment to achieve submental lift for at least 6 months. Another study reported that using bipolar RF to treat submental laxity in 22 participants was a potential option for skin tightening with few side effects (Prapawan et al., 2022).

Microneedle added up with an RF device.was an option to create microwound in the skin.A micro-needling RF is a minimally invasive device that uses ultrafine needles to emit radiofrequency waves into the skin thus triggering the production of elastin and collagen (Tan, Jo, Chapas, Khetarpal, & Dover, 2021).

A prospective, double-blind, randomized, controlled, split-face study aimed to evaluate the efficacy and safety of non-insulated RFMN for periorbital wrinkles and the synergistic effect of polynucleotides after non-insulated radiofrequency micro-needling (RFMN). It can be concluded that non-insulated RFMN is safe and effective for treating periorbital wrinkles and can be used as a modality for transdermal drug delivery (Yuri et al., 2022).

Multiple studies illustrated the improvement of facial skin after using micro-needling RF. However, there are no current studies on the use of micro-needling RF for treating submental skin laxity. Therefore, this study aimed to evaluate the efficacy of radiofrequency micro-needling devices in treating submental skin laxity. The submental area received 24-coated pin tips with RF energy levels of 15 millijoules. The treatment was performed 2 times at an interval of 4 weeks and the same type of pin on its side was used. The results from pretreatment and 1-month post-treatment in all participants were evaluated by subjective and objective measurements. The authors expect a better outcome after treatment with minimal complications and the participants can have their normal daily routine.
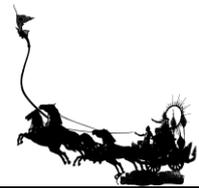
2. Objectives

1)To evaluate the efficacy of micro-needling radiofrequency in the treatment of submental skin laxity by two-blinded dermatologists' assessment

2)To evaluate the improvement of the skin wrinkles, textures, and pores by using Antera 3D analysis

3)To evaluate the satisfaction of the physician and the participants

4)To evaluate the side effects and adverse events

3. Materials and Methods

Twenty-three participants with neck laxity from grade II to IV following the Submental Skin Laxity Grade Scale (Figure 1) were treated in the Dermatology Department of Benchakitti Park Hospital, Bangkok, Thailand from November 2022 to January 2023. The study protocol was approved by the Human Research Ethics Committee of Thammasat University (MTU-EC-OO-0-175/65).

Table 1 Submental Skin Laxity Grade scale

Grade	Description
1	None
2	Mild skin laxity
3	Moderate skin laxity
4	Severe skin laxity

Figure 1 Photonumeric guide for the assessment of skin laxity using the Submental Skin Laxity Grade Scale
(Humphrey et al., 2016)

3.1 Inclusion criteria:

        1) Participants aged 20 years and older

        2) Participants with grade II-IV on submental skin laxity

        3) Fitzpatrick skin type II-V

3.2 Exclusion criteria:

        1) History of botulinum toxin injection at the neck within 6 months before the study

        2) History of filler injection or any soft tissue augmentation procedures at the neck not later than 1 year prior to the study

        3) History of using energy-based devices at the neck for rejuvenation not later than 2 years prior to the study

        4) History of taking isotretinoin not later than 6 months before the study

        5) Active skin infection or skin disease on the neck skin

        6) History of abnormal scars or keloids

        7) Precancerous skin or skin cancer

        8) Thyroid disease

        9) Any nervous system disorders (e.g. cervical dystonia, myasthenia gravis, Lambert-Eaton syndrome, Amyotrophic lateral sclerosis)

        10) Metal plaques or screw insertion

        11) Pacemaker or internal defibrillator insertion

        12) Taking estrogen or progesterone

        13) Pregnancy or breastfeeding

        14) A body mass index (BMI) of more than 25

        15) Personality disorders or psychiatric conditions that could affect the self-assessment questionnaires or compliance with follow-up

3.3 Sample size calculation

        The sample size was calculated using Cochran's formula.

$$n = \frac{Z^2 p(1-p)}{d^2}$$

        Z = 1.96 (for a 95 percent confidence level)

        p = 0.95 (the results of the previous study which showed the improvement of the neck skin laxity after the treatment by fractional bipolar radiofrequency device (Alexiades-Armenakas, 2013).

        d =0.10 (The research assumed that the acceptable margin of error for the proportion being estimated was not more than 10%)

N = 18

Drop-out subjects = 25%

As a result, the sample size of the present study was 23.

3.4 Study design

A prospective, clinical trial, full submental area.

3.5 Equipment

Twenty-four coated pin tips of a radiofrequency micro-needling device were used (Fractora[R]; Invasix, Irvine, CA USA).

Parameters for treatment in this study:

Configuration	:	6x4 coated tips
Pin length	:	3000μ
Ablation depth (mm)	:	3
RF energy levels	:	15 millijoules/pin

3.6 Study protocol

The objectives, materials and methods, and potential adverse effects were provided to individuals who were eligible and willing to participate in the study. According to inclusion criteria, physicians l performed history taking and physical examination before enrollment. Standardized 2D photographic documentation and Antera3D^{TM} images using identical camera settings, lighting, and patient positioning were obtained at baseline and again following the treatment (2 times for all participants; at the 1st visit: baseline (before treatment) and at the 2nd visit (1 month after the second treatment)). All digital photographs were acquired with a facial photo fixture using a SonyA7II (Sony, Japan), and images of skin wrinkles, textures, and pores were collected by using Antera3D^{TM}. The fixture ensured a collection distance and fixed angles between the patient and the camera. The imaging station provided preset camera angles for the frontal, 45° left lateral, 45° right lateral, 90° left lateral, and 90° right lateral regions through the total profile and an identical set in set positions on the camera ensured even illumination of all parts of the neck and the ability to examine subjects under controlled lighting.

The submental area was anesthetized using topical EMLA cream (2.5% lidocaine and 2.5% prilocaine) about 40 minutes before the procedure. The treated area was cleaned with mild soap and 70% alcohol. Submental areas were treated with a micro-needling fractional RF device by using a 24-coated pin tip. The treatments were delivered in a 20% overlapping pass over the indicated area. Participants were all marked in a standardized manner. Micro-needling RF was performed 2 times at a 1-month interval. Adverse effects were observed by physicians and participants. The participants had to avoid anti-inflammatory drugs or steroid drugs to maximize the healing processes. The petrolatum jelly was allowed to apply onto the participants' neck skin for 7 days after each procedure. After 7 days of each procedure, the participants were allowed to apply only sunscreen and the same plain emollients from start to finish.

3.7 Evaluation of results

3.7.1 Subjective evaluation

3.7.1.1) Two dermatologists who were not involved in the trial compared participants' photographs taken before and after the treatment, viewing them on a computer screen. They were shown front-view and lateral-view photos taken before and after the procedure without knowing when the photographs were taken. The degree of change was assessed on a 4-point scale:

- 0%   defined as no change (score = 0)
- 1-25%   defined as slight change (score = 1)
- 26-50%   defined as mild change (score = 2)
- 51-75%   defined as moderate change (score = 3)

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- >75%   defined as significant change (score = 4)

3.7.1.2) The degree of patient satisfaction was assessed on a 10-point scale (0-10), where 10 points indicated maximum satisfaction while 0 point indicated maximum dissatisfaction. The assessment was performed at the end of the study by asking the patients about their satisfaction. The degree of physician satisfaction (also on a 10-point scale) was based on both clinical observations and photographic results.

3.7.1.3) The adverse effects were assessed by the therapist and participants and recorded after each follow-up visit. The side effects included erythema, edema, erosion, ulceration, the period of debris removal, alteration of pigmentation, scarring, and infection.

3.7.2 Objective evaluation

Antera 3D was used to assess the change of the skin wrinkles, textures, and pores on the submental area. The index of each variable was noted as a number and calculated to compare the change in the same area of each participant.

3.8 Statistical analysis

A statistical evaluation was performed using SPSS® software (SPSS statistics 15.0; Chicago, IL, USA). The demographic data (sex, age, BMI, comorbidity, Fitzpatrick skin type, Submental skin laxity scale, and drug allergy) were analyzed and shown as percentages. Interrater reliability and paired T-test were used to analyze the dermatologists' assessments of a clinical score of improvement and the differences in wrinkles, textures, and pores compared between pretreatment and posttreatment. P-values of <0.05 was employed to evaluate statistical significance. The physician and patient satisfaction scores were expressed in percentages.

4. Results and Discussion
4.1 Results

4.1.1 Clinical results

Twenty-three participants, five males and eighteen females, enrolled in the study. All participants completed 2 sessions of treatment and follow-up visits. The age range was 25 to 66, and the average age was $53\pm$ years. All participants had Fitzpatrick skin type II-V. Submental Skin Laxity Grading Scale was grade 2-4. The participants' demographic data are shown in Table 1.

Table 1 Demographic data of participants (n=23)

Demographic data	n(%)
Gender	
- Male	5 (22%)
- Female	18 (78%)
Age	
mean $\pm$ SD	53 $\pm$ 13.3 SD
(min-max)	(25-66)
BMI (mean $\pm$ SD)	59.4 $\pm$ 12.65 SD
Comorbid	
- No	22 (69%)
- Yes	1 (4%)
Drug allergy	
- No	23 (100%)
- Yes	0
Submental skin laxity grading scale	
2	9 (39%)
3	6 (26%)
4	8 (35%)

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4.1.2 Subjective results

To test the effectiveness of the treatment, an improvement in the mean values of pretreatment to posttreatment according to the dermatologists' evaluation indicated a positive effect of the treatment. The average score of dermatologists' assessment by comparing pretreatment and posttreatment was 1.13 (from a 4-point score scale) as shown in Table 2. Cohen's kappa coefficient was 0.498 (moderate agreement).

The average degree of participants' satisfaction score was 7.7 points (Range = 5 - 10). The degree of the physician's satisfaction score with the results obtained was 4.8 points (Range =1-10).

Table 2 Subjective score assessment

Demographic data	Mean ± SD	Confidence interval
Dermatologist assessment scores		
Doctor 1	1.13 ± 0.81 SD	(0.78, 1.48)[*]
Doctor 2	1.04 ± 1.36 SD	(0.45-1.63)[*]
Average score change	1.09 ± 1.11 SD	(0.61, 1.57)[*]
Cohen's kappa coefficient	0.498	
(Inter-rater reliability)		

Note: [*]Statistically significant

4.1.3 Adverse effects and complications

The average degree of participants' pain score was 4.65 (Range = 1-8).

Immediately following the treatment, all participants developed varying degrees of erythema which spontaneously decreased.

One participant (4.3%) presented hyperpigmentation for 6 weeks from the second treatment which was resolved spontaneously. One participant (4.3%) experienced itching in the entire treated area for 1 week after each treatment which was resolved by using topical steroids and oral antihistamines.

4.1.4 Objective results

The changes in the skin wrinkles, pores, and pigmentation in the submental area were assessed by using Antera 3D camera. The changes in images before and after treatment are presented (Figure 2). The means of the index showed a decrease in the average of all categories of posttreatment compared to pretreatment, which indicated an improvement in overall objective results but no statistical significance. (Table 3)
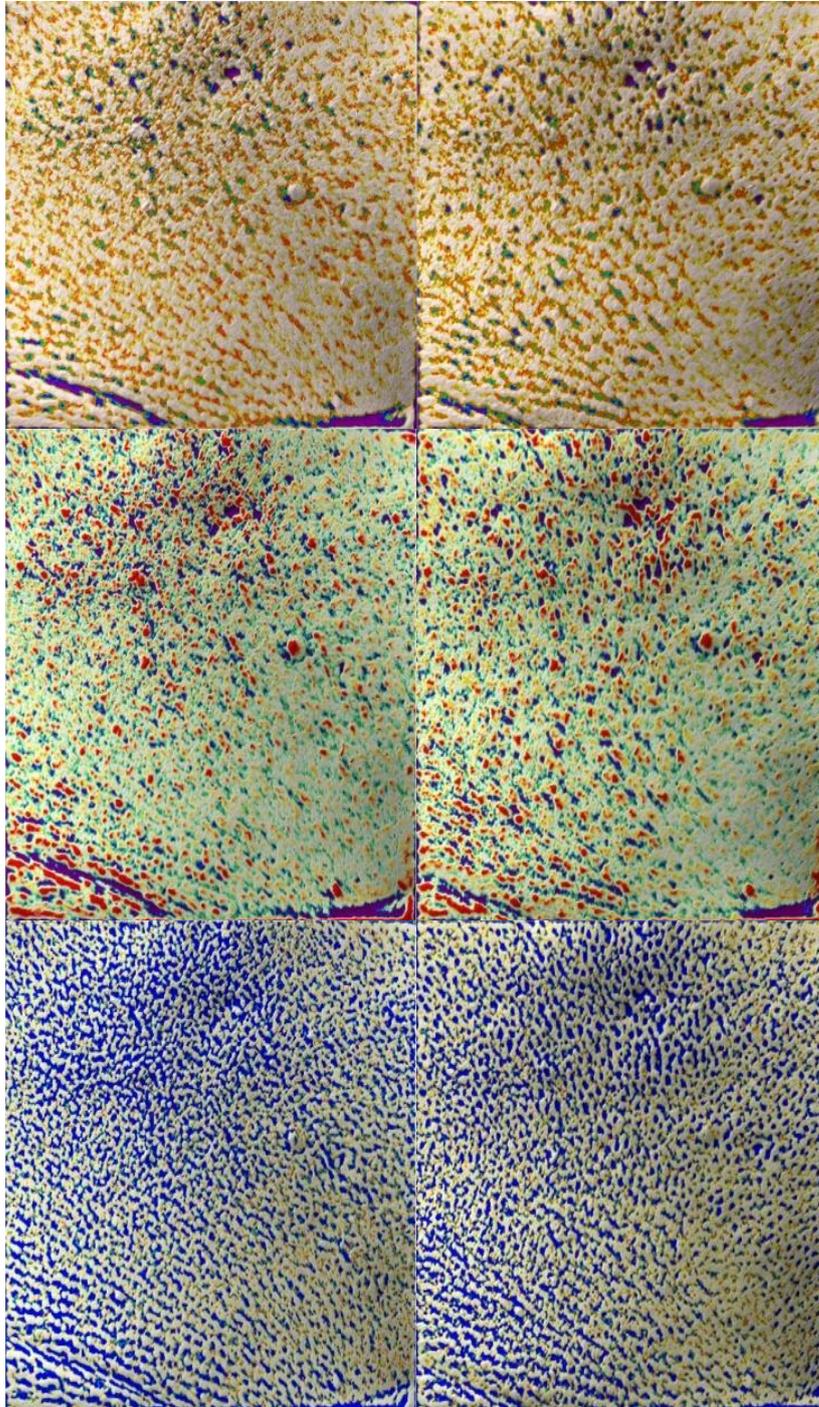
The wrinkles change from Antera 3D camera before treatment (Left) and after treatment 1 month of the 2 sessions of treatment (Right)

The textures change from Antera 3D camera before treatment (Left) and after treatment 1 month of the 2 sessions of treatment (Right)

The pores volume changes from Antera 3D camera before treatment (Left) and after treatment 1 month of the 2 sessions of treatment (Right)

Figure 2 Compared the changes of images using Antera3D analysis

Table 3 Objective score assessment using Antera3D analysis

Category	Mean $\pm SD$	Confidence interval
Wrinkles		
Before treatment	13.72 $\pm$ 4.28 *SD*	
After treatment	13.3 $\pm$ 4.63 *SD*	
Mean change	-0.42 $\pm$ 1.7 *SD*	(-1.15, 0.32)
Textures		
Before treatment	14.47 $\pm$ 5 *SD*	
After treatment	13.96 $\pm$ 5.36 *SD*	
Mean change	-0.51 $\pm$ 2 *SD*	(-1.37, 0.35)
Pores volume		
Before treatment	0.97 $\pm$ 0.73 *SD*	
After treatment	0.9 $\pm$ 0.76 *SD*	
Mean change	-0.07 $\pm$ 0.32 *SD*	(-0.21, 0.07)

4.2 Discussion

One of the major aesthetic issues was skin aging, given its contrast to facial skin in the era of facial rejuvenation therapy. Neck skin aging, especially the submental area, has received less attention in recent years. Submental skin laxity is a noticeable and unpleasant sign of aging skin. The two main factors causing these s phenomena are the gravitational pull and age-related changes in the mechanical characteristics of the skin.

Among the modalities for treating skin wrinkles and laxity, radiofrequency devices are one of the most widely used. RF describes technology that comes as low risk, minimizes downtime, and improves skin structural changes without disruption of skin integrity. According to the mechanism of action, radio frequency micro-needling can use radio wave wavelengths to heat the tissue to a therapeutic endpoint of the thermal micro-coagulation zone, stimulating collagen remodeling in the dermis.

This present study demonstrated the effectiveness and safety of using radiofrequency micro-needling equipment to reduce submental laxity. Micro-needling RF was performed twice, separated by a month. Clinical images taken before and after the treatment were compared by two dermatologists who were blinded to their judgments, with positive outcomes. In terms of objective skin analysis, antera3D was used. Changes in the volume of pores, skin textures, and wrinkles were inclined to have an improvement. The participants were satisfied with the results of the reduction of skin laxity with few complications.

However, the study had some restrictions. Since there were no long-term follow-ups in this investigation, long-term consequences of rejuvenation were not examined. It is necessary for further studies to use a larger sample size. RF energy levels should be further studied at more variable rates. Multiple treatment sessions were recommended to create more obvious visible change. The subjective evaluation by dermatologists might not be a good evaluation method since it had intra-observer variation.

Figure 3 Clinical photographs comparing pretreatment (1A, 1B)
and posttreatment follow-up at 1 month after 2 sessions of treatment (2A, 2B)

5. Conclusion

Fractional radiofrequency with micro needling is a safe and effective modality for mild to moderate submental skin laxity. It yields significant clinical improvement and patient satisfaction with minimal and temporary side effects.

6. Acknowledgements

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