Comparison of Insulated and Non-insulated Radiofrequency Microneedling for the Treatment of Striae Distensae

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Abstract

Striae distensae (SD), also known as stretch marks, are dermal scars that could induce psychological problems. Despite numerous studies, no conventional therapies have been developed. Fractional radiofrequency microneedling (RFMN) is a novel treatment for atrophic scars and wrinkles. Energy fractions thermally damage deep dermal collagen near unaffected parts. The treated areas recover, remodel, and produce new collagen. Fractional RF delivery depends on microneedle insulation and frequency. The main objective of this study is to compare the efficacy of non-insulated and insulated fractional RFMN for the treatment of SD at 1 and 2 MHz frequencies. Eighteen subjects with striae alba on their thighs, abdomens, or buttocks were enrolled. Each patient was divided into four treatment zones with similar shapes and sizes. Each area was randomly treated with 1 MHz insulated, 2 MHz insulated, 1 MHz non-insulated, and 2 MHz non-insulated RFMN. Clinical outcome was assessed after 4 weeks by comparing pre- and post-treatment measurements of lesion depression volume, depth, and width (using Antera 3D™). At week 4 after treatment, the results showed all techniques were effective. The depression volume and the depth of SD significantly decreased from the baseline in all groups. The 2 MHz insulated and 1 MHz non-insulated RFMN groups performed slightly better, but the difference was not statistically significant. ($p = 0.90$). In conclusion, both insulated and non-insulated RFMN at 1 MHz and 2 MHz are effective, safe and have minimal adverse effects for treating SD.

Keywords**:** *Striae Distensae, Fractional Radiofrequency Microneedling, Insulated Microneedle, Non-Insulated Microneedle*

1. Introduction

Striae distensae (SD), also known as stretch marks, are a common cosmetic issue due to its psychological impact, particularly in females (Al-Muriesh, Huang, Ye, & Yang, 2020). They are a common disfiguring cutaneous condition characterized by linear, smooth bands of atrophic-appearing skin in areas of dermal damage caused by stretching (Singh & Kumar, 2005). This condition has been managed with a variety of treatmentsand varying degrees of success. Proposed treatments were topical treatments, chemical peels, microneedling, lasers, and energy-based devices, as well as microdermabrasion (Elsaie, Baumann, & Elsaaiee, 2009).

In recent years, the fractional radiofrequency microneedling (RFMN) device has been introduced as a therapeutic tool for skin tightening and rejuvenation (Dayan, Chia, Burns, & Theodorou, 2019). The tool delivers energy fractions that cause thermal damage in the deep dermal collagen adjacent to unaffected areas. This promotes wound healing, dermal remodeling, and the formation of new collagen in the treated areas (Levy, Grant, & Rothaus, 2016).

Each commercial RFMN energy configuration is determined by angling the needles, varying the number of needles in the array, insulating the needles with a number of different materials to control RF diffusion, utilizing non-insulated needles to achieve non-insulated RF needle impact and frequency, and controlling RF energy to target different tissue depths. When compared to a 1 MHz non-insulated needle, histology results showed that using an insulated needle at 2 MHz could result in similar tissue coagulation histology (Wootten, Zawacki, Rheins, Meschter, & Draelos, 2021). Unfortunately, no comparative studies were available to guide conclusions about which was superior for which clinical indication.

Therefore, the current study aimed to evaluate and compare the efficacy and safety of non-insulated and insulated fractional radiofrequency microneedling for the treatment of striae distensae at 1 and 2 MHz frequencies.

2. Objectives

1) To compare the efficacy of non-insulated and insulated fractional radiofrequency microneedling for treatment of striae distensae at 1 and 2 MHz frequencies after 4 weeks of treatment, evaluated by a blind assessor

2) To evaluate the adverse events after the treatment

3. Materials and Methods

3.1 Study design

The study was approved by the Human Research Ethics Committee of Thammasat University in accordance with the Declaration of Helsinki, the Belmont Report, the CIOMS Guidelines, and the International Good Clinical Practice (ICH-GCP). The research was a randomized controlled trial. The protocol was conducted from December 2021 to January 2022 at the Dermatology Clinic, Benjakitti Park Hospital, Bangkok, Thailand.

3.2 Participants

Eighteen participants (4 males and 14 females, aged 25–32 years; Fitzpatrick skin types III–IV) were enrolled in the study. Inclusion criteria were striae distensae in the abdomen, buttocks, or thighs. Participants were excluded if they had been treated with any kind of laser, RF, dermabrasion, microdermabrasion, or chemical peeling within 6 months prior to the study or had a history of keloidal tendency, bleeding, or platelet disorder. Participants who were pregnant, lactating, and on pacemakers, or had a local skin infection in the treated area, photosensitive dermatosis, or other metallic implants were also excluded.

3.3 Intervention

Each striae distensae lesion on the abdomen, buttocks, or thighs was divided into four treatment zones that were similar in shape and size. Each patient's striae distensae were divided into four regions based on their top-to-bottom or left-to-right location in the same anatomical area. These areas were labeled as A, B, C, and D. The computer randomly assigned treatment sequences of 1 MHz insulated, 2 MHz insulated, 1 MHz non-insulated, and 2 MHz non-insulated RFMN to area A, B, C, and D. The order of randomization is different for each participant. A normal saline solution was used to clean the area where the action was performed. Prior to the procedure, a local anesthetic cream containing 5% lidocaine HCl and 5% prilocaine (EMLA™, AstraZeneca, Sodertalje, Sweden) was applied onto the treated area and left for 60 minutes under occlusion and removed. Then, the topical anesthetic cream was wiped off using gauze and an alcohol swab.

Full striae distensae at the treated areas were treated with the same parameters as in group 4, a microneedle fractional RF device (VIVACE™, SHENB Co., Ltd., South Korea). using a cartridge with 36 insulated microneedles. Two passes were done over the striae, and the parameters were power level 8, depth 3-3.5 mm, and pulse time 500-700 ms. The treatment was delivered in a single, non-overlapping pass over the indicated area. Intraoperatively, pinpoint bleeding was controlled with sterile gauze dampened with saline solution. All the patients were treated by a doctor using the same technique.

Patients were advised to clean the lesions with normal saline solution and cover them with sterile Vaseline gauze for 24 hours after treatment. Patients were instructed not to use saunas, swim in pools, remove any scabs, or expose themselves to ultraviolet rays for one week following the procedure.

3.4 Outcomes

The primary outcome is to evaluate the improvement of depression volume, width, and depth using the Antera 3D™ camera (Miravex Limited, Ireland) after 4 weeks of treatment. The secondary outcome is to evaluate possible adverse events by a blind assessor.

3.5 Statistical analysis

To conduct statistical analysis, IBM statistical package for the social sciences (SPSS) version 27 (SPSS, Chicago, IL, USA) was used. Descriptive statistics were summarized using mean, standard deviation, minimum, and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Repeated-measures analysis of variance (ANOVA) was used to compare the depression volume, the width, and the depth of the SD measured by Antera 3D™ software at week 4 with the baseline data. P values less than 0.05 were considered statistically significant.

4. Results and Discussion

4.1 Clinical Demographics

Eighteen cases of striae distensae were enrolled in this study. The cases' ages ranged from 25 to 32 years, with a mean age of 28.28 ± 2.19 years. Fourteen cases were female (77.8%), and four cases were male (22.2%). Fifteen cases were of Fitzpatrick skin type III (83.3%), and three cases were of Fitzpatrick skin type IV (16.7%). The duration of the striae in the cases ranged from 10 to 16 years, with a mean of 12.83 ± 2.26 years. Two cases had striae on the abdomen (11.1%), six cases on the buttock (33.3%), and ten cases on the thighs (55.6%) (Table 1).

Table 1 Demographic data

Demographic data	**Result (n=18)**
Age, mean±SD (years)	28.28 ± 2.19
Age, min-max (years)	25 - 32
Duration of disease, mean±SD (years)	12.83 ± 2.26
Duration of disease, min-max (years)	10 - 16
Sex, n (%)	
Female	14 (77.8%)
Male	4 (22.2%)
Fizpatrick's skin type, n (%)	
III	15 (83.3%)
IV	3 (16.7%)
Lesion location, n (%)	
Abdomen	2 (11.1%)
Buttock	6 (33.3%)
Thighs	10 (55.6%)

SD, standard deviation.

4.2 Primary Outcomes (the depression volume, the width, and the depth of the SD)

4.2.1 Depression volume (mm^3)

The depression volumes of SD measurements obtained from an application of the Antera 3D™ software before treatment were 1.33 ± 0.89 mm^3, 1.81 ± 1.16 mm^3, 1.67 ± 1.02 mm^3, and 1.95 ± 1.4 mm^3 in the 1 MHz insulated, 2 MHz insulated, 1 MHz non-insulated, and 2 MHz non-insulated RFMN groups, respectively; these values did not show statistically significant differences. However, after 4 weeks of treatment, the depression volumes of the 1 MHz insulated, 2 MHz insulated, 1 MHz non-insulated, and 2 MHz non-insulated RFMN groups were 0.83 ± 0.63 mm^3, 1.19 ± 0.96 mm^3, 1.07 ± 0.75 mm^3, and 1.32 ± 0.99 mm^3, respectively. The depression volumes of the 2 MHz insulated and 1 MHz non-insulated RFMN groups significantly decreased ($P<0.001$). Compared with the 1 MHz insulated and the 2 MHz non-insulated RFMN groups, the 2 MHz insulated and 1 MHz non-insulated RFMN groups showed greater improvements with no statistically significant difference ($P = 0.90$). (Table.2). Figure 1 shows Antera 3D images of striae distensae (SD) obtained before and after treatment.

4.2.2 The width (mm)

Before treatment, the width measurements by Antera 3D™ software were 2.65 ± 0.61 mm, 2.8 ± 0.81 mm, 2.52 ± 0.4 mm, and 2.63 ± 0.77 mm in the 1 MHz insulated, 2 MHz insulated, 1 MHz non-insulated, and 2 MHz non-insulated RFMN groups, respectively; these values were not statistically significant. After 4 weeks of treatment, the widths of the 1 MHz insulated, 2 MHz insulated, 1 MHz non-insulated, and 2 MHz non-insulated RFMN groups were 2.65 ± 0.67 mm, 2.73 ± 0.9 mm, 2.45 ± 0.43 mm, and 2.57 ± 0.76 mm, respectively. However, statistical significance was not observed among the treatment groups (Table 2).

4.2.3 The depth (mm)

The average means ± SD of the depths of the striae measured by Antera 3D™ software were 0.06 ± 0.02 mm, 0.07 ± 0.01 mm, 0.07 ± 0.02 mm, and 0.07 ± 0.02 mm in the 1 MHz insulated, 2 MHz insulated, 1 MHz non-insulated, and 2 MHz non-insulated RFMN groups, respectively, at the baseline visit; these values were not statistically significant. The depths of the striae had decreased from the baseline measurement to the 4-week follow-up visit: 0.06 ± 0.01, 0.06 ± 0.02, 0.06 ± 0.01, and 0.06 ± 0.02 for the 1 MHz insulated, 2 MHz insulated, 1 MHz non-insulated, and 2 MHz non-insulated RFMN groups, respectively. The depth of the stiae in the 1 MHz non-insulated RFMN groups showed greater improvements. Compared with the 1 MHz insulated, 2 MHz insulated, and the 2 MHz non-insulated RFMN group, the difference was not statistically significant (P = 0.978) (Table 2).

Table 2 To show the baseline data and the change in depression volume, width, and depth of the SD at 4 weeks and the pain score

Clinical outcomes	**1 MHz insulated**	**2 MHz insulated**	**1 MHz non-insulated**	**2 MHz non-insulated**	***p* value***
Depress volume, mean ± SD (mm^3)					
Baseline	1.33 ± 0.89	1.81 ± 1.16	1.67 ± 1.02	1.95 ± 1.4	0.399
Week 4	0.83 ± 0.63	1.19 ± 0.96	1.07 ± 0.75	1.32 ± 0.99	0.354
Mean change	-0.5	-0.63	-0.59	-0.63	0.900
(95%CI)	(-0.77, -0.24)	(-0.88, -0.38)	(-0.83, -0.35)	(-1, -0.27)	
p value*	0.001	<0.001	<0.001	0.002	
Width, mean ± SD (mm)					
Baseline	2.65 ± 0.61	2.8 ± 0.81	2.52 ± 0.4	2.63 ± 0.77	0.654
Week 4	2.65 ± 0.67	2.73 ± 0.9	2.45 ± 0.43	2.57 ± 0.76	0.678
Mean change	0	-0.07	-0.06	-0.07	0.762
(95%CI)	(-0.1, 0.1)	(-0.18, 0.05)	(-0.17, 0.05)	(-0.18, 0.05)	
p value*	1	0.255	0.238	0.250	
Depth, mean ± SD (mm)					
Baseline	0.06 ± 0.02	0.07 ± 0.01	0.07 ± 0.02	0.07 ± 0.02	0.809
Week 4	0.06 ± 0.01	0.06 ± 0.02	0.06 ± 0.01	0.06 ± 0.02	0.815
Mean change	-0.01	-0.01	-0.01	-0.01	0.978
(95%CI)	(-0.01, -0.01)	(-0.01, 0)	(-0.01, -0.01)	(-0.02, 0)	
p value*	0.001	0.001	<0.001	0.003	
Pain score (0-10)	6.11 ± 1.84	4.94 ± 1.7	6.11 ± 1.49	5.39 ± 1.33	0.084

*Repeated-measures ANOVA or analysis of variance. P-value < 0.05, determined as significant value.

4.3 Secondary outcomes

During the treatment, the pain scores in the 1 MHz insulated, 2 MHz insulated, 1 MHz non-insulated, and 2 MHz non-insulated RFMN groups were 6.11 ± 1.84, 4.94 ± 1.7, 6.11 ± 1.49, and 5.39 ± 1.33, respectively. The 1 MHz groups experienced the highest degree of pain. However, the difference was not statistically significant among the groups (P = 0.084) (**Table 2**). The side effect was pruritus, which was observed in one patient (5.6%). However, it could be improved after treatment with topical Vaseline.

4.4 Discussion

Striae alba is a common, difficult-to-treat condition. Despite a variety of treatment options, there are no standard treatment options that provide complete healing (Abdel-Motaleb et al., 2022). The use of lasers and energy-based devices to treat striae is being extensively researched due to their safety and potential efficacy (Wollina & Goldman, 2017).

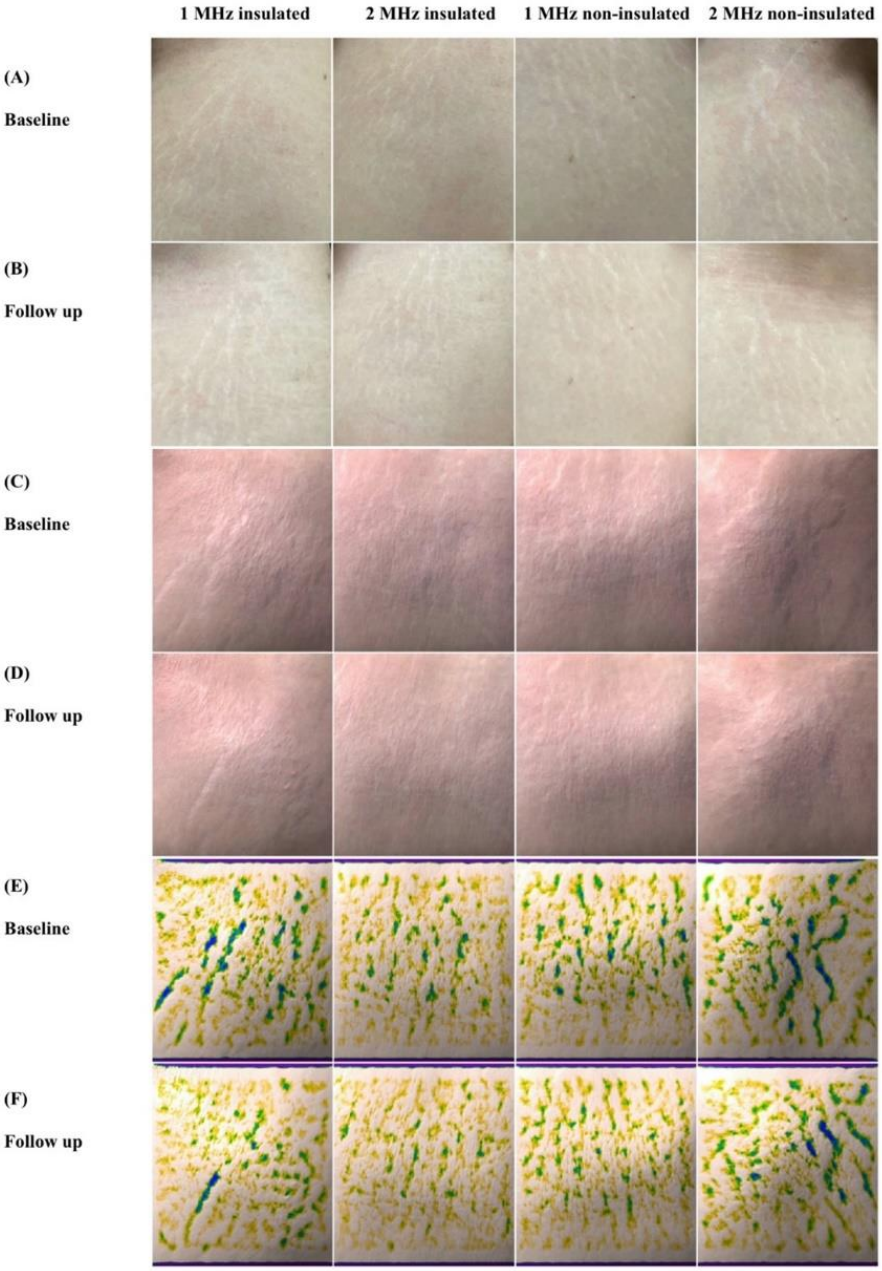

Figure 1 Antera 3D images of striae distensae (SD) before and after treatment. Green and blue hues represent depression in rendered color relief images. In the follow-up rendered 3D image (F), there is a decrease in green and blue color compared to the baseline rendered 3D image (E)

Fractional RFMN utilizes either insulated or non-insulated needles to deliver heat to the dermis. As a result of this thermal injury, various growth and vascular growth factors are released, leading to collagen denaturation and the subsequent remodeling of neocollagen and hyaluronic acid formation. (Chun, 2018).

Insulated needles are capable of delivering radiofrequency energy to the dermis without heating the epidermis. When heat dissipates, proximity and conduction should always transfer some heat to the surface through proximity and conduction (Weiner, 2019). When compared to insulated needles, non-insulated needles produce a greater radiofrequency thermal zone (RTZ) across the electrode. Greater fractional RTZs recover more slowly than several small RTZs. Non-insulated needles might cause epidermal injuries, and those with darker skin are at an increased risk. In addition, while these wounds heal, wound care and recovery time may be prolonged (Munavalli, Childs, & Ross, 2020). RFMN devices have variable electrode configurations and pulse durations and frequencies (Weinkle, Sofen, & Emer, 2015). Lower frequencies have longer wavelengths and consequently deeper tissue penetration (Sieber & Kenkel, 2018).

A previous study found that a 2 MHz insulated needle generated similar tissue coagulation histology as a 1 MHz noninsulated needle did. This discovery allows the user to switch between insulated and noninsulated needles with different frequencies, giving the physician improved control over tissue coagulation without changing needles (Wootten et al., 2021). Unfortunately, clinical trials of non-insulated and insulated needles at 1 MHz and 2 MHz have not been conducted. This study then aimed to assess and compare the efficacy of non-insulated and insulated fractional RFMN at 1 and 2 MHz frequencies for the treatment of striae distensae.

According to the results of this study, all four groups of RFMN—1 MHz insulated, 2 MHz insulated, 1 MHz non-insulated, and 2 MHz non-insulated—were effective in improving depression volume and depth. There was no statistically significant difference among the results from all groups. Concerning the width of the SD, there was no statistically significant difference between any of the groups. When compared to previous literature, Pongsrihadulchai, Chalermchai, Ophaswongse, Pongsawat and Udompataikul (2017) also found similar results. They demonstrated a statistically significant improvement in the total surface area of the striae ($p = 0.001$). Patients recieved three treatments at 4-week intervals. This device provided RF energy via 160 pins per tip, with a maximum energy per pin of 62 mJ. In this study, 150x20 non-insulated needles were employed.

Postinflammatory hyperpigmentation was a frequent adverse event that had previously been observed. However, similar to our findings, Fatemi et al. (Fatemi Naeini, Behfar, Abtahi-Naeini, Keyvan, & Pourazizi, 2016) reported no PIH after non-insulated RFMN treatment, although Ryu et al. (2013) reported that thirty percent of patients developed PIH. All adverse effects, including pain and pruritus, were discovered in this study. The adverse effects were tolerable and transient.

However, this study found that SD improved within four weeks after treatment. If the treatment was performed for a longer period of time, neocollagenesis might be more significant. To compare the clinical improvement of SD among all groups, further studies with larger sample sizes and prolonged treatment are recommended.

5. Conclusion

Both insulated and non-insulated RFMN at 1 MHz and 2 MHz were found to be effective and safe for treating SD with no serious side effects. In previous studies, using insulated and non-insulated needles and different frequencies resulted in either similar or different histology; however, when the results of each group were compared clinically for the treatment of SD, there was no significant difference. To determine group differences, additional studies with prolonged treatment and follow-ups are needed.

6. Acknowledgements

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