



A comparative study for clinical efficacy and safety between a combination of fractional radiofrequency and microneedling with fractional radiofrequency alone in the treatment of striae distensae

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ABSTRACT

Introduction: Striae distensae present with structural change of collagen bundles, elastolysis and cellular infiltration, that led to skin flattening, discoloration, and scarring. There is no standard treatment nowadays. Fractional radiofrequency (RF) is a radio transmission that generates thermal effect that promote wound healing effect and stimulate collagen and elastin production. Microneedling is an alternate modality that can also stimulate collagen production.

Objective: This study aimed to compare the efficacy and the safety of a combined fractional radiofrequency and microneedling versus fractional radiofrequency alone for treating striae distensae.

Methods: This was a prospective, randomized-controlled, assessor-blinded, intra-individual split-side comparative, experimental study. Inclusion criteria included all participants aged 18-50 years with Fitzpatrick's skin type III and IV with bilateral sides of striae alba. All participants were randomly assigned to be treated with combined fractional RF and microneedling therapy on one side of the body or fractional RF alone in contralateral side for 3 sessions. The primary outcome was the Global Aesthetic Improvement Scale (GAIS). The secondary outcomes included the width and length of striae, patient's satisfaction's score, and adverse events.

Results: There were 22 participants with the mean (SD) of 29 (7.8) years and 90.9% were female (n=20). The GAIS, assessed by two blinded dermatologists was significantly better improved in the combination group than fractional RF alone group at 4, 8, and 12 weeks ($p < 0.05$). The striae width and length significantly decreased in both groups without significant differences. There was no difference in patient's satisfaction score at week-12 visit between the 2 groups. Common adverse event included post-inflammatory hyperpigmentation (PIH) (36.4%) in the combination group and (27.3%) in fractional RF alone group without significant difference.

Conclusion: A combination of fractional radiofrequency and microneedling had better clinical efficacy in term of GAIS than fractional radiofrequency alone in treating striae distensae.

Keywords: striae distensae; fractional radiofrequency; microneedling

Introduction

Stretch marks or Striae distensae (SD) are common skin problems. It looks like a long line or streak on the skin. It is found in females 2.5 times more than males and is common in pregnant women. The common locations were on the lateral side of the thighs and lower back in adolescent male and on the thighs, upper arms, hips, and chest area in female teenager [1]. Striae distensae can occur from various etiologies, including growth spurts, pregnancy, obesity, collagen disorders

like Marfan syndrome, hormonal abnormalities such as Cushing's syndrome and long-term use of external steroid [2,3]. Striae have two stages. The first stage is characterized by pink, red, or purple streaks and may be accompanied by itching, known as "striae rubra". Later, striae fade into white or the same color as the skin together with the flattening of the skin, which look like skin scarring, known as "striae alba" [3,4]. Treatment of newly occurrence or early stage of striae is highly responsive than older striae [5]. The pathogenesis of

stretch marks is not truly known but hypothesize that to be related to the change in the composition of the extracellular matrix, including fibrillin, elastin, and collagen [6]. Although striae may not cause major impacts but can cause skin problems because of its thinner and impaired skin integrity than usual. It results in itching or blistering more easily. Striae often impact their psychological effects such as anxiety and stress especially in women. There is no specific treatment on striae and most of them disappointingly showed with non-promising result. Previous study showed that laser treatment is more effective than topical medications. However, the efficacy of the treatment is uncertain. Moreover, some lasers have side effects, and the results are not satisfactory [7]. One promising treatment for striae is radiofrequency (RF) wave. RF wave is based on the principle of resistance to tissue current flow in a radio frequency field [8]. RF can be divided into three categories according to the number of electrodes used to generate electricity: monopolar, bipolar, and multipolar. The principle of radiofrequency is different from the laser. It does not involve chromophores absorbing energy, so even dark-skinned people can use it safely [9]. Fractional RF produces thermal effect to small areas of skin, causing the injury in alternating rows with normal tissue, resulting in better wound healing effect [10,11]. Following RF treatment will stimulate the production of collagen and new elastin, a change in the structure of the dermis layer, and make the skin smoother [12]. Fractional RF can be used for the treatment of various dermatological diseases, including wrinkles, and acne scars, with few side effects [10-12], even in darker skin [13]. Microneedling or percutaneous collagen induction therapy has recently been increasingly used in dermatology. It can treat atrophic acne scars, rhytides, surgical scars, skin rejuvenation, and striae [14]. Microneedling is also safe, cost-effective, and can be used to treat a large area. The other advantage of microneedling is that it takes shorter down time for skin recovery period, safe to be used on darker skin [14,15]. This study aimed to determine clinical efficacy and safety of the combination between fractional RF, and skin microneedling in striae distensae by comparing with fractional RF alone.

Methodology

This study is a prospective, randomized-controlled, assessor-blinded, intra-individual split side comparative study. The study protocol was reviewed and approved by Mae Fah Luang Ethics Committee on Human Research with COA number 317/2021.

Inclusion criteria

Participants aged 18 - 50 years with Fitzpatrick's skin type III or IV with bilateral sides of striae alba at buttocks or thighs.

Exclusion criteria

Participants who have had any laser, radiofrequency, chemical peeling, dermabrasion, or microdermabrasion at the study site within 6 months, oral steroid within 3 months, vitamin A derivative within 6 months in oral form and 3 months in topical form prior the study, intralesional collagen, fat (autologous fat transfer), dermal filler or other mesotherapy within 12 months, pregnant women, breast-feeding, concurrent skin lesions at the enrollment visit such as atopic dermatitis, skin infection, or photosensitivity rashes, previous history or current infection of herpes simplex (HSV) or herpes zoster virus (HZV), history of hypertrophic scar and keloid, or abnormal wound healing, current cigarette smoking, overweight or obese if body mass index greater than or equal to 25, cardiac pacemaker or metallic implantation and history of allergic reaction to local anesthetic agents such as lidocaine or prilocaine.

Discontinuation criteria

Participants who developed serious adverse effects from fractional radiofrequency or microneedling; participants who did not comply with study protocol or loss to follow-up visit or pregnancy during the study period or weight gain at least 10% from the baseline during the study period.

All participants require the measurable lesion of striae at both sides of their buttocks or thighs, with total area per side at least 3 but not more than 10 cm². All participants were randomly assigned by block randomization, to receive either a combination of fractional RF and skin microneedling on the one side of the body or fractional RF alone on contralateral side. Photographic examination was performed using high-resolution digital camera (Canon 5D MkIII, Tokyo, Japan) for clinical evaluation by blinded dermatologists. The measurement of the width and length of striae using caliper were performed.

Anesthetic cream (2.5% lidocaine- 2.5% prilocaine) was applied to numb the skin using occlusive dressing. Fractional RF used in this study is the Fractora® handpiece with a 60-pin tip powered by the BodyTite platform (InMode, Yokneam, Israel). The parameter of fractional RF will use the energy with 20-25 mJ per pin to cover all the given striae area without a skip area for two passes. A treatment using microneedling (Dermapen, Dr.pen®, Guangzhou Ekai Electronic Technology, Guangdong, China), uses disposable 42-needle and 3 mm depth was undergone on the assigned combination side after the completion of Fractional RF for 2 passes or reach clinical endpoint with fine pinpoint bleeding. Topical mupirocin ointment will be applied immediately after the procedure. The follow-up visit will be at 4th, 8th, and 12th week after enrollment. The adverse effect was reported.

Primary outcome was global aesthetic improvement scale (GAIS) from photographic examination on each visit, assessed by two blinded dermatologists and given scoring range from (1) to (4)

as follows; (1) = 1-25% improvement, (2) = 26-50% improvement, (3) = 51-75% improvement, (4) = improvement more than 75% from the baseline visit. Secondary outcomes include the width and length of striae on each visit. Overall participant's satisfaction score using a 5-score rating scale as follows; (0) = unsatisfied, (1) = less satisfied, (2) = moderately satisfied, (3) = very satisfied, (4) = most Satisfied. Adverse effects were reported.

Statistical analysis

The sample size was calculated by using the formula for two samples, comparing two proportions in the dependent outcome, based on the results of a study from Naeini et al. (2016) [49] with 80% power ($\beta = 0.20$) and type I error of 5% ($\alpha = 0.05$) with a total of twenty-five subject enrollment plan. Descriptive statistics were reported with the means and standard deviation or frequency and percentage. Two-way, repeated measure Analysis of variance (ANOVA) was used to compare continuous data between the two groups at different visits. For comparing two categorical data, such as GAIS score greater than or equal to two points and adverse effect, the McNemar test was used. *P* value less than 0.05 was clinical significance. All data were analyzed by using Statistical Package for the Social Sciences (SPSS) for window version 23.0 (SPSS, Chicago, IL, USA).

Results

This study was conducted between January 18 to May 29, 2022. A total of 25 volunteers were initially screened and enrolled, but 3 subjects dropped out because of COVID-19 situation effect. AS total of 22 subjects completed the study protocol. The mean $\pm$ SD age was 29 ± 7.8 years. Twenty participants (90.1%) were female. There were 13 participants (59.1%) had Fitzpatrick's skin type III, and nine participants (40.9%) had type IV. The locations of striae were at buttock (63.6%) and thigh (36.4%) (table 1).

Primary outcome

Using the McNemar test to compare the proportion of at least score (2) or more than or equal to 26% improvement by compare with eh baseline, the combination of fractional RF and skin microneedling had significantly better in term of GAIS measurement than fractional RF alone group at 4, 8, and 12 weeks ($p = 0.0390, 0.0010, \text{ and } 0.0310$, respectively) (table 2).

Secondary outcome

The mean width at baseline visit in the combination treatment group was 0.31 ± 0.07 cm, while the mean width of the fractional RF group was 0.31 ± 0.07 cm. When comparing the widths of the two treatment groups at baseline using paired *t* test was found with no statistically significant difference ($p\text{-value} = 0.8759$). Both treatment groups were statistically reduced the striae width when comparing with the baseline ($p\text{-value} < 0.001$). Moreover, there were no significant difference between the groups at different visits ($p\text{-value} > 0.05$) (figure 1). The length of striae follows the same trend as the width. The mean pre-treatment length in the combination treatment group was 8.1 ± 3.1 cm and was 8.09 ± 2.5 cm in the Fractional RF alone group. After treatment, the length in each group was significantly reduced compared to the baseline ($p\text{-value} < 0.001$). Nevertheless, when comparing between the two group of treatments, found no statistical difference. A combination of fractional RF and microneedling group found 68.3% most satisfied (score = 4) or very satisfied (score = 3) satisfaction score and 45.5% in fractional RF alone group with no significance ($p\text{-value} = 0.6871$). There were 8 participants (36.4%) were in the combination treatment group and 6 participants (27.3%) in the Fractional RF alone group, developed post-inflammatory hyperpigmentation without significant difference ($p\text{-value} = 1.00$).

Table 1 Base characteristics

Clinical data	Results (n = 22)
Age	
mean (years) $\pm$ SD	29 ± 7.8
Age < 30 yr., n (%)	10 (45.5)
Age $\geq$ 30 yr., n (%)	12 (54.5)
Gender, n (%)	
Male	2 (9.1)
Female	20 (90.1)
Fitzpatrick's skin type, n (%)	
III	13 (59.1)
IV	9 (40.9)
Location, n (%)	
buttock	14 (63.6)
thigh	8 (36.4)

Table 2 Global aesthetic improvement scale (GAIS) comparing two groups' results at each visit.

GAIS, n (%)	Fractional RF + Microneedling group (n = 22)	Fractional RF group (n = 22)	p-value*
Week 4			
(1) = improve 1 - 25%	8(36.4)	15(68.2)	0.0390
(2) = improve 26 - 50%	13(59.1)	6(27.3)	
(3) = improve 51 - 75%	1(4.5)	1(4.5)	
(4) = improve > 75%	0	0	
Week 8			
(1) = improve 1 - 25%	6(27.3)	17(77.3)	0.0010
(2) = improve 26 - 50%	7(31.8)	5(22.7)	
(3) = improve 51 - 75%	7(31.8)	0	
(4) = improve > 75%	2(9.1)	0	
Week 12			
(1) = improve 1 - 25%	4(18.2)	10(45.5)	0.0310
(2) = improve 26 - 50%	7(31.8)	9(40.9)	
(3) = improve 51 - 75%	9(40.9)	3(13.6)	
(4) = improve > 75%	2(9.1)	0	

*McNemar test comparing GAIS of greater or equal to two scores (improvement $\geq 26\%$) between two groups.

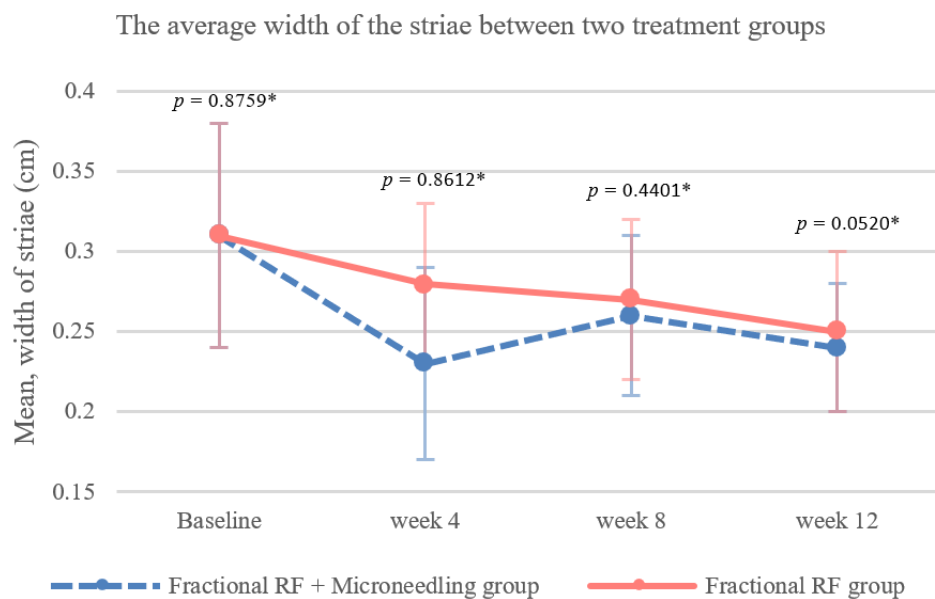


Figure 1 A comparison of striae width at different visits between the two groups

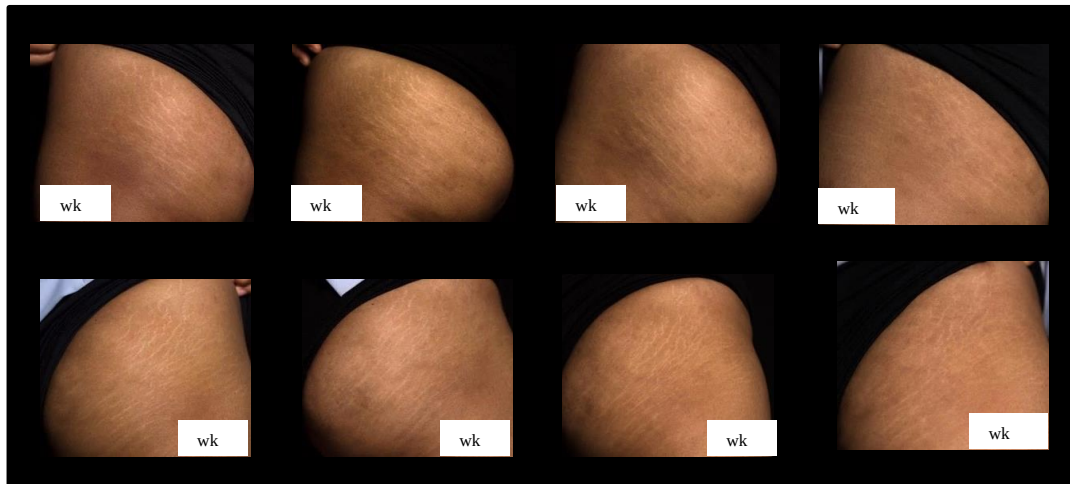


Figure 2 Representative clinical photographs for evaluation in GAIS in each visit compared to baseline. The upper row shows the striae in a combination of fractional RF with the microneedling group. In comparison, the lower row shows the striae in the fractional RF alone group. By week 12, the striae from the upper image have a faded appearance. The skin is smoother than in the picture below.

Discussion

This research is an early study comparing the combination of fractional RF and microneedling treatment to the fractional RF treatment alone. The primary outcome is the overall improvement of striae from two dermatologists' scores using GAIS. The combination treatment has a better score than the fractional RF alone, with statistically significant differences in the 4th, 8th, and 12th week (p -value < 0.005). This result is consistent with research by Seong et al (2021) [17] and Ryu et al (2013) [18], which found that fractional radiofrequency microneedle was effective in treating striae based on overall clinical evaluation by dermatologists as well. There was a statistically significant reduction in width and length in both combination therapy and fractional RF alone group (p -value < 0.001). Consistent with the research by Phongsrihadulchai et al (2016) [19]. They found that the width and length of striae were statistically significantly reduced when measured by caliper. However, when comparing treatment between the two groups, there were no statistically significant differences. The main treatment side effects were post-treatment hyperpigmentation (PIH), with an incidence of 36.4% in combination treatment and 27.3% in fractional RF alone. This incidence of PIH was higher than the reported PIH from Ryu et al. (2013) [18], which happened with 20% PIH from non-ablative fractional microneedle RF and 18.1% PIH from nano fractional radiofrequency in Phongsrihadulchai et al study (2016) [19]. This figure is close to research by Yang YJ et al (2011) [20] using a fractional Erbium glass laser reporting 36.4% PIH, compared to a fractional CO₂ laser producing 81.8% PIH. There was no statistically significant difference in participants' satisfaction between the two groups. However, in fractional RF

alone treatment, one participant was dissatisfied with the treatment because she discovered that there were more striae than before. When taking more history, she said she had gained 2 kg between week 8 and week 12. The limitation of this study is that there was a relatively small number of volunteers and more lost to follow-up of participants than expected dropout calculation due to the COVID-19 situation. So, the suggestion for further study may weight participants in each visit as weight changes may affect the research results. Should increase the time for follow-up, such as follow-up after the last treatment for three months. to see the long-term treatment effect. Furthermore, it may add the depth of striae to the width and length measurement using a 3D camera such as Antera 3D™.

Conclusion

A combination of fractional radiofrequency and microneedling had better clinical efficacy in term of GAIS than fractional radiofrequency alone in treating striae distensae.

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