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ORIGINAL ARTICLE

Treatment of striae distensae with a TriPollar radiofrequency device: A pilot study

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Abstract

Background: Striae distensae are a frequent skin condition for which treatment remains a challenge. *Objectives*: To determine the efficacy and safety of a TriPollar radiofrequency (RF) device for the treatment of striae in skin phototypes IV–V. *Methods*: Seventeen females with striae received six weekly treatments with a TriPollar RF device. The participants were evaluated using standardized photographs and a UVA-light video camera at baseline, and at 1 and 6 weeks after the final treatment. Side effects of treatment were recorded at every session. *Results*: At 1 week after the final treatment, 38.2% and 11.8% of the subjects were assessed to have 25–50% and 51–75% improvement of their striae, respectively. Compared with the 1-week follow-up, at the 6-week follow-up a higher percentage of the subjects were rated to have improvement of their striae. There were no significant differences in the striae surface smoothness at the 1- ($p = 0.907$) and 6-week ($p = 0.057$) follow-ups, compared with that of baseline. Twelve percent (2/17), 23% (4/17), and 65% (11/17) of the study subjects rated their satisfaction of the overall improvement as slightly satisfied, satisfied, and very satisfied, respectively. No adverse effect was reported. *Conclusion*: TriPollar RF appears to be a promising alternative for the treatment of striae distensae.

Key words: *Collagen remodeling, radiofrequency device, striae, volumetric heating*

Introduction

Striae distensae or stretch marks are an undesirable cutaneous disorder commonly found in adolescents and young adults. Clinically, stretch marks appear as erythematous (striae rubra) or hypopigmented (striae alba) linear bands of atrophic skin, usually involving the abdomen, thighs, buttocks, breasts, and extremities. Histologically, striae distensae demonstrate the characteristic appearance of scars with evidence of thinning and flattening of the epidermis, attenuation of the rete ridges, a normal or decreased number of melanocytes, as well as thinning and retraction of the dermal collagen and elastin. Causes of striae include pregnancy, obesity, weight loss, high corticosteroid levels, application of high potency topical cortico steroids, protease inhibitor ingestion, endocrine disorders, and connective tissue disease (1,2).

Multiple modalities of treatment including topical applications of tretinoin (3,4), glycolic and ascorbic acids (5), microdermabrasion (6), 585-nm pulsed dye laser (PDL) (7,8), short pulsed CO_2 laser (9), 308-nm excimer laser (10,11), 1450-nm diode laser (12), 1064-nm long-pulsed Nd:YAG laser (13), 1550-nm erbium-doped fiber laser (14), 1320-nm Nd:YAG laser (15,16), intense pulsed light (IPL) (17), and targeted phototherapy (18) have been advocated with variable success and side effects. A recent study investigating the uses of RF combined with 585-nm PDL for the treatment of striae distensae has shown a promising clinical outcome with histological evidence of increased collagen and elastic fibers (19). As yet, no study has reported whether RF treatment alone provides clinical benefit to the treatment of striae distensae.

The TriPollar radiofrequency (RF) device, a novel RF system, is designed to deliver focused RF current into the skin via three electrodes, thus generating heat through resistance in both the dermal and subcutaneous layers. One of the three electrodes acts as a positive pole while the other two act as negative poles.

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The current flowing through the common, positive pole is twice that which flows through each of the negative poles. To avoid overheating this common pole and the tissue in contact with this pole, a sequence of electrical modulation is applied so that each electrode, in turn, acts as the common pole (Figure 1).

Previous studies demonstrated that selective and focused electro-heating of the skin can induce collagen remodeling. This is confirmed by a recent study using a TriPollar RF device to treat ex vivo human skin models showing statistically significant increases in collagen synthesis in the superficial and mid dermis when compared to the control, untreated skin (20).

The purpose of this study was to evaluate the efficacy of a TriPollar RF device on the treatment outcome of striae distensae in Asian subjects, as well as to determine any adverse effects of such a treatment.

Methods and materials

Treatment regimen

Seventeen females, aged 19–53 years with skin phototypes IV ($n = 14$), and V ($n = 3$), were recruited to this prospective study. All participants had striae distensae (striae rubra: one subject; striae alba: 16 subjects) on the abdomen and/or upper thighs, present at least 6 months prior to entering into this study. Informed consent was obtained from all study subjects and the study was approved by the Ethical Committee on Research Involving Human Subjects, Faculty of Medicine Siriraj Hospital, Mahidol University, and conformed to the guidelines of the 1975 Declaration of Helsinki. Subjects were instructed to adhere to their regular diet, exercise program and lifestyle with weight fluctuations not exceeding 2 kilograms in the preceding month. Exclusion criteria were a history of keloids, photosensitivity, collagen or elastin disorders, or usage of topical or oral retinoids, or other striae treatment in the past. No other treatment of striae was allowed during the study.

All subjects were treated with a TriPollar RF device (Apollo™; Pollogen Ltd, Tel Aviv, Israel) once a week for a total number of six treatment sessions. Pre operatively no local anesthesia was used. After applying a thin layer of glycerin oil on the treatment area, the applicator was moved with slight pressure in a continuous sweeping motion over the skin, simultaneously heating the subcutaneous fat layer and the dermis. An average of 47 W (range, 40–50) of RF energy was administered through a TriPollar RF electrode configuration at a frequency range of 1 MHz to the treatment area. The energy levels were adjusted according to the subjects' feelings and the skin reactions. During the treatment, heat sensation was regularly monitored verbally and physically. A sensation similar to a warm massage without pain was set as an ideal feeling during the treatment. The applicator was moved more rapidly or the energy level was reduced if there was an unpleasant feeling reported by a participant. The target sites were treated until the skin temperature was increased to 40–42°C, which was often accompanied with the appearance of erythema. No active cooling of the electrodes or the skin was used during the treatment. Each treatment session lasted approximately 40–45 minutes. An increased temperature (40–42°C) was maintained for approximately 2 minutes on each particular treatment site. The skin temperature was regularly measured using an infrared thermometer (Mini-Temp MT4; Raytek Corp, Santa Cruz, CA, USA). No postoperative care was required.

Treatment evaluations

Evaluations including body weight, clinical photographic assessments, striae surface smoothness, and abdomen circumference were obtained at baseline, and at 1 and 6 weeks after the final treatment. Clinical photographs were standardized using consistent patient positioning, camera angling, lighting, and backdrop conditions. Side effects of treatment were recorded at every session.

Subjective assessment

Clinical improvement in the appearance of the stretch marks shown in comparable, standardized, digital photographs, using a quartile grading scale (0 = < 25%, 1 = 25–50%, 2 = 51–75%, 3 = > 75% improvement) were made by two non-treating, masked physicians (R.W. and S.E.) after the series of treatments. The masked assessors were not aware which photograph was taken before or after treatment.

On the last follow-up visit (6 weeks after the final treatment), the subjects were asked to rate their overall satisfaction of the treatment received. Satisfaction was rated using the following scale: I = not satisfied, II = slightly satisfied, III = satisfied, IV = very satisfied, V = and extremely satisfied.

Objective assessment

The striae surface smoothness was objectively evaluated by using a UVA-light video camera (Visioscan® VC 98; Courage-Khazaka, Köln, Germany) with analysis software (Surface Evaluation of the Living Skin; SELS) as described previously (21). A designated area of the striae was marked on every patient and mapped with a translucent sheet on the first visit to ensure

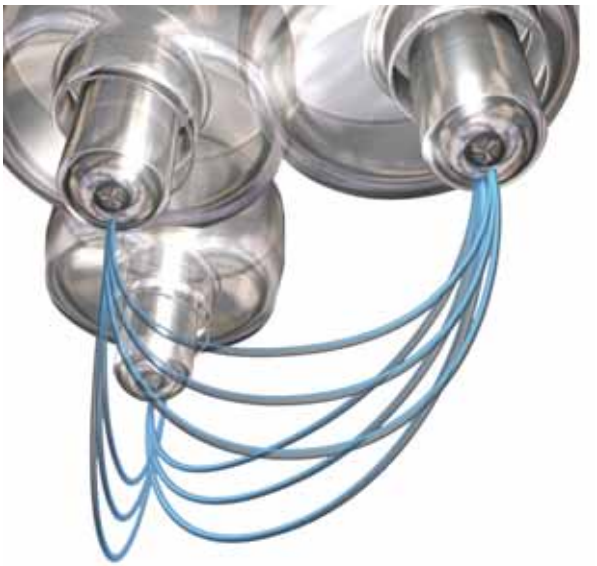

Figure 1. TriPollar radiofrequency applicator. The three-electrode configuration of TriPollar RF is aimed to deliver focused RF current into the skin tissue.

Table I. Clinical improvement of striae distensae assessed by two non-treating, masked physicians.*

Clinical improvement	Percent of patients (number of subjects)	
	1 week after the last treatment (n = 34)	6 weeks after the last treatment (n = 34)
< 25%	50% (17/34)	35.3% (12/34)
25–50%	38.2% (13/34)	32.3% (11/34)
51–75%	11.8% (4/34)	26.5% (9/34)
> 75%	– (0)	5.9% (2/34)

*Calculated based on the evaluation by two evaluators.

consistency of location. An average value of two measurements on a representative area was obtained. In brief, the instrument measures the skin surface characteristics based on a graphic depiction of the living skin under UVA-light illumination and the electronic processing and evaluation of this image according to its clinical parameters. The SELS is used to calculate striae surface smoothness (SEsm) from the average width and depth of the surface wrinkling. A higher SEsm value indicates increased surface smoothness.

The circumference of the abdomen was measured by using one designated tape measure. The measurements were always performed at the umbilical level while the participants were standing in an identical position. The height or distance from the floor to the umbilicus was taken at the beginning of the study for each subject to serve as a reference point each time measurements were taken to ascertain the same location of the measurement. An average value of two measurements for each individual subject was recorded.

Statistical analyses

Analysis of repeated measures, including repeated measures analysis of variance (ANOVA) and multivariate analysis were performed to test the differences in the means of the abdomen circumference, body weight, and SEsm, over time (baseline and 1 and 6 weeks after the final treatment). Analysis of repeated measures is a statistical test used to refer to such a situation in which measurements of the same variable are made on each subject at two or more different points in time (22). The tests were two-sided, and a probability value of less than 5% was considered statistically significant.

Results

The average body weights of the 17 subjects at baseline and 1 and 6 weeks after the final treatment were 58.9 ± 8.9, 58.5 ± 9.2, and 58.7 ± 9.0 kg, respectively. No significant body weight reduction compared to base-line was demonstrated at any follow-up visit (p = 0.358).

Immediately after the treatment, the treated skin became warm to the touch. All subjects reported that there was minimal erythema and edema, which lasted from a few hours to a maximum of overnight. Treatment was well tolerated in all study subjects. The feeling during treatment was described as comfortable in 29.4% (5/17) of the subjects, very comfortable in 64.7% (11/17), and extremely comfortable in 5.9% (1/17). The sensation most often described was a mild heating with occasional pinching. No further adverse effects, such as postoperative purpura, bullae, crusts, ulcerations, or dyschromia were observed and no subject interrupted the treatment due to pain or discomfort.

Clinical improvement in the appearance of the striae

Inter-rater agreement was tested by the Kappa (K) statistic. Weighted kappa (K) equaled 0.873 (p < 0.001) and 0.807 (p < 0.001) at 1- and 6-week follow-up visits, respectively, which meant the two independent assessors had very good strength of agreement (23). Table I demonstrates the clinical improvement of the stretch marks using a quartile grading scale assessed by two blinded dermatologists at 1 and 6 weeks after the final (sixth) treatment. At 1 week after the final (sixth) treatment, 38.2% and 11.8% of the subjects were assessed to have 25–50% and 51–75% improvement in the appearance of their striae, respectively. Compared

to the 1-week follow-up, at 6 weeks after the final treatment, a higher percentage of the subjects were rated to have improvement of their stretch marks, including 26.5% and 5.9% showing 51–75% and > 75% improvement, respectively (Figure 2). The only one subject with striae rubra was rated as having 25–50% and 51–75% improvement at 1 and 6 weeks after the final treatment, respectively (Figure 3). None of the subjects was rated as having no improvement in their clinical appearance of striae when measured by the two non-treating evaluators.

Straie surface smoothness (SEsm)

The values of SEsm measurements (mean ± SD) were 95.06 ± 25.12, 95.74 ± 24.92, and 111. 14 ± 35.40 at baseline and 1 and 6 weeks after the treatment was discontinued, respectively. There were no significant differences in the SEsm at the 1-week (p = 0.907) and 6-week (p = 0.057) follow-ups, compared with that of baseline.

Abdomen circumference measurement

The average abdomen circumference at baseline was 101.1 cm which reduced to 99.5 cm at 1 week after the last treatment, representing an average reduction of 1.6 cm in abdomen circumference with statistical significance (p = 0.001). There was a minor increase in abdomen circumference (less than 0.5%) between the visit at 1 week after the final treatment and that of 6 weeks after the final treatment.

Patient satisfaction rating

Twelve percent (2/17), 23% (4/17), and 65% (11/17) of the study subjects rated their satisfaction of the overall improvement as slightly satisfied, satisfied, and very satisfied, respectively. None of the subjects rated the overall satisfaction as not satisfied or extremely satisfied.

Discussion

Treatment of striae distensae remains a challenge. Multiple treatment modalities have been employed with varying degrees of success. The efficacy of topical tretinoin in improving the appearance of stretch marks is uncertain (3,4). The 585-nm pulsed dye laser (PDL) may offer beneficial effects in improving the appearance of striae rubra but was not helpful in treating striae alba (7). In addition, the use of PDL in dark-skinned individuals is often complicated with post-inflammatory hyperpigmentation (PIH) as melanin acts as a competing chromophore with hemoglobin for the 585–595-nm pulsed light (9). Intense pulsed light (IPL) has demonstrated beneficial effects in treating striae alba in a previous study, but PIH developed in 40% of the study subjects with skin phototypes III and IV (17). The 308-nm excimer laser has been shown to temporarily help improve the appearance of striae alba by increasing the striae's color toward that of the adjacent skin color but without correcting the atrophy (10,11). The non-ablative 1450-nm diode laser has not been useful in the treatment of striae in patients with skin phototypes IV–VI and has been associated with significant PIH (12). Recently, the 1064-nm long-pulsed Nd:YAG laser has demonstrated promising results in treating immature striae (striae rubra) (13). However, 20% of the study subjects were rated as having poor responses to the treatment. Moreover, early inflammatory striae (striae rubra) has been found to respond to treatment better than late-stage hypopigmented striae (striae alba) (7). A subject having striae rubra in the present study also demonstrated a more favorable response when compared with the other subjects with striae alba.

A recent study has demonstrated promising results in treating striae distensae with a combined RF device and 585-nm PDL (19). An increase in collagen and elastic fibers noted in the post-treatment biopsy specimens was thought to contribute to the improvement seen in the study's patients. Previous studies demonstrated that collagen fibril contraction occurs immediately after volumetric RF heating and gives rise to tissue contraction as well as a thermally mediated wound healing process, which subsequently induces neocollagenesis (19,24,25). Similarly, a recent study using ex vivo human skin models showed a statistically significant increase in collagen synthesis following treatment with a TriPollar device (20).

The present study demonstrated that TriPollar RF alone also provided a clinically beneficial effect on improving the appearance of stretch marks. The sample size of the present study may be too small to detect the objective improvement of skin surface smoothness compared with that of baseline. We concur with the assumption of the aforementioned study (25) that collagen remodeling induced by RF heating may be the most likely mechanism that underlies the improvement of the surface appearance of the stretch marks. Moreover, skin tightening following RF heating as shown in previous studies (25,26) and the present study may also help shorten the width of the striae, resulting in less visibility of the marks.

Further improvement of the striae was noted over time, as shown at the 6-week follow-up visit compared with that of the 1-week follow-up in the present study. Twelve percent versus 32% of the study subjects were

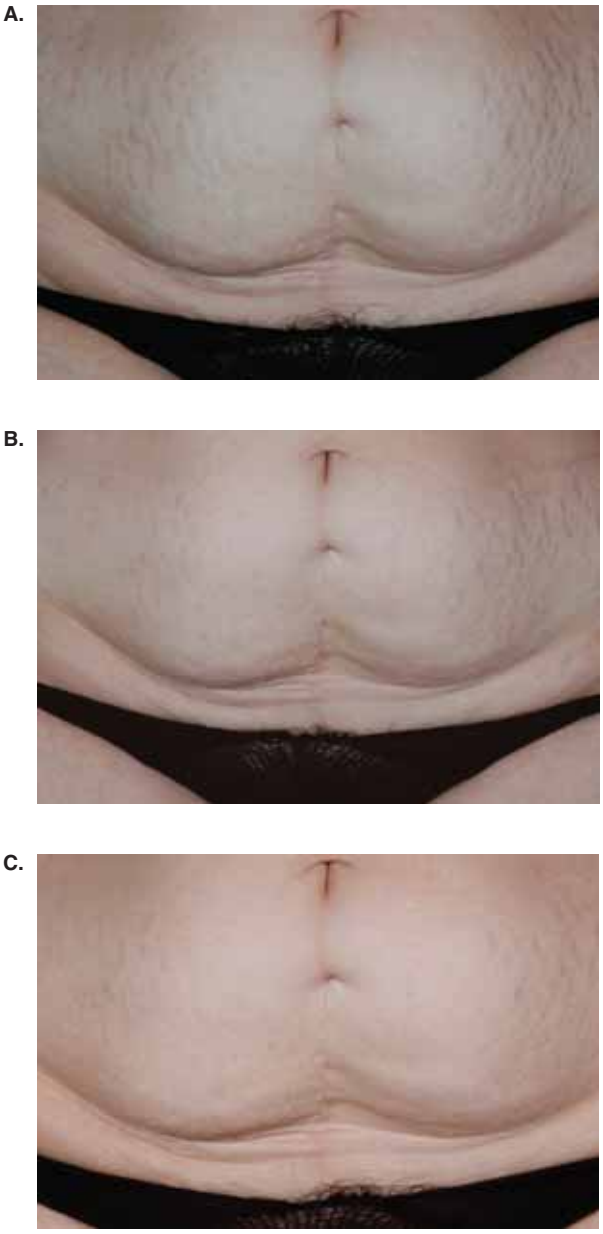

Figure 2. Striae alba in the abdomen: (A) before treatment; (B) 1 week after six weekly TriPollar RF treatments. The subject was assessed to have 51–75% and > 75% improvement in the appearance of her striae at 1 and 6 weeks after the final treatment, respectively; (C) 6 weeks after the treatment was discontinued.

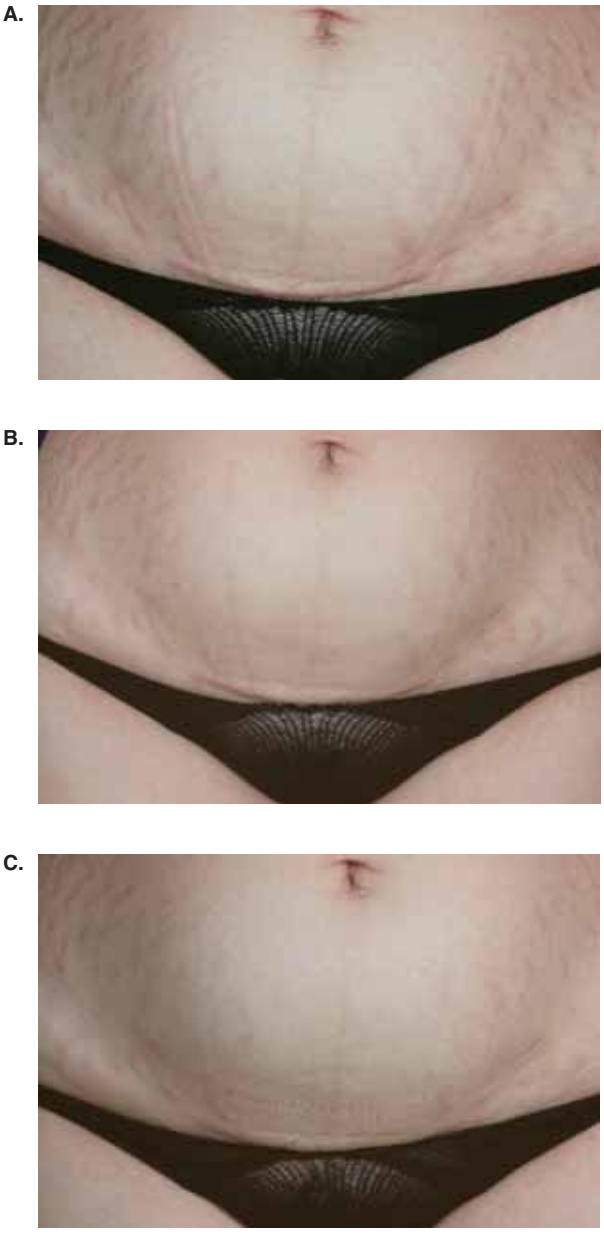

Figure 3. Striae rubra in the abdomen: (A) before treatment; (B) 1 week after six weekly TriPollar RF treatments. The subject was assessed to have 25–50% and 51–75% improvement in the appearance of her striae at 1 and 6 weeks after the final treatment, respectively; (C) 6 weeks after the treatment was discontinued.

rated as having 50% improvement or more at the 1- and 6-week follow-up visits, respectively. There may be advantages if the clinical follow-up can be extended beyond 6 weeks, as more favorable changes may be noted with prolonged follow-up. The continued improvement of striae may be influenced by several factors occurring during the cutaneous wound-healing cascade, including persistent collagen shrinkage and the new collagen formation. Dermal remodeling is the final phase of the wound-healing process which is initiated after the proliferative phase of wound healing, and normally persists for 1–2 years after the initial injury until it achieves maturation (27).

In conclusion, TriPollar RF appears to be an effective and safe treatment option for striae distensae in skin phototypes IV–V. The therapeutic effect appeared to continue as long as 6 weeks after the treatment was discontinued. Future controlled studies with an increased

number of treatment sessions and longer follow-up periods, together with a histological examination, are essential to accurately address the efficacy of such a device.

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