EVALUATION OF SAFETY AND EFFICACY OF USING VENUS FREEZE™ SYSTEM FOR THE TREATMENT OF STRIAE (STRETCH MARKS)

a Post Marketing Study

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INTRODUCTION

PatStriae or stretch marks are a common skin condition, occurring in both genders but are more prevalent among women. These are linear dermal scars accompanied by epidermal atrophy. They usually occur frequently in numerous physiological and pathological conditions such as adolescent growth spurts, pregnancy, obesity, Cushing's and Marfan syndromes, and long-term systemic or topical steroid use. Decreased expression of collagen and fibronectin genes has also been associated with striae[5].

Although they do not cause any significant medical problems, aesthetically they can be a cause of great concern or psychological stress for many women. Patient demand for non-surgical, non-invasive, and no-downtime skin rejuvenation procedures has grown dramatically over the past decade as new treatments and technologies have been introduced. During this period there has been a substantial increase in the utilization of medical prescriptive skin care. The effects of dermal heating are well recognized to include the modification of collagen structure and stimulation of neocollagenesis (by induction of inflammation that will end in new collagen production by fibroblasts recruited to the heated area). These changes can help improve the appearance of striae due to the increased collagen and elastin. Electrical energy can be advantageous for deep dermal heating as the movement of electrons is not impeded by tissue proteins.

Radiofrequency (RF) energy heats tissue by creating electric fields between two electrodes causing molecules to vibrate. Optical medical devices have been developed in the last 2 decades to treat signs of skin aging. While ablative lasers are used for full or partial skin ablation, intense pulsed light devices are helpful for non ablative elimination of dyschromias but provide minimal value for collagen remodelling. In addition, use of optical energy devices is limited by skin color – restricting its effective use mostly to fair skinned patients.

Venus Freeze is a non-invasive Multi Polar Magnetic Pulses (MP)[2] radiofrequency (RF) energy generating system with 2 applicators; DiamondPolar™ (4 RF electrodes) for treatment of small areas and OctiPolar™ for treatment of large areas. The treatment applicators transmit Bi-Polar RF energy in a method that creates an organized bi-polar RF energy matrix which produces homogeneous heating in the entire treatment area for maximum safety and efficacy, eliminating the need for pre/post cooling mechanisms.

The RF energy transmitted by Venus Freeze mediates thermal stimulation of the extracellular matrix (ECM) in the dermis. This results in an immediate and temporary shrinkage of the collagen triple helix[1,2,3] and subsequently, micro-inflammatory stimulation of the fibroblast which in response produces new collagen (neocollagenesis), new elastin (neoelastogenesis) and ground substances[2,3]. This treatment enhances the tensile strength and elasticity of the dermis with the aid of the newly produced proteins and protoglycans[1,2,4.]

OBJECTIVES

The objective of this study was to evaluate the safety and effectiveness of using Venus Freeze system for the treatment of striae. The safety of the Venus Freeze system for striae treatment was established by physician's assessment/observation of adverse events or side effects such as signs of pain, edema, burn, localized infection, skin pigmentation and texture alterations.

Efficacy of using Venus Freeze system for striae treatment was established by the level of improvement seen visually and by macro photography.

MATERIALS AND METHODS

Sixteen (16) female subjects between the ages of 30 and 72 (mean age = 46.06 years, SD = 10.247) with varying degree of striae participated in this 2 –centre, single-arm pilot study. The subjects were enrolled into the study after meeting all the inclusion/exclusion criteria and providing signed informed consent.

Each subject had a screening assessment and pre-treatment photograph (baseline), six (6) treatment visits which included 5 measurements of striae bands and pre-treatment photographs and 2 post-treatment visits (1 week and 1 month post treatments). The treated areas were photographed using high-resolution macro photography. The pre and post treatment photographs were compared by two independent physicians. A sterile 6" skin ruler was used to measure the length and width of each striae band on the first appointment, prior to each treatment and at the follow up appointments of one week and one month post treatment series.

Each subject received 6 treatments using the Venus Freeze system. Prior to treatment, the treated areas were assessed visually in order to determine skin relevant parameters. The treated areas were photographed and measured in order to allow comparison and assessment of striae improvement following treatment. The treatment area was cleaned thoroughly with soap and water. The skin surface was dried prior to the treatment.

The treatment parameters such as time (10 minutes for an area approximately 4x5 inches) and output energy (60 – 80% with goal is to reach therapeutic in the first minute of treatment) was determined by the physician depending on patient skin type and area of treatment.

For treatment safety evaluation, treated areas were visually assessed for side effects such as edema, erythema, burn, localized infection and skin pigmentation immediately after the treatment. Subjects were also asked questions to assess their willingness to continue with the treatment as well as their rating on observed improvements.

The pre-treatment, during treatment and post treatment measurement of length and width of each striae bands in the treatment area were recorded per subject. The pre-treatment and post treatment photographs were assessed and graded by 2 physicians.

RESULTS

All 16 subjects enrolled in the study completed the treatment and the following results were recorded:

No side effects or undesirable safety events were recorded for any subjects throughout the study.

Fourteen (14) out of the 16 subjects agreed that they noticed visible improvement, one was not sure while one did not see any improvement.

All subjects (100%) agreed that the treatment was comfortable. Figure 1 below shows the graphical analysis of the outcome of the patient survey conducted during the study.

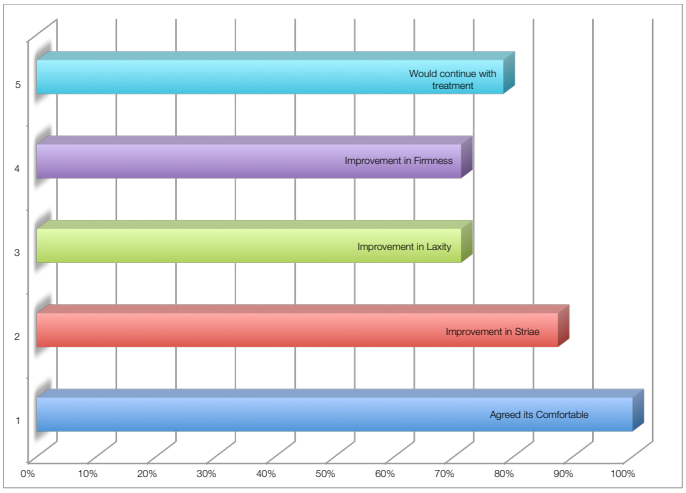
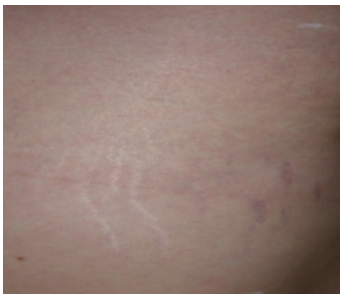
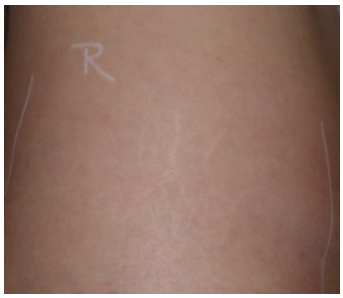


Figure 1

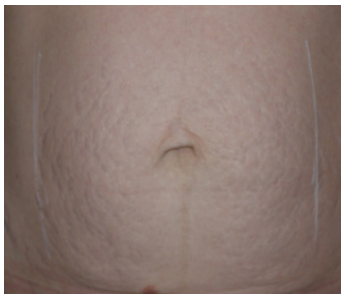
Visual evaluation of pre-treatment (baseline) and post-treatment photographs by the 2 physicians agreed that there was reduction in the visibility of striae after treatment in some of the pairs of photographs reviewed. The Kappa statistical method was used to establish almost perfect agreement on decisions of the 2 physicians at 95% confidence interval (Kappa value of 0.88, SE(κ) = 0.083, 95% CI = 0.71 to 1.04). The following photographs show reduction in the visibility of striae after 6 treatments with Venus Freeze system (Figure 2).



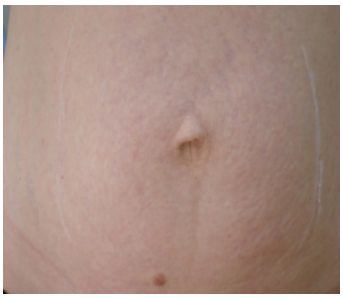
Pre-treatment Photo



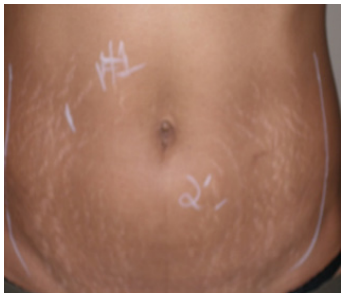
Post-treatment Photo



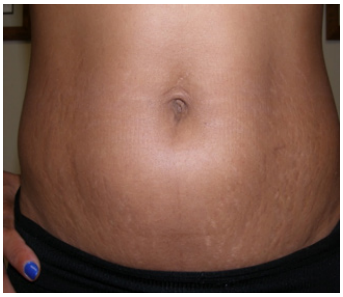
Pre-treatment Photo



Post-treatment Photo



Pre-treatment Photo



Post-treatment Photo

Measurements of length and width of striae bands were statistically analysed to determine the efficacy of Venus Freeze in the treatment of striae (Figure 3). The mean reduction in length of striae bands measured in the 16 subjects after the treatment was 1.031, standard deviation (SD) 0.853. The mean reduction in width of striae bands measured in the 16 subjects after the treatment was 0.160, SD 0.171. Using paired t-test, the reduction in both length and width of striae bands measured at one month post treatment visit compared to baseline measurements were found to be statistically significant at 95% ($p<0.001$).

DISCUSSION AND CONCLUSION

All 16 subjects that participated in this study agreed that the treatment was comfortable and no side effects or undesirable safety events were recorded throughout the 6 weeks treatment. These results support the safety of Venus Freeze.

Fourteen (87.5%) out of the 16 subjects agreed that they noticed visible changes. Further, there were statistically significant reductions in both length and width of striae bands measured at one month post treatment visit compared to baseline measurements in these subjects.

Subjects	Reduction in Length (cm)	Reduction in Width (cm)
1	3.180	0.239
2	0.804	0.159
3	0.638	0.318
4	1.744	0.636
5	2.065	0.000
6	0.635	0.239
7	1.133	0.083
8	-0.067	-0.067
9	1.950	0.125
10	1.533	0.133
11	0.100	0.100
12	0.650	0.200
13	0.700	0.267
14	0.500	0.200
15	0.533	-0.033
16	0.400	-0.033
n (# of subjects)	16.000	16.000
μΔ (mean of Reduction)	1.031	0.160
SD (Standard Deviation)	0.853	0.171
SE (Standard Error)	0.213	0.043
Upper 95% Confidence Interval	1.236	0.201
Lower 95% Confidence Interval	0.826	0.119

Figure 3

In conclusion, the data generated in this study support the safe and effective use of the Venus Freeze system in the treatment of striae.

REFERENCES

1. Nonablative cutaneous remodeling using radiofrequency devices.
   Alster TS, Lupton JR. Clin Dermatol. 2007 Sep-Oct;25(5):487-91

2. Histological and ultrastructural evaluation of the effect of radiofrequency-based nonablative dermal remodeling device.
   Zelickson BD, Kist D, Bernstein E, et al. Arch Dermatol 2004;140:204–9

3. Bipolar Fractional Radiofrequency Treatment Induces Neoelastogenesis and Neocollagenesis;
   Basil M. Hantash, MD, PhD, Anan Abu Ubeid, BS, Hong Chang, PhD, Reza Kafi, MD, and Bradley Renton, PhD. Lasers in Surgery and Medicine 41:1–9 (2009)

4. Emilia del Pino M, Rosado RH, Azuela A, et al. Effect of controlled volumetric tissue heating with radiofrequency on cellulite and the subcutaneous tissue of the buttocks and thighs.
   J Drugs Dermatol. 2006;5(8):714–722.

5. Decreased expression of collagen and fibronectin genes in striae distensae tissue,
   Lee K, Rho Y, Jang S, et al. Clin Exp Dermatol 1994; 19:285-288;