ABSTRACT

Stretch marks are common skin disorders that are dermal scars with associated epidermal atrophy. They are of significant concern or psychological concern to many. This manuscript describes the use of multipolar radiofrequency with pulsed magnetic fields that was successfully used to diminish these lesions in 16 subjects undergoing a series of treatments. The improvements noted were statistically significant and no serious adverse events were noted. (J Clin Aesthet Dermatol. 2014;7(9):30–33.)

DISCLOSURE: Dr. Dover has a relationship with Allergan, CVS/Skin Effects, Cutera, Cynosure, Kythera, Lumenis, Medisys, Merz, Myoscience, Shaver, Solta, Suneva, Syneron, and Zeltiq. Dr. Rothaus reports no relevant conflicts of interest. Dr. Gold is a consultant and performs research for Venus and is a stockholder in Venus.

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Venus Freeze (Venus Concept, Toronto, Ontario, Canada) is a noninvasive multi-polar (MP) pulsed electromagnetic field (PEMF) and RF energy generating system with two applicators—Diamondpolar\textsuperscript{TM} (4 RF and PEMF electrodes) for treatment of small areas and Octipolar\textsuperscript{TM} (8 electrodes and 9 PEMF) for treatment of large areas. The treatment applicators transmit bipolar RF energy in a method that creates an organized 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 mediates thermal stimulation of the extracellular matrix (ECM) in the dermis. This results in an immediate and temporary shrinkage of the collagen triple helix\textsuperscript{3,4} and subsequently, micro-inflammatory stimulation of the fibroblast, which, in response, produces new collagen (neocollagenesis), new elastin (neoelastogenesis), and ground substances.\textsuperscript{3,4} This treatment enhances the tensile strength and elasticity of the dermis with the aid of the newly produced proteins and proteoglycans.\textsuperscript{2,3,5}

**OBJECTIVES**

The objective of this study was to evaluate the safety and effectiveness of using RF and PEMFs for the treatment of striae. The safety of RF and PEMFs for striae treatment was established by physicians' 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 RF and PEMFs for striae treatment was established by the level of improvement seen visually and by macro-photography.

**MATERIALS AND METHODS**

Sixteen female subjects between the ages of 30 and 72 (mean age=46.06 years, SD=10.247) with varying degrees of striae participated in this two-center, 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 pretreatment photograph (baseline), six treatment visits, which included five measurements of striae bands and pretreatment photographs and two 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 six-inch 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 six treatments using RF and PEMF. 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 being 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 pretreatment, during treatment, and post-treatment measurement of length and width of each striae bands in the treatment area were recorded per subject. The pretreatment and post-treatment photographs were assessed and graded by two 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 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 shows the graphical analysis of the outcome of the patient survey conducted during the study.
- Visual evaluation of pretreatment (baseline) and post-treatment photographs by the two 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 two physicians at 95% confidence interval (Kappa value of 0.88, SE(κ)=0.083, 95% CI=0.71 to 1.04). Figure 2 shows reduction in the visibility of striae after six treatments with RF and PEMFs.

Measurements of length and width of striae bands were statistically analyzed to determine the efficacy of RF and PEMFs in the treatment of striae (Table 1). The mean reduction in length of striae bands measured in the 16 subjects after the treatment was 1.031, 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 six-week treatment period. These results support the safety of RF and PEMFs.
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.

In conclusion, the data generated in this study support the high degree of patient satisfaction and demonstrate the safe, effective use of RF and PEMFs in the treatment of striae.

LIMITATIONS

Although results are promising, the long-term sustainability of the reduced visibility of the striae is not known, and further investigation is required. Patients may achieve a noticeable improvement; however, the complete elimination of the striae is not achieved using this method.

REFERENCES