
Synergistic Multi-polar Radiofrequency and Pulsed Magnetic Fields in the Non-Invasive Treatment of Skin Laxity and Body Contouring.

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INTRODUCTION

Much of the surgical effort in Plastic Surgery and Cosmetic Medicine is devoted to the enhancement of patients with skin laxity and/or body contouring concerns. The gold standard of skin laxity therapy has always been, and remains, skin excision. Whether facelift, breast-lift, abdominoplasty or brachioplasty, the removal of excess skin, through well-placed incisions, most often results in excellent clinical results and a happy patient. Similarly, the most consistent and impressive results in the management of multifocal lipodystrophy, with good skin tone, remains the various techniques of liposuction. However, the scars, stigmata, morbidity and fear of excisional and liposuction procedures keep the majority of patients looking for less invasive skin tightening and body contouring procedures, away from the plastic surgeons and cosmetic physician offices that do not offer these modalities.

The consumer demand for, and hence the sales of non-invasive devices for skin tightening, wrinkle reduction, body contouring and cellulite enhancement remain very strong, despite the disruptive economy of the past three years. The ideal technology in this space would address skin tightening, cellulite improvement and body contouring in one device, with efficacious, expeditious treatments and little discomfort. Such technology would have no disposables and would be affordable to the physician.

BASIC SCIENCE

The technology options in the skin tightening and body contouring space have included vacuum massage, infrared laser technologies, high frequency focused ultrasounds, cryolipolysis, radiofrequency energy and various hybrid energy device options.

Radiofrequency energy devices have remained the most common and dominant technology in the non-invasive management of skin tightening, wrinkle reduction, cellulite improvement and body contouring enhancement, as they can treat all these conditions with relatively consistent results. Radiofrequency (RF) devices may be mono polar, bipolar (with or without other energy sources synergistically pulsed), tri-polar or, now, multi-polar. The RF energy is high frequency alternating electrical current that passes into the dermis and hypodermal tissues without disruption of the epidermal-dermal barrier. The high frequency oscillating electrical current results in collisions between charged molecules and ions and the micro-molecular mechanical energy from these collisions is transformed into heat^{1,2,3}. This biological RF heat occurs irrespective of chromophore or skin type and is not dependent upon selective photothermolysis. The RF heat has different biological and hence, clinical effects, depending upon the tissue targeted. In the dermis, where the primary cellular element is the fibroblast and the extracellular matrix (ECM) is comprised of collagen, elastin and ground substances, the RF mediated thermal stimulation of the ECM results in an immediate and temporary shrinkage of the collagen triple helix^{1,2,3}. Further, the RF thermal stimulation results in a micro-inflammatory stimulation of the fibroblast which in response produces new collagen (neocollagenesis) and new elastin (neaelastogenesis), and ground substances^{2,3}. If the RF thermal dermal stimulation treatments are performed with enough frequency, duration and supra-physiological impact, then the dermis will exhibit, over time, enhanced tensile strength, elastic properties from the newly produced proteins and proteoglycans, and will appear clinically smoother and more youthful^{1,2,4}. RF thermal stimulation of adipose tissue results in a thermal mediated stimulation and augmented activity of Lipase mediated enzymatic degradation of adipocyte derived Triglycerides into free fatty acids and glycerol⁴.

This amplification of the physiologic breakdown and egress of the Triglycerides out of the adipocyte, while keeping the adipocyte cell membrane and cell function intact, results in RF induced shrinkage of the fat cells and body contouring and cellulite improvements.

THE VENUS FREEZE DEVICE

This paper introduces a novel RF device, the Venus Freeze® (Venus Concept Ltd., Israel) that combines Multi-Polar RF current and Pulsed Magnetic Fields in synergy. The company calls this synergistic Multi Polar Magnetic Pulsed technology (MP)². The Freeze system delivers the energy through hand held applicators with Multi-polar electrodes. There is a larger Octipolar applicator with 8 electrodes arranged in a circle, designed for the treatment of larger zones and body contouring, and a smaller applicator with 4 electrodes for the treatment of face, neck laxity and rhytides, and smaller body contouring areas. Each magnetized electrode simultaneously emits RF and a Pulsed Magnetic Field. The RF current is produced between any two electrodes in the array and by rapidly alternating RF current between the different electrodes, the device can raise the temperature of treatment area quickly and homogenously, without the RF focal “hot spots” and pain seen with other RF devices.

The Pulsed Magnetic Field is induced by short pulses of electrical current through coil in the applicator. The magnetic field penetrates into the skin and results in Foucault (Eddy) electrical currents around the cell membranes of the treated tissues. Foucault currents change the electrical potential of charged receptors on the bi-lipid cell membrane layer of dermal cells, which results in the stimulation of molecular and cellular activities and reactions^{5,6,7}.

Magnetic Fields have been shown to increase fibroblast derived collagen production through a non-thermal mechanism of membrane stimulation, and the stimulation of fibroblast mediated angiogenesis, and hence facilitate and enhance wound healing in tissues^{5,6,7}.

Theoretically then, the Synergistic RF and Pulsed Magnetic Fields would create RF thermal collagen stimulation and Pulsed Magnetic Field non-thermal stimulation of collagen, RF thermally mediated reduction in adipose size and Pulsed Magnetic Field micro-tissue healing effects to minimize edema, swelling and downtime that are associated with pure RF thermal therapies.

This paper reviews our clinical experience with the Freeze, synergistically utilizing Multi-polar RF and Pulsed Magnetic Fields in the treatment of skin laxity, rhytides, as well as circumferential body contouring and cellulite.

MATERIALS AND METHODS

The study is a cohort study of 15 patients that were treated with the Freeze Multi-polar RF and Pulsed Magnetic Fields device. 14 patients were female and 1 patient was male. The age range was 30-66 years old. Patients were weighed and photographed before and after the study and were instructed to continue with their current lifestyle and not to change their nutrition, caloric intake or physical activity routines. 7 patients had their face and neck treated for skin tightening and rhytide reduction. 8 patients had treatments on their abdomen and hips for circumferential reduction. Finally, 8/15 patients also had synchronous treatments performed on an additional site for cellulite.

All study patients were treated for 8 weeks, twice the first week, then once weekly for 7 weeks, using the following protocol. Body areas were treated for 10 minutes for a 20 X 25 cm area. Facial treatments were performed for 12 minutes for each side of the face and 6 minutes for each side of the neck. The patients were treated lying down comfortably, with the treatment area exposed. After turning on the device, the relevant treatment program was selected from the available treatment options, and correct treatment head (OctiPolar or DiamondPolar applicator) was selected. The treatment area was cleaned with an alcohol wipe and make up was removed. Glycerin was applied to the treatment area.

The energy and treatment times were adjusted according to the area being treated. The starting energy was 30% for the face and 50% for the body. The applicator was applied to the skin, and the area was treated using sweeping motions. Applicator was not allowed to stop moving. The treatment technician deployed continuous sweeping motions, "figure 8", "swirls", "snakes" and "wave" shaped movements. During treatment, the energy was adjusted up or down, as tolerated, to achieve at least 40-42°C epidermal temperature within the first few minutes of treatment, and throughout the entire treatment. Infrared thermometer was deployed to measure the epidermal temperature. Treatment endpoint was 10 minutes of treatment per area with a uniform temperature of 40-42°C throughout the surface area.

All patients had before and after photography taken. The body contouring patients had circumferential measurements taken of the treatment zones.

RESULTS

All patients completed the study and follow-up photographs were taken at 3 months following last treatment. The author reviewed all facial photographs for evidence of wrinkle reduction and facial and cervical skin tightening. All skin tightening patients (7/7) demonstrated moderate to significant visual improvements in their rhytides, laxity and facial contours (figure 1).

The average circumferential reduction for the abdominal-hip body contour patients was 3.1cm (range 1.4cm – 4.3cm). All body contouring patients (8/8) responded with some measurable circumferential reduction (Figure 2).

For the cellulite cohort, 6/8 patients demonstrated noticeable and pleasing improvement in the appearance of their cellulite (Figure 2). The treatments were well tolerated, there were no complaints of significant pain or discomfort during any treatment, no major complications reported and only two cases of minor erythema reported on face or neck treatments that resolved within one hour.

CONCLUSIONS

The use of a synergistic Multi-polar Radiofrequency and Pulsed Magnetic Field device (The Freeze) appears to produce consistent and demonstrable skin tightening, circumferential reduction and cellulite improvement. When compared to other RF devices on the market, the Freeze appears to have the following advantages:

1. Freeze works much faster to achieve the thermal endpoint.
2. The soft tissue heating is more uniform and therefore is much more tolerable by the patient.
3. The device and treatments appear very safe.
4. The Freeze device has versatile clinical applications and revenue streams through the use of the DiamondPolar and OctiPolar applicators. Face and neck aging concerns, as well as small and large zone lipodystrophy and cellulite, can be treated.
5. Consistent and efficacious outcomes are achieved.
6. The Ergonomically designed applicators are friendly and easy to use by technicians.
7. No disposable cost to the physician.

Synergistic Multi-polar RF and Pulsed Magnetic Field treatments can be a versatile, efficacious and economically desirable addition to an aesthetic medical practice.

REFERENCES

1. Alster, TS, Lupton JR. Nonablative cutaneous remodeling using radiofrequency devices. *Clin Dermatol* 2007;25:487-91.
 2. Zelickson BD, Kist D, Bernstein E, et al. Histological and ultrastructural evaluation of the effects of a radiofrequency based non-ablative dermal remodeling device: a pilot study. *Arch Dermatol*. 2004;140:204-9.
 3. Hantash BM, Ubeid AA, Chang H, et al. Bipolar fractional radiofrequency treatment induces neoenlastogenesis and neocollagenesis. *Lasers Surg Med*. 2009;41:1-9.
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4. Emilia del Pino, M, Rosado RH, Azuela A, et al. Effect of controlled volumetric tissue heating with radiofrequency on cellulite and subcutaneous tissue of the buttocks and thighs. *J Drugs and Dermatol.* 2006;5:714-22.
 5. Akira Soda et al. Effect of exposure to an extremely low radiofrequency-electromagnetic field on the cellular collagen with respect to signaling pathways in osteopath-like cells. *J Med Invest.* 2008;55:267-78.
 6. Murray JC, Farndale RW. Modulation of collagen production in cultured fibroblasts by a low-frequency, pulsed magnetic field. *Biochem Biophys Acta.* 1985 Jan 28;838:98-105.
 7. Tepper OM, Callaghan MJ, Chang EL, et al. Electromagnetic fields increase in vitro and in vivo angiogenesis through endothelial release of FGF-2. *FASEB J* 2004; 18:1231-3.



Figure 1



Figure 2