Bipolar RadioFrequency, Infrared Heat and Pulsatile Suction in the Non-Surgical Treatment of Focal Lipodystrophy and Cellulite.

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Abstract

15 Patients and 66 anatomical sites were treated with a Bipolar Radiofrquency, Infared heat and Pulsatile suction device (VelaSmooth, Syneron Medical Ltd., Israel). The protocol consisted of 12 treatments over 6 weeks (two treatments per week). Each treatment consisted of 3-6 passes over focal areas of lipodystrophy and cellulite. The end point for each treatment zone was warmth and erythema. Each treatment required 45 minutes. Weekly measurements included circumferece of the thighs, hips and abdomen, each measured standard distances form stable bony landmarks. Weekly body weight was measured and metabolic indices were recorded monthly, including a complete blood count, electrolytes, cholesterol, triglycerides, VLDL, HDL and LDL as well as liver enzymes and a liver and kidney ultrasound. All study patients were females, with an average age of 46 years. The average pre-treatment weight was 76.73 kg and the post-treatments weight 76.64 kg. Mean circumferential reductions of the thigh of 4.00cm, abdomen 5.53 cm and hips 5.66 cm were achieved. Patient based assessment of cellulite and skin texture improvement was 62% (range 20-80%). Blinded evaluation by the doctor shows 40% improvement. There were no complications in the study and overall patient happiness was over 80%. We conclude that the VelaSmooth, bipolar Radiofrequency, Infrared energy and Vacuum suction device can achieve predictable and safe reduction of focal lipodystophic regions, smoothening of cellulitic skin and skin firming.

Introduction

Liposuction is the most commonly performed invasive cosmetic surgery procedure in the world. Liposuction surgery has traditionally boasted high patient happiness scores, but still carries with it significant peri-operative morbidity including death or medical illness, pulmonary emboli, scarring, seroma, skin irregularity and dysaesthesia.

Cellulite is estimated to affect over 80% of women over 50 years of age and can affect women with focal lipodystophy and also very thin women with no areas of excess fat. The demand for non-surgical and minimally invasive cosmetic enhancement procedures has witnessed the rapid growth of products and procedures such as botox, soft tissue fillers, peels, laser hair removal, fotofacial and photorejuvenation, micro-dermabrasion, thread and suture based face-lifting. In the past, minimally invasive body contouring and cellulite improvement services have included Endermology, Mesotherapy and Carboxytherapy, with only modest and generally inconsistent fat contouring or cellulite outcomes. There would be significant demand and interest in a non-surgical procedure that delivered "liposuction-like" contour reductions of focal lipodystophies as well as significant smoothening of cellulite.

Materials and Methods

15 female patients with 66 treatment site were selected for study. Inclusion criteria were areas of focal fat accumulation and cellulite, an understanding of the potential risks and benefits, were medically well and not pregnant. The average age was 46 years old. All patients underwent a standardized protocol of twice weekly treatments with the VelaSmooth device (Syneron Medical Ltd, Israel). The VelaSmooth delivers Bipolar Radiofrequency energy, Infared heat energy and Pulsatile vaccum suction through a hand-held applicator that is administered directly to the skin, (Figure 1). Each treatment lasted approximately 30-45 minutes and each zone was treated with 3-6 passes of the VelaSmooth applicator with the end point being significant erythema and warmth radiating from the treated skin.

Fig 1 VelaSmooth applicator

The VelaSmooth applictor has two rollers which act as RF electrodes with an IR light source placed above and between the two electrodes.
The clinical treatment is performed on each area of fat and/or cellulite twice a week for an average of six weeks.
64 zones were treated in the 15 patients. All patients had their inner and outer thighs, abdomen, waist and hips treated for lipodystropy and the back and front of thighs for cellulite. There were no special dietary, exercise or water consumption instructions to participate in the study. Patients had weekly circumferential measurements taken of their thighs, waist-abdomen and hips as well as body weight. The circumferential measurements were always conducted at a specific and consistent distance from an anatomical boney landmark, the ASIS for the hips, the umbilicus for the abdomen-waist and an inferior distance from the inguinal tubercle and greater trochanter for the thighs. Pre-study and post-study analysis were made of the following indices, complete blood count, electrolytes, liver enzymes, renal function, cholesterol, triglyceride and lipoprotein levels and liver and kidney ultrasounds. Pre and Post-study digital photographs were take of the anatomical lipodystrophic regions as well as areas of cellulite. Following the study patients were asked to grade their cellulite improvement on a linear analogue scale (0-100%) and the before and after photos of the cellulite underwent independent blind evaluation by a dermatologist, using a standardized cellulite score.

Results

All study patients completed the six week, 12 treatment study. The average circumferential reductions were 4.00cm for the outer-inner thighs, (range 1.5-6.0 cm), 5.53 cm for the abdomen-waist, (range 3-8.0 cm) and 5.66 cm for the hips, (range 3 – 9.0 cm). Table 1 details all the circumferential lipodystrophy data.

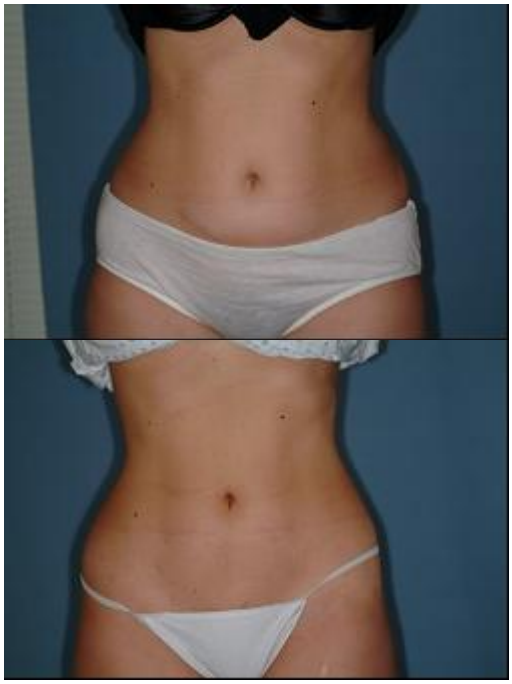

Figure 2. Patient pre-treatment (top) and post-treatment (bottom). Hip And abdomen lipodystrophy circumferential reduction of 6.5cm Reduction on the hips of 5.5 cm.

All patients underwent a metabolic profiling before and after the study and despite altering significantly the fat depositions, there were no significant alterations in the metabolic indices as summarized in Table 2.
Patients were asked to complete the perception according to linear analog score grading their perceived cellulite improvement. The average score was 62%, with a range of 20 to 80%. Pre- and Post-study digital photographs were analyzed using blind evaluation method by a dermatologist who applied a standard cellulite grading score to the photographs and the unblended analysis revealed an average 40% improvement in the cellulite.
Patients were also asked to record their level of happiness with their fat contouring and cellulite smoothening results. 81% of study patients were very happy or happy with their results, 13% were satisfied and 6% were unhappy. 90% of patients would recommend the program to their friends. All patients made subjective comments that their skin was “tighter” or “firmer” after the program and several commented on improved stretch marks over the abdomen, but these outcome variables were not objectified by the study design.

Figure 3.Pre-treatment (top) and post treatment (bottom) back, with 7.5 cm reduction of hip-braline and 6 cm of the hip.

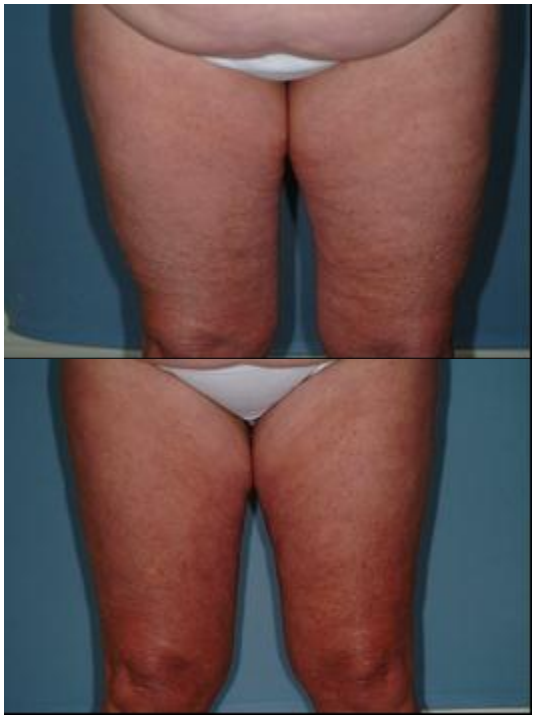

Figure 4. Cellulite of anterior thigh, pre-treatment (top) and post treatment (bottom)

Table 1.

Pre-treatment and post-treatment circumferential reduction measurements.

Number of patients = 15	Pre-Tx Average	Post-Tx Average	Average Change
Weight	76.64 kg	76.73 kg	**0.09 kg**
Thigh Circumference	65.50 cm	61.52 cm	**4.00 cm**
Abdomen-Waist Circumference	87.64 cm	82.11 cm	**5.53 cm**
Hip Circumference	107.64 cm	101.97cm	**5.66 cm**
Braline (n=2)	95.4 cm	91.0 cm	**4.4 cm**
Calves (n=2)	34.6cm	32.2 cm	**2.2cm**
Arms (n=2)	18.8 cm	17.4 cm	**1.4 cm**

Table 2

Pre- and post-treatment metabolic indices and profiles

	Pre-Tx	Post-Tx
Hb	134	133
Urea	3.0	2.9
Creatinine	70	72
Na+	139	140
K+	3.4	3.2
Cl-	110	109
Cholesterol	3.2	3.1
Trigylcerides	1.35	1.25
VLDL HDL/LDL	Normal	Normal
AST	28	25
Alkaline Phosphatase	76	70
Liver Ultrasound	Normal	Normal
Kidney Ultrasound	Normal	Normal

Discussion

The tremendous growth in interest in aesthetic plastic surgery has been fuelled in large part by minimal and non-invasive procedures. Most of non-invasive enhancements have been aimed at rejuvenation of the face and neck. Mesotherapeutic

chemical modulation and subcutaneous carbon dioxide insufflation (carboxytherapy) of localized fat and cellulite have been common in Europe, South America and Canada for some years, but the results in body contour alteration and cellulite improvement have been inconsistent and modest at best. Endermology provides early promise in the treatment of cellulite and body contouring, but the results and long-term success have not been overwhelming, which has limited the success of this modality in the offices of most plastic surgeons. By contrast, the use of radiofrequency and infrared heat, together with pulsatile suction in the form of the VelaSmooth™ device provides consistent reduction in focal lipodystropy, cellulite smoothening and skin tightening.

In this study, there was a 100% response in circumferential reduction in lipdystrophic regions. In the absence of weight loss or dietary manipulations one can conclude that the fat reduction contouring was a result of adipose tissue redestribution. The author postulates that the RadioFrequency and Infrared energy deliveries a critical amount of thermal effect to the deep fat with each treatment. Patients describe their treated areas was actually worm for 1-2 hours after each treatment. This critical heating of the fat stimulates a Lipolytic pathway that continues over the 6 week program to break down and metabolize the triglyceride contents of the localized Lipocyte into its component free fatty-acid, choline and glycerol. The bodies normal transport mechanisms and lipoproteins take the broken down triglyceride back to the liver for metabolism, utilization or excretion. During the study, none of the lipoprotein, triglyceride, cholesterol or liver function tests changed, suggesting that the slow metabolic triglyceride consumption stimulated by the treatments appears to be safe.

Thermogenic RF mediated focal break down of fat has also been reported using the Thermage monopolar Thermcool system, however, this focal fat loss has been irregular and aesthetically displeasing. The thermogenic lipolytic contour improvements with the VelaSmooth proved to be very safe and the contour alterations smooth and consistent. With proper weight maintenance, patient might be expected to last for a long time. If, however, you add a caloric stimulus, the shrunken lipocyte will likely expand.

Over the first month of treatments, the local fat reduction was just starting to be measurable, but it was not until after 6 weeks that the reductions had maximized and had started to plateau. Some larger patients may benefit from an additional month of treatment. There is definitely some technique and finesse involved in the Treatments, particularly in achieving an endpoint.

Cellulite is a poorly understood disease, likely of chronic lymphatic and microcirculatory compromise, lipolymphedema, fibrosis and contraction and, ultimately, the clinical manifestation of cellulite. The Bipolar RF, IR and suction treatments showed noticeable and consistent cellulite improvements. The mechanism is possibly related to mechanical and thermal enhanced blood flow, lymphatic drainage and an increase in metabolic oxygenation to the cellulite tissue with a resultant decompression of the lipolymphedema and reduced sclerosis and fibrosis. However, unlike the fat contouring which may be long lasting, the improvements in cellulite, will need a maintenance treatment every 4-6 weeks.

The overall patient observation of increased skin tightness, may be related to the dermal matrix heating observed with bipolar RF and skin tightening noticed on the face and upper torso. A majority of patient with stretch marks, even mature hypotrphic striatum, reported improvement.

The use of this device has other potential benefits employed by the author, but not a formal part of this study, specifically after liposuction. The device and twice weekly protocol is instituted around 8-12 weeks postoperatively and the authors incidence of post-liposuction revision has decreased by approximately 50% and the cellulite or skin texture irregularity incidence has also significantly decrease.

Conclusion

1. RF-IR and Pulsatile suction provide consistent and pleasing fat contour results in areas of focal lipodystrophy without a knife, surgery or recovery.
2. Cellulite and skin tone also improves.
3. Overall, the treatment of focal liposdystrophy and cellulite using RF-IR and vacuum suction has a high patient acceptance, low incidence of complication and a high patient satisfaction score.
4. Bipolar RF, IR and suction may help reduce post-liposuction contour irregularities and lowered revision rates.