Treatment of cellulite with a bipolar radiofrequency, infrared heat, and pulsatile suction device: a pilot study

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Summary

Background Very few therapeutic options have proven effective in the treatment of cellulite.
Aims To evaluate the effectiveness and adverse effects of a bipolar radiofrequency (RF), infrared (IR) heat and pulsatile suction device for the treatment of cellulite.
Methods Twelve subjects were treated with the RF-light-based device. All subjects were treated twice weekly for a total number of eight to nine treatments. Subjects were evaluated using standardized photographs, and measurements of body weight and circumference of treatment sites at baseline, immediately after the last treatment, and four weeks and one year after the last treatment. Clinical improvement scores of comparable photographs using a quartile grading scale (0 = <25%, 1 = 25–50%, 2 = 51–75%, 3 = >75% improvement) were judged independently by two non-treating dermatologists after the series of treatment.
Results The average body weights at baseline, immediately after the last treatment, and four weeks and one year after the complete treatment were 56.30, 56.05, 56.23, and 56.53 kg, respectively. The average circumferential reductions of the abdomen and thigh at the last treatment visit were 5.17 ± 1.04 cm (6.32% ± 1.82%) and 3.50 ± 2.16 cm (6.23 ± 3.58%), respectively. At four weeks after the last treatment, the average circumferential reductions of the abdomen and thigh were sustained at 3.17 ± 2.75 cm (4.04% ± 3.69%) and 3.50 ± 2.04 cm (6.26% ± 3.52%), respectively. At one year follow-up visit, the average circumferential reductions of the abdomen and thigh were maintained at 3.83 ± 0.76 cm (4.64% ± 1.15%) and 3.13 ± 3.54 (5.50% ± 6.12%), respectively. Average clinical improvement scores of the abdomen and thigh after the series of treatments were 0.75 (corresponding to ~25% improvement), and 1.75 (corresponding to ~50% improvement), respectively.
Conclusions A bipolar RF, IR heat and pulsatile suction device provides a beneficial effect on reduction of abdomen and thigh circumference, and smoothening of the cellulite.

Keywords: cellulite, circumferential reduction, infrared heat, pulsatile suction, radiofrequency

Introduction

Cellulite is a common condition affecting over 80% of postpubertal women. It is characterized by a dimpled or "orange-peel" appearance of the skin, frequently found on the thigh and buttock regions.[1,2] The cause of cellulite remains unknown, although there are a number of different hypotheses including sexually dimorphic skin architecture, altered connective tissue septae, vascular changes, and inflammatory factors.[2,3]

A functional defect of the dermal vasculature has been postulated, particularly loss of the capillary networks. As a result, fluid is accumulated within the dermal and

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subcutaneous tissues. This loss of the capillary network is thought to be the result of engorged fat cells clumping together and inhibiting venous return. After the capillary networks have been damaged, vascular changes begin to occur within the dermis, resulting in decreased protein synthesis and inability to repair tissue damage. Clumps of protein are deposited around the fatty deposits beneath the skin, ultimately leading to sclerosis, interstitial fibrosis, and decreased venous return and lymphatic flow, causing adipocyte deformity and the characteristic skin contour irregularities of cellulite.

Multiple treatment modalities including application of topical agents, massage-based therapies, subcision, and liposuction have been employed with little scientific evidence that any of these therapies are beneficial.[4,5] Although liposuction seems to be the procedure of choice, it is an invasive surgery with adverse effects and downtime. Nonsurgical and minimally invasive procedures, including endermologie,[6] mesotherapy,[7] and subcutaneous carbon dioxide insufflation (carboxytherapy),[8] provide minimal and inconsistent fat contouring and cellulite outcome.

Endermologie or skin kneading is a machine-assisted body-contouring system enabling positive pressure rolling in conjunction with applied negative pressure to the skin and subcutaneous tissue. This technique is claimed to make cellulite less visible by stretching of the fibrous septae of the subcutaneous tissue and stimulating lymphatic drainage. There is little evidence to support its efficacy in reducing cellulite.[9] Mesotherapy, a method of delivering a multiplicity of medications locally with the use of numerous cutaneous injections, has recently become a popular treatment for cellulite. Experimental studies using individual mesotherapy ingredients for other conditions suggest a number of mechanisms, including lipolysis, disrupting connective tissue, and augmenting circulation, which may supposedly improve cellulite. Until further studies are performed, practitioners who use mesotherapy for cellulite treatment must be aware that the substances currently being injected to treat this cosmetically disturbing, but medically benign, condition have not been thoroughly evaluated for safety and efficacy. Subcutaneous administration of carbon dioxide biweekly for three consecutive weeks in 48 female patients presenting with localized adipose accumulations showed a significant reduction in circumferences of the thigh, knee, and abdomen. Side effects following the procedure included transient cracking sensation beneath the skin (100% of the patients), slight hematoma (30%), and pain at the site of injection (70%).[8] The efficacy of subcutaneous carbon dioxide application in improving cellulite is believed to result from the improvement of local tissue perfusion and stimulation of oxidative lipolytic process.[10] Recently, applications of laser or radiofrequency (RF) and infrared (IR) light, combined with mechanical manipulation, have been shown to improve cellulite appearance.[2,11]

This study was designed to determine the effectiveness and adverse effects of a bipolar RF, IR heat, and pulsatile suction device for the treatment of cellulite.

Materials and methods

Twelve female patients were recruited to the study between November 2004 and January 2005. The patients were between 26 and 52 years of age (mean age 38.5), with cellulite on the abdomen and thigh, and skin phototypes III–V. All patients were treated with an RF-light-based device (VelaSmooth™, Syneron Medical Ltd, Yokneam, Israel) at the abdomen and/or thigh. The device delivers bipolar RF, IR heat energy, and pulsatile vacuum suction through a hand-held applicator that is pressed directly against the skin surface. All subjects were treated twice weekly for a total number of eight to nine treatment sessions with an IR light and RF power of 20 W and vacuum level of 200 millibars (750 mm Hg negative pressure). Prior to initiating treatment, the skin surface was hydrated using conductive fluid. Each treatment consisted of four passes of therapy over the treatment sites. Each pass consisted of eight stacking pulses given to a same area. The endpoint of treatment was when significant erythema and warmth radiating from the treated skin was observed. Each treatment session lasted 30–45 min. The applicator was in full contact with the treatment area to allow the vacuum to be most effective and ensure that the electrode rollers were fully coupled to the skin.

Standardized digital photographs using consistent patient positioning, camera angling, lighting, and measurements of body weight, and circumference of treatment sites was obtained at baseline, immediately after the last treatment, and 4 weeks and then 1 year after the last treatment. Clinical improvement scores of comparable photographs using a quartile grading scale ($0 \leq 25\%$, $1 = 25–50\%$, $2 = 51–75\%$, $3 \geq 75\%$ improvement) were graded independently by two nontreating dermatologists after the series of treatments. The circumferential measurements were always taken at a specific and consistent distance from an anatomical landmark including the umbilicus of the abdomen and a superior distance from the upper pole of patella for the thigh. All subjects were instructed to maintain their normal lifestyle, and diet and fluid consumption.

Results

Of all 12 patients, seven patients and nine anatomical sites including four abdomen and five thigh regions completed

Table 1 Pretreatment and posttreatment body-weight reduction measurement.

Body weight (kg)	Complete protocol (excluding obese subject) (n = 6)	Obese subject (n = 1)	Not complete protocol (n = 5)
Baseline	56.30 ± 6.24 (51.00–68.00)	105.00	57.80 ± 11.28 (43.80–74.20)
Immediately after the last treatment	56.05 ± 6.32 (51.00–68.00)	105.00	57.96 ± 11.38 (43.40–74.40)
Weight reduction	0.25 ± 0.76 (–1.00–1.00)	0.00	–0.16 ± 0.52 (–1.00–0.40)
Weight reduction (%)	0.45 ± 1.42 (–1.89–1.88)	0.00	–0.25 ± 1.02 (–1.89–0.91)
4 weeks after the last treatment	56.23 ± 6.69 (51.00–68.70)	105.00	–
Weight reduction	0.07 ± 1.21 (–1.80–2.10)	0.00	–
Weight reduction (%)	0.17 ± 1.21 (–2.83–3.94)	0.00	–

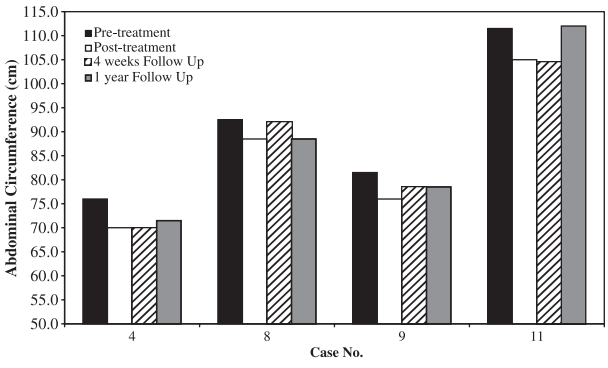

Figure 1 Abdominal circumferential measurement.

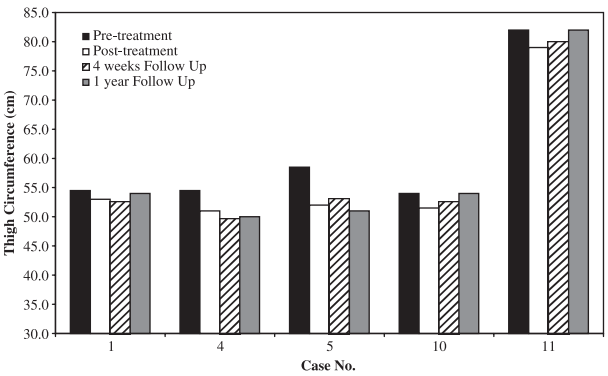

Figure 2 Thigh circumferential measurement.

the treatment protocol and were followed up at 4 weeks and then 1 year after the last treatment (Table 1). One of the 12 subjects who completed the treatment protocol of two anatomical sites weighed 105 kg. In order to avoid a large deviation of the data, the following results were analyzed by excluding the data of that heavyweight patient (a total of six patients and seven anatomical sites including three abdomen and four thigh regions).

The average body weights of the subjects who completed the treatment protocol at baseline, posttreatment, and 4 weeks and 1 year after the last treatment were 56.30, 56.05, 56.23, and 56.53 kg, respectively (Table 1). For all subjects who completed the study protocol, the average circumferential reductions of the abdomen and the thigh at the last treatment visit were 5.17 ± 1.04 cm (6.32 ± 1.82%) and 3.50 ± 2.16 cm (6.23 ± 3.58%), respectively. At 4 weeks after the last treatment, the average circumferential reductions of the abdomen and the thigh were 3.17 ± 2.75 cm (4.04 ± 3.69%) and 3.50 ± 2.04 cm (6.26 ± 3.52%), respectively (Figs 1 and 2). At the 1 year follow-up visit, the average circumferential reductions of the abdomen and the thigh were 3.83 ± 0.76 cm (4.64 ± 1.15%) and 3.13 ± 3.54 cm (5.50 ± 6.12%).

Average clinical improvement scores of the abdomen and thigh after the series of treatments were 0.75 (corresponding to ~25% improvement) and 1.75 (corresponding to ~50% improvement), respectively (Fig. 3A,B). Body weight and shape of the subjects had no influence on degree of clinical improvement score and circumferential reduction.

Adverse effect

A blister developed on the thigh of one patient following her sixth treatment session. This was treated with a topical antibiotic ointment. The blister eventually healed without scarring.

Discussion

Cellulite remains a common and difficult problem that predominantly affects the buttocks and thighs of postpubertal women. A number of topical and systemic treatments and invasive and noninvasive procedures have been developed. However, most therapies have little scientific validation. In fact, much of the evidence is anecdotal, subjective, or based on patient self-assessment.

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Figure 3 (A) Cellulite and thigh contour before treatment in a representative patient weighing 53.3 kg, with a thigh circumference of 54.5 cm. (B) Cellulite and thigh contour at 4 weeks after eight treatment sessions with weight and circumferential reductions of 2.1 kg (3.94%) and 5 cm (9.17%), respectively.

Evaluation of therapeutic interventions for cellulite is difficult secondary to confounding factors, such as diet and exercise, as well as the absence of standard criteria used to assess or to compare treatment responses.

The present study showed that a bipolar RF, IR heat, and pulsatile suction device safely reduced the abdomen and thigh circumferences, and provided a beneficial effect on cellulite appearance. This finding was comparable to the results of two recent studies using the same device.[11,12] A preliminary study by Sadick and Mulholland reported the mean decrease in thigh circumference of 0.8 inches (2.03 cm) after 8–16 treatments, and 100% of all patients demonstrated some degree of improvement in skin texture and cellulite.[12] Similarly, Alster and Tanzi[11] recently evaluated the efficacy of such a device and found that 90% of patients noted overall improvement following eight biweekly treatments. A clinical improvement of approximately 50% was observed in all patients, and circumferential thigh measurements were reduced by 0.8 cm after the last treatment. Interestingly, the present study noted that the reductions of the circumferences were still maintained 1 year after the last treatment. In addition, all patients had not changed their lifestyles and had followed their regular diet and exercise program.

Conservative treatment of cellulite with lifestyle modification, especially dietary control and regular exercise, does not demonstrate significant improvement in cellulite reduction.[13] Although many topical treatments including xanthines, retinoids, lactic acid, and herbals are available over the counter, there is no large-scale study demonstrating the effectiveness of these products.[1,14]

Noninvasive massage and suction techniques have been used for cellulite treatment on an assumption that cellulite might be caused by impaired blood and lymphatic circulation. Endermologie is a device developed to employ mechanical massage to mobilize the fat in the affected area. Collis *et al*. found no significant reduction of thigh circumferential measurements after either endermologie or topical aminophylline treatment, vs. a combination of both.[9]

The TriActive system (Cynosure, Chelmsford, MA) is another device that is approved by the US Food and Drug Administration for the treatment of cellulite. This device was designed to reduce the appearance of cellulite through the combined action of a localized cooling system, rhythmic massage, and deep (810-nm diode) laser stimulation. The system was believed to increase lymphatic drainage and blood circulation, and tightening of the skin. TriActive treatment three times a week for 2 weeks and then biweekly treatments for 5 weeks are suggested.[2]

The device used in the present study involves the simultaneous heating of the subcutaneous tissue with a controlled IR and conducted RF energies, combining with mechanical manipulations of the skin and fat layer with the rolling action of a massage unit. The light energy is a broad spectrum IR light source emitting a wavelength of 700–1500 nm. The RF is conducted to deliver the heat to the adipose tissue at a depth of 5–10 mm, which results in lipolysis and shrinkage of the fat chamber, thereby reducing the bumpiness of skin. The heating also increases peripheral circulation and molecular diffusion in the tissue,

leading to fat metabolism enhancement. The rollers knead the skin inward so the RF can penetrate deeper in the skin. The repeated kneading of the skin between the rollers physically breaks fat cell clusters and temporarily stretches the vertical septa and connective tissue, resulting in an improvement of the dimpled appearance. The negative pressure of suction at 750 mm Hg is applied to dilate the blood vessels and acts to improve local circulation to the skin. Mechanical action also enhances lymphatic drainage, and stimulates the evacuation of fat decay products.

The limitations of the current study include the small sample size due to dropout of some patients, and the lack of objective assessment of the cellulite condition. Documenting skin tone and surface irregularities photographically is difficult. Gherardini *et al.*[15] suggested that the patient should be photographed in dark bikini underwear with bikini overhang to demonstrate the degree of skin flaccidity or tightening. An overhead lighting without flash or a single lateral light source in the foreground from a 75- to 90-degree angle should be used to illustrate skin irregularities.[15] Three-dimensional ultrasound[16] and magnetic resonance imaging (MRI)[17] may be used as an objective and standardized tool to accurately evaluate the cellulite condition. Ultrasound focuses on imaging of the dermis-hypodermis tissue interface to measure the roughness of the upper layer of fat cells, whereas high spatial resolution MRI demonstrates the topography of the dermo-hypodermal junction, and the three-dimensional architecture of the subcutaneous fibrous septae.

In conclusion, a bipolar RF, IR heat, and pulsatile suction device is a nonsurgical and minimally invasive therapeutic option that can improve body contouring, reduce abdomen and thigh circumferences, and smoothen the bumpy and dimpling appearance of the skin. However, a larger patient sample size and an objective assessment method are essential to accurately address the efficacy of such a device.

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