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Original Research

A prospective clinical study to evaluate the efficacy and safety of cellulite treatment using the combination of optical and RF energies for subcutaneous tissue heating

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BACKGROUND: There have not been any published studies on the use of radiofrequency (RF)–light-based technologies for the treatment of cellulite. Only preliminary results have recently been reported (ASDS Proceedings, September 2004).
OBJECTIVE: This two-center study investigated the safety and effectiveness of combined energies for cellulite treatment using the VelaSmooth™ system.
METHODS: Thirty-five female subjects with cellulite and/or skin irregularities on the thighs and/or buttocks were treated with the VelaSmooth device. Patients received from eight to 16 treatments twice weekly. All patients maintained their normal lifestyle, and diet and fluid consumption. The circumference of the right and left medial thighs was measured at both baseline and approximately 4 weeks after the last treatment. During the last follow-up visit, the physician graded the level of improvement in skin smoothing and/or cellulite improvement using pre- and post-treatment photographs. Three patients provided biopsy specimens for histological assessment.
RESULTS: All study patients showed some level of reduction in thigh circumference after 8 weeks of treatment; indeed, 70% of all patients showed such a reduction after 4 weeks of treatment. Also, 100% of all patients showed some level of improvement in skin texture and cellulite. The mean decrease in circumference was 0.8 inches. Some patients demonstrated reductions of more than 2 inches. There were minimal complications associated with treatment.
CONCLUSION: This preliminary study demonstrates that the VelaSmooth system can have a beneficial effect on cellulite appearance. Further studies are needed to better define the mechanisms by which RF and light energies affect subdermal tissues and develop a method of quantified cellulite analysis. *J Cosmet Laser Ther* 2004; **6**: 1–4

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Introduction

Irregularities of the natural skin contour are an undesirable condition that can occur secondary to trauma, surgical intervention, or from a natural genetic expression. Cellulite, a version of the irregularity, is a mottled, dimpled appearance of the skin, often described as resembling 'cottage cheese' or 'orange peel'. This condition tends to gather around the thighs, hips, and buttocks of women. It is estimated that 85% of women over the age of 20 years have some degree of cellulite.[1,2] Fat is deposited immediately below the dermis and is contained in fat chambers that can become swollen. As the fat cells grow in size, the surrounding tissue becomes compressed and hardened, making blood circulation more difficult and trapping fluids. This results in reduced elasticity of the adipose tissue, producing an undesirable tension between layers and the pitting characteristic of cellulite.[3]

Fat and cellulite treatments are performed for aesthetic reasons by a large segment of the population worldwide. Varying results have been obtained with invasive procedures such as liposuction and non-invasive technologies such as massagers (e.g. the LPG Endermologie, a machine-assisted body contouring system that enables positive pressure rolling in conjunction with applied negative pressure to the skin and subcutaneous tissues).[4,5] The LPG Endermologie may reduce the appearance of cellulite and alter fat distribution by pulling on vertical connective tissues and stimulating lymphatic flow. This system has also been used in combination with liposuction.

VelaSmooth™ (Syneron Medical Ltd, Yokneam, Israel) is a new non-invasive device that is based on the ELOS™ technology (a combination of radiofrequency [RF] and light energies), and is specifically designed to improve skin texture and to reduce the appearance of cellulite. The VelaSmooth system involves the simultaneous application of light energy to the tissue at a controlled infrared wavelength, conducted RF energy, and mechanical manipulations of the skin and fat layer. It is not yet known if light and RF devices have a therapeutic effect on cellulite. This article reports the preliminary efficacy and safety of the VelaSmooth technology, including a histological analysis.

Materials and methods

This was a prospective two-center study designed to evaluate the preliminary efficacy and safety of the VelaSmooth system, a system that functions by heating the subcutaneous tissue using a combination of infrared light and RF energies. Vacuum suction is applied to shape the skin for optimal delivery of RF energy to the depth of approximately 10 mm. Patients were eligible to participate in the study if they were female, at least 21 years of age or older, with the presence of cellulite and/or skin irregularities on the thighs and/or buttocks. Exclusion criteria included scarring or infection of the area to be treated, known photosensitivity, pregnancy, type 1 or 2 diabetes mellitus, use of medication known to induce photosensitivity, known anticoagulative or thromboembolic condition, use of pacemaker or internal defibrillator, and use of non-steroidal anti-inflammatory drugs or aspirin 2 weeks prior to and 2 weeks following the treatment.

Thirty-five female patients were enrolled in the study. The women were between 23 and 62 years of age (mean age 43) with cellulite and/or skin irregularities on the thighs and/or buttocks, and Fitzpatrick skin types II–VI. The protocol was approved by an Institutional Review Board, and all participants signed an informed consent. Subjects were free to discontinue their participation at any time during the study.

Patients were divided into two groups: the first group (20 patients) received treatments with the VelaSmooth twice weekly for 4 weeks and the second group (15 patients)[6] received treatments for 8 weeks, for a total of eight and 16 treatments respectively. The last follow-up visit occurred 3–4 weeks after the last treatment. The energy levels administered were as follows:

RF: 7, 14 or 20 J/cm^3
light energy: 5, 10 or 15 J/cm^2
pulsed vacuum levels: 200 mbar with duration of 100, 200 and 300 ms.

Energy levels were adjusted depending on the patient's sensation and skin response. The specifications for the VelaSmooth unit are shown in Table 1.

Prior to initiating treatment, the skin surface was hydrated using conductive fluid. The VelaSmooth handpiece was applied to the skin using gentle but firm pressure to ensure adequate coupling. The area was treated by moving the handpiece in a backward and forward motion. This action was repeated several times over a 30-minute period to cover the entire treatment area. After the first 5–10 minutes of treatment, the treated area was observed for skin erythema which was a proper end point. Additional treatments were conducted at higher energy levels if results were not satisfactory and if adverse effects were not observed after the first treatment.

The circumference of the right and left medial thighs were measured at both baseline and the last follow-up visit. Photographs of the treatment site were also taken at these time points (Figure 1). During the last follow-up visit, both the patient and physician judged the level of improvement in skin smoothing and cellulite appearance by comparing pre- and post-treatment photographs. The appearance of the treatment site was rated using the following grading scale: excellent (E), 75–100% improvement; very good (VG), 50–<75% improvement; good (G), 25–<50% improvement; mild (M), 1–<25% improvement; or no improvement, 0%.

Patients kept a daily diary to record possible complications for a period of 14 days after the initial treatment

Infrared power	Up to 20 J/cm^2
RF power	Up to 20 J/cm^3
Light spectrum	700–2000 nm
Vacuum	100–300 ms pulsed
Treated area	40 × 40 mm

Table 1
VelaSmooth system specifications.

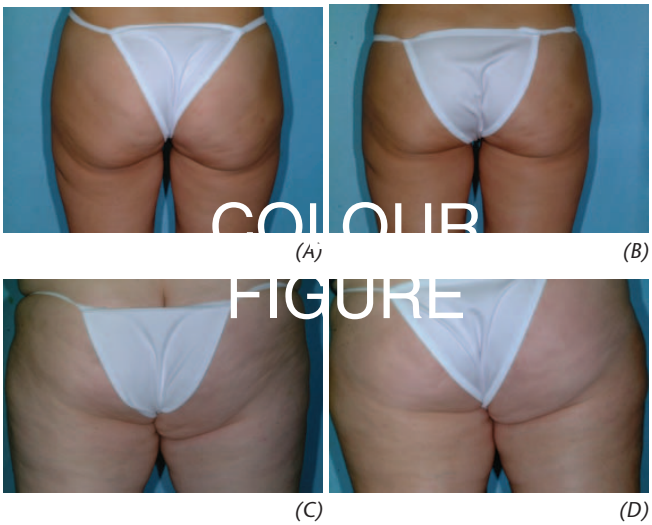

Figure 1

session with the VelaSmooth. Instructions were provided on the possible complications of treatment, including brownness, redness, blisters, crusting, and pain.

Biopsies of the lateral thighs were obtained from three study participants in order to evaluate the histological changes at the molecular level: 2 mm punch biopsies were taken before treatment (baseline), at week 1 (after two treatments) and week 4 (after eight treatments). Specimens were routinely processed and examined with hematoxyline and eosin, and special stains for elastic tissue (van Gieson), collagen (Masson) and reticuline fibers.

Results

All the patients in two study groups completed eight and 16 treatments, respectively. At the first treatment, patients were typically administered lower energy settings. By the last treatment, nearly all the patients were receiving the highest energy levels for treatment (third level). Target sites were treated until there was the appearance of erythema. Some patients reported feeling a moderate pain sensation while the applicator was applied to the same area for longer than 4 seconds.

At baseline, patients in the first study group (20 patients) had mean circumferences of the right and left thigh of 22.40 inches and 22.18 inches, respectively. At 3–4 weeks after the last treatment, mean circumferences were 22.22 inches and 22.11 inches, respectively. The mean change was −0.16 inches and −0.11 inches for the right and left thighs, respectively. Patients in the second study group (15 patients) had pre-study average thigh circumferences of 25.78 inches and a post-study average of 24.14 inches (Table 2).

In the two study groups, the physician ratings of the level of improvement in skin smoothing and cellulite appearance are shown in Table 3. The physician's measurements showed that 100% of patients had some level of improvement in skin smoothing and cellulite appearance, including 26% who showed 'excellent' or 'very good', 35% who showed 'good', and 38% who showed 'mild' improvement. Overall, 90% of the patients would recommend the treatment to their friends. Pre- and post-study digital photographs were analyzed by a blinded dermatologist who applied a standard cellulite grading score[6] to the photographs and the unblended analysis revealed an average 40% improvement in the cellulite.

Histological assessment showed no evidence of morphologic damage to any of the skin structures, either epithelial or mesenchymal. Also, there were no significant morphologic differences between the treated and untreated specimens. This histological analysis indicates that the VelaSmooth, used at the specified energy levels, does not result in any significant damage to skin structures. Therefore, any clinically evident changes are probably associated with deeply located alterations, either in the subcutaneous tissue or sub-fascial structures.

Following treatment with the VelaSmooth, a small number of patients reported minimal discomfort and temporary swelling, while two patients reported local crusting, which resolved within 72 hours. These occurrences may be associated with improper vacuum contact and coupling of electrodes.

Thigh circumference	Pre-study average (inches)	Post-study average (inches)	Average change (inches)
$n=20$	22.29	22.16	0.13
$n=15$	25.54	23.91	1.63

Table 2
Thigh circumference measurements (in inches) at baseline and 4 weeks after the last treatment with the VelaSmooth system.

	Rating				
	Excellent (75–100%)	Very good (50–<75%)	Good (25–49%)	Mild (0–24%)	No improvement (0%)
$n=20$ (%)	0 (0)	1 (5%)	7 (35%)	12 (60%)	0 (0)
$n=15$ (%)	2 (18%)	4 (36%)	4 (36%)	1 (9%)	0 (0%)

Table 3
Physician ratings of the level of improvement in skin smoothing and cellulite appearance.

Discussion

This study supports the preliminary efficacy and safety of the VelaSmooth system for skin smoothing and cellulite treatment. The VelaSmooth system is a novel technology based on the simultaneous application of light energy to the tissue at a controlled infrared wavelength, conducted RF energy, and mechanical manipulations of the skin and fat layer.

The mechanism of therapeutic effect is theorized to occur in the following manner: The initial tissue reaction to the VelaSmooth technology is an increase in local blood supply to the adipose tissue. Simultaneous to this increased availability of oxygen is an increase in oxygen dissociation from oxyhemoglobin. This increase in available oxygen may facilitate an increase in fat metabolism. By delivering infrared light and electrical conducted RF energy, the VelaSmooth increases ambient local tissue temperature, which theoretically increases the available oxygen for fat metabolism. Additionally, a mechanical action was incorporated in the treatment to physically break the fat cell clusters and to stretch the fibrous bands. This mechanical action may also promote lymphatic drainage by stimulating the evacuation of fat decay products. In summary, during treatment with the VelaSmooth, heat created by infrared light and RF energies increases the dissociation of oxygen from oxyhemoglobin and its diffusion to adipose tissue. Mechanical elements of the device were also designed to break the intercellular fat connection.

In this two-center study, twice-weekly treatments with the VelaSmooth for 4 and 8 weeks in the thigh area showed an overall mild to moderate improvement in skin smoothing and cellulite appearance for many patients. The primary noticeable effect was an evening out of skin contour that minimized the mottled and dimpled appearance of cellulite. There was an overall mean decrease in thigh circumference of 0.8 inches. Decreases in thigh circumference, however, did not necessarily correlate with subjective patient and physician ratings, indicating that the improvement in cellulite appearance was primarily related to an alteration in adipocyte distribution and not a decrease in fat volume.

By the last treatment, 80% of patients were receiving the maximum specified energy levels. In terms of safety, adverse effects were mild and transient.

It is not known to what extent the clinical improvement in cellulite treatment was due to mechanical manipulation versus the combination RF/light energy treatment. Mechanical manipulation with LPG Endermologie has been shown in clinical studies to be an effective method for fat mobilization and body contouring, with decreases in overall body circumference ranging from -0.52 to -0.72 inches following seven to 14 treatment sessions, respectively.[2] In this study, the VelaSmooth was found to decrease thigh circumference by approximately 0.8 inches. Further reductions in thigh circumference may be achieved by altering the different parameters of the machine. Further studies are currently underway to determine the optimal settings for the system.

Since it is known that infrared light penetrates to 1–3 mm and does not penetrate to adipose tissue, it might have some effect on dermfat junction.[7] Since RF energy does not have such limitations, it can penetrate to deeper levels and may be responsible for the observed reduction in circumference.

Adipose tissue has high electrical resistance because of pure blood content and electrical current should generate strong heat according to the following joule equation:

$$H = j^2 \rho$$

where j is electrical current density and p is tissue resistance.

Adipose tissue has a lower nerve concentration and the correlation between patient sensation and energy settings requires further investigation. In addition, further basic science studies are underway investigating RF and its effect on adipose tissue.

Conclusions

Based on the observations from this preliminary study, the VelaSmooth system appears to have some therapeutic effect in skin smoothing and cellulite treatment. These data support additional studies with well-defined study parameters that can determine the true impact of the VelaSmooth for cellulite treatment.

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