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ORIGINAL ARTICLE

A study evaluating the safety and efficacy of the Velasmooth™ system in the treatment of cellulite

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Abstract
Background: Most cellulite treatments are limited in their effectiveness. A combination of radiofrequency energy, infrared light and mechanical manipulation of the skin and fat merits further examination. *Objective*: Subjects were treated with a device combining these energies to evaluate its safety and efficacy. *Methods*: Sixteen subjects with cellulite were treated twice weekly for 6 weeks with the VelaSmooth™ system. One thigh was treated while the other served as a control. Treatment efficacy was measured through circumferential measurements of both thighs and by having the investigator and an independent evaluator grade visual improvement during follow-up visits. Five patients provided blood specimens for assessment of lipid and hormone levels and liver function. Two subjects provided three biopsies each in order to monitor the level of estrogen and progesterone receptors. *Results*: The overall thigh circumference decreased in 71.87% of the treated legs. The mean decrease was 0.44 cm of the lower thigh and 0.53 cm of the upper thigh. There was significant visual improvement in cellulite and skin texture. At the final follow-up visit, 50% of subjects had greater than 25% improvement (good be very good). *Conclusion*: This study showed positive results. Future studies employing higher energy levels and additional treatments will likely augment the results of the present study.

Key words: *Cellulite, laser, VelaSmooth™*

Introduction

Given the common occurrence of cellulite in women over 20 (1), it is not surprising that safe, effective treatments are in high demand but few studies have examined the causes of this condition (2). Cellulite is a condition characterized by a dimpling of the skin that results in a 'cottage cheese' effect (3). From a pathogenetic perspective, its basis is one of perpendicular orientation of the adipocyte septae leading to a herniation of underlying fat cells. Other theories have hypothesized that metabolic and hemodynamic alterations may lead to the clinical appearance of cellulite. While cellulite can occur anywhere on the body, it is commonly found on the buttocks and thighs.

There are many treatment options available at present, including liposuction, which has been utilized to reduce cellulite, as has subcision. Numerous pharmacological agents have also been used for the treatment of cellulite without success. It has also been recommended that individuals with cellulite consider dieting and exercise to improve their appearance. A decrease in weight may result in an improved appearance; nonetheless, there is no correlation between obesity and cellulite. However, cellulite may become more apparent in cases of weight gain and, conversely, less apparent when weight is lost (3). All of the treatments noted have had limited if any positive results in the reduction of cellulite (4).

Recently, non-invasive devices have gained acceptance and credibility in the treatment of cellulite. These include the Cellu M6 Keymodule (LPG Systems, France), employing the endermologie technique and the Triactive (Cynosure™, USA), a laser. More recently, the VelaSmooth™ system (Syneron Medical Ltd, Yokneam, Israel) has had some success in this field. VelaSmooth combines bipolar radiofrequency (RF) energy, infrared light and mechanical manipulation of the skin and fat. The VelaSmooth is a non-invasive approach to cellulite that requires less infrared energy to be delivered as RF energy is simultaneously delivered as a supplemental form of energy. This reduction in the amount of infrared light that is being administered to the individual reduces the occurrence of adverse

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effects such as skin pigmentation and scarring. Since RF energy does not target melanin, heating of the epidermis is much lower. It is believed that heat created by the two energies increases the dissociation of oxygen from oxyhemoglobin and its diffusion to adipose tissue. The increase in available oxygen may facilitate an increase in fat metabolism (5). The accompanying manipulation of the skin helps to improve circulation while possibly stretching the bands of connective tissue that surround the fat deposits (6).

Materials and methods

Initially, a two-center study was devised to examine the safety and effectiveness of a cellulite treatment system consisting of infrared light, and RF and mechanical manipulation of the skin and fat layer. The goal was to enroll up to 40 women at both sites. However, one of the two sites was unable to participate. As a result the data from this study is from one site only. The enrollment goal was 20 subjects.

Criteria for enrollment

Inclusion criteria: females, 21 years or older; presence of cellulite and/or skin irregularities on the thighs and/or buttocks; postmenopausal or surgically sterilized, or using an acceptable form of birth control.

Exclusion criteria: scarring or infection of the treatment area; photosensitivity; use of medications that are known to cause photosensitivity; pregnancy; diabetes mellitus, type I or II; anticoagulation or thromboembolic states; use of pacemaker or internal defibrillator; use of non-steroidal anti-inflammatory drugs (NSAIDs) 2 weeks before or after treatment; previous treatment of the area within 1 year of the baseline visit; known allergy to lidocaine (biopsy group only).

Scope and duration of the study

Twenty subjects were enrolled in the study. Subjects ranged in age from 28 to 59 years. All skin types from I to VI were enrolled. Sixteen of the 20 subjects remained in the study until completion. Of the four subjects who did not continue, one chose to discontinue treatment and three were discontinued due to non-compliance. All of the participants met the inclusion criteria of the study. All subjects signed the informed consent form previously approved by the Institutional Review Board. All subjects were counseled against weight gain during the study.

Each participant had one of her legs randomly chosen for treatment with the VelaSmooth system while the other leg served as a control. Subjects were treated twice weekly 3 days apart for a period of 6 weeks for a total of 12 treatments. Each leg was measured at two locations: one measurement was 18 cm from the superior pole of the patella and the other measurement was 26 cm from the superior pole of the patella, thus reflecting both the lower and upper thigh respectively. The two different circumferential measurements of both thighs were taken before the first treatment as well as after the 2nd, 4th, 6th, 8th, 10th and 12th treatments and during post-treatment follow-up visits. Follow-up visits were scheduled 4 and 8 weeks after the last treatment. The twice-weekly treatments were performed at the same time and same day of the week for each visit. The subject's weight was taken at baseline and the last treatment visit as well as during the follow-up visits. The treated leg was photographed after each session and also at the post-treatment follow-up visits (Table I).

Subjects were informed that erythema would be an expected clinical endpoint of the treatment. Furthermore, subjects were also counseled about possible reactions including edema, scarring, blistering, scaling, infection and either hypopigmentation or hyperpigmentation, of either a transient or permanent nature.

Each subject was asked to keep a daily diary for a total of 14 consecutive days beginning with the day of the first treatment. Subjects were instructed to keep track of the level of redness, swelling, blisters, crusting and pain at the treatment site. They rated these possible outcomes on a scale from 0 to 10, where 0 was none and 10 was severe. The investigator and the staff members were also asked to track the subjects' level of pain, erythema, edema, hyperpigmentation and hypopigmentation after each visit. These conditions were measured on a scale from 0 (absence) to 3 (severe). In addition, visual improvement was tracked by both the investigator and an independent evaluator. They each rated the overall progress on a grading scale from 'no improvement' to 'excellent improvement' by looking at photographs of the treatment area employing the following quartile scale with increments from 0% to 25%, 26% to 50%, 51% to 75% and 76% to 100%. Improvement was noted immediately after the last treatment, and at 4 and 8 weeks after the last treatment.

Each treatment with the VelaSmooth applicator took approximately 30 minutes, with each zone treated with three to six passes. A zone was demarcated as a major surface: posterior thigh, outer thigh and hip, inner thigh, anterior thigh and buttocks.

The results of the treatments were evaluated using photography, circumferential leg measurements, and visual improvement as rated by the investigator.

Biopsies. Three biopsies were taken from each of the two willing subjects. The biopsies were taken before

Table I. Treatments with the Velasmooth system.

	Week 1		Week 2		Week 3		Week 4		Week 5		Week 6		Week 10[a]	Week 14[b]
	Visit 1 Baseline	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12	Visit 13	Visit 14
Treatments	×	×	×	×	×	×	×	×	×	×	×	×		
Measurements of both thighs	×	×		×		×		×		×		×	×	×
Weight	×	×	×	×	×	×	×	×	×	×	×	×	×	×
Photographs	×											×	×	×
Follow-up visits													×	×

[a]Occurs 4 weeks (1 month) after the final treatment. [b]Occurs 8 weeks (2 months) after the final treatment.

Table II. Output specifications for the Velasmooth system.

RF power	10–100 W
Optical power	10–100 W
Light spectrum	680–1500 nm
Vacuum level	150 mbar
RF frequency	1 MHz

the first treatment, after the final treatment and 4 weeks later at the follow-up visit. The 2–3 mm biopsy was taken from the treated leg. The purpose of the biopsy was to assess morphologic changes that could potentially account for clinical evidence of cellulite reduction. The biopsies were placed in formalin and embedded in paraffin. Routine light microscopy was conducted.

Blood draws. Three blood draws were taken from five willing subjects. As with the biopsies, the draws were taken before the first treatment, after the final treatment and at the post-treatment follow-up visit, which occurred at 4 weeks. Blood was processed for lipid and hormone levels as well as liver function.

Energy levels. Treatment energy levels (between 1 and 3) were determined by the subject's skin type as well as the anatomic location being treated. See Table II for the output specifications of the VelaSmooth system. The amount of RF energy, optical energy and the vacuum levels were adjusted from patient to patient in order to ensure that the optimal treatment parameters were reached. It was recommended that the highest level be used if possible, except in cases when sensitive areas were being treated, such as the inner thigh. In such cases it was recommended that level 2 be used. Overall, patient tolerance and comfort were used to determine the appropriate energy settings for treatment.

Results

Sixteen subjects completed the study. At 18 cm from the superior pole of the patella, 10 subjects (62.5%) showed a reduction of between 0.5 cm and 2.5 cm of their treated leg, four (25%) showed no change and two (12.5%) showed an increase of 1.5 cm. Overall the average decrease was 0.5 cm. At 26 cm, 13 (81.25%) subjects showed a reduction of between 0.5 cm and 2 cm of their treated leg, two (12.5%) showed no change and one (6.25%) presented an increase of 1 cm. Overall the average decrease was 0.84 cm. From baseline to the end of the study, the mean change in the circumference of the treated right thigh was −0.125 cm and −0.875 cm (18 cm and 26 cm from the superior pole of the patella, respectively). For the treated left thigh the mean change was −0.75 cm and −0.188 cm, respectively (Figure 1 and Table III).

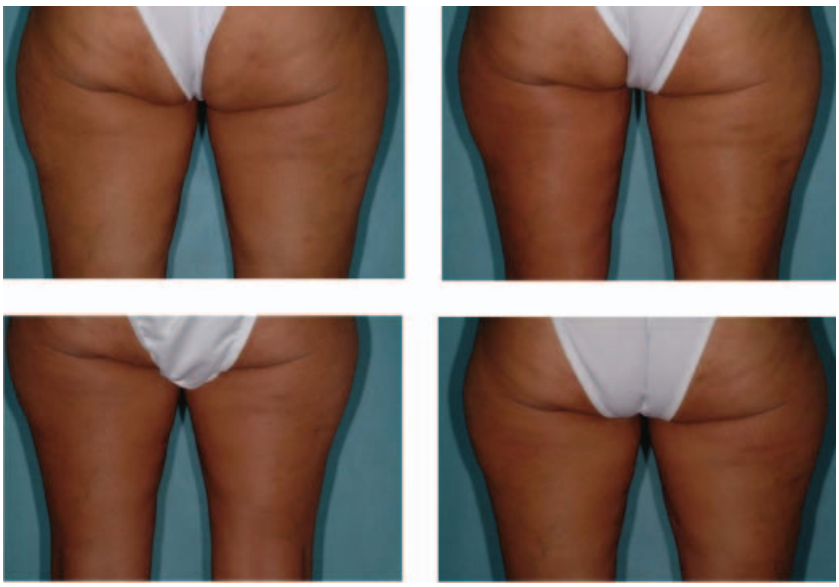

Figure 1. Left leg treated. Upper left photo: pre-treatment, baseline. Upper right photo: 12 weeks after final treatment. Lower left photo: 4 weeks after final treatment. Lower right photo: 8 weeks after final treatment.

At the same time, at 18 cm, seven subjects (43.75%) showed a reduction of between 0.5 cm and 2.5 cm on their untreated leg, eight (50%) showed an increase of between 1 cm and 2.5 cm, and one (6.25%) showed no change. The overall average was a decrease of 0.28 cm. At 26 cm, six subjects (37.5%) showed a reduction of between 0.5 cm and 1.5 cm, seven (43.75%) showed an increase of between 0.5 cm and 2.5 cm, and three (18.75%) showed no change. Overall, the average increase was 0.0625 cm. Even though there was no significant weight loss among the participants, it is difficult to pinpoint why there was a decrease in the size of some of the untreated legs, although the above change in circumference was not as dramatic as was seen in the treated leg. Thus, at 18 cm, 62.5% of the treated legs decreased in size, while 12.5% increased and 25% stayed the same. At 26 cm, 81.25% saw a decrease in size, while 6.25 % saw an increase and 12.5% saw no change. As for the untreated legs, the percentages were 43.75%, 50% and 6.25%, respectively, at 18 cm and 37.5%, 43.75% and 18.75%, respectively, at 26 cm.

A statistical analysis of the measurements of the thighs shows a significant decrease 4 weeks after treatment ($p < 0.01$) but none immediately and 8 weeks after treatment. This suggests that the best results are seen at 4 weeks and that a subject would need to have regular treatments in order to see continual positive results.

Twelve of the 16 subjects who completed the study also completed at least part of the diary. Six of these subjects experienced a desired clinical outcome of mild redness. Seven subjects complained of mild transient discomfort and one of swelling, while five subjects cited mild bruising even though this was not an included category. Most of study participants stated that their discomfort occurred intermittently throughout the 14-day tracking period but the levels were relatively mild, usually a 1 or 2 on a 0–10 scale.

No subjects exhibited edema, hyperpigmentation or hypopigmentation. Subjects who suffered pain or erythema did so consistently after each treatment but the levels were usually mild, while two cases were moderate. Mild, asymptomatic, self-limiting bruising within the first 2 weeks was noted by the investigator in 31.25% of subjects. These areas were avoided during treatment until resolution and did not require additional intervention.

Table III. Comparison of thigh circumference (in centimeters) of treated thighs at baseline and at end of study (based on results from 16 subjects).*

Baseline		End of study		Average decrease	
18 cm		18 cm		18 cm	
Right thigh	Left thigh	Right thigh	Left thigh	Right thigh	Left thigh
52.875	52	52.75	51.25	0.125	0.75
26 cm		26 cm		26 cm	
Right thigh	Left thigh	Right thigh	Left thigh	Right thigh	Left thigh
60.25	58.3125	59.375	58.125	0.875	0.1875

*Measurement starts from the superior pole of the patella.

Table IV. Visual improvement of cellulite appearance as charted by the investigator and rated after the final Velasmooth treatment (based on results from 16 subjects).

	Immediately after treatment	At 4 weeks after treatment	At 8 weeks after treatment
0–25% (none to mild)	11	8	8
26–50% (good)	5	7	4
51–75% (very good)	0	1	4
76–100% (excellent)	0	0	0

The investigator and the independent evaluator looked for a reduction in skin irregularities such as dimpling and puckering, which are often seen in cases of cellulite. The investigator's results were as follows: immediately post-treatment, 11 patients were rated to have 0–25% improvement while five had 26–50% improvement. At the 4-week follow-up, eight subjects had 0–25% improvement, seven subjects had 26–50% improvement and one subject had 51–75% improvement. By the 8-week follow-up, eight subjects had 0–25% improvement, four subjects had 26–50% improvement and four subjects had 51–75% improvement (Table IV). The independent evaluator's results were as follows: immediately post-treatment, 12 patients were rated to have 0–25% improvement while three had 26–50% improvement and one had 51–75% improvement. At the 4-week follow-up, eight subjects had 0–25% improvement, seven subjects had 26–50% improvement and one subject had 51–75% improvement. By the 8-week follow-up, five subjects had 0–25% improvement, six subjects had 26–50% improvement, four subjects had 51–75% improvement and one subject had 76–100% improvement. Results from the investigator and the independent evaluator were in line with each other. In particular, the results at 4 weeks post-treatment were the same. For the other two follow-up evaluations, the independent evaluator noted slightly more positive results (Table V).

All blood tests results were normal throughout the study.

Table V. Visual improvement of cellulite appearance as charted by an independent evaluator and rated after the final Velasmooth treatment (based on results from 16 subjects).

	Immediately after treatment	At 4 weeks after treatment	At 8 weeks after treatment
0–25% (none to mild)	12	8	5
26–50% (good)	3	7	6
51–75% (very good)	1	1	4
76–100% (excellent)	0	0	1

Both the pretreatment and post-treatment biopsy results appeared normal. There was no change from biopsy to biopsy. There was no extension into the subcutaneous fat, thus the biopsies were superficial.

The overall decrease in thigh circumference was 0.44 cm (0.17 inches) for the lower thigh measurement and 0.53 cm (0.21 inches) for the upper thigh. Visual improvement of greater than 51% was seen in 50% of the subjects at the final follow-up visit. While all patients noted some degree of improvement following the study protocol, the improvement continued to increase in 37.5% of subjects up to 8 weeks after the last treatment as noted by the investigator and in 50% as noted by the independent evaluator. It should be acknowledged that positive results are not solely based on thigh circumference but that the smoothness and appearance of the thigh is particularly significant as well.

Discussion

Cellulite is a condition that poses no medical risk but is considered aesthetically unattractive by many people. The search for a treatment that will ameliorate the physical appearance of this condition is a continual one. Imaging studies have confirmed that its basis is one of herniations or deep indentations of subcutaneous adipose tissue into the dermis. The basis of the herniation may reflect an increase in the inner fat layer and certain unique aspects of the intrinsic architecture of the fat lobule and associated septae. Specifically, there is a greater number of septae that assume a perpendicular orientation to the skin surface in women with cellulite (7).

There has been a small number of previous studies that have looked at the VelaSmooth technology. Alster and Tanzi looked at 20 women who were treated for cellulite in the region of the thigh (6). They received two treatments per week for 4 weeks. The overall results were positive. The treated thighs were reduced by an average of 0.8 cm and visual improvement averaged 50% on the quartile grading scale. Another study enrolled 35 subjects, all of whom saw some degree of improvement (5). Subjects, at two different sites, received either eight or 16 treatments on their thighs over the course of 1 or 2 months, respectively. The mean decrease in the circumference of the treated thigh was 2 cm. Improvement in skin texture, as noted through the examination of photographs of the treatment area, was seen in all patients enrolled in the study. In both of these studies, minimal complications were seen.

More updated treatment protocols indicate that greater than 12 treatments are required for maximum benefit.

Mechanical manipulation of the skin was likely responsible for the mild bruising in five patients. It should be noted that this was asymptomatic and

transient and was not associated with a change in clinical results in this patient subset.

We could not document at a morphologic level the precise effects of this treatment on reducing cellulite. It is interesting to note that there is limited precedent literature regarding morphologic changes in the fat that could account for the positive treatment effects observed with various cellulite treatments. In the setting of phosphatidylcoline/deoxycholate injections (i.e. mesotherapy), a mixed septal and lobular panniculitis with attendant fat necrosis and serous lipoatrophy (8) is seen. We plan to conduct further morphologic assessments in future studies using the VelaSmooth system to see whether or not the effects are analogous to those observed with mesotherapy. If the true effect of the laser is to enhance fat metabolism there may not be any structural alteration of the fat per se, in terms of either fat necrosis or inflammation.

Conclusions

A total of 65% of the subjects enrolled presented a circumference reduction and 50% of subjects had greater than 51% improvement by the end of the study. Most study subjects noted some degree of improvement in the appearance of cellulite.

Non-invasive lasers and RF energy sources merit further examination employing more treatments. As our results were more definitive and positive compared to prior studies using the VelaSmooth system, it would be worthwhile conducting additional studies employing higher RF energy levels, an increased number of treatments and advanced application tips. Further investigations employing this pioneering technology will improve the treatment modalities for cellulite.

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