ORIGINAL ARTICLE

Post-pregnancy body contouring using a combined radiofrequency, infrared light and tissue manipulation device

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Abstract
Background: Non-invasive body contouring is an increasingly popular aesthetic application. Previous data support the efficacy of combined radiofrequency, infrared and skin manipulation for cellulite treatment. Objectives: To evaluate the performance of a high-power device (50 W as opposed to 25 W) combining these energies for reshaping and improvement of skin texture/laxity in postpartum women. Methods: Twenty women received five weekly treatments to the abdomen, buttocks and thighs with the VelaShape™ system. We followed up each patient’s weight and nutritional habits. Outcome was assessed using reproducible circumference measurements, digital photography, the physician’s scores of cellulite and improvement as well as patient satisfaction. Safety was evaluated by recording subjects’ comfort and tolerance. Results: The overall mean circumferences reduction was 5.4 ± 0.7 cm (p < 0.001). Significant (p < 0.02) improvement in skin laxity and tightening was noted by both the physician and patients. Treatments were well tolerated with no major safety concerns (one purpura, one mild burn). Conclusions: The enhanced capabilities of the evaluated system enabled significant results in fewer and shorter sessions without compromising patients’ safety or comfort. These data suggest that postpartum reshaping via circumferential reduction and skin laxity improvement can be effectively and safely achieved using a high-energy combination of radiofrequency, infrared and mechanical manipulation.

Key Words: Cellulite, circumference, light, radiofrequency

Introduction
Childbearing is a period in the life cycle during which some women may gain weight, increase general circumference and develop the unsightly appearance of cellulite in the buttocks area and lower extremities. It is estimated that up to 20% of women have retained at least 5 kg by 6–18 months postpartum (1). Besides being a risk factor for several diseases (2), postpartum weight retention is associated with psychological and social consequences and is therefore considered to be a major health issue worldwide.

As medical practice ventures further into ‘quality of life’, we notice a growing number of techniques developed to answer this increasingly popular demand for body contouring and skin laxity treatments. Current available aesthetic solutions vary from invasive to minimally invasive as well as fully non-invasive procedures. The invasive modalities, mainly liposuction and abdominoplasty, offer profound improvement and thus remain popular procedures. However, their associated risks and drawbacks (3) have made them unsuitable for treating younger individuals with relatively minor contouring alterations or those who are unwilling to tolerate prolonged down time. Through this window of opportunity emerge minimally invasive techniques, such as subcision and laser-assisted lipolysis, as well as various non-invasive technologies. The latter include massage-based devices that are based on mechanical manipulation and more recently on non-ablative lasers and radiofrequency (RF)-based systems (3,4).

It has been suggested that mechanical manipulation causes vasodilatory effects which enhance lymphatic drainage and improve the microcirculation. Combined infrared (IR) and RF energies have the ability to induce deep tissue heating that leads to collagen contraction, controlled tissue inflammation and collagen remodeling, thereby inducing skin tightening. Hence, it has been proposed that combined RF, IR and mechanical massage when applied simultaneously to treat cellulite may recover the skin to its near normal texture. On this basis, the VelaShape™ system (Syneron Medical Ltd, Yokneam, Israel) has been developed. The safety and effectiveness of an
older version of the device have already been shown in relation to cellulite improvement and circumferences reduction, mainly in thighs and buttocks, but the treatment regime required 8–16 bi-weekly treatments (3–9). We hypothesized that the cosmetically unappealing form of postpartum abdominal cellulite may require enhanced impact to improve skin texture and laxity. For this purpose we conducted the current study in which we determined the contouring effect in postpartum women treated with this new, stronger device for a short series of weekly sessions.

Materials and methods

Device description
The VelaShape system combines 700–2000 nm IR light and conducts 1 MHz bipolar RF energies with mechanical manipulation in the forms of suction and massage. The system has an improved vacuum pattern as compared to the previous VelaSmooth™ prototype by the same manufacturer, with a maximal negative pressure of 400 mbar, and is electrically capable of administering up to 50 W RF and 35 W IR.

The device is composed of a base unit, to which two types of applicators may be connected via an umbilical. The applicators are fitted with a replaceable cap that has a treatment chamber, into which the skin is repeatedly drawn during treatment via mechanical manipulation and is exposed to IR and RF. The system enables the user to adjust the energies and vacuum levels per subject or anatomical area.

Patients
Twenty healthy women were recruited for this prospective self-controlled study. Patients were eligible for entry into the study if they were at least 21 years of age, Fitzpatrick skin types I–IV, had had at least one pregnancy and were at least 9 months post-pregnancy with the resultant presence of sagging skin, cellulite, and skin irregularities or modified contours in their abdominal area. Additional treated areas could be buttocks and/or thighs. Patients had to adhere to a regular diet and exercise program without having any weight change fluctuations of more than 4.55 kilograms in the preceding month. The study was approved by an institutional review board, and all participants signed an informed consent form. Subjects were free to discontinue their participation at any time during the study.

Clinical evaluation
Patients received five weekly treatments and were then followed-up 4 weeks after their last treatment. At baseline, patients were classified according to their skin type as well as their degree of cellulite based on the Nurnberger–Muller cellulite scale (10). Subjects were asked to adhere to their usual diet and exercise routine for the duration of the trial and had to complete habits diaries.

Treatments were performed using an enhanced treatment mode in which the operator reaches the endpoint of tissue radiant heat and erythema twice for each area, with a break between the end of the first treatment stage and the beginning of the second. This means that the skin’s temperature, when measured from the outside by means of, for example, a laser thermometer, rises from approximately 30–32°C to ∼42°C as a result of treatment. The skin is left to cool off for about 10 minutes until it is ∼37°C and is then treated again until it reaches the endpoint once more, which is usually compatible with ∼42°C surface skin temperature.

Prior to the first treatment, before the third treatment, before the fourth and at the 4-week follow-up visit, patients’ weight and their treated areas’ circumferences were recorded. Patients’ circumferences were measured using a stand with set markings and a movable clamp; this simple apparatus enables consistent measurement of various anatomical areas and subjects with different heights. The measurement is performed at exactly the same location per area every time regardless of any contour changes that may have taken place. The base of the stand and the patient’s feet were always at the same level and a measuring tape with a user-independent tension gauge was used to further contribute to the accuracy of the measurement. At the same time points of the trial, standardized high-quality digital photographs were taken. All measurements and photographs per area were obtained with the patient standing in the same position.

Efficacy was assessed clinically by both investigator and patients at the third and fourth treatment and at the 4-week follow-up visit. The circumference reduction was based on the difference between the baseline circumference and each subsequent measurement – immediately prior to treatment 3 (after two sessions), immediately prior to treatment 5 (after four sessions), and at the follow-up visit scheduled 4 weeks after the fifth and last treatment. Notably, treatment was conducted on both the right and the left thighs in those patients undergoing thigh treatment. Since there was no significant difference between the two sides at any of the time points (t-test for paired data, p > 0.05), the results for the thighs per patient were analyzed as an average of right and left. Improvements in skin texture and cellulite appearance compared to baseline photographs and according to the Nurnberger–Muller cellulite scale were rated by a non-treating investigator using a 10-point scale (0, 1–10, 11–20, 21–30, up to 91–100%). Side effects and complications were recorded for the safety evaluation.
Patients were asked to grade their own impression on the overall improvement and their satisfaction with the treatment. Subjects were also asked to rate their pain on a 0–4 scale (0 = none, 1 = slight, 2 = moderate, 3 = severe, 4 = intolerable) and received instructions regarding reporting any possible complications of treatment.

**Results**

Twenty women (aged 27–56 years, mean 43.7 ± 1.7 years) completed the study with the full five treatment sessions. Only one patient (treated on her abdomen and buttocks) missed the follow-up visit. Most patients (18) were of Caucasian origin, one was Asian and one Hispanic. The skin type allocation in this group was 15% type II, 75% type III and 10% type IV. All patients had had at least one pregnancy (on average 10.7 ± 1.7 years prior to enrollment) and were treated for resultant sagging skin or modified contours in their abdominal area. Twelve of these subjects were additionally treated in their buttock area and the other eight received thigh treatment, noting that these areas are also sometimes affected by pregnancy and generally tend to present more cellulite. Hence, the total number of treated areas in this study was 40. The patients’ weight was well maintained during the treatment course, with a slight decrease of 0.9 ± 0.3 kg over the follow-up period, which was found to be significant in comparison to the baseline weight (Wilcoxon signed rank test for paired data, \( p \leq 0.02 \)).

Table I shows the mean circumference reduction after two and four sessions and at the follow-up visit for all areas together and also separately for the abdomen, buttocks and thighs sub-groups. After two sessions, all treated areas as a group showed significant improvement already after 4 weeks (one treatment session to the following one, each time being significantly better than the baseline and the preceding treatment \( (p < 0.001) \), reaching a peak at the 4-week follow-up, when the mean circumference reduction was 5.4 ± 0.7 cm and most treated areas (87%) demonstrated a circumference reduction above 2 cm. Moreover, as the treatments progressed, more areas were pushed into the higher circumference reduction categories, with more than 15% of the areas having greater than 8 cm reduction by the follow-up. Notably, while 17.5% of the areas had no change after two sessions, after four sessions this value decreased to 5% and then diminished completely by the follow-up. The abdomen showed a significantly greater degree of circumferential reduction in comparison to both buttocks and thighs (Mann-Whitney test for unpaired data, \( p < 0.02 \)). There were no significant differences between buttocks and thighs in this regard \( (p > 0.05) \).

At the clinical assessment carried out by the physician 1 month following the last treatment, most areas (84%) were classified under moderate or good improvement. The cellulite improvement at all time points was found to be statistically significant in comparison to baseline (Wilcoxon signed rank test for paired data, \( p < 0.02 \)). Of the 28 areas that had cellulite at baseline, 24% had a reduction of one unit in the cellulite scale and 8% showed a reduction of two whole units.

Patients also perceived improvement in their treated areas. Patients’ assessments were divided more equally between slight to good improvement, with 8% regarded as showing excellent improvement. The distribution of the subjective and objective assessments of the skin’s texture and tightness at the follow-up visit, as well as the patients’ satisfaction levels, is portrayed in Figure 1.

Patients tolerated the procedure well with no discomfort: 67.5, 82.5 and 92.5% of the subjects reported treatment as being somewhat to very comfortable at sessions 1, 3 and 5, respectively. Statistically, the level of comfort reported at treatments 1 and 3 was similar, while treatment 5 was significantly more comfortable \( (t\text{-test for paired data}) \). The response to treatment was limited to erythema, edema and radiant warmth that mostly persisted for several hours following treatment. These responses are considered indicative of the desired effect. Two cases of temporary adverse events occurred: one subject had moderate purpura and another had a mild superficial

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**Table I. Mean absolute and percentage circumference reduction at each measurement point for all treated areas together and per anatomical area category.**

<table>
<thead>
<tr>
<th></th>
<th>Abdomen n=20</th>
<th>Buttocks n=12</th>
<th>Thighs n=8</th>
<th>Overall n=40</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 2 sessions</td>
<td>3.6 ± 0.8 cm</td>
<td>2.6 ± 1.0 cm</td>
<td>1.2 ± 0.7 cm</td>
<td>2.8 ± 0.6 cm</td>
</tr>
<tr>
<td></td>
<td>3.5 ± 0.8%</td>
<td>2.3 ± 0.9%</td>
<td>2.0 ± 1.1%</td>
<td>2.9 ± 0.5%</td>
</tr>
<tr>
<td>After 4 sessions</td>
<td>5.4 ± 1.0 cm</td>
<td>3.7 ± 1.1 cm</td>
<td>1.9 ± 0.7 cm</td>
<td>4.2 ± 0.6 cm</td>
</tr>
<tr>
<td></td>
<td>5.3 ± 0.8%</td>
<td>3.3 ± 0.9%</td>
<td>3.3 ± 1.2%</td>
<td>4.3 ± 0.6%</td>
</tr>
<tr>
<td>4 weeks post-tx</td>
<td>7.4 ± 0.9 cm</td>
<td>4.3 ± 1.0 cm</td>
<td>2.2 ± 0.7 cm</td>
<td>5.4 ± 0.7 cm</td>
</tr>
<tr>
<td></td>
<td>7.2 ± 0.8%</td>
<td>3.9 ± 0.9%</td>
<td>3.8 ± 1.1%</td>
<td>5.6 ± 0.6%</td>
</tr>
</tbody>
</table>
both adverse reactions occurred on abdominal areas and were resolved without complication.

Discussion

The current study provides a first insight to the clinical performance of the VelaShape system. We opted not to perform a randomized controlled trial since we wanted to focus on abdominal areas that cannot be properly investigated in a controlled manner. However, we know from previous reports that the Vela-Smooth treatment concept was proven in a controlled setting on thighs (5, 6). In addition to their postpartum abdomen, patients were allowed to undergo treatment in buttocks or thighs. Four weeks following only five weekly sessions, circumference reductions of 7.4, 4.3 and 2.2 cm were achieved in the treated abdomens, buttocks and thighs, respectively. However, significant and visually noticeable improvement was already noted after two sessions and definitely after four. Following five sessions, all areas responded to treatment and none had increased in circumference. All of the areas also showed improved skin laxity and texture, which is notable considering that the treated abdominal areas were 1–24 years (median 10 years) postpartum and presented with considerable textural ramifications (see Figures 2, 3 and 4).

Non-invasive body reshaping revolves around structural and functional alterations of the superficial connective tissue. To offer a viable solution to this sought-after clinical application, one must consider the etiology for its occurrence, which mainly stems from atrophic degeneration of hypodermal and dermal layers, involving collagen fibers, fat cells, blood perfusion and venous and lymphatic drainage. The physiological disturbances that occur in these layers over time, which are further enhanced by processes such as pregnancy, lead to an advantageous environment for larger fat cells with low metabolism and to accumulation

Figure 1. Physician’s aggregated assessments of improvement and patients’ improvement and satisfaction ratings at follow–up. Figure scale based on the following scales actually used for evaluation. Physician improvement scale: 0=0%, 1=1–10%, 2=11–20%, 3=21–30%, 4=31–40%, 5=41–50%, 6=51–60% until 91–100%. Patient improvement scale: 0=No change, 1=Slight improvement, 2=Moderate improvement, 3=Good improvement, 4=Excellent improvement. Patient satisfaction scale: 0=Not satisfied, 1=Slightly satisfied, 2=Satisfied, 3=Very satisfied, 4=Extremely satisfied.

Figure 2. A 37-year-old woman 8 years following pregnancy: before (A) and after two abdominal treatments (B), with noticeable circumference reduction.
of extra-cellular fluids. This in turn further impacts the local metabolism and is reflected by distended contours and a bumpy skin surface (11,12). Hence, to turn back time, as subjects wish could be done, one would need to initiate anabolic processes in the dermis, alongside catabolic processes in the hypodermis. Specifically, the requirements include an increase in the following aspects:

- Fibroblast activity to initiate collagenesis.
- Fat cell activity to decrease the individual cell and fat cluster size.
- Blood circulation and oxygen dissociation from hemoglobin to enable more oxygen and nutrients for this increased metabolism.
- Lymphatic and venal drainage to remove excess fluids from the area, reduce pressure from the blood inflow and support the local inflammatory response.

Two physical parameters that have an impact in this desired direction are mechanical manipulation and heat (13–15). Heating may be achieved by various energy forms, including light and RF, which further contribute via skin tightening through a direct effect on septae and collagen fibers (14,15). The main remaining challenge is how to direct this energy safely and effectively to the appropriate location; this may be achieved with a proper suction apparatus that determines the location into which the energy is administered.

VelaShape combines of all of the aforementioned modalities, thereby offering a comprehensive synergetic solution that encompasses each of the discussed biological and technical aspects. As part of the Elos (Electrical Optical Synergy) concept, IR light heats up to 3 mm into the tissue and bipolar RF heats 2–20 mm deep; there is also mechanical manipulation in the form of location-determining suction (with or without massage). Endermologie® (LPG Systems, FL, USA) was one of the first devices that utilized mechanical massage to achieve temporary cellulite improvement and some circumference reduction. According to one of the largest reports available on the use of this device (85 patients), the average circumference reduction following a series of seven or 14 treatments was 1.34 and 1.83 cm, respectively (16). The TriActive™ laser (Cynosure, Inc., MA, USA), which combines low-energy diode laser, contact cooling,
suction and massage, has been shown to achieve similar results to the older VelaSmooth system (17). There are also devices which employ either monopolar or unipolar RF that are being used for ophthalmic skin tightening and contouring. These devices lack the ability to accurately direct the administered energy or to know how deep it is actually entering. Following six Accent® (Alma Lasers, Israel) unipolar RF treatments on upper thigh areas, 27 out of 30 patients showed clinical improvement with an average circumference reduction of 2.45 cm (18). Another modality that has entered this arena involves ultrasound, which is profusely different by virtue of its lipolytic and fat removal effect versus increased adipocyte metabolism. One such device that combines computerized massage, suction and ultrasound (MedScupl™; General Project, Srl, Italy) achieved circumference reductions of 2.25 cm on thighs and 6.5 cm on the abdomen following 12 bi-weekly sessions (19). A large patient group (137 treated, 27 control) treated only once with a focused ultrasound device (Contour I; UltraShape Ltd, Israel) had an average circumference reduction of 2 cm on the abdomen, thighs and flanks (20). Using the same system, another author reported an almost 4 cm reduction following three sessions at a monthly interval (21).

In terms of percentage reduction in relation to the baseline circumference of each area, the results were 7.2, 3.9 and 3.8% for the abdomen, buttocks and thighs, respectively. It was also noticeable that the pattern of circumference reduction was different for each anatomical area sub-group – while the abdomen showed a steady slope between the measurement time points, the thighs and buttocks showed a steeper reduction at first and then a more moderate one at the later measurement time points (for the thighs, there was no significant difference between the mean result at the last treatment and the follow-up). The significant differences between the response of the abdomen and the buttocks or thighs can be attributed to the varying characteristics of these anatomical areas. The first is the concentration of water versus fat or muscle, leading to impedance differences and hence also to a different heating pattern, as was also noted with another RF system (22). In addition, possible differences in blood circulation may further explain why the abdominal areas respond better. Indeed, we have noticed that during treatment the abdomen tends to become red and radiate heat sooner than the buttocks, for example. Finally, there are structural aspects: the fact that the abdomen is softer makes it more susceptible to the administered mechanical manipulation and the fact that it engulfs a cavity instead of muscle or bone enables it to shrink more in response to treatment.

Interestingly, we noted that while the cellulite assessments remained completely steady between the last treatment and the follow-up visit, the circumferences of most areas (77.5%) continued to decrease. This suggests that in order to achieve a reduction of circumferences, deeper tissue layers have to be affected while cellulite improvement is likely to be related to involvement of the more superficial layers. At both depths, the process would involve fat cell shrinkage and lymphatic drainage. However, the effect is allowed to continue for a longer period in the deeper layers since they tend to retain the administered heat for longer durations than the skin surface, which is strongly influenced by the surrounding conditions.

Since this was a study setting, patients were asked to maintain their existing diet and exercise regimen. Outside of a study setting, we may recommend an increased water consumption following treatment to facilitate the lymphatic drainage, but there is no need to change dietary habits. Patients may view treatment as an opportunity to improve their diet and exercise habits and some clinics combine such consultation with treatment.

We have noticed that although there are no non-responders, some patients tend to benefit from treatment more than others. Such variation is likely to be related to basic morphological and genetic inter-individual differences. However, the biological mechanism through which VelaShape achieves its effect has yet to be revealed and scientifically validated. Perhaps when the answer to this is unraveled, for example via biopsies, it will also shed light on the results variance.

Finally, body dimensions may change dramatically and rapidly not only after having given birth, but also after undergoing extreme fat removal, for example via liposuction. In both cases, the elasticity of the skin is not compatible with the sharp declines in body dimensions. Therefore, it is not surprising that Kulick reported particularly dramatic improvement following a series of VelaSmooth treatments in a patient who 10 years earlier underwent a liposuction procedure which left significant surface irregularities (7).

Conclusion

VelaShape – a device based on a combination of tissue manipulation, IR and bipolar RF – has been shown to be safe and effective for the reshaping of postpartum abdominal areas, buttocks and thighs via circumferential reduction and improvement of skin laxity. Thanks to the enhanced capabilities of this device, significant results are achieved in fewer and shorter sessions.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.
Body contouring using RF, IR and tissue manipulation

References