VelaShape III White Paper | No. 1

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Clinical Evaluation on the Efficacy and Safety of the VelaShape III Device for Abdominal Circumferential Reduction Treatments

Background: An ever-growing patient demand for non-invasive body-shaping procedures has led to the development of many different technologies and techniques that can achieve a more aesthetic body shape. The VelaShape III (Syneron Medical Ltd.) system is a non-invasive aesthetic body shaping device. VelaShape technology was cleared by the Food and Drug Administration (FDA) for the temporary reduction in the circumference of the abdomen. This clearance was based on a multicenter clinical trial conducted in the United States. In parallel, the performance of the VelaShape III device was assessed in terms of its safety, efficacy and patient comfort at an additional clinical site outside of the U.S. The data was used to further support the device's clinical trial results. This paper presents the data and results from the VelaShape III clinical trial performed at this site.

Objective: The evaluation of the safety, efficacy and patient tolerability of the VelaShape III device, for the non-invasive treatment of excess fat in the abdominal region manifested by circumferential reduction.

Methods: Forty-two female patients received one single treatment with the VelaShape III device on the abdominal region, which were followed-up at 4, 7 and 10 weeks post-procedure. Clinical photographs were taken. Patient circumferences were measured at baseline and at each follow-up visit. Followed by comparisons at the end of the clinical trial. Treatment safety was assessed by the frequency, severity and type of adverse events.

Results: Significant circumference reductions in the abdominal area were observed already at the 4-week follow-up, and remained significant throughout the assessment period. Moreover, the average circumference reductions increased throughout the course of the study, and were 0.8±2.3 cm, 1.8±2.0 cm and 2.6±1.0 cm, at 4, 7 and 10 weeks, respectively. No adverse events were seen throughout the study period.

Conclusion: The clinical data presented here supports both the safety and efficacy of the VelaShape III system for the treatment indication of temporary reduction in circumference of the abdomen.

Introduction: Cosmetic procedures aimed at reducing the subcutaneous fat deposits have become very popular in aesthetic medicine. This growing interest has led to the continued research and development of numerous technologies and techniques that can help achieve a more favorable body shape in cosmetic patients. Although more invasive surgical procedures remain the gold standard approach as they can achieve significant clinical improvement in body contouring, these are also associated with inherent risks as well as prolonged recovery times, beckoning the need for more non-invasive body shaping treatment solutions for this patient population. Moreover, in contrast to invasive surgical procedures that can achieve a reduction in the subcutaneous fat, novel non-invasive energy-based technologies are able to impact both the subcutaneous fat and connective tissue, resulting in a reduction of the subcutaneous fat as well as collagen remodeling and neocollagenesis, leading to a more improved body shape and contour, as well as skin tightening effects.

Device Description: Numerous non-invasive energy-based technologies are currently employed for the improvement of body contour and shape as well as skin laxity. These include devices based on optical energy, radiofrequency (RF) electrical current, vacuum and massage, a combination of the above-mentioned technologies, as well as Ultrasound (US). Based on proprietary elōs (electro-optical synergy) technology, the VelaShape III device incorporates bipolar RF energy, controlled infrared (IR) light and pulsed vacuum (or suction). The device is capable of delivering bipolar RF energy up to 150 Watts, and IR LED power up to 1.7 Watts at a light spectrum of 850 nm. The VelaShape III system consists of three core modules including a base

unit (console), a treatment applicator that is connected to the console via an umbilical cable, and a touch-screen control panel. During treatment, the applied suction repeatedly draws the skin into a vacuum chamber at the center of the treatment cavity, where the skin is then exposed to IR light and RF energies, while the skin surface temperature is continually monitored. The system enables the user to adjust the RF and optical energy levels as well as vacuum levels, allowing for optimal treatment parameters to be used in each individual patient.

Study Design: This was a prospective, single-center clinical trial in patients with appreciable localized subcutaneous abdominal fat who received one single treatment with the VelaShape III device on the abdominal region. Study participants were followed-up at 4, 7 and 10 weeks post-procedure. Clinical photographs were taken. Patient circumferences were measured at baseline and at each follow-up visit. Followed by comparisons at the end of the clinical trial. All clinical photographs were taken with the Canfield camera system intended for standardized body photography. In addition, all measurements were taken by the same staff member while subjects' positioning and body posture are kept the same for all evaluation time points. Treatment safety was assessed by the frequency, severity and type of any adverse events. All study participants met the inclusion/ exclusion criteria and signed an informed consent prior to the initiation of the study.

Standardized Treatment Protocol:

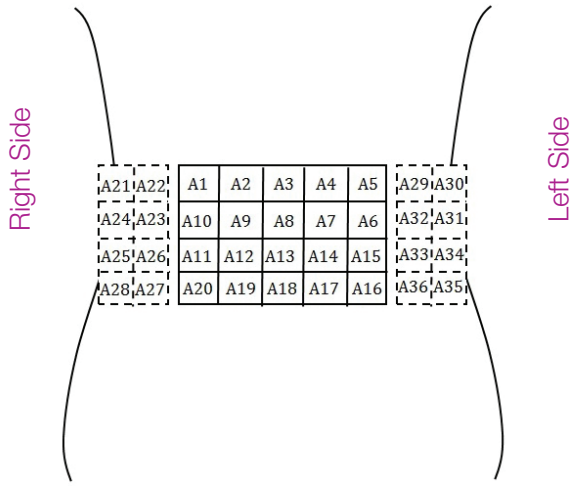
- VelaSpray Ease body emulsion was applied to the treatment area in order to ensure optimal coupling and RF conductivity. The treatment area was moistened with the lotion that massaged well into the skin with gloved hands. During all treatment duration approximately 1 mm thick layer of the lotion remained on the target skin.
- Before each treatment the RF electrodes were cleaned and intact, and the replaceable cap of the VelaShape III applicator was fitted with a new disposable cover.
- Patient's skin was carefully examined prior to treatment in order to determine the appropriate power settings to be used, ensuring an effective treatment with minimal risk of skin damage. The appropriate selection of power settings is essential for a successful treatment outcome. Following the examination, each subject waited to ensure that the chosen parameters indeed led to the appropriate immediate response.
- The RF level was set to level 3. When safety concerns raised or if the patient reported intolerable "stinging" sensation, lower RF levels was used (2, 1).
- The IR level was set to level 0.
- Vacuum levels for sensitive areas, such as over loose skin areas, were set to level 1 and were increased according to the patient's tolerance.
- Pressing the trigger applied vacuum that drew the target treated area into the treatment chamber and RF energy was released to the skin.

Treatment Instructions – Stacking mode with the VelaShape III

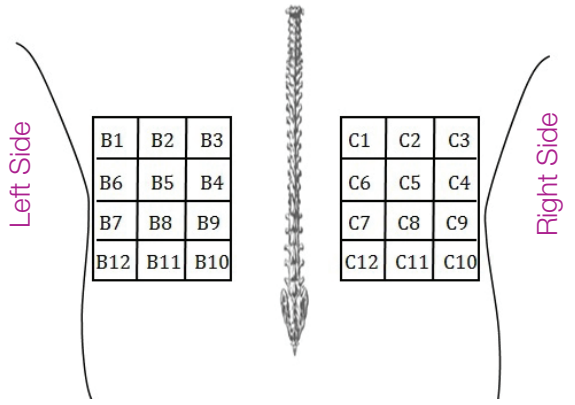
- Three sets of sub-areas were marked as follows (see illustration below):
- One set of 5x4 sub-areas (A1–A20) in the front anterior abdomen (see illustration below)
- One set of 3x4 sub-areas (B1-B12) in the posterior left abdomen (see illustration below)
- One set of 3x4 sub-areas (C1–C12) in the posterior right abdomen (see illustration below)

* For high BMI patients two additional sub-area sets were added in right and left anterior abdomen, which include the flanks areas (sub-areas A21-A28 and A29-A35). Each set being adjacent one to the other and each one of the sub-areas is the size of the treatment area of the VelaShape III applicator.

Anterior Abdomen



Posterior Abdomen



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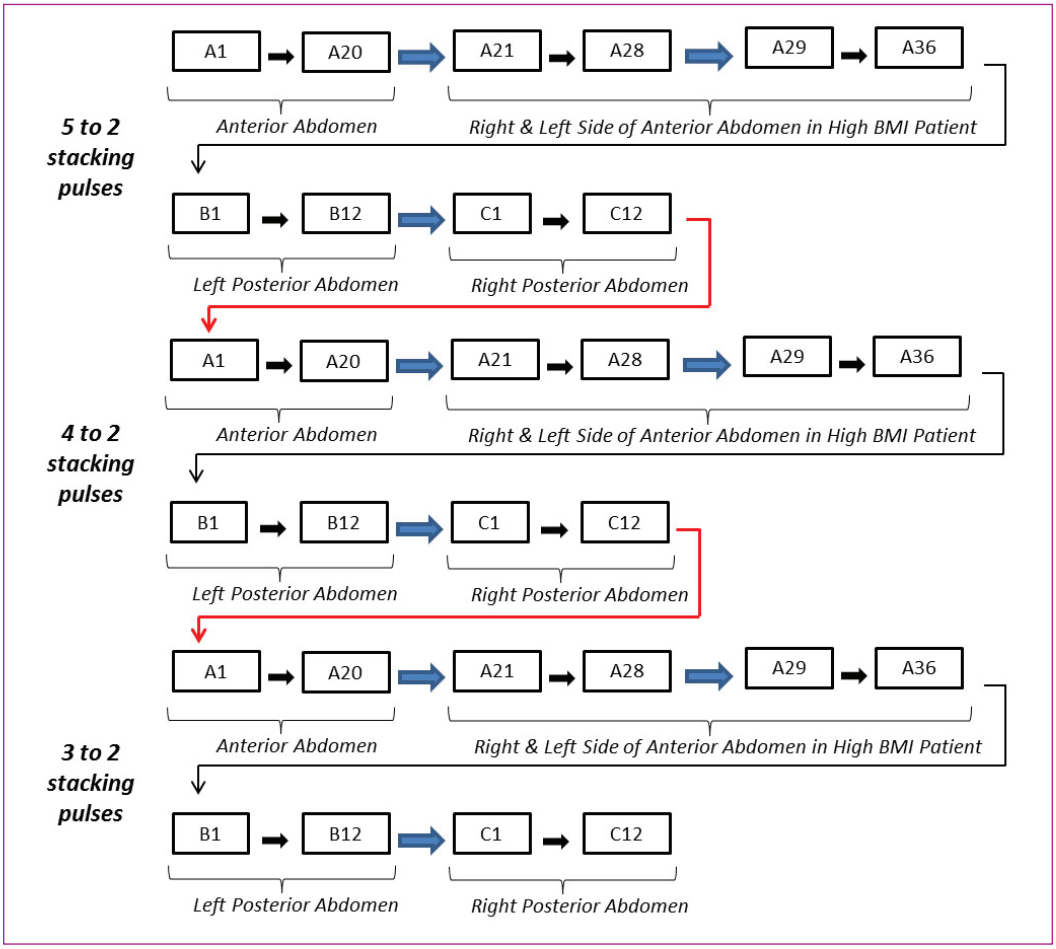
Treatment started with the sub-area set located at the anterior abdomen (A1-A20). Each sub-area from A1 to A20 within that set was treated with 5 consecutive stacking pulses, then 4, 3 and 2 consecutive pulses. Each sub-area from A1 to A20 was then continuously treated with two stacking pulses until the surface temperature reached 45 degrees Celsius or the patient could not tolerate further heat.

*High BMI patients were also treated using 5-2 stacking pulses technique in the sub-area set located at the right anterior and left anterior abdomen which includes the flank area (from A21 to A28, and from A29 to A36, respectively).

Treatment was continued in the sub-area set located at the left posterior abdomen (from B1 to B12) followed by the right posterior (from C1to C12) abdomen, using the 5-2 stacking pulses technique, 5 consecutive stacking pulses were delivered in each sub-area, then 4, 3 and 2 pulses in each sub-area until the skin temperature reached 45 degrees Celsius or the patient could not tolerate the heat.

A second treatment phase of the same sets of sub-areas was performed in the same fashion (Sub-area set A1 to A20, then Sub-area set A21 to A28 and sub-area set A29 to A35 if high BMI patients are treated, and the two posterior sets) using the 4-2 stacking pulses technique.

A third treatment phase of the same sets of sub-areas was performed in the same fashion using 3-2 stacking pulses technique.



Post Treatment

Tanning of any sort was forbidden in the treated areas during the entire course of evaluation. Patients were instructed to use sunscreen with an SPF of at least 30 and to appropriately protect the treated areas from direct sunlight throughout the entire study period.

Photography

To achieve high-quality before and after images, photographs were taken in a private room or an area of the clinic under controlled conditions that allow appropriate and consistent, distance, background, lighting and angles (global frontal photo-0°, and the right and left sides of the treated area-90°).

Results

Demographic

The clinical trial included a total of 42 female patients (mean ±std age 41±9 years) who received one single VelaShape III treatment on the abdominal region. Patients' weights ranged from 53-96 Kg (mean ±std 69±9) and the BMI range was 20.1-30.6 (mean ±std 25.3±2.7).

Table 1: Demographic

	Age	Weight	Height	BMI
Mean	41	69	1.65	25.34
S.D.	9	9	0.06	2.65
Minimum	25	53	1.51	20.1
Maximum	58	96	1.77	30.6

Circumference Reduction

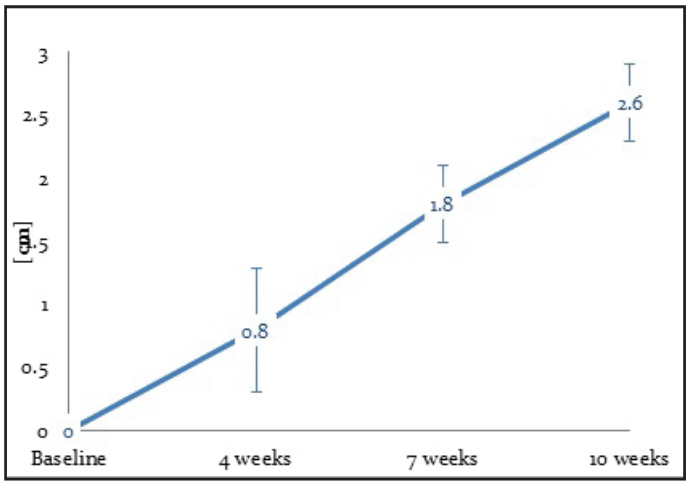
At the 4 weeks follow-up visit, significant circumference reductions could already be appreciated, and remained significant throughout the course of the study (p-value<0.05, Single t-test/ Wilcoxon signed rank test for single group median). Moreover, an increase in the average circumference reduction was observed at each follow-up visit, measured at 0.8±2.3, 1.8±2.0 and 2.6±1.0, at 4, 7 and 10 weeks, respectively (see Table 2 and Figure 1).

Table 2: Abdomen Circumference reduction by time point

	4 weeks	7 weeks	10 weeks
Mean	0.8	1.8	2.6
S.E.M.	0.488195	0.305357	0.30443
S.D.	2.341303	1.978938	0.962693
Variance	5.4817	3.916196	0.926778
Coef. Var.	-2.76154	-1.12775	-0.37459
Minimum	-4	-5	-4.5
Maximum	8.5	7	-1.5
Sum	-19.5	-73.7	-25.7
P-value*	0.000616	9.92E-07	0.004753

**t-test/ Wilcoxon Singed Rank Test for Single Group Median*

Figure 1: Mean ±S.E abdomen circumference reduction by time point

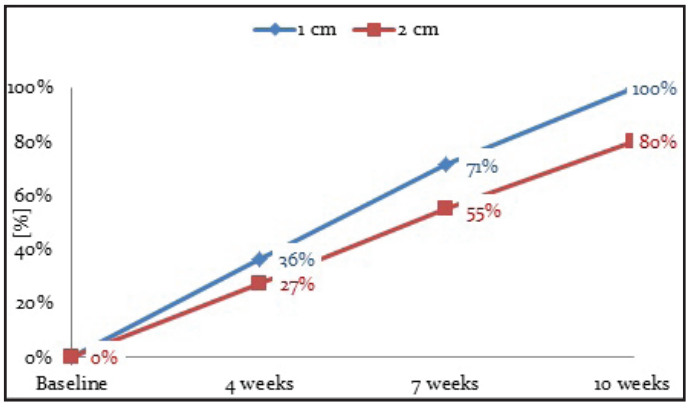


Responders' rate

The rate of patients who responded to the single VelaShape III treatment increased throughout the assessment period. Data showed that only 36% of patients achieved at least a 1 cm circumference reduction at the 4-week follow-up however, this rate increased to 71% and 100% at the 7- and 10-week follow-up visits, respectively.

Similarly, 27%, 55% and 80% of study participants achieved a circumferential reduction of more than 2 cm at the 4, 7 and 10 week follow-up visits compared to baseline, respectively (see Figure 2).

Figure 2: Responders rate: % reduced at least 1 and 2 cm by time point



Safety

Treatment with the VelaShape III device was found to be very safe. No adverse events were observed throughout the study and all patients found the treatment to be tolerable.

Discussion

We present the results of a prospective single-center clinical trial in which 42 female patients received one treatment with the VelaShape III system for the temporary reduction in abdominal circumference. At each of the follow-up time points, all of the study participants demonstrated measureable significant reductions in abdominal circumferences, also appreciable in the before and after clinical photographs. The reductions were noticeable as soon as the 4 weeks follow-up, and improvements in circumference reduction continued throughout the assessment period. All of the patients completed the clinical trial and none experienced any adverse events.

Radiofrequency technology delivers a thermal stimulus to the skin and superficial adipose tissue causing a thickening of the dermis and enhancement of fat cell metabolism, resulting in a reduction in skin laxity and adipocyte volume. The combination of the IR and vacuum coupled RF technologies causes deep heating of the adipocytes, their surrounding connective tissue septae and the underlying dermal collagen fibers. While the RF energy level of Syneron's VelaShape II device can reach 60 Watts, the new VelaShape III device can deliver up to 150 Watts of RF power. It is believed that the increase in the RF energy of the VelaShape III device can result in enhanced treatment results with the possibility of fewer and shorter treatment sessions, as well as improved aesthetic outcomes. The increased RF power of the VelaShape III device allows for the endpoint temperature to be achieved much quicker, and is thought to be the primary factor responsible for increasing the speed and depth of treatment as well as reducing the number of treatment sessions, while achieving significant reductions in circumference. Moreover, the system's closed loop RF mechanism (bi-polar RF) allows for the consistent delivery of energy, which is thought to help minimize the rate of non-responders, the positive results of which were reflected in our results over the assessment period.

Conclusion

We conclude that the VelaShape III system is both safe and effective for the treatment of excess fat and body contouring. The data ascertained in this clinical trial further support the positive outcomes and findings in terms of the temporary reduction in the circumference of the abdomen as witnessed in the device's FDA approval study.

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