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Safety and Efficacy of UltraShape Contour I Treatments to Improve the Appearance of Body Contours: Multiple Treatments in Shorter Intervals

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Abstract

Background: The UltraShape Contour I System (CE 0344; UltraShape Ltd., Yoqneam, Israel) is a noninvasive fat reduction and body contouring system currently approved for use outside the United States that utilizes focused ultrasound to selectively disrupt adipocytes.

Objective: To evaluate the clinical safety and efficacy of the Contour I system when the intervals between treatments are shortened.

Methods: Twenty-five healthy Caucasian women were selected from the patient population at two clinics in Paris, France, and received three 30- to 90-minute Contour I treatments in the abdominal region at two-week intervals. Safety parameters evaluated included adverse events, local skin reaction, and pain. Efficacy parameters evaluated included treatment area circumference, body weight, and comparison of before and after photos. Untreated thigh areas served as an internal control. Subjects were followed for 84 days after the last treatment (day 112).

Results: No adverse events occurred. The majority of subjects ($n = 23$; ~90%) reported no pain. Mean midline circumference (2 cm below midline) was reduced by 2.47 cm ($P < .001$) on day 14 after the first Contour I treatment, 3.51 cm ($P < .001$) on day 56, and 3.58 cm ($P < .001$) on day 112. Peak midline circumference reduction was 3.12 cm on day 112. Most patients ($n = 14$; 63%) reported a positive change in body contour. Mean thigh circumference (the control area) was unchanged; the relative change between treated and untreated areas of the abdomen was significantly different at all time points. Circumference and weight reduction were significantly correlated ($r = 0.42-0.71$) at all time points; mean weight decrease was not statistically significant. Circumference reduction on day 112 positively correlated with patients' subjective satisfaction scores.

Conclusions: Our data showed that successive Contour I treatments at two-week intervals were safe and tolerable and also significantly reduced treatment area circumference.

Keywords

UltraShape, body contouring, fat reduction

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Body contouring is the targeted removal of limited amounts of adipose tissue to achieve a more aesthetic body shape. Liposuction is one of the currently available invasive technologies for body contouring; it was introduced in 1982 by Illouz^{1,2} and has since been refined and improved by many surgeons.³⁻⁷ In the 1990s, Zocchi⁸⁻¹⁰ introduced ultrasound-assisted liposuction (UAL),⁷ which accounted for 21% of the liposuction procedures performed in 2005¹¹ and approximately 26% of those in 2007 in the U.S.^{12,13} The UAL technique involves the destruction of adipocytes with ultrasonic energy and evacuation through suctioning or syringe aspiration; a major drawback of this procedure is its invasiveness. Additionally, the magnitude of energy required to destroy adipocytes may damage adjacent body structures, including skin, blood vessels, nerves, and muscle.¹⁴

Overall, less than 0.5% of 130 million overweight Americans opt to undergo liposuction due to its invasive nature, inherent risks, and relatively long recovery period.¹⁵⁻¹⁷ Even when the liposuction procedure is clinically well tolerated, hemodynamic and metabolic changes occur in the immediate postsurgical period.¹⁸⁻²² A noninvasive method for fat reduction and body contouring would

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therefore be a welcome tool for physicians wishing to provide low-risk procedures and for patients seeking treatment with no downtime.

Some noninvasive and minimally invasive technologies for improving the appearance of skin and subcutaneous fat (such as deep body massage, radiofrequency, infrared, other light-based treatments, nonfocused ultrasound, and phosphatidylcholine/sodium deoxycholate injections) have gained popularity due to their relative safety and cosmetic benefit in the temporary reduction of the appearance of cellulite.²³⁻²⁶ These methods are suboptimal for body contouring, however, as they provide only a modest and temporary reduction in circumference, require multiple treatments, provide short-term results, and may require maintenance therapy. Their use is therefore limited to treatment of superficial fat for temporary improvement in the appearance of cellulite.

Ultrasound has been used as a therapeutic tool (in contrast to its uses for diagnostic and imaging modalities) for more than 50 years, since the first papers by Fry et al.²⁷ It is currently used for lithotripsy,²⁸⁻³⁰ cataract treatment with phacoemulsification,^{31,32} surgery (harmonic scalpel),³³⁻³⁶ and ultrasound-assisted lipoplasty. The CE Mark 0344-cleared Contour I system, developed by UltraShape Ltd. (Yoqneam, Israel), is a novel technology for noninvasive ultrasonic fat reduction and body contouring. This system applies focused ultrasound through the skin and selectively destroys subcutaneous adipose tissue at the target site. The focused ultrasound does not damage neighboring structures such as blood vessels, nerves, connective tissue, or muscle.³⁷ The procedure is well tolerated, can be performed in any office setting, and requires no anesthesia, sedation, or topical anesthetic.

The Contour I system comprises several subsystems. The system console and stand contain the computer, which controls the performance of the system. The therapeutic ultrasonic transducer includes an acoustic contact feedback sensor and delivers the focused ultrasonic beam. A real-time video tracking and guidance system guides the operator through the treatment, ensuring that it is focused only within the designated area, in a homogeneous manner.

The safety and efficacy of the Contour I system were previously evaluated in feasibility clinical studies. In the preclinical phase of the evaluation, *ex vivo* animal (porcine) skin/fat flaps and human abdominoplasty excision specimens were used to address safety concerns.³⁷ Human studies demonstrated the device's excellent safety profile and confirmed that it reduced the treatment area circumference relative to baseline following a single Contour I treatment.^{37,38} The aim of this study was to investigate the safety and efficacy of multiple treatments with the Contour I at shorter treatment intervals (two weeks instead of four weeks) and to evaluate the cumulative effects of three successive treatments at that shorter interval.

METHODS

This postmarketing, prospective, open, internal-control clinical trial conducted at two sites in Paris, France, evaluated

the safety and efficacy of multiple treatments using the Contour I with two-week treatment intervals. The study began on November 9, 2007, and was completed on May 15, 2008. The study protocol conformed to the tenets of the Declaration of Helsinki for human research. Written informed consent was obtained from all subjects.

Twenty-five healthy Caucasian female subjects, ages 21 to 46, were enrolled into the study and received three sequential Contour I treatments in the abdominal region, 30 to 90 minutes each, two weeks apart. A body mass index (BMI) of ≤ 26 was required for inclusion, although the authors routinely treat patients with a BMI of ≤ 30 in their clinical practice. Patients with hernias, scars, diastasis recti, and pregnancy were excluded. Although the study was originally planned as a single-center study, two sites eventually participated. The two sites are private plastic surgery clinics located in Paris: 13 subjects were enrolled under Dr. Marc Slama and 12 subjects under Dr. Benjamin Ascher. As no intercenter differences were observed, the data from the two sites were combined to increase the sample size and statistical analysis power.

Adverse events (AE), including evaluation of local skin reaction in the treatment area, were recorded throughout the study. Efficacy evaluations were conducted at baseline (first treatment), day 14 (second treatment), day 28 (third treatment), day 56 (28-day follow-up after last treatment), and day 112 (84-day follow-up after last treatment). To assess the efficacy, we evaluated treatment area and internal control area circumference in the thighs, body weight, feedback from a subjective patient satisfaction form, and qualitative observations of before and after photographs of the treated area (abdomen).

Treatment Procedure

A trained operator performed the abdominal contouring treatment at baseline (first treatment), day 14 (second treatment), and day 28 (third treatment). During each treatment, the subject was in a supine position with arms under the head or at the sides of the body, with the marked treatment area exposed. Blue drapes were placed outside the premarked line at a distance of approximately 10 cm from the treatment area. Colored markers were adhered to the blue drapes. At least six markers were applied for each treatment. The acoustic coupling medium (castor oil) was applied to the skin and navel before and during the treatment. Treatment was controlled by the tracking and guidance system during the procedure. The system allowed activation of a pulse of energy only when the transducer was accurately positioned; the operator continually moved the transducer over the treatment area until the tracking system indicated "End of Treatment." If a subject complained of discomfort during the treatment, additional castor oil was applied or a node was skipped.

Circumference Measurement Procedure

Circumference measurements were calculated at each site by two different individuals who were trained by

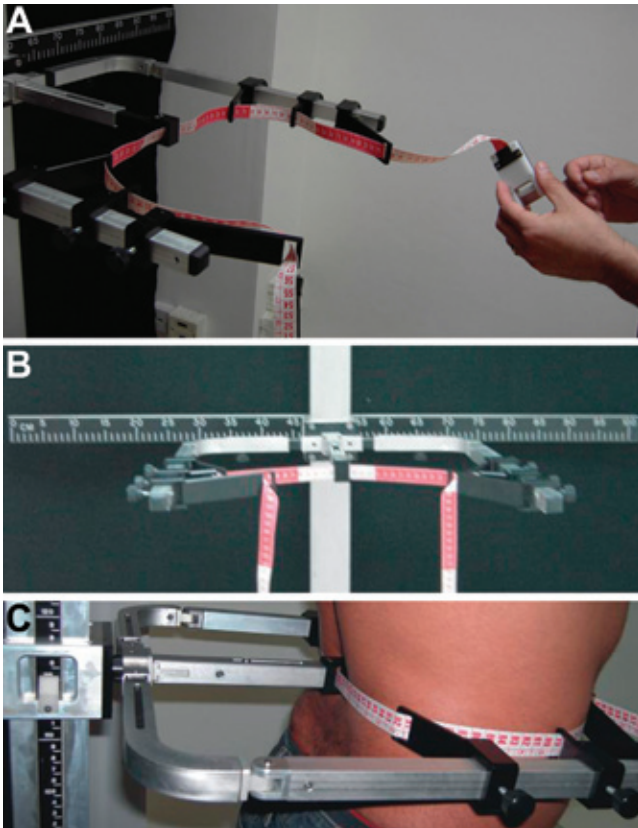


Figure 1. (A, B) Fixed-tension tape measure device. (C) Device being applied to a patient.

UltraShape personnel. In most cases, the same person recorded the measurements for the same subject throughout the study.

Treatment area circumferences were measured using a special device developed, supplied, and calibrated by UltraShape. The device, which contains measuring tape and a ratchet system, applies a constant force and eliminates the potential bias introduced by measuring methods from different amounts of pressure applied by the operator when determining circumference (Figure 1). The measuring tape was placed horizontally, parallel to the floor at a constant height for each subject. The fixed-tension tape measure was mounted on a device constructed by UltraShape Ltd. for this purpose.

For each subject, four circumference measurements were taken: two measurements of the treatment area (abdomen) and two measurements of the internal control area (left and right thighs). For the abdomen, the first circumference measurement was taken at the widest part of the treatment area, and the second measurement was taken 2 cm below the first measurement. At the baseline visit, the height of the first measurement was noted on the measuring device and used at subsequent visits; the second measurement was always 2 cm below the first measurement. The untreated thigh area served as an internal control for the abdominal treatment area. The circumference measurement of the thigh area was obtained by first measuring the height from the floor to the level of the

widest part of the thigh (4-6 cm below the pubis) at both sides of each thigh, where the circumference of each thigh was then measured. At the baseline visit, the height measurements of the right and left thighs were recorded and used at subsequent follow-up visits.

Statistical Methods

There were two analysis study groups: the intention-to-treat (ITT) population, which contained all enrolled subjects who were analyzed for safety ($n = 25$; demographic data were missing for subject 12), and the ITT "per protocol" subset (ITT_{pp}), which contained the subjects who completed all treatments and at least one follow-up visit ($n = 23$ at day 56; $n = 22$ at day 112). Subjects 3 and 10 were excluded from the efficacy analysis because they did not complete the follow-up visits on day 56 and day 112. The data for the internal control circumference measurement on day 56 from four subjects (19, 23, 24, and 25) were missing.

Several statistical tests were used for data analysis in the present study. A paired *t* test or nonparametric sign rank test was applied to determine the statistical significance of the circumference reduction at each of the time points (days 14, 28, 56, and 112) from baseline. A two-sample *t* test or a nonparametric test was applied to evaluate differences between treated and control areas for quantitative parameters. Pearson's correlation was applied to test the strength of relationships between study parameters. All tests applied were two-tailed, and *P* values $\leq .05$ were considered statistically significant.

RESULTS

Subject Disposition and Baseline Characteristics

Twenty-five subjects completed three Contour I treatments. Twenty-three subjects completed the day 56 follow-up visit, and 22 subjects completed the day 112 follow-up visit. Demographic data were available for 24 subjects. All subjects were Caucasian women with a mean age of 38.9 years and mean BMI of 24.5. Mean baseline fat thickness, as measured by calipers, was 3.24 cm. The majority of subjects ($n = 20$) reported no or only a slight body change during their menstrual period, which lasted a mean of 4.6 days and occurred approximately every 28 days. All subjects were eligible for participation in the study according to the previously defined parameters. Four subjects (7, 19, 23, and 25) had a BMI greater than 26, but their participation in the study was approved by UltraShape Ltd.

Treatment Parameters

The mean number of nodes across treatments ranged from 703.92 (treatment 1) to 675.48 (treatment 3). The mean treatment duration ranged from 63.56 minutes (treatment 3) to 68.12 minutes (treatment 2). The mean treatment duration per node was 5.8, 6.0, and 5.6 seconds during treatments 1, 2, and 3, respectively.

Tolerability Results

Overall, the majority of the subjects reported either no sensation or some sensation but no pain associated with the Contour I treatment (80.0% at treatment 1, 92.0% at treatments 2 and 3); the remaining subjects (five at treatment 1 and two at treatments 2 and 3) reported minimal pain (Table 1).

Safety Results

No adverse events were reported throughout the study. Smooth skin texture and even fat texture were recorded in all subjects in a local physical exam at screening and following each treatment, with the exception of one subject (subject 2 from the Ascher clinic site) who had an uneven fat texture (contour irregularity) observed at screening before and after treatment 1 and before treatment 2. Thereafter, no irregularity was noted. No spot discoloration, dermal plexus thrombosis, or local inflammatory response was observed in any of the study subjects on day 112.

Efficacy Results

Primary Endpoint: Midline Circumference in Treated Area (Abdomen)

A statistically significant reduction in the circumference of the treated area (abdomen) was measured at all treatment intervals and compared to baseline ($P < .001$), with the difference increasing over time (Table 2). On day 14, following a single Contour I treatment, there was a mean circumference reduction from baseline of 2.47 cm ($P < .001$; Table 2).

Similar circumference reductions were obtained for circumference measurements 2 cm below the midline for all time points compared to baseline ($P < .001$), and the difference increased over time (Table 3). These results are consistent with those reported in other studies in which the UltraShape device was used. To determine the treatment effect of the Contour I, we compared the circumference reductions of the treated area (abdomen) to the internal untreated control area (thigh) within the same subject. In the control areas, there was no significant change in the mean circumference at any study interval. On the other hand, the relative change between the treated (abdomen) and untreated (thigh) areas was statistically significant at all time intervals (Table 3). The stability of the results is demonstrated by the constant values at post-treatment follow-up visits on days 56 and 112.

Secondary Endpoint: Effect After Three Treatments

The reduction in circumference at midline and 2 cm below midline increased over time. The effect appeared to peak at day 28 for circumference measurements 2 cm below the midline and at day 112 for midline circumference measurements. A cumulative midline circumference reduction from baseline was observed following three successive Contour I treatments, two weeks apart, averaging 3.51 cm ($P < .001$) at day 56 and 3.58 cm ($P < .001$) at day 112. Figure 2 shows photographs of subject 2 before the first

Table 1. Subject Pain Sensation

Day in Study	Treatment	Response	n	%
1	1	Sensation during the treatment	3	12.0
		Did not feel anything		
		Some sensation but no pain	17	68.0
14	2	Minimal pain	5	20.0
		Did not feel anything	13	52.0
		Some sensation but no pain	10	40.0
28	3	Minimal pain	2	8.0
		Did not feel anything	14	56.0
		Some sensation but no pain	9	36.0
		Minimal pain	2	8.0

Table 2. Change in Circumference (2 cm Below Midline) From Baseline

Day in Study	Treatment	n	Mean \pm SEM, cm	Range, cm	P
14	2	23	-2.47 \pm 0.44	-7.50 to 0.85	< .001
28	3	23	-3.52 \pm 0.46	-8.00 to 0.50	< .001
56	—	23	-3.51 \pm 0.56	-8.50 to 2.50	< .001
112	—	22	-3.58 \pm 0.55	-10.00 to 1.0	< .001

Table 3. Differences in Mean Circumference Change From Baseline Between Treated (Midline) and Control Areas by Study Visit Day

Day in Study	Treatment	n	Treated Area	n	Control Area	P
14	2	23	-2.46	23	-0.04	.0008
28	3	23	-3.49	23	-0.25	< .0001
56	—	23	-3.30	19 ^a	-0.03	.0006
112	—	22	-3.12	21	+0.75	.0279

^aCircumference measurement for internal control area is missing for four subjects.

treatment and after three treatments given at 15-day intervals; this subject lost 3.5 cm in circumference. Figure 3 shows photographs of subject 13 before the first treatment and after three treatments given at 15-day intervals; this subject lost 7.5 cm in circumference.

Other Outcomes

Weight

The mean weight decrease from baseline was small and not statistically significant at any time point. A mean

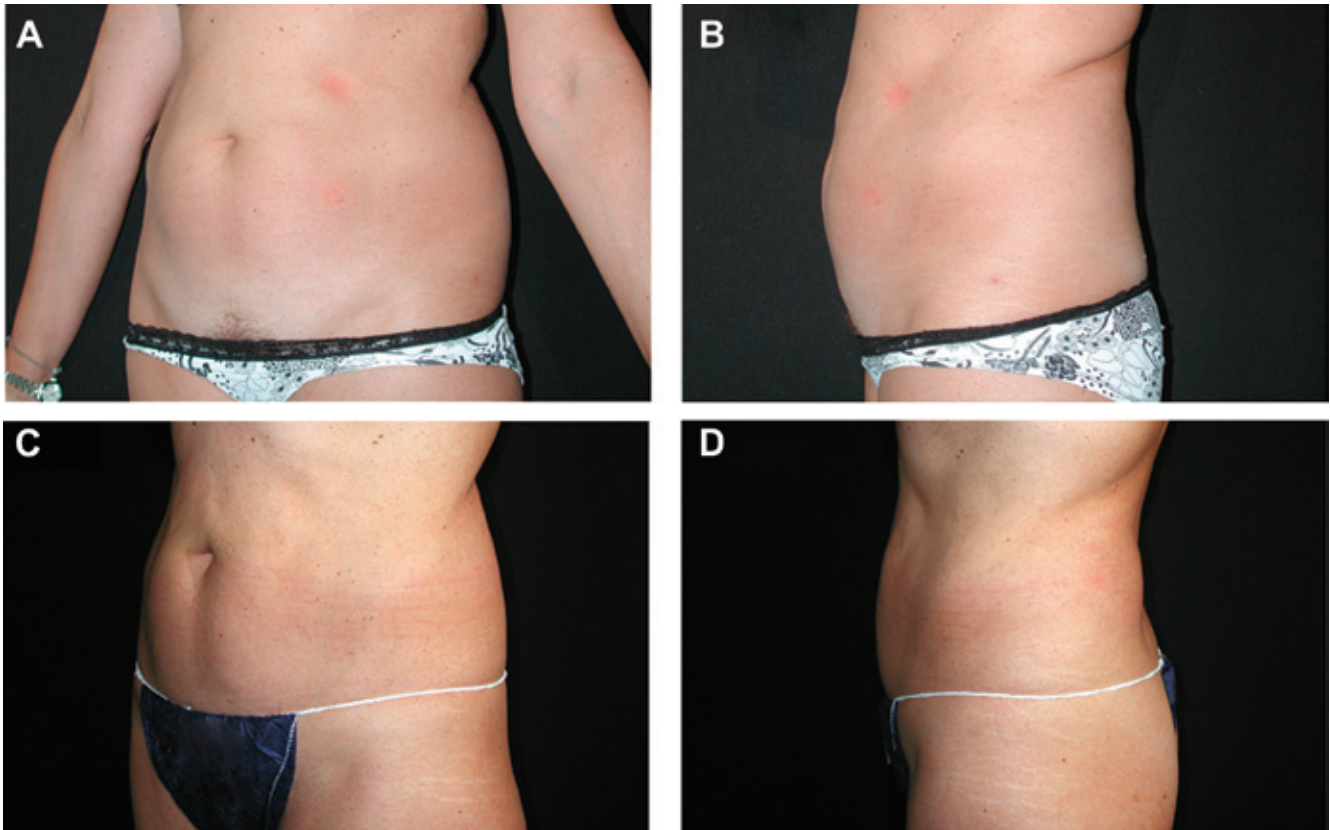


Figure 2. Subject 2, a 43-year-old female being treated at Dr. Ascher's clinic, is shown before the first treatment (A, C) and after the third treatment (B, D). After three treatments given at 15-day intervals, the patient (body mass index = 22.2 kg/m²) had a 3.5-cm reduction in waist circumference.

cumulative reduction of 0.02 kg was observed at day 56 and 0.79 kg at day 112.

Subject satisfaction feedback

The subject satisfaction feedback obtained before treatment indicated that 70.8% (n = 17) of subjects expected the treatment to improve body contour. At days 14 and 28, approximately half of subjects experienced a favorable visible change (day 14: 48%, n = 12; day 28: 56%, n = 14), with the rest experiencing no change at all. Following three successive treatments, favorable visible and measurable changes were reported by 63.6% (n = 14) of subjects on day 56 and 52.2% (n = 12) of subjects on day 112. It is important to note that the inclusion criteria in this study were limited to a BMI up to 26 compared to the typical BMI of less than 30 in clinical practice.

Circumference changes and subject satisfaction

Mean midline circumference change from baseline at day 112 was compared to subject satisfaction feedback.

Overall, self-assessment of external feedback ($r = 0.59$, $P = .0039$) was positively correlated with overall effect of treatment ($r = 0.53$, $P = .0107$).

DISCUSSION

The UltraShape Contour I has been available in Europe since late 2005. It is now widely accepted as a safe, reliable, low-risk, noninvasive fat reduction and body contouring treatment option for patients who are not candidates for liposuction or do not wish to undergo a surgical procedure. Although minimally invasive procedures (eg, laser lipolysis and mesotherapy) may also have a place in the aesthetic practitioner's collection of techniques, they do not fill the rapidly growing need for a truly noninvasive, no-pain, no-downtime alternative. Patients who seek "walk-in/walk-out" treatments want quick results with no downtime required for recovery. In the present study, therefore, we examined whether the time

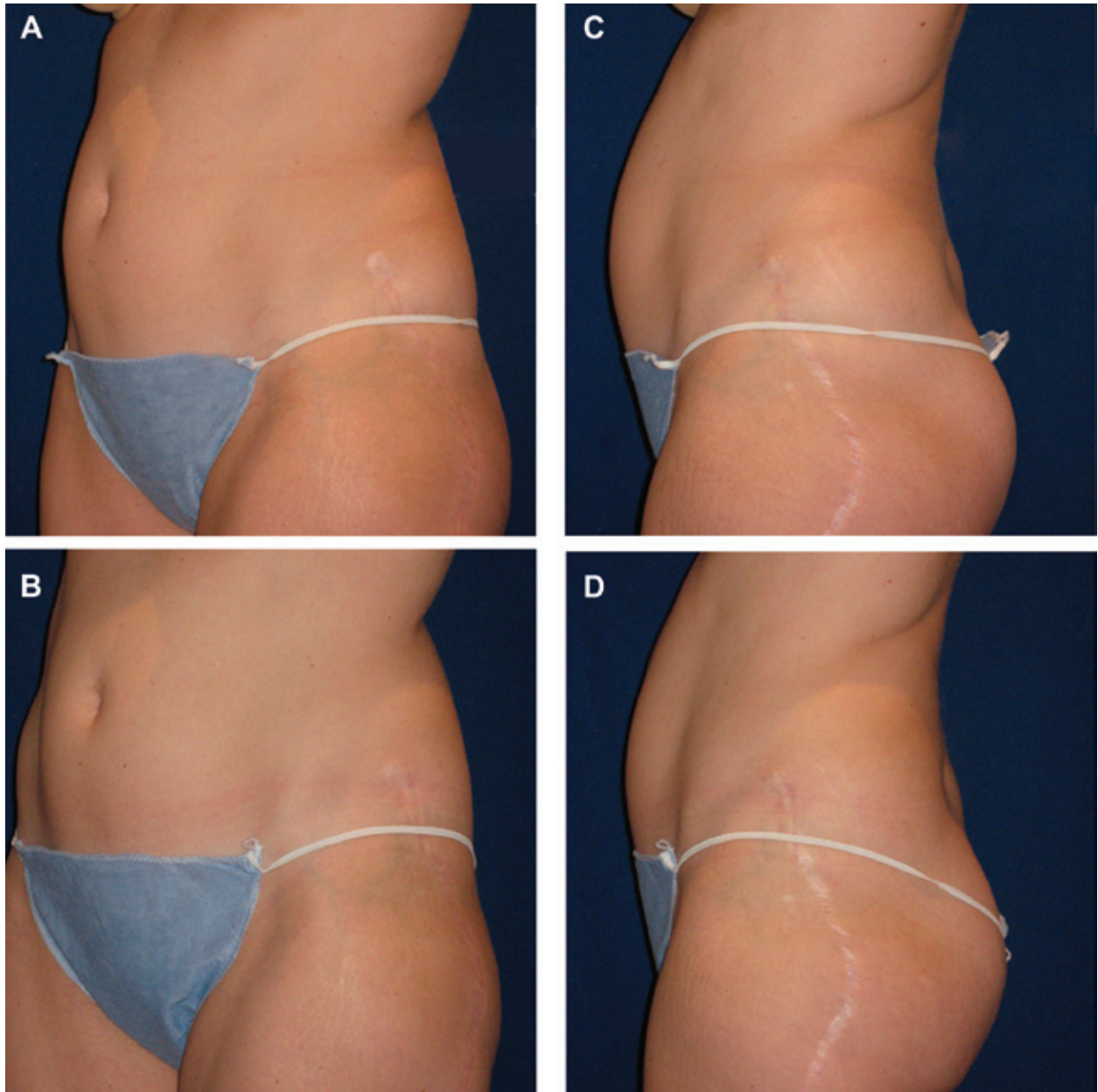


Figure 3. Subject 13, a 36-year-old female being treated at Dr. Ascher's clinic, is shown before the first treatment (A, C) and after the third treatment (B, D). After three treatments given at 15-day intervals, the patient (body mass index = 21.7 kg/m²) had a 7.5-cm reduction in waist circumference.

between Contour I treatments could be reduced to achieve the desired results faster with greater patient acceptance.

Both preclinical and clinical studies have provided data to support the validity of the Contour I as a noninvasive fat reduction and body contouring treatment system. The results from a series of bench and preclinical experiments support the scientific bases for the effect of nonthermal (mechanical) focused ultrasonic energy.³⁹ Physics modeling, preclinical models, and histologic analyses have demonstrated that energy can be specifically delivered to

the designated target, creating a cavitation effect within a well-defined focal volume (treatment zone). To date, there is no evidence that the mechanical ultrasonic energy has any adverse effect on the dermis, and histologic analyses have demonstrated the selective disruption (lysis) of adipocytes in the treatment area with no observable damage to associated nerves and blood vessels.³⁹

A controlled, multicenter clinical study demonstrated the safety and effectiveness of a single treatment with the Contour I system.³⁷ In that study, a single treatment with

the Contour I reduced the circumference of the treated area by an average of 1.91 cm. No safety issues were reported in the study or during the three-month follow-up period. Another clinical study,³⁸ which was conducted to evaluate the safety and effectiveness of a series of three treatments at four-week treatment intervals with a one-month follow-up using the Contour I, reported a mean reduction in circumference of the treatment area of 3.95 ± 1.99 cm and no severe AE. The two-week treatment interval results demonstrated in the present report are comparable to those in the previously published reports and establish a basis for allowing flexibility in treatment schedules to further meet the needs of the patient.

Although high-intensity focused ultrasound (HIFU) is an established modality for tissue heating and ablation in a variety of applications (mostly in oncology),⁴⁰ its use in body contouring is still under evaluation. The HIFU energy rapidly raises tissue temperature over 70°C and therefore has the potential to cause nonselective instantaneous cell necrosis at the designated target. Whether the HIFU technology can be modified to provide a safe, comfortable, office-based, no-downtime procedure with acceptable clinical results has not yet been determined. Cryolipolysis, another thermal technology that employs transcutaneous cooling of the target tissue to very low temperatures to induce a slow lysis of adipocytes, has been shown in a preclinical study on pigs to damage subcutaneous fat without damaging the overlying skin.⁴¹ A recent pilot clinical study used this procedure in 10 subjects but concluded that cryolipolysis was associated with modest, reversible, short-term (several weeks) changes in peripheral nerve function.⁴² There is currently no commercial clinical experience with either of these thermal technologies.

Body contouring procedures, whether invasive, minimally invasive, or noninvasive, must be scientifically and clinically proven as safe and effective, with a risk-benefit profile that meets the needs of patients seeking these types of aesthetic treatments.

Disclosures

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