Noninvasive Body Contouring by Focused Ultrasound: Safety and Efficacy of the Contour I Device in a Multicenter, Controlled, Clinical Study

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Background: The removal of unwanted body fat using a noninvasive technique is desirable to patients and physicians. The authors describe a controlled, multicenter, clinical trial assessing the safety and efficacy of a focused therapeutic ultrasound device for noninvasive body contouring.
Methods: Eligible healthy adult subjects were enrolled to the experimental group or the control group at five sites. The experimental group received one treatment with the Contour I device (UltraShape Ltd., Tel Aviv, Israel) in the abdomen, thighs, or flanks and were evaluated over a 12-week period. Efficacy outcomes were reduction of circumference and fat thickness. Circumference reduction was compared with the untreated group and with an untreated area (thigh) within the treated group. Safety monitoring included laboratory testing (including serum lipids), pulse oximetry, and liver ultrasound.
Results: One hundred sixty-four subjects participated in the study (137 subjects in the experimental group and 27 in the control, untreated group). A single Contour I treatment was safe and well tolerated and produced a mean reduction of approximately 2 cm in treatment area circumference and approximately 2.9 mm in skin fat thickness. The majority of the effect was achieved within 2 weeks and was sustained at 12 weeks. No clinically significant changes in the measured safety parameters were recorded. Seven adverse events were reported, all of which were anticipated, mild, and resolved within the study period.
Conclusion: The Contour I device provides a safe and effective noninvasive technology for body contouring. (*Plast. Reconstr. Surg.* 120: 779, 2007.)

Body contouring by liposuction is the most frequently performed cosmetic surgery procedure in the United States, with an estimated 455,000 cases in 2005.[1] This number repre-

sents less than 1 percent of the potential pool: 45 million Americans diet every year to improve health and enhance body contour, and even this is a small portion of the 130 million Americans who are overweight.[2,3] Liposuction methodology has evolved over several decades to yield a procedure that is safer and amenable to regional anesthesia or conscious sedation and can be performed in an outpatient setting.[4–7] Despite the many advances in liposuction technique, it retains risk and discomfort by virtue of its invasive nature, and postprocedure recovery may require extensive downtime and compression garments.[8] Even when the procedure is clinically well tolerated, hemodynamic and metabolic changes occur in the immediate postsurgical days.[9–13]

Ultrasound-assisted liposuction accounted for 21 percent of liposuction procedures in 2005.[1] Internally applied ultrasound improves liposuction technique by disrupting adipose tissue.[14–18] This advantage is offset to some degree by the increased technical skill required and the increased risk of injury to the skin at sites of direct contact between the probe and the skin as a result of the thermal effects of the currently available ultrasonic probes.

Existing noninvasive and minimally invasive technologies for improving the appearance of skin and subcutaneous fat appearance, such as deep body massage, radiofrequency, and light-based treatments, have gained popularity because of their minimal downtime, relative safety, and cosmetic benefit in temporary reduction in the appearance of cellulite.[19–22] However, they are suboptimal for body contouring, as they provide only modest and temporary circumference reduction, require multiple treatments for effect, provide short-term results, and may require maintenance therapy. Their use is therefore limited to treatment of the superficial subcutaneous layer for temporary reduction in the appearance of cellulite.[23–25] Furthermore, unlike liposuction, they aim not to remove excess subcutaneous fat but rather to tighten the overlying skin or to improve circulation, with theorized secondary effects of reducing edema and mobilizing intracellular fat by inducing biochemical lipolysis in intact adipocytes. There is a need for a technology that provides improved durability.

A method of delivering ultrasound to the fat without depositing significant ultrasound energy in the skin would provide the benefits of ultrasound disruption of fat with greater safety. Furthermore, an ideal noninvasive method of delivering energy would reduce periprocedural morbidity such as infection, scarring, anesthesia-related complications, and other risks associated with surgical procedures.

We describe here the pivotal clinical trial that demonstrates the safety and efficacy of the Contour I (UltraShape Ltd., Tel Aviv, Israel), a noninvasive device for body contouring. This device uses pulsed ultrasound at parameters designed to produce nonthermal effects in the subcutaneous fat.

PATIENTS AND METHODS

This pivotal phase II clinical trial, conducted at five centers (two in the United States, one in the United Kingdom, and two in Japan) between August of 2004 and June of 2005, was approved by the relevant institutional review boards and ethics committees for the protection of human subjects. All participants provided informed consent before their enrollment in the study.

Screening and Enrollment

One hundred sixty-four healthy volunteers were enrolled in this prospective, multicenter, comparative study designed to assess the safety and efficacy of a single treatment with the Contour I system at different body areas (abdomen, thighs, or flanks). One hundred thirty-seven (25 to 30 at each clinical site) participants were assigned to the experimental (treated) group and 27 (five or six at each clinical site) participants were assigned to the control (untreated) control group. The male-to-female participant ratio was 1:2. Participants were aged 18 to 65 years and had subcutaneous fat thickness of at least 1.5 cm in the area to be treated, as measured with a commercial pinch caliper. At the screening visit, subjects underwent physical examination and liver ultrasound, and serum was isolated from whole blood by means of venipuncture for laboratory testing. Individuals with cardiac pacemakers, abdominal wall hernias, pregnancy, diabetes, hepatitis, human immunodeficiency virus positivity, coagulation disorders or recent ingestion of anticoagulants, or history of exposure to highly fat-soluble compounds were excluded, as were those who failed the screening testing. Females of child-bearing potential were enrolled only if using two methods of contraception. Treatment area assignment was dictated by clinical assessment of each subject by the investigator.

Measurements

Immediately before the procedure (day 0), the area to be treated (abdomen, thighs, or flanks) was marked and fat thickness in the marked area was confirmed with a pinch caliper by the investigator to be at least 1.5 cm. Each participant was weighed and measured for circumference (in centimeters) at the treatment area and at the internal control area (thigh). Circumference was measured by means of a standardized measuring technique using a specially designed and validated apparatus that provides measurements at a constant height and under constant tension. Ultrasound assessment of fat thickness (in millimeters) was performed with a specially designed apparatus that held the diagnostic ultrasound transducer on the skin at a constant pressure. Photography was performed with a dedicated 35-mm camera set at fixed focal length and under constant lighting.

Treatment with the Contour I

A topical anesthetic containing lidocaine 2.5% and prilocaine 2.5% (EMLA Cream; AstraZeneca, London, England) was applied under occlusion for 90 minutes before the procedure. The EMLA Cream was removed and a skin-compatible treatment oil, provided by the manufacturer, was ap-
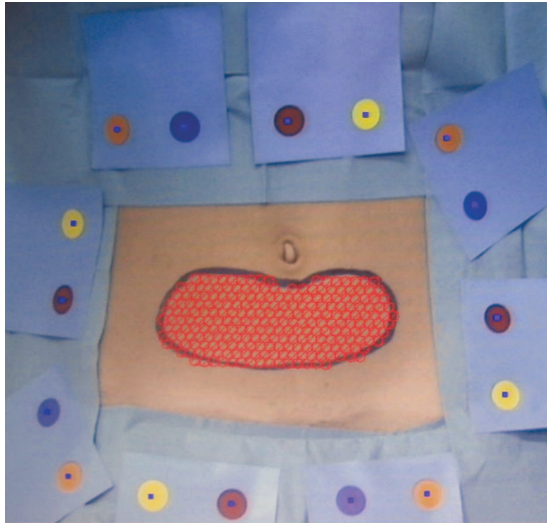
Fig. 1. Treatment area (abdomen) homogeneously covered by individual treatment nodes, as guided by the Contour I real-time video monitoring and guidance system. During treatment, a video camera captures the treatment area and the transducer in real time and guides the user, by means of graphic overlays displayed on the system monitor, to place the transducer on the next treatment spot ("node"). The nodes homogeneously cover the treatment area, which is detected by the system, without overlap and without extension beyond the marked boundaries of the treatment area. This image is a screen shot of the treatment area as it appears at the completion of treatment, when the entire area has been evenly covered with individual nodes (*red circles*).

plied to serve as an acoustic coupling medium. Treatment was applied using a handpiece whose positioning was monitored and guided by the Contour I real-time video tracking and guidance system manufacturer's preset and unchangeable settings. Pulse oximetry was assessed throughout the procedure (Fig. 1).

The experimental group received a single Contour I treatment on day 0. Control values were derived from subjects who were untreated but followed over the time of the protocol. No subject underwent a sham procedure. After treatment, participants were instructed to resume regular daily activities and eating habits to maintain baseline body weights. Follow-up visits for both experimental and control groups were scheduled on days 1, 3, 7, 14, 28, 56, and 84.

Efficacy Assessments

At each follow-up visit, participants underwent photography, weighing, and measurement of the circumference of the treated and internal control areas. The untreated thigh was used as an internal control to indicate circumference changes that were unrelated to treatment (e.g., induced by weight loss). Change in circumference was assessed as the difference between circumferences measured at follow-up visits and the pretreatment circumference. Ultrasound measurements of subcutaneous fat thickness were obtained before treatment and on days 14 and 28.

Safety Assessments

Safety assessments included laboratory testing, pulse oximetry, liver ultrasound, and adverse event monitoring. The laboratory evaluation included complete blood count, serum chemistry (sodium, potassium, creatinine, urea, calcium), fasting lipids (total cholesterol, high-density lipoprotein, low-density lipoprotein, and triglycerides), liver markers (alanine aminotransferase, aspartate aminotransferase, lactate dehydrogenase, alkaline phosphatase, total bilirubin, albumin), and complete urinalysis at all study visits. Pulse oximetry was monitored continuously during treatment and was measured before and after treatment and on day 1 to assess potential pulmonary adverse effects. Liver ultrasound was performed before treatment and on days 14 and 28 to identify treatment-induced fatty infiltration of the liver. Two-point discrimination testing was performed at baseline and at day 28.

Statistical Analysis

Circumference reduction and fat thickness reduction from the three treated body areas were combined for analysis. Data were analyzed using SAS software (SAS Institute, Inc., Cary, N.C.). All tests applied were two-tailed, and a value of $p \leq 0.050$ was considered statistically significant. Within each group, the paired t test was applied for testing differences between baseline (day 0) assessment and follow-up assessments for quantitative parameters. The two-sample t test was applied for testing differences between the treated and untreated study groups for quantitative parameters (fat thickness reduction and circumference reduction, participant demographics). The data were expressed as mean and SEM.

RESULTS

Subject Disposition and Baseline Demographic Characteristics

A total of 164 subjects participated in the study: 137 were treated and 27 were untreated. Overall, 96 women and 41 men received treatment, and 21 women and six men were untreated.

Table 1. Subject Baseline Characteristics by Study Group for Age, Weight, Height, BMI, and Fat Thickness*

Baseline Characteristic	Untreated			Treated			
	No.	Mean	SEM	No.	Mean	SEM	p
Age, years	27	41.3	2.02	137	40.1	0.95	0.587
Weight, kg	27	66.5	3.44	137	68.3	1.48	0.609
Height, cm	15	160.4	1.42	84	163.9	0.93	0.129
BMI, kg/m²	15	22.3	1.11	84	23.8	0.42	0.195
Fat thickness, mm	23	24.5	1.83	111	24.7	0.88	0.936

BMI, body mass index; SEM, standard error of the mean.
*These characteristics were not statistically different between treated and untreated groups.

No significant differences in subject baseline characteristics were observed among any of the study centers. The proportions of experimental and control subjects were similar across study centers. Assessments of demographic and baseline parameters (age, weight, height, body mass index, and fat thickness by ultrasound) showed no statistically significant differences between the experimental and control groups (Table 1). The distribution of participants across treatment area groups (abdomen, flanks, and thighs) is summarized in Table 2. Only women underwent treatment in the thigh area. The control group for thighs was composed only of women.

Efficacy of the Contour I in Circumference Reduction

A single treatment resulted in a mean circumference reduction of 1.9 cm at 12 weeks, with a response rate of 82 percent (Fig. 2). In the experimental (treated) group, the mean circumference reduction from baseline was significant at all time points except day 1 ($p < 0.001$ on days 14, 28, and 84; $p = 0.223$ on day 1). Approximately 77 percent of the observed circumference reduction occurred within 14 days of treatment. The response of the abdomen, thighs, and flanks was comparable: there was no statistically significant difference in the mean circumference reduction at any of these treatment areas [abdomen, -2.3 ± 0.32 cm, flanks, -1.8 ± 0.31 cm, thighs, -1.6 ± 0.39 cm; differences among sites, not significant ($p = 0.366$)]. The response of men and women was similar, with a mean circumference reduction of 1.8 cm in women and 2.2 cm in men on day 84 ($p = 0.368$). Responses across the five clinical sites were comparable ($p > 0.100$ at all time points).

In the control group, circumference reductions were combined for comparative analyses to the experimental group. When compared with the control (untreated) group, the circumference reduction in the experimental group was significant at all time points, except day 1 ($p < 0.001$ on day 14 and day 28, and $p < 0.006$ on day 84; $p = 0.227$ on day 1). Within the control group, no statistical differences were observed in the mean circumference reduction from baseline (Fig. 2) ($p = 0.149$ at day 84).

An untreated thigh area served as an internal control area for the treatment area in the same participant for both the treated and untreated groups. This internal control was included to indicate circumference changes that were unrelated to treatment (e.g., induced by weight loss). No statistical differences were detected between the experimental and control groups for circumference reduction of the internal control area at any of the time points ($p = 0.195$ at day 84). In the experimental group, the treated area circumference was significantly reduced ($p < 0.001$) at day 84 relative to the internal control area circumference at all time points except day 1 (Fig. 3). No statistically significant weight reduction was observed in the treated or untreated group ($p = 0.288$ at day 84).

Six participants are shown in Figures 4 and 5. A posttreatment response in the lower abdomen of a male participant is shown in Figure 4, *above*. At day 28, the circumference at the abdomen was reduced by 4.5 cm from baseline measurement, whereas his weight remained stable during the

Table 2. Distribution of Study Groups by Treatment Area*

	Treatment Area			
	Abdomen (%)	Flank (%)	Thigh (%)	All (%)
Experimental	56 (80)	47 (85)	34 (87)	137 (84)
Control	14 (20)	8 (15)	5 (13)	27 (16)
Total	70 (100)	55 (100)	39 (100)	164 (100)

*The participant distribution across treatment areas in the experimental group was as follows: abdomen, 41 percent; flank, 34 percent; and thigh, 25 percent. Only women underwent Contour I treatment in the thigh area. The participant distribution across treatment areas in the untreated group was as follows: abdomen, 52 percent; flank, 30 percent; and thigh, 18 percent. Only women had thigh measurements.
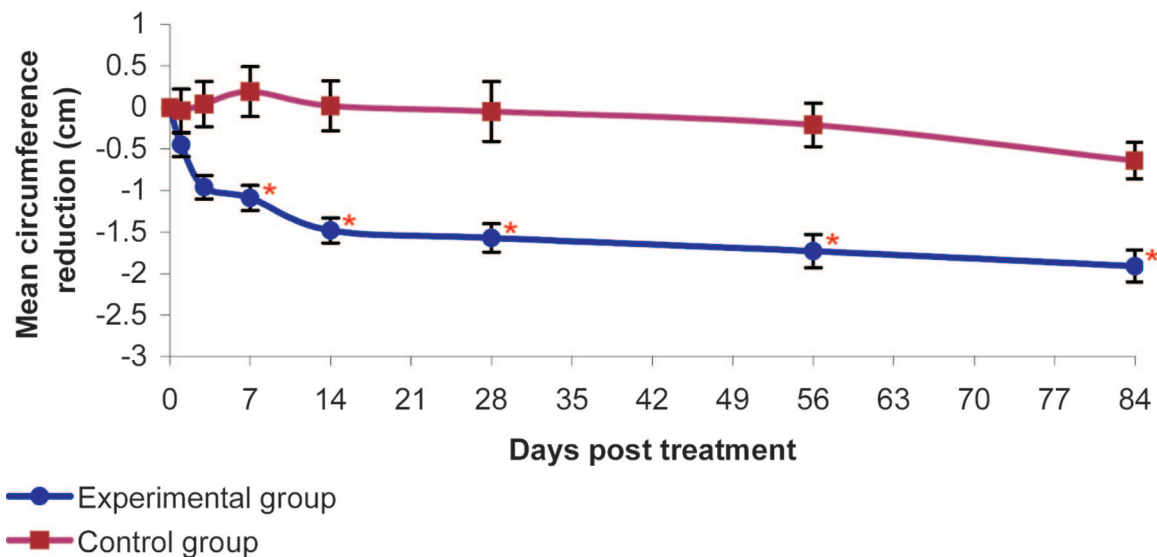
Fig. 2. Mean circumference change from baseline in the experimental and control groups. The effect of a single Contour I treatment on circumference reduction from baseline at each study visit point (baseline and days 1, 3, 7, 14, 28, 56, and 84) for the treated and untreated groups is shown in this graph. The number of treated participants evaluated at each time point from day 1 to day 84 was as follows: 133, 130, 132, 132, 127, 115, and 118; the number of untreated participants evaluated at each time point from day 1 to day 84 was as follows: 27, 26, 27, 26, 26, 25, and 23. The mean circumference reduction in the treated group was 1.9 ± 0.2 cm at day 84 (12 weeks). In the treated group, the circumference reduction from baseline was significant at all time points, except day 1 ($p < 0.001$ on days 14, 28, and 84). There were no statistical differences in circumference reduction from baseline in the untreated group. Overall, there were statistical differences between the treated and untreated group at all time points, except day 1 ($p < 0.001$ on day 14 and day 28, and $p < 0.006$ on day 84). *$p < 0.001$ (compared with baseline circumference).

study period ($+0.2$ kg relative to baseline). A female participant experienced a reduction of 4.0 cm in circumference of the upper thighs at day 28, with a small change in weight (-2.5 kg) (Fig. 4, *center*). In Figure 4, *below*, the posttreatment flank contour of a male participant had a reduction of 3.5 cm in circumference, with a small increase in weight ($+1.8$ kg). Figure 5, *above* demonstrates reduction in the flanks of a female participant, with a 2.6-cm reduction and a small weight loss of 1.8 kg at day 28. In Figure 5, *center*, a woman had her abdomen treated and a 3.4-cm reduction was measured; she had a 2.1-kg weight loss during the 28 days. Figure 5, *below* consists of photographs of a male participant who had an abdominal reduction of 3.0 cm in circumference at day 28, with a decrease in weight of 3.1 kg.

Fat Thickness Evaluation

In the experimental group, the fat thickness was reduced from baseline by 2.6 mm on day 14 and by 2.9 mm on day 28 ($p < 0.001$ for both day 14 and day 28) (Fig. 6). Approximately 85 percent of the reduction in fat thickness occurred within 14 days of treatment. Figure 7 shows a represen-

tative sonogram, demonstrating a 4-mm reduction in fat thickness at day 14. No statistical differences were observed in the control group ($p = 0.368$ at day 14 and $p = 0.246$ at day 28). Responses across the five clinical sites were comparable ($p = 0.037$ at day 14 and $p = 0.068$ at day 28).

Safety

The treatment is safe and well tolerated, and no clinically significant treatment-associated changes in laboratory values were observed. Notably, no treatment-induced elevations in serum lipids or lipoprotein levels were detected (data not shown). Pulse oximetry readings during the treatment and at day 1 were within the normal range (94 to 99 percent oxygen saturation). Analysis of liver sonograms showed no treatment-induced changes. No clinically significant changes in two-point discrimination were observed.

No serious adverse events were reported throughout the study. Seven localized adverse events were observed during the treatment session, and no further events were reported during the follow-up period. All adverse events were related to the treatment procedure and were antic-
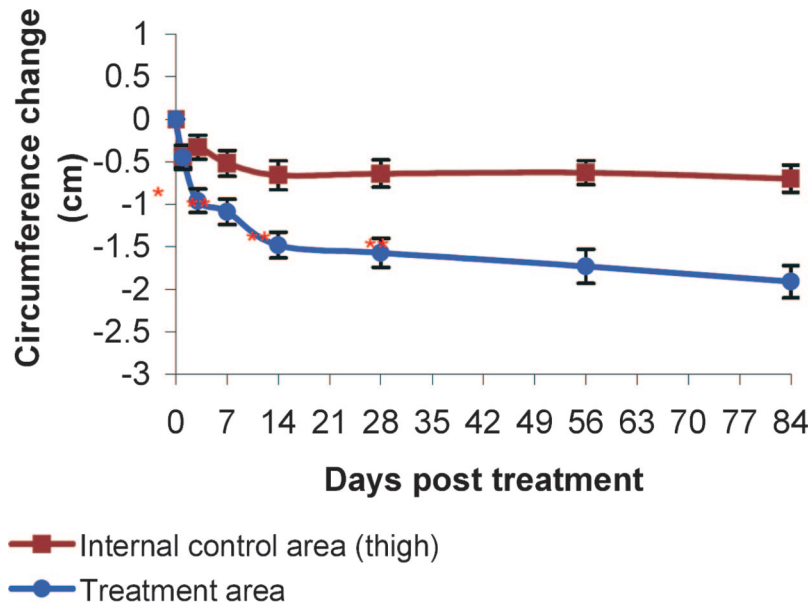
Fig. 3. Mean circumference change of the treated area versus mean circumference change of the internal control area (thigh). Circumference changes from baseline at the treated area and the internal control area, within the same subject, in the treated group are depicted in this graph. The circumference of the treated area was reduced significantly relative to the internal control area at all time points except day 1 ($p <$ 0.001 at day 84). The circumference reductions of the treated area and internal control area were similar between baseline and day 1 and therefore are shown on the same line. *$p = 0.001$ and **$p < 0.001$ (p represents the difference between the treated area change and the internal control area change).

ipated. One participant reported a mild tingling sensation during treatment, which resolved immediately on completion of treatment. Three participants were noted to have mild erythema, which resolved by the day-1 follow-up visit. One participant developed sparse purpuric lesions that resolved by the day-7 visit. Two participants developed small blisters. Of these, one resolved within 3 days; the other progressed to a dermal erosion and was treated with topical antibiotics. At the day-84 visit, the erosion was healed, with mild residual erythema.

DISCUSSION

Our clinical study shows that the Contour I, the first noninvasive focused ultrasound technology for body contouring, is safe and effective. These results were consistent among five international clinical sites with a total of 164 subjects. The devices were preset with a single power setting and one treatment protocol, and all clinical sites had control subjects. All principal investigators were trained by the manufacturer before initiation of the study.

This focused ultrasound procedure reduced the circumference in the treated areas. Average reduction in the circumference was approximately 2 cm in the abdomen, thighs, and flanks. The reduction in circumference was corroborated by a reduction in fat thickness, as assessed by ultrasound measurement. The majority of the effect—77 percent of the circumference reduction and 85 percent of the fat thickness reduction—was seen within the first 14 days after treatment, and additional reduction was seen over the following weeks. The effect was maintained for at least the study period of 12 weeks after a single treatment. Neither the control group nor the internal control area exhibited significant reduction during the 12-week study follow-up. Reduction in circumference could not be correlated with weight loss, as no statistically significant weight reduction was observed in the experimental or control group.

The procedure was well tolerated. Ninety-two percent of treated subjects reported that they experienced minimal or no discomfort during or after the procedure (data not shown). In the clinical studies, a topical anesthetic cream (EMLA)
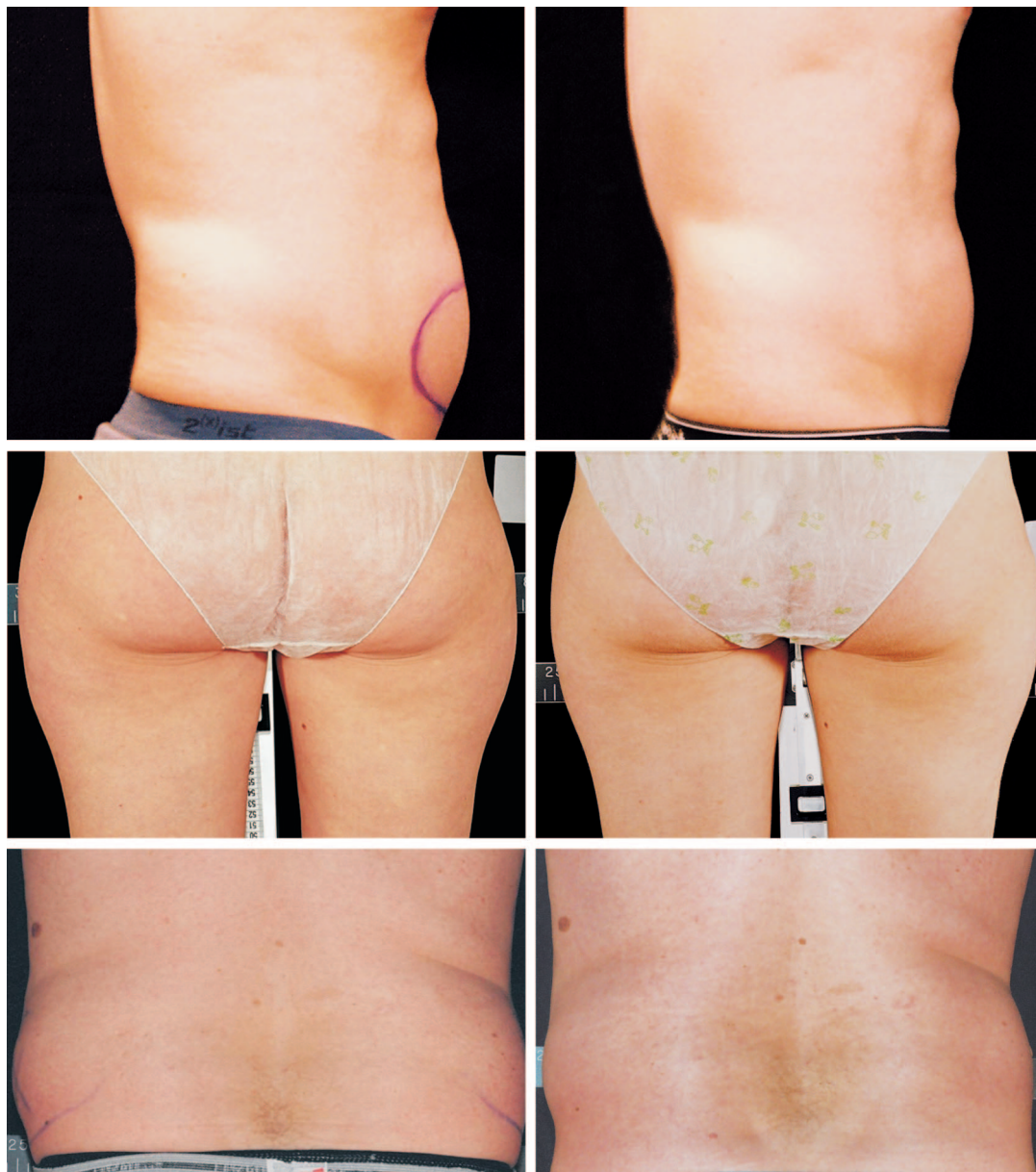
Fig. 4. Response to a single Contour I treatment in (*above*) a man, whose treatment area was the abdomen, (*center*) a woman, whose treatment area was the thighs, and (*below*) a man, whose treatment area was the flanks.

was applied 90 minutes before treatment. In post-trial experience, in countries where the device is commercially available, we have performed numerous treatments without EMLA and found it to be equally well tolerated. UltraShape has confirmed that pretreatment with EMLA is not required.

Physical examination and laboratory assessments throughout the study period demonstrated no clinically significant changes. No subject withdrew from the study because of treatment-associated events at any study site. Of importance, assessment of hepatic function revealed no changes

in serum transaminases, lactate dehydrogenase, alkaline phosphatase, bilirubin, albumin, prothrombin time/partial thromboplastin time, or plasma lipids. Liver ultrasound at day 14 and day 28 showed no increase in liver fat content. No hematomas, seromas, or ecchymoses were seen, and hematocrit and hemoglobin remained stable, suggesting no significant bleeding. No leukocytosis was observed. Pulse oximetry, performed during the procedure and 1 day after the procedure to assess potential pulmonary events, revealed normal oxygen saturation. There was no clinically
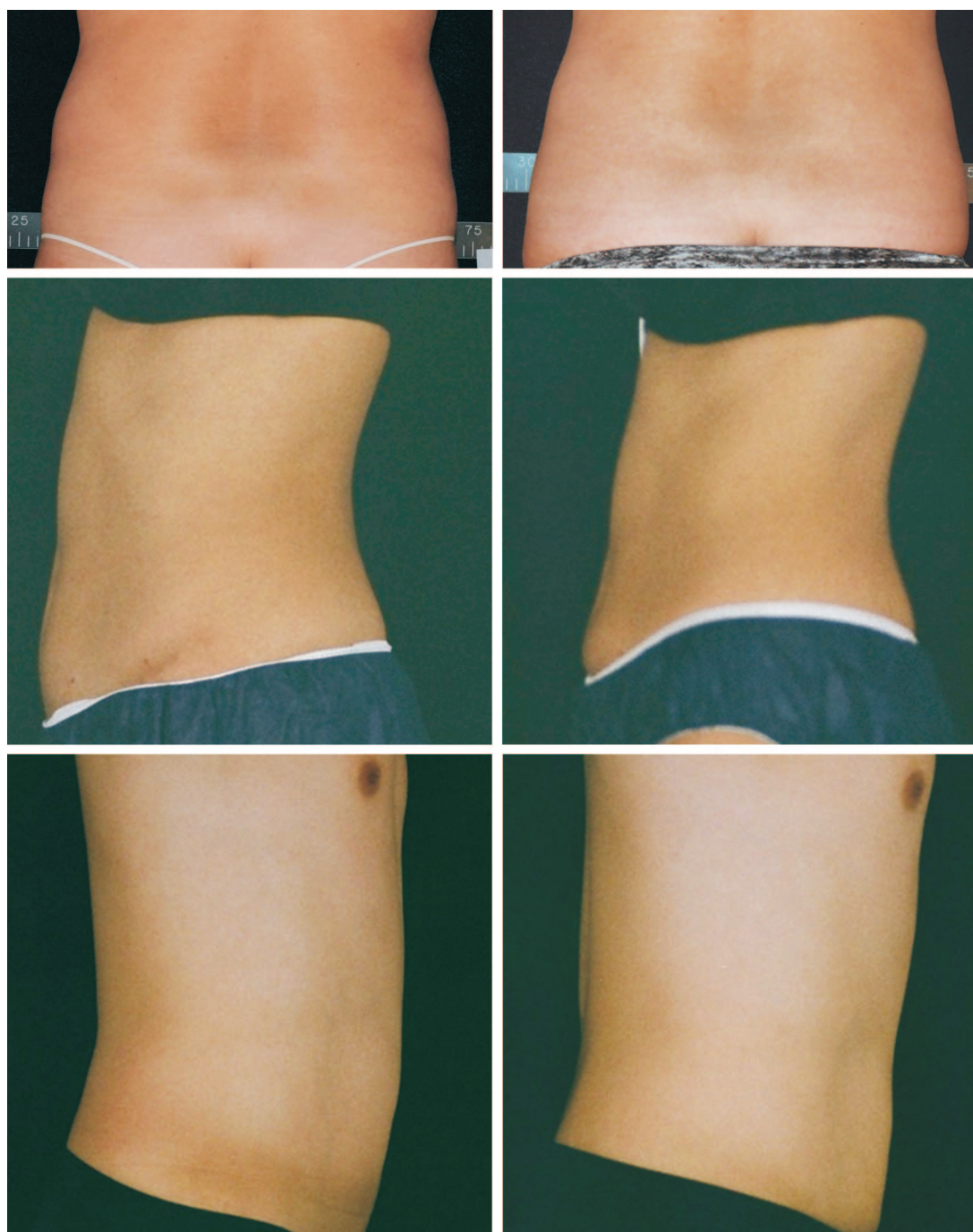
Fig. 5. Response to a single Contour I treatment in (*above*) a woman, whose treatment area was the flanks, (*center*) a woman, whose treatment area was the abdomen, and (*below*) a man, whose treatment area was the abdomen.

significant change in two-point discrimination. No hyperpigmentation or hypopigmentation was reported. Fat texture in the treated area remained smooth, with no nodules or irregularities in texture reported.

Seven adverse events were observed during the treatment. These were mild and were anticipated as outlined in the consent form. One patient was treated on the thigh, where the subcutaneous fat over the greater trochanter was very thin, and where the ultrasound could potentially be reflected from the bone. Erythema, the most common event (three of seven), was painless and resolved within hours.
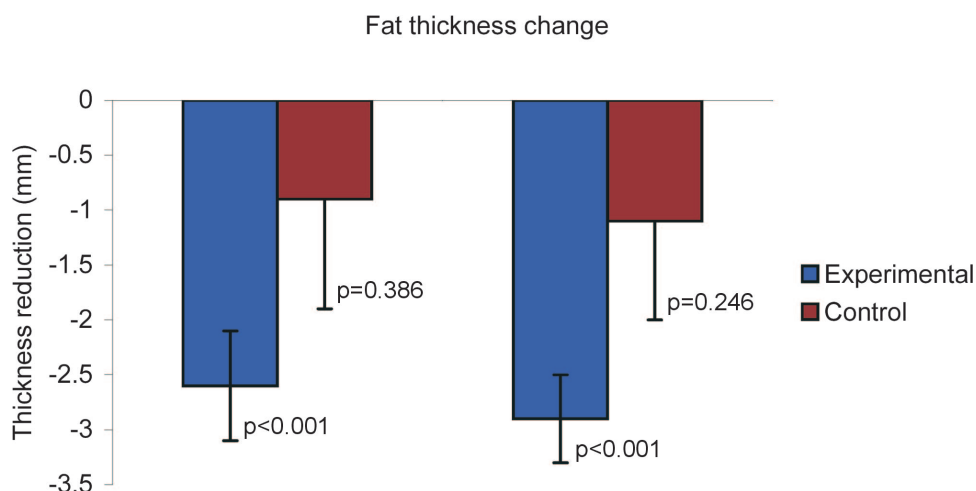
Fat thickness change

Fig. 6. The mean fat thickness reduction from baseline, assessed by ultrasound, in the experimental and control groups. Change from baseline of fat thickness, as measured by ultrasound, at days 14 and 28 in the treated and untreated groups is depicted in this graph. In the treated group, fat thickness was statistically reduced by 2.6 mm on day 14 ($p < 0.001$) and by 2.9 mm on day 28 ($p < 0.001$) relative to the baseline measurements. No statistical differences were observed in the untreated group ($p = 0.368$ at day 14 and $p = 0.246$ at day 28).

This new technology from UltraShape uses focused ultrasound to deliver a finite amount of acoustic energy at a controlled distance from the ultrasound transducer to achieve noninvasive body contouring. Ultrasound energy is emitted from a hemispherical transducer (Fig. 8). In this geometry, the energy is low near the transducer surface and is concentrated in an additive manner at a distant focus. The transducer is placed directly on the skin and focuses the energy at the depth of the subcutaneous fat. As a result, the energy can be delivered through the skin, with low energy density at the epidermis and dermis, and with a high energy density in the subcutaneous fat. The ultrasound energy is delivered in pulses, using parameters that provide a nonthermal effect. High levels of ultrasound energy within the subcutaneous fat can disrupt adipose tissue safely and effectively, as has been demonstrated in ultrasound-assisted liposuction.[14,15]

A unique central tracking and guidance system provides a crucial element of safety and quality control. A real-time video image of the treatment area is displayed on the LCD monitor. The tracking component captures the region of interest and generates
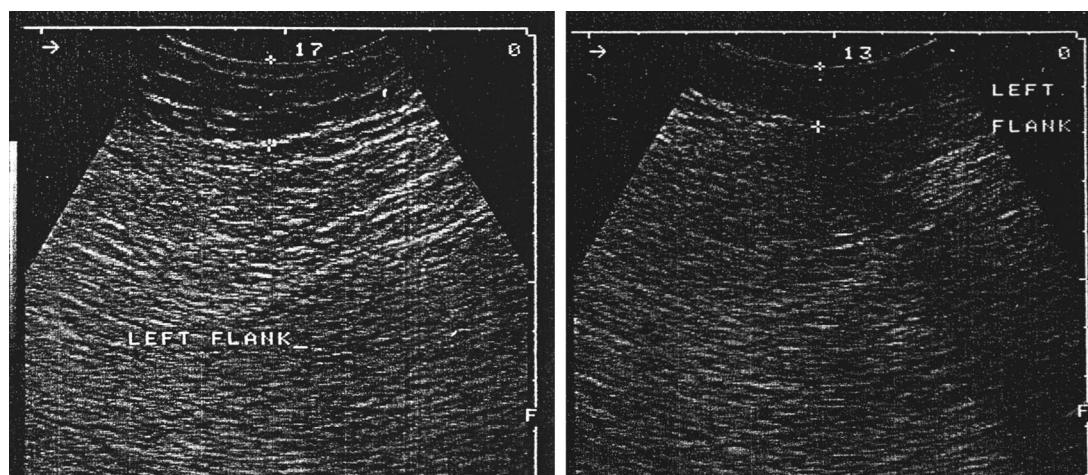

Fig. 7. Sonograms of representative fat thickness assessment. Fat thickness at baseline (*left*) and 14 days after treatment (*right*) shows thinning of the subcutaneous fat layer from 17 mm to 13 mm (reduction of 4 mm). This participant was treated on the flanks.
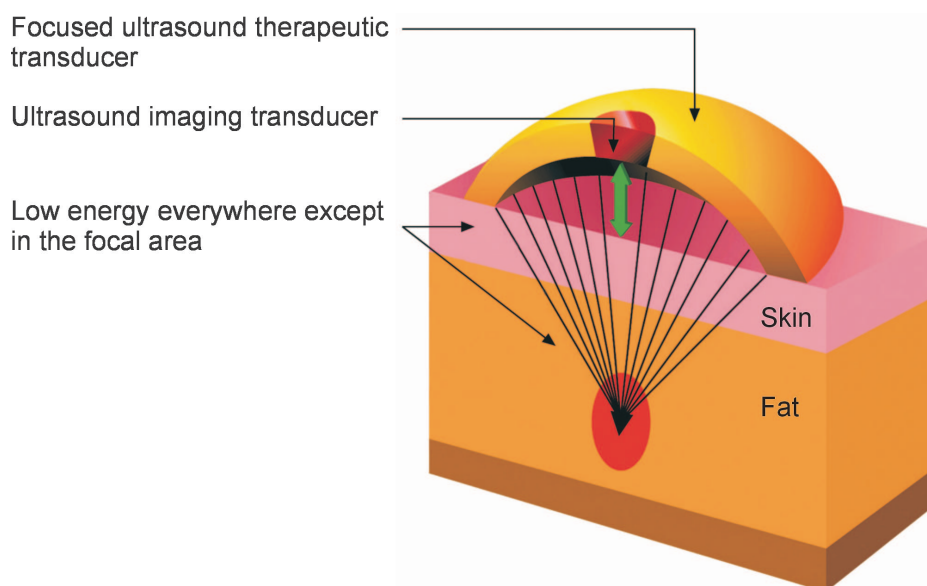
Fig. 8. Cross-section of the Contour I transducer. (Courtesy of UltraShape Ltd., Tel Aviv, Israel.)

a treatment algorithm, such that each spot is treated once and only once. The tracking system does not allow a pulse of energy to be delivered outside the region that the physician marked before initiating the treatment, obviating the potential for accidental treatment in undesired areas.

All patients resume normal activities immediately after treatment, without downtime, pain, or compression garments. The procedure is performed as an office-based procedure, without the need for additional equipment, garments, or medication. The procedure time ranges from 60 to 120 minutes, depending on the size of the treatment area. The ease of device operation along with the real-time video tracking and guidance system make the procedure amenable to use by physicians or properly trained medical staff, under medical supervision. Physician expertise is required, however, for patient selection, marking of treatment areas, and determination of medical eligibility for treatment.

There is a challenge in presenting an approximate change of a mean reduction of 2.3 cm for the abdomen, 1.8 cm for the flanks, and 1.6 cm for the thighs with digital images. This posttreatment change represents a small change in the percentage of total body circumferences in these population groups. However, the change in circumferences after treatment was quantifiable and significant compared with the control group and with baseline values. In addition, the majority of subjects reported overall satisfaction with their results (data not shown).

A single treatment dose was used to show safety first and then efficacy. The response rate, as assessed by a reduction in treatment area circumference, was 82 percent. The factors that may have contributed to nonresponse are not defined but may include weight fluctuation, body fluid levels, physical activity levels following treatment, among other factors. Furthermore, one must note that the treated areas were not mapped out for maximal circumference change. The treated areas were marked in the same fashion as that used for lipoplasty. For example, if maximal abdominal circumference change was the endpoint, the "fat handles" of an individual would have been treated. Multiple treatments could provide additional benefit for subjects with more excess fat (fat thickness >1.5 cm).

What is actually happening to the fat released from the treated adipocyte? Where does it or the byproducts of its dissolution go? This clinical protocol was designed to monitor known metabolic pathways of fat metabolism (fatty liver, plasma triglycerides, lipoprotein lipid levels, and free fatty acid levels). In all of these parameters, no clinically significant level in any of these endpoints was observed after treatment. The body has a tremendous capacity to move water-insoluble fat, as documented by fat-loading challenge tests. Future studies will examine the relative clearance rates of triglycerides and the hydrolytic products (water-soluble glycerol and albumin-bound free fatty acid). There are no other metabolic pathways in which fat is handled by the body that are related to any known clinical problem.

CONCLUSIONS

This clinical study, to the best of our knowledge, is the first assessment of the safety and efficacy of noninvasive focused ultrasound in an aesthetic application. Focused ultrasonic body contouring is an ideal procedure for patients who would require small or moderate amounts of adipose tissue removal over time using single or multiple treatments or who otherwise would not be considered for large-volume liposuction procedures. Greater application of this technology in body contouring will be achieved by performing clinical trials to assess whether serial treatments produce incremental fat reduction. Future clinical studies will provide insights into whether greater fat reduction can be achieved through various treatment algorithms, in conjunction with weight loss strategies or other aesthetic technologies to treat obesity related fat depots.

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DISCLOSURES

Steven A. Teitelbaum, M.D., is a member of the UltraShape Scientific Advisory Board and was compensated for performing this clinical trial; John L. Burns, M.D., Junichiro Kubota, M.D., Hidenori Matsuda, M.D., Morkel J. Otto, M.B.Ch.B., Yukio Shirakabe, M.D., and Yoshiro Suzuki, M.D., were compensated for work related to performing this study; and Spencer A. Brown, Ph.D., is a member of the UltraShape Scientific Advisory Board.

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