

Randomized Sham-Controlled Trial to Evaluate the Safety and Effectiveness of a High-Intensity Focused Ultrasound Device for Noninvasive Body Sculpting

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Background: High-intensity focused ultrasound presents a noninvasive approach to body sculpting for nonobese patients. The purpose of this study was to evaluate the safety and effectiveness of a high-intensity focused ultrasound device for sculpting of the abdomen and flanks.

Methods: Adults (aged 18 to 65 years) with subcutaneous abdominal fat greater than or equal to 2.5 cm thick who met screening criteria were randomized to receive high-intensity focused ultrasound treatment of the anterior abdomen and flanks at energy levels (a total of three passes each) of 47 J/cm² (141 J/cm² total), 59 J/cm² (177 J/cm²), or 0 J/cm² (no energy applied, sham control). The primary endpoint was change from baseline waist circumference at the iliac crest level at posttreatment week 12. Subjective aesthetic assessments included the Global Aesthetic Improvement Scale and a patient satisfaction questionnaire. Safety assessments included adverse events, laboratory values, and physical examinations.

Results: For the primary endpoint, in the intent-to-treat population, statistical significance versus sham was achieved for the 59-J/cm² (-2.44; $p = 0.01$) but not the 47-J/cm² treatment group (-2.06 cm; $p = 0.13$). In a per-protocol population, statistical significance versus sham was achieved for both the 59-J/cm² (-2.52 cm; $p = 0.002$) and the 47-J/cm² treatment groups (-2.10 cm; $p = 0.04$). Investigator subjective measures of global aesthetic improvement and patient satisfaction also favored each active treatment versus sham. Adverse events included mild to moderate discomfort, bruising, and edema. Laboratory values and physical examinations were unremarkable.

Conclusions: Treatment with this high-intensity focused ultrasound device reduced waist circumference and was generally well tolerated for noninvasive body sculpting. Reduction in waist circumference was statistically significant with both active treatments (per protocol). (*Plast. Reconstr. Surg.* 128: 253, 2011.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, II.

Body sculpting refers to the optimization of the smoothness, definition, or silhouette of the human physique, particularly the torso, by means of diet and exercise or medical interventions. The most common medical procedure for body sculpting is surgical liposuction, which can be used for focal or large-volume fat removal.¹

Despite technical advances that have reduced complications,² liposuction may not be an appealing option for patients with limited focal adiposity.

Current noninvasive or minimally invasive alternatives to liposuction include cryolipolysis,^{3,4} radiofrequency,^{5,6} laser-based^{7,8} or light-based⁹ therapies, injection lipolysis,¹⁰ and low-frequency nonthermal ultrasound.^{11,12} High-intensity fo-

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cused ultrasound generates high-energy ultrasonic waves (100 to 10,000 W/cm²) that converge at a specific focal point in subcutaneous tissue¹³ where temperatures are rapidly raised to greater than 65°C, the temperature at which cell necrosis occurs in adipocytes.¹⁴ The technique allows localized destruction of adipose tissue at precise tissue depths without damage to the surrounding tissue or skin surface.¹³

The efficacy and safety of high-intensity focused ultrasound are suggested by two large case series presenting results for 387 patients who received treatments for the reduction of waist circumference.^{15,16} However, data from sham-controlled, randomized trials are lacking. The current randomized controlled trial sought to evaluate the safety, tolerability, and effectiveness of a high-intensity focused ultrasound device (LipoSonix system; Medicis Technologies Corp., Scottsdale, Ariz.) for body sculpting.

PATIENTS AND METHODS

Design

This was a multicenter, randomized, sham-controlled, single-blind trial evaluating the effectiveness and safety of a high-intensity focused ultrasound device for waist circumference reduction. The study received institutional review board approval and was conducted in accordance with the Declaration of Helsinki. All patients provided written informed consent. Trial registration (ClinicalTrials.gov NCT00906815) occurred on May 19, 2009; the first patient was enrolled on June 17, 2009.

Patients

Men and women aged 18 to 65 years with a body mass index less than or equal to 30 kg/m² and a thickness of subcutaneous adipose tissue in the abdomen and flanks greater than or equal to 2.5 cm were eligible. Thickness of subcutaneous

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adipose was first assessed by a manual pinch test. If thickness was greater than or equal to 2.5 cm, the assessment was repeated using standard calibrated, spring-loaded skin fold calipers, and, if also greater than or equal to 2.5 cm, confirmed using diagnostic ultrasound (M-Turbo with L-38 7- to 5-MHz linear array probe; SonoSite, Inc., Bothell, Wash.).

Exclusion criteria included coagulation disorders or use of medications/dietary supplements that limit coagulation or platelet aggregation; diabetes or cardiovascular disease; any prior aesthetic procedure, surgical scar, or laparoscopic surgery in the treatment area; skin disease, abnormalities of the skin or soft tissues of the abdominal wall, sensory loss, dysesthesia, or metal implants in the treatment area; weight-loss medication or programs; weight-reduction surgical procedures; skin or superficial tissue that did not independently lie flat when the patient was supine; current use of chronic steroid or immunosuppressive therapy; implantable electrical device; history of cancer; illicit drug use or alcohol abuse (i.e., four or more drinks per day); and problems adhering to the study schedule. Pregnant and lactating women were also excluded.

Patients agreed to not change their diet or exercise routine; participate in any weight-loss program; use any substance for promoting weight loss; or undergo any cosmetic procedure (including surgery) of the trunk, torso, or abdomen. Adherence to these guidelines was reemphasized and monitored by means of queries at each visit.

Treatment

Study participants were assigned randomly 1:1:1 to receive high-intensity focused ultrasound at total doses of 177 J/cm² (three passes at 59 J/cm²), 141 J/cm² (three passes at 47 J/cm²), or 0 J/cm² (three passes; sham group) to the treatment area defined by the investigator. This area was marked with a grid of 2.8 × 2.8-cm sites to be treated with each pass of the transducer and was limited to the anterior abdomen and flanks; investigators were advised to treat only areas accessible with the patient in the supine position. Analgesia during and after the procedure was administered entirely at the discretion of the treating investigator.

Study Endpoints

The primary efficacy endpoint was change from baseline waist circumference at 12 weeks, determined as the average of two measurements

taken at the height of the iliac crest. Waist circumference was measured with a standardized calibrated tape measure using a standardized and validated technique that considered patient positioning, posture, height, dress, and breathing.¹⁷

Secondary endpoints included change from baseline waist circumference at 4 and 8 weeks. At week 12, patients completed a patient satisfaction survey rating their perceived improvement with the flatness of their abdomen (i.e., 1, much worse; 2, worse; 3, no improvement; 4, improved; and 5, much improved), likeliness to pursue additional treatments (i.e., 1, very unlikely; 2, unlikely; 3, neutral; 4, likely; and 5, very likely), and general satisfaction with results (i.e., 1, very dissatisfied; 2, mildly dissatisfied; 3, neutral; 4, satisfied; and 5, very satisfied). Overall satisfaction was calculated as the mean of the three item scores, with a mean score greater than 3.0 defined as “satisfied.”

On the first 7 days following treatment, patients rated discomfort using a 100-mm visual analogue scale (i.e., 0 to 4, no pain; 5 to 44, mild pain; 45 to 74, moderate pain; and 75 to 100, severe pain). Concomitant medications were recorded at baseline and at each visit.

Investigators rated global aesthetic improvement at weeks 4, 8, and 12 using the Global Aesthetic Improvement Scale (i.e., 0, much worse; 1, worse; 2, no change; 3, improved; and 4, much improved). Ratings were based on review of standardized digital photographs of the anterior abdomen (straight-on view) and the right and left flanks (lateral views). Photographic technique was consistent with American Society of Plastic Surgeons standards.

Safety endpoints included adverse events, serious adverse events, and unanticipated adverse device events, which were recorded at all follow-up visits. A serious adverse event was defined as any event that was life-threatening, resulted in permanent damage or impairment of a body function or structure, or required medical or surgical intervention to avoid such outcomes. Unanticipated adverse device events were defined as any serious effect on health or safety or any life-threatening problem or death caused by or associated with the device, if not previously identified in the investigational plan, or any other unanticipated serious problem associated with the device that relates to the patient’s rights, safety, or welfare.

Blood samples for clinical chemistry were obtained before treatment; 1 hour after treatment; and at weeks 1, 4, 8, and 12. The samples were analyzed for lipid profiles; markers of inflammation, coagulation, and liver or renal function; he-

matologic assessments; and blood chemistry. Full physical examinations were performed at baseline and at week 12; the treatment area was examined at each visit.

Statistical Methods

Effectiveness and safety were assessed in the intent-to-treat population, which included all treated patients. Effectiveness was also assessed in a per-protocol population, which included only patients who did not have major protocol violations, completed treatment as planned, and did not develop any new conditions or experience exacerbations of existing conditions that might confound analysis of the primary endpoint.

Least squares mean changes from baseline waist circumference were evaluated using analysis of covariance, with treatment and study site as fixed effects and baseline waist circumference and weight change from baseline as covariates. The least squares mean (the group mean, corrected for imbalances in other variables by holding them at the mean value) was used to attempt to correct for weight change. For missing waist circumference measurements at week 12, the last nonmissing observation was carried forward.

Overall patient satisfaction was assessed using analysis of covariance. Missing values were replaced with the mean value of patients from the same treatment group with nonmissing data. Group differences in the proportion of patients reporting overall satisfaction and having investigator-rated aesthetic improvements (Global Aesthetic Improvement Scale score ≥ 3) were evaluated using the Cochran-Mantel-Haenszel test. Patient discomfort (visual analogue scale diary) and adverse events were summarized using descriptive statistics.

RESULTS

Patients and Treatment Compliance

One hundred eighty patients were randomized at nine sites between June 17, 2009, and January 6, 2010, to receive total high-intensity focused ultrasound doses of 141 J/cm² [three passes at 47 J/cm²; $n = 63$ (35.0 percent)] or 177 J/cm² [three passes at 59 J/cm²; $n = 59$ (32.8 percent)] or sham treatment [$n = 58$ (32.2 percent)]. Patients were predominantly women (85 percent) and white (87 percent), with a mean age of 42.1 years and a mean body mass index of 25.2 kg/m² (Table 1).

All 180 patients were included in the intent-to-treat and safety populations. Four patients (2.2 percent) did not complete the 12-week follow-up visit. The per-protocol population ($n = 168$) excluded 12 patients for failure to complete treatment (discomfort, $n = 6$; device malfunction, $n = 1$), exclusion criteria ($n = 3$), or the worsening of a preexisting medical condition (Graves disease, $n = 1$; irritable bowel syndrome, $n = 1$) (Fig. 1).

The mean number of 2.8 × 2.8-cm sites on the abdomen and flanks treated with each energy pass was 30.8 (sham), 35.1 (47 J/cm²), and 31.6 (59 J/cm²). The mean area treated was 241.5 cm² (range, 117.6 to 470.4 cm²) in the sham group, 275.2 cm² (range, 133.3 to 611.5 cm²) in the 47-J/cm² group, and 247.7 cm² (range, 54.9 to 533.0 cm²) in the 59-J/cm² group; mean exposure time was 41.6, 47.4, and 42.7 minutes, respectively. Body weight remained stable (mean change, ≤ 0.55 kg per group) throughout the study, suggesting good compliance with diet and exercise requirements (Table 2).

Table 1. Patient Demographic Characteristics

Characteristic	Treatment Group*			
	Sham	47 J/cm ²	59 J/cm ²	Total
No. of patients	58	59	63	180
Age (mean \pm SD), yr	41.1 \pm 10.7	42.2 \pm 10.8	42.8 \pm 11.2	42.1 \pm 10.9
Women, n (%)	47 (81.0)	52 (88.1)	54 (85.7)	153 (85.0)
Race, n (%)				
White	51 (89.9)	52 (88.1)	53 (84.1)	156 (86.7)
Nonwhite	7 (12.1)	7 (11.9)	10 (15.9)	24 (13.3)
Height (mean \pm SD), cm	167.7 \pm 9.6	166.1 \pm 9.3	165.2 \pm 8.1	166.3 \pm 9.0
Weight (mean \pm SD), kg	69.8 \pm 13.3	70.4 \pm 11.2	69.6 \pm 10.6	69.9 \pm 11.6
BMI (mean \pm SD), kg/m ²	24.6 \pm 2.6	25.4 \pm 2.6	25.4 \pm 2.7	25.2 \pm 2.6

BMI, body mass index.

*Treatment consisted of three passes at the specified energy level.

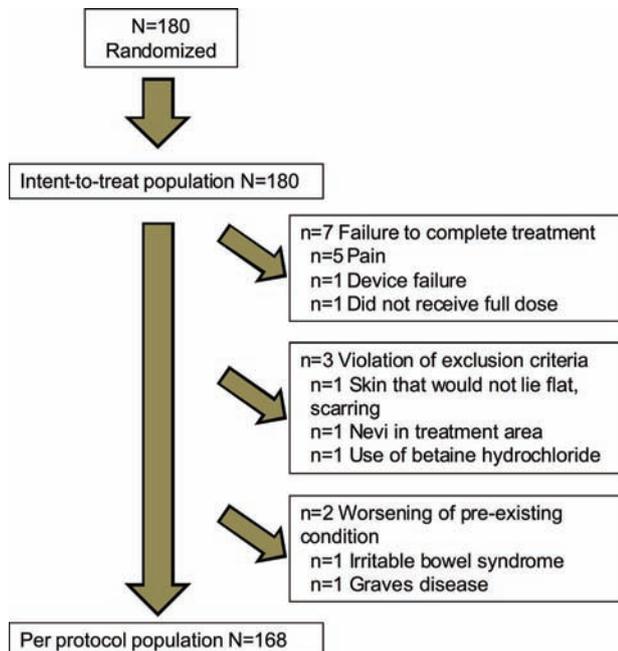


Fig. 1. Patient disposition.

Table 2. Mean Weight Change from Baseline

Treatment Group*	Week 1 (kg)	Week 4 (kg)	Week 8 (kg)	Week 12 (kg)
Sham	0.11	-0.03	0.25	0.51
47 J/cm ²	0.34	-0.07	0.08	0.55
59 J/cm ²	0.24	0.14	0.00	0.01

*Treatment consisted of three passes at the specified energy level.

Primary Effectiveness Endpoints

In the intent-to-treat population, patients treated at the energy level of 59 J/cm² (three

passes) had a statistically significantly greater least squares mean change from baseline waist circumference at 12 weeks compared with sham-treated patients (-2.44 versus -1.43 cm; *p* = 0.014) (Fig. 2). In the per-protocol population, there was a statistically significantly greater least squares mean change from baseline waist circumference at week 12 versus sham in both the 47-J/cm² (-2.10 versus -1.21 cm; *p* = 0.04) and 59-J/cm² (-2.52 versus -1.21 cm; *p* = 0.002) groups. The extent of response varied between groups (Table 3). Baseline and week-12 photographs of one patient from each active treatment group are shown in Figure 3.

Secondary Effectiveness Endpoints

In the intent-to-treat population, a significantly greater least squares mean change from baseline waist circumference was observed at 4 and 8 weeks in patients treated with 59 J/cm² compared with the sham group (Fig. 4). In the 47-J/cm² group, there was a significant difference only at week 8. In the per-protocol population, both active treatments were significantly superior to sham at 4 and 8 weeks.

At week 12, patient overall satisfaction was higher in the active treatment groups versus the sham group, but the difference was significant only in the 59-J/cm² group (Table 4). Significantly more patients receiving either active treatment versus sham rated the flatness of their stomach as “improved” or “much improved,” and no patient receiving active treatment reported a worsening. A similar proportion of patients receiving active treatment at either energy level were “likely” or

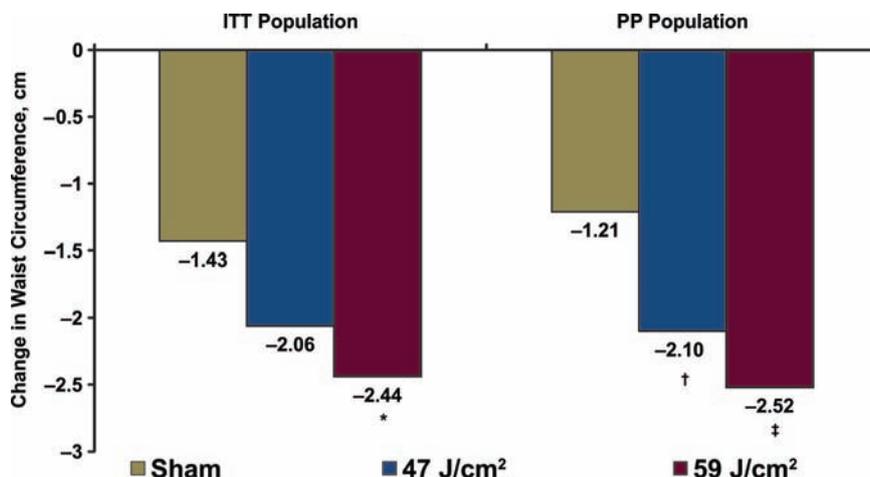


Fig. 2. Least squares mean change from baseline in waist circumference at 12 weeks (last observation carried forward) in the intent-to-treat and per-protocol populations. *ITT*, intent to treat; *PP*, per-protocol. **p* = 0.014 versus sham. †*p* = 0.035 versus sham and ‡*p* = 0.002 versus sham, both significant at the 0.05 level according to the Hochberg procedure. Treatment consisted of three passes at the specified energy level.

Table 3. Summary of Change from Baseline Waist Circumference at Week 12

	Treatment Group*		Combined Active Treatment
	47 J/cm ²	59 J/cm ²	
No. of patients	58	60	118
Response			
Any reduction in waist circumference			
No. (%)	45 (77.6)	50 (83.3)	95 (80.5)
Mean	-2.61	-3.26	-2.95
≥1-cm reduction			
No. (%)	37 (63.8)	45 (75.0)	82 (69.5)
Mean	-3.03	-3.57	-3.33
≥2-cm reduction			
No. (%)	25 (43.1)	32 (53.3)	57 (48.3)
Mean	-3.78	-4.46	-4.16
≥3-cm reduction			
No. (%)	15 (25.9)	20 (33.3)	35 (29.7)
Mean	-4.64	-5.68	-5.23

*Treatment consisted of three passes at the specified energy level.

“very likely” to pursue additional treatment if it were required (range, 51.7 to 53.4 percent). There was a nonsignificant trend for more patients with active treatment (47.5 percent) to be “satisfied” or “very satisfied” with treatment results compared with sham (36.2 percent).

The majority of patients receiving active treatment judged the results as “improved” or “much improved” at weeks 4, 8, and 12 (Global Aesthetic Improvement Scale) (Fig. 5 and Table 5). Differences between both active treatment groups and the sham group were statistically significant at all time points.

Posttreatment discomfort (assessed using a 100-mm visual analogue scale) on the day of treatment was greater with active treatment (47 J/cm², 23.5 mm; 59 J/cm², 32.5 mm) versus sham (3.0 mm). At all time points, mean scores were higher with active treatment (range across all time points and active treatments, 2.4 to 32.5 mm; no pain to mild pain) compared with sham (≤4 mm; no pain) but, by day 5, had decreased to the level of no pain (3.9 mm) in the 47-J/cm² group and almost to the level of no pain (7.4 mm) in the 59-J/cm² group (Fig. 6). Analgesic products (primarily acetaminophen, ibuprofen, and naproxen) were administered to 40 patients (22.2 percent) before, during, or after the procedure. Use was greater before (sham, 10.3 percent; 47 J/cm², 20.3 percent; 59 J/cm², 28.6 percent) versus during (sham, 5.2 percent; 47 J/cm², 13.6 percent; 59 J/cm², 20.6 percent) or after (sham, 6.9 percent; 47 J/cm², 11.9 percent; 59 J/cm², 22.2 percent) treatment.

Safety

The most common treatment-emergent adverse events were pain, bruising, and edema (Table 6). Severe procedural pain was reported in three patients (5.1 percent) in the 47-J/cm² group and in six patients (9.5 percent) in the 59-J/cm² group. All other patients reported mild or moderate pain during the procedure. No patient experienced severe postprocedural pain. All pain resolved within 7 to 10 days. Bruising and edema resolved within 12 to 14 days and 13 to 16 days, respectively, and were almost exclusively mild to moderate in intensity. The single exception was a patient in the 59-J/cm² group who experienced severe bruising.

There were no unanticipated adverse events or unanticipated adverse device events. Two serious adverse events (i.e., pneumonia and breast cancer) were reported, but neither was considered by the investigator to be related to treatment.

Clinical laboratory tests did not reveal any abnormalities with regard to lipid profiles, markers of inflammation, coagulation, liver or renal function, hematologic assessments, or blood chemistry. There were no notable findings from the physical examinations. There were no findings of skin burns, skin laxity, indurations, dimpling, or other adverse skin effects besides the expected bruising.

DISCUSSION

In this randomized, controlled, multicenter, single-blind, sham-controlled study, noninvasive ablation of subcutaneous adipose tissue using high-intensity focused ultrasound at total doses of 141 J/cm² (three passes at 47 J/cm²) and 177 J/cm² (three passes at 59 J/cm²) reduced waist circumference from baseline and improved subjective measures of aesthetic appearance compared with sham treatment and was generally well tolerated. There was only a small difference in time required to perform the treatment with 59 J/cm² (mean duration, 42.7 minutes) versus 47 J/cm² (47.4 minutes), which may have been attributable to the slightly larger (mean) treated surface area in the 47-J/cm² group.

In the intent-to-treat population, treatment with three passes at 59 J/cm² was associated with a significantly greater reduction in waist circumference from baseline versus sham beginning at week 4 and continuing through week 12 (primary endpoint). There was a nonsignificant trend toward greater reduction at week 12 in the 47-J/cm² group versus sham, with significant separation between active treatment and sham only at week 8.



Fig. 3. Patient photographs at baseline (*first and third columns*) and posttreatment week 12 (*second and fourth columns*). (*Above*) Patient from the 47-J/cm² group with change from baseline waist circumference of –2.45 cm at posttreatment week 12. (*Below*) Patient from the 59-J/cm² group with change from baseline waist circumference –2.55 cm at posttreatment week 12.

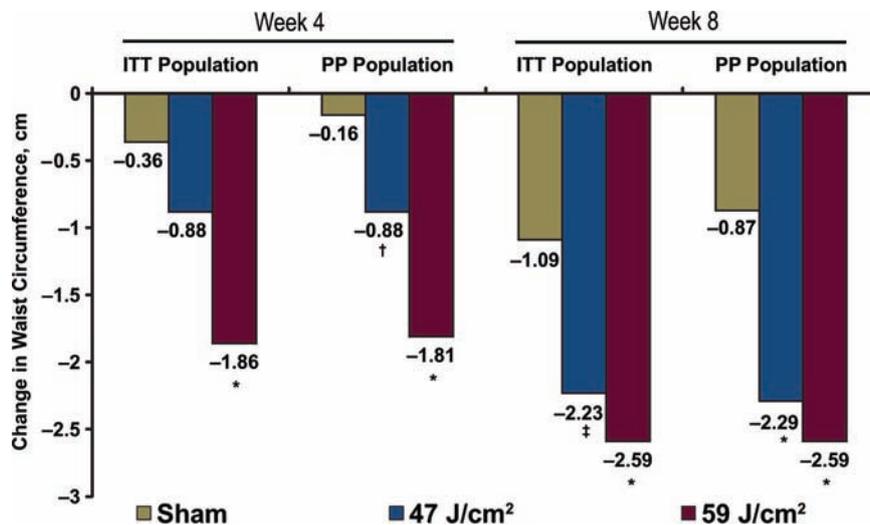


Fig. 4. Least squares mean change from baseline waist circumference at 4 and 8 weeks (last observation carried forward) in the intent-to-treat and per-protocol populations. *ITT*, intent to treat; *PP*, per protocol. **p* < 0.001 versus sham; †*p* = 0.037 versus sham; ‡*p* = 0.005 versus sham. Treatment consisted of three passes at the specified energy level.

In the per-protocol population, significantly greater reductions from baseline waist circumference were observed with either active treatment versus sham beginning at week 4. A greater than or equal to 3-cm reduction was observed in 26 percent of the 47-J/cm² group (mean, –4.64 cm) and 33 percent of the 59-J/cm² group (mean, –5.68 cm).

In the intent-to-treat population, the lack of a statistically significant treatment effect in the 47-J/cm² group versus sham at week 12 was likely because three of these patients received one or fewer of three passes (≤ 33.3 percent of total energy dose) because of discomfort or device malfunction and were included in the intent-to-treat analysis. The results for the per-protocol popula-

Table 4. Results from the Patient Satisfaction Survey at Week 12

Patient Response	Treatment Group*			
	Sham, No. (%) (n = 58)	47 J/cm ² , No. (%) (n = 58)	59 J/cm ² , No. (%) (n = 60)	Combined Active Treatment, No. (%) (n = 118)
Question 1. "Please rate how much the flatness of your abdomen improved after treatment with the LipoSonix system."				
5 (much improved)	2 (3.4)	5 (8.6)	4 (6.7)	9 (7.6)
4 (improved)	12 (20.7)	27 (46.6)	37 (61.7)	64 (54.2)
3 (no improvement)	43 (74.1)	26 (44.8)	19 (31.7)	45 (38.1)
2 (worse)	1 (1.7)	0	0	0
1 (much worse)	0	0	0	0
<i>p</i> vs. sham	—	0.004	<0.001	<0.001
Question 2. "Assume that to achieve the best effects you would need to have a repeat treatment with the LipoSonix system. Please rate how likely you would be to come back for an additional treatment."				
5 (very likely)	20 (34.5)	16 (27.6)	13 (21.7)	29 (24.6)
4 (likely)	11 (19.0)	15 (25.9)	18 (30.0)	33 (28.0)
3 (neutral)	14 (24.1)	12 (20.7)	13 (21.7)	25 (21.2)
2 (unlikely)	10 (17.2)	10 (17.2)	9 (15.0)	19 (16.1)
1 (very unlikely)	3 (5.2)	5 (8.6)	7 (11.7)	12 (10.2)
<i>p</i> vs. sham	—	0.824	0.386	0.481
Question 3. "Please rate how satisfied you are with the results of your treatment."				
5 (very satisfied)	4 (6.9)	7 (12.1)	9 (15.0)	16 (13.6)
4 (satisfied)	17 (29.3)	19 (32.8)	21 (35.0)	40 (33.9)
3 (neutral)	16 (27.6)	18 (31.0)	16 (26.7)	34 (28.8)
2 (mildly dissatisfied)	11 (19.0)	9 (15.5)	8 (13.3)	17 (14.4)
1 (very dissatisfied)	10 (17.2)	5 (8.6)	6 (10.0)	11 (9.3)
<i>p</i> vs. sham	—	0.458	0.313	0.294
Overall satisfaction, mean score >3	28 (48.3)	34 (57.6)	42 (66.7)	76 (62.3)
<i>p</i> vs. sham	—	0.323	0.028	0.070

*Treatment consisted of three passes at the specified energy level.

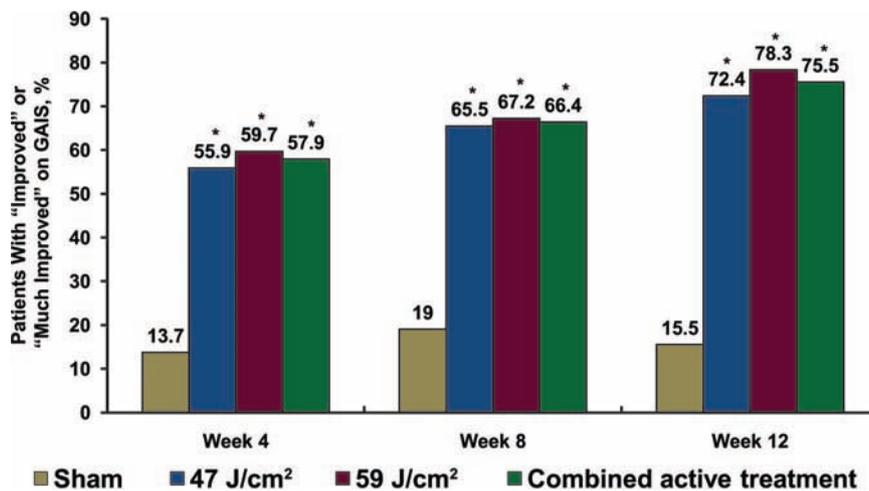


Fig. 5. Global Aesthetic Improvement Scale (GAIS) scores at weeks 4, 8, and 12. **p* < 0.001 versus sham. Treatment consisted of three passes at the specified energy level.

tion may be more clinically relevant than those for the intent-to-treat population because the per-protocol results omit outcomes for partially treated patients.

Results from this study are consistent with those of a Canadian trial in which three different energy levels (total energy doses of 141, 156, or 177 J/cm²) directed at multiple tissue depths

Table 5. Improvement in Global Aesthetic Improvement Scale Scores at Weeks 4, 8, and 12*

Treatment†	Week 4, n/N (%)	Week 8, n/N (%)	Week 12, n/N (%)
Sham	8/58 (13.7)	11/58 (19.0)	9/58 (15.5)
47 J/cm ²	33/59 (55.9)‡	38/58 (65.5)‡	42/58 (72.4)‡
59 J/cm ²	37/62 (59.7)‡	41/61 (67.2)‡	47/60 (78.3)‡
All active	70/121 (57.9)‡	79/119 (66.4)‡	89/118 (75.5)‡

*The percentage of patients rated by investigators as “much improved” or “improved.”

†Treatment consisted of three passes at the specified energy level.

‡*p* < 0.001 versus sham.

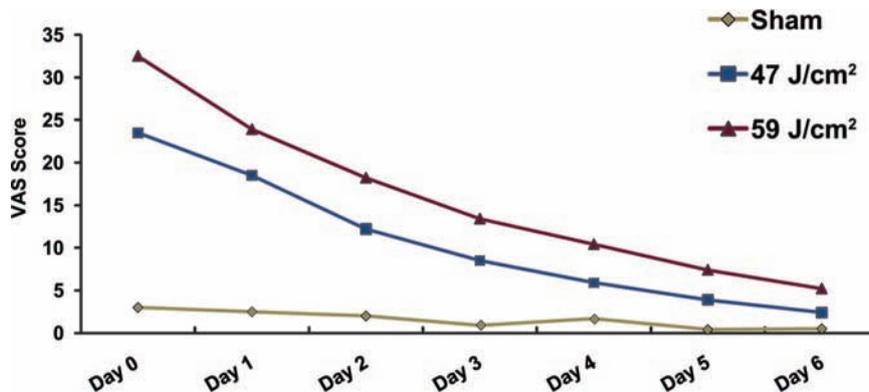


Fig. 6. Changes in visual analogue scale (VAS) score during week 1 (0 to 4, no pain; 5 to 44, mild pain; 45 to 74, moderate pain; and 75 to 100, severe pain). Treatment consisted of three passes at the specified energy level.

Table 6. Common Treatment-Emergent Adverse Events*

Adverse Events	Sham (n = 58)	47 J/cm ² (n = 59)	59 J/cm ² (n = 63)	Combined Active Treatment (n = 122)
Pain during the procedure	7	50	60	110
Postprocedure pain	8	36	33	69
Bruising/ecchymosis	0	39	42	81
Edema/swelling	0	5	6	11

*Treatment consisted of three passes at the specified energy level.

achieved similar reductions of waist circumference from baseline 12 weeks following treatment of the anterior abdomen.¹⁸ Patients in our study reported a high degree of compliance with diet and exercise restrictions (97.8 percent completed the 12-week follow-up visit). The stability of body weight suggests that the effects of high-intensity focused ultrasound are independent of changes to diet and exercise.

Nonetheless, the small changes from baseline waist circumference in the sham group suggest modest effects independent of active treatment. These effects may be an unintended consequence of patients’ attempts to comply with the requirement to make no changes to their routine. Patients may not have previously followed any routine with respect to diet or exercise, and committing consciously to one may have been beneficial in the overall analysis of data.

Aesthetic outcomes are often difficult to assess because of the subjective nature of satisfaction. Change from baseline waist circumference at week 12, assessed by trained staff using standardized and validated tools and methodology, was chosen as the primary endpoint. Subjective aesthetic assessments were consistent with the primary endpoint, with 75.5 percent of patients receiving active treatment showing improvement on the Global Aesthetic Improvement Scale and 62.3 percent of patients reporting an overall satisfaction score greater than 3. This suggests that change from baseline waist circumference is a reliable surrogate marker of aesthetic outcome for body sculpting of the abdomen and flanks.

The treatment sessions were of acceptable duration (<50 minutes to treat an average of 30 to 35 sites). Less discomfort was reported with 47 versus 59 J/cm². Most patients reported mild to

moderate discomfort (5 to 74 mm on the 100-point visual analogue scale) during treatment; however, this quickly resolved. Few patients reported severe pain during treatment, and none reported severe pain following treatment. Only 22 percent of patients across groups used analgesics. Lower discomfort levels and fewer patients reporting pain were observed with 47 versus 59 J/cm², and pain resolved more quickly in the 47-J/cm² group; this may indicate a tolerability advantage. This energy level was associated with a less than 5-minute increase in the mean procedure duration compared with 59 J/cm².

There were no treatment-related unanticipated or serious adverse events. This is consistent with expectations based on the mechanism of action of high-intensity focused ultrasound treatment, which is to facilitate localized tissue destruction at the focal point and avoid damage to the skin or surrounding tissue.^{13,19}

CONCLUSIONS

Treatment with high-intensity focused ultrasound at total doses of 141 J/cm² (three passes at 47 J/cm²) and 177 J/cm² (three passes at 59 J/cm²) was associated with average reductions in waist circumference of more than 2 cm and was given satisfactory subjective aesthetic assessments by patients and investigators, indicating that this is an effective noninvasive technique for body sculpting. Less patient discomfort was reported with 47 J/cm² versus 59 J/cm².

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