ORIGINAL ARTICLE

A Randomized, Single-Blind, Postmarketing Study of Multiple Energy Levels of High-Intensity Focused Ultrasound for Noninvasive Body Sculpting

Nowell Solish, MD, FRCP (C),[*] Xiaoming Lin, MS, RN,[†] Robert A. Axford-Gatley, MSc, MThS, MD,[‡] Nicole M. Strangman, PhD,[‡] and Michael Kane, MD, FACS[§]

BACKGROUND High-intensity focused ultrasound (HIFU) is a nonsurgical, noninvasive body sculpting method.

OBJECTIVE To investigate preferences for treatment settings using a HIFU device.

MATERIALS AND METHODS HIFU was applied to the anterior abdomen in three passes of decreasing depth (1.6, 1.3, and 1.1 cm) in patients randomized to HIFU energy levels (each of 3 passes [total]) of 47 (141), 52 (156), or 59 (177) J/cm^2. The primary assessment was week 12 post-treatment change from baseline waist circumference at the level of the iliac crest for all treatment groups combined.

RESULTS The primary assessment achieved statistical significance (least squares mean 2.51 cm, 95% confidence interval [CI] = −3.14 to −1.88; $p < .001$), with no significant differences between groups. At week 12, 69% to 86% of patients and 73% to 79% of investigators rated appearance as improved or much improved. The average worst pain (100-mm visual analog scale) experienced during treatment was mild (47 J/cm^2: 17.1 mm, 95% CI = 4.33–29.81 mm; 52 J/cm^2: 24.6 mm, 95% CI = 12.24–36.95 mm; 59 J/cm^2: 30.9 mm, 95% CI = 18.71–43.17 mm). There were no serious adverse events.

CONCLUSION HIFU treatment at different energy levels and multiple tissue depths was well tolerated and effective in reducing waist circumference.

Drs. Solish and Kane received compensation from Medicis (Scottsdale, AZ) for conducting this study. Robert Axford-Gatley and Nicole M. Strangman are employees of Complete Healthcare Communications, Inc. (Chadds Ford, PA), which received compensation from Medicis for editorial assistance.

Noninvasive body sculpting using high-intensity focused ultrasound (HIFU) is achieved using thermomechanical ablation of subcutaneous adipose tissue (SAT).[1,2] Molecular vibrations and shear forces generated using HIFU raise local tissue temperature and produce rapid focal cell death by coagulative necrosis.[3–5] With HIFU, heat intensity and depth of penetration are precisely controlled by adjusting wavelength and energy level. HIFU is able to penetrate skin and superficial tissue to reach precise levels within deeper SAT without damaging the dermis or other collateral tissues.[3,6] The high-intensity energy is focused in a small area, enabling controlled application.[3]

A HIFU device with user-adjustable focal depth (*LipoSonix* system, Medicis Technologies Corp., Scottsdale, AZ) is approved and marketed in Canada and the European Union for the treatment of anterior abdominal SAT. The primary objective of this study was to investigate preferences for treatment settings with HIFU. The primary assessment

[*]*Director of Dermatologic Surgery, University of Toronto, Toronto, Ontario, Canada;* [†]*Clinical Research and Development, Medicis Aesthetics Inc., Scottsdale, Arizona;* [‡]*Complete Healthcare Communications, Inc., Chadds Ford, Pennsylvania;* [§]*Kane Plastic Surgery, New York, New York*

ISSN: 1076-0512 • Dermatol Surg 2011;1–10 • DOI: 10.1111/j.1524-4725.2011.02148.x

was change from baseline waist circumference (CBWC) at the level of the iliac crest at 12 weeks. Secondary assessments included assessment of waist circumference 4 and 8 weeks after treatment, overall patient experience, and patient and investigator ratings of aesthetic improvement. Safety was assessed using a visual analog scale (VAS) to assess pain and monitoring of adverse events (AEs).

Methods

Study Design

This randomized, single-blind postmarketing surveillance study was conducted at one clinical site in Canada between November 2009 and May 2010. Patients underwent HIFU treatment at baseline (day 0) and returned for follow-up visits at weeks 4, 8, and 12. The study was performed in compliance with Good Clinical Practice guidelines of the International Conference on Harmonisation and the Declaration of Helsinki, and the Quorum Institutional Review Board reviewed and approved the protocol. All patients provided written informed consent.

Patients

Men and women aged 18 to 65 were required to be in good overall health and candidates for treatment of localized abdominal fatty deposits with aesthetic body sculpting as judged by the physician. Additional inclusion criteria were body mass index of 30.0 kg/m^2 or less, adipose tissue thickness of 2.6 cm or more ($\geq$1 cm beyond the selected focal depth) in the treatment region, and adequate skin elasticity and tone. Patients had to agree not to change their diet or exercise routines during the study. Exclusion criteria were pregnancy or breast feeding; history of liposuction, injection lipolysis therapy, abdominoplasty, or surgery in the treatment region; weight reduction medication, surgery, or program; implantable electrical device; neurosurgical cerebrospinal shunt, hernia, or sensory loss or dysesthesia in the treatment region; cancer; coagulation disorder or anticoagulant therapy; and medical care for systemic or chronic disease.

Treatments

Patients were randomized into the study in a single-blind fashion to receive three passes of HIFU at energy levels of 47 J/cm^2 (total energy = 141 J/cm^2), 52 J/cm^2 (156 J/cm^2), or 59 J/cm^2 (177 J/cm^2) applied to the anterior abdomen. The flanks (sides of the abdomen) were not treated. Each pass was delivered at a different depth below the skin: pass 1 at 1.6 cm, pass 2 at 1.3 cm, and pass 3 at 1.1 cm. In preparation, an outline of the treatment region and a grid marking individual 2.8-cm^2 sites to be treated with each pass were drawn on the abdomen. The need for pain medication was discussed with patients before, during, and after treatment and was provided at the investigator's discretion.

Effectiveness Assessments

Waist circumference was measured at baseline, after treatment on day 0, and at follow-up visits in three zones: the level of the iliac crest, 2 cm above the umbilicus, and 2 cm below the umbilicus. The same individual took each patient's measurements in duplicate at the same time of day using a validated method (height of iliac crest [HIC]).

Before each measurement, patients were required to fast for 4 hours or longer and void their bowels and bladder. Wearing only the modesty garments provided, patients stood facing forward with arms crossed and hands in the axillary folds, thumbs pointing up, and feet 8 inches apart. They were instructed to relax the abdominal muscles, exhale, and hold their breath throughout each measurement. The investigator palpated to find the most superior point of the iliac crest and marked it at the midaxillary line on the patient's right side. This marking was aligned with the plate of a wall-mounted measuring stick, and the distance from the floor to the iliac crest starting in line with the lateral malleolus was recorded in centimeters to

the nearest millimeter. Moving around the body, three other points were marked. Waist circumference was measured by aligning a calibrated, spring-loaded tape measure provided by the sponsor around the patient just beneath the markings. An analogous procedure was followed for measurements above and below the umbilicus.

Each patient and investigator rated improvement relative to baseline appearance using a 5-point Global Aesthetic Improvement Scale (GAIS; 0 = much worse, 1 = worse, 2 = no change, 3 = improved, 4 = much improved) at follow-up visits. At each visit, patients also completed a three-item patient experience questionnaire, and weight was measured to assess compliance.

Safety Assessments

Abdominal examination was performed at each visit. Patients completed a validated VAS pain assessment (0 mm = no pain; 100 mm = worst possible pain) at baseline, rating discomfort before treatment and, immediately after treatment (day 0), rating the worst pain experienced during treatment. The investigator assessed AEs at each visit. Serious AEs were defined as those that are life threatening, result in permanent impairment of a body function or permanent damage to a body structure, or necessitate intervention to prevent such outcomes. Unanticipated adverse device effects were defined as any serious effect on health or safety, a life-threatening problem, or a death associated with the device that was not identified in the investigational plan or labeling information.

Statistical Analysis

All analyses were performed using the intent-to-treat population, comprising all patients who received HIFU treatment, with SAS version 9.2 (SAS Institute Inc., Cary, NC).

Primary Assessment The primary assessment was CBWC at week 12 measured at the HIC for all treatment groups combined. Significance was determined using analysis of covariance (ANCOVA) of the least squares (LS) mean with baseline circumference and weight change from baseline as covariates; LS mean was chosen to account for additional factors in the model (e.g., weight change).

Secondary Assessments CBWC at follow-up visits obtained at each zone and differences between treatment groups were analyzed as for the primary assessment. GAIS scores and patient satisfaction were analyzed descriptively (n [%]). VAS scores were categorized as no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm)[7] and analyzed using an ANCOVA model with treatment as a fixed effect and baseline VAS score as a covariate. As a post hoc analysis, agreement between CBWC at the HIC and GAIS scores (patient and physician ratings) was assessed using kappa statistics as well as the exact agreement. AEs were analyzed descriptively (n [%]).

A sample size of 45 patients was planned to achieve 90% power to detect a 1cm or more CBWC ($p < .05$) for all treatment groups combined and 80% power to detect a CBWC of 2 cm or more within each treatment group.

Results

Patient Disposition and Characteristics

Forty-five patients were randomized to three passes of 47 J/cm^2 (total energy dose of 141J/cm^2, $n = 14$), 52 J/cm^2 (156 J/cm^2, $n = 16$), or 59 J/cm^2 (177 J/cm^2, $n = 15$). All completed the study and were included in the intent-to-treat population. Demographic and clinical characteristics were comparable across treatment groups (Table 1). Mean age was 42 to 44 years for each group, and the majority of patients were female (86–94%) and white (79–93%); mean body mass index was 25.0 to 27.0 kg/m^2 for each group.

TABLE 1. Patient Demographic and Clinical Characteristics

Characteristic	Energy Level		
	47 J/cm² n = 14	*52 J/cm²* n = 16	*59 J/cm²* n = 15
Age, y, mean ± SD	42 ± 7	43 ± 11	44 ± 11
Female, n (%)	12 (86)	15 (94)	13 (87)
Race, n (%)			
White	11 (79)	14 (88)	14 (93)
Black	1 (7)	0	1 (7)
Asian	1 (7)	1 (6)	0
Other	1 (7)	1 (6)	0
Height, cm, mean ± SD	165 ± 10	164 ± 6	168 ± 9
Body mass index, kg/m², mean ± SD	27 ± 3	25 ± 2	25 ± 3

SD = standard deviation.

Treatment Characteristics and Protocol Compliance

The mean number of 2.8 × 2.8-cm abdominal sites treated with each pass was similar (33–34) across the three passes and treatment groups. Treatment time was shorter with 52 J/cm² (20 s/pass per site) than with 47 and 59 J/cm² (both 27 s/pass per site). Mean weight fluctuated by 0.5 kg or less versus baseline (Table 2).

Effectiveness

Waist Circumference Statistical significance was achieved for the primary assessment; LS mean CBWC at post-treatment week 12, measured at the HIC with all treatment groups combined, was 2.51 cm (95% confidence interval [CI] = −3.14 to −1.88; $p < .001$). Comparison between groups revealed a similar CBWC at each time point, with no statistically significant difference between the three treatment groups at any time point. However, comparison within groups revealed that a statistically significant CBWC at the HIC was achieved only with 59 J/cm² at week 4 (LS mean −1.28 cm, 95% CI = −2.38 to −0.18; $p = .02$) and with all groups at week 8 (LS mean −1.37 to −1.87 cm; $p < .05$) and week 12 (LS mean −2.30 to −2.70 cm; $p < .001$; Table 3). There appeared to be continual improvement over the three follow-up visits, with optimal results at week 12, but this was not statistically analyzed (Table 3). Figure 1 shows photographs at baseline and week 12 for three patients (1 each group) with CBWC similar to their group mean.

Statistically significant CBWC at week 12 was also observed in all treatment groups when using the umbilicus as a marker (Table 4). At week 4, there was no statistically significant CBWC using these measurements, and at week 8 there was a statistically significant CBWC with 59 J/cm² when measuring above the umbilicus (LS mean −2.42 cm, 95% CI = −3.70 to −1.15; $p < .001$; Table 4).

GAIS Ratings Scores for the GAIS improved during the study, with a trend toward best results at week 12, as with CBWC, although change in scores over time was not statistically analyzed (Figure 2). Patient self-rated GAIS scores were improved or much improved for 54% to 60% of patients in each treatment group at week 4, 44% to 86% at week 8, and 69% to 86% at week 12 (Figure 2A). Investigator-rated GAIS scores were improved or much improved for 14% to 47% of patients at week 4, 46% to 71% at week 8, and 73% to 79% at week 12 (Figure 2B). At week 12, investigator and patient GAIS ratings were similar across the treatment groups.

Of those patients who had a 1 cm or greater CBWC, using the GAIS, the investigator rated 97% as improved or much improved, and 93%

TABLE 2. Summary of Change in Weight (kg) from Baseline According to Visit

Statistic	*47 J/cm²*	*52 J/cm²*	*59 J/cm²*
Baseline			
n	14	16	15
Mean ± SD	73.1 ± 12.2	66.1 ± 8.1	69.1 ± 11.7
Median	72.5	66.0	67.5
Minimum	58	53	53.5
Maximum	91	85	90
Change from Baseline to Week 4			
n	14	16	15
Mean ± SD	−0.14 ± 2.27	0.50 ± 0.86	0.27 ± 1.75
Median	0	0.5	1
Minimum	−6.5	−1	−3
Maximum	3	2.5	3
Change from Baseline to Week 8			
n	13	16	14
Mean ± SD	−0.35 ± 2.86	0.19 ± 1.46	0.25 ± 1.61
Median	0	0.5	0.25
Minimum	−9	−3	−2.5
Maximum	2	2	3.5
Change from Baseline to Week 12			
n	14	16	15
Mean ± SD	−0.36 ± 2.71	0.41 ± 2.15	0.00 ± 2.08
Median	0.25	0.75	−0.5
Minimum	−8.5	−5	−3
Maximum	2	3.5	4.5

SD = standard deviation.

TABLE 3. Change from Baseline Waist Circumference (cm) Measured at the Level of the Iliac Crest

	47 J/cm²	*52 J/cm²*	*59 J/cm²*
Week 4			
LS mean	−0.60*	−0.89*	−1.28†
95% CI	−1.75 to 0.56	−1.97 to 0.20	−2.38 to −0.18
Week 8			
LS mean	−1.63†	−1.37†	−1.87†
95% CI	−3.01 to −0.25	−2.62 to −0.12	−3.18 to −0.55
Week 12			
LS mean	−2.30‡	−2.70‡	−2.50‡
95% CI	−3.46 to −1.13	−3.80 to −1.60	−3.61 to −1.39

*Not significant.
†$p < .05$.
‡$p < .001$.
LS = least squares; CI = confidence interval.

reported themselves as improved or much improved. Agreement between a 1-cm or greater CBWC and GAIS improvement was 91% ($\kappa = 0.77$) for the investigator assessment and 78% ($\kappa = 0.43$) for the patient assessment.

Patient Experience Questionnaire Dramatic improvements in satisfaction with the flatness of the abdomen were evident between day 0 post-treatment and week 12. At week 12, the majority of patients in each group indicated that they were

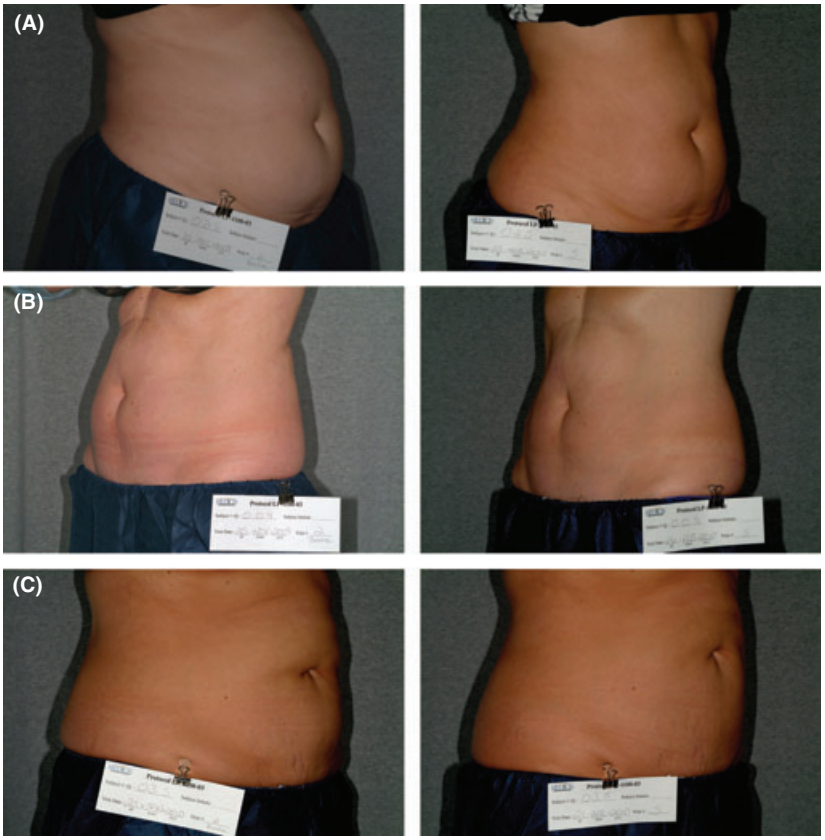

Figure 1. Patient photographs at baseline (left) and post-treatment week 12 (right). (A) Patient treated with 47 J/cm^2 with change from baseline waist circumference of −3.1 cm at post-treatment week 12. (B) Patient treated with 52 J/cm^2 with change from baseline waist circumference −3.4 cm at post-treatment week 12. (C) Patient treated with 59 J/cm^2 with change from baseline waist circumference −4.2 cm at post-treatment week 12.

TABLE 4. Change from Baseline Waist Circumference (cm) Measured Relative to the Umbilicus

	Above Umbilicus			*Below Umbilicus*		
	47 J/cm^2	*52 J/cm^2*	*59 J/cm^2*	*47 J/cm^2*	*52 J/cm^2*	*59 J/cm^2*
Week 4						
LS mean	−0.13*	−0.16*	−1.07*	−0.31*	−0.10*	−0.24*
95% CI	−1.57 to 1.32	−1.52 to 1.19	−2.46 to 0.32	−1.23 to 0.61	−0.96 to 0.77	−0.64 to 1.12
Week 8						
LS mean	−0.43*	−1.14*	−2.42§	−0.55*	−0.37*	−0.4*
95% CI	−1.76 to 0.89	−2.34 to 0.06	−3.70 to −1.15	−1.67 to 0.57	−1.37 to 0.63	−1.47 to 0.66
Week 12						
LS mean	−1.74†	−2.38§	−2.96§	−1.66‡	−1.33†	−1.38†
95% CI	−3.07 to −0.41	−3.63 to −1.13	−4.24 to −1.67	−2.64 to −0.68	−2.25 to −0.41	−2.32 to −0.45

*Not significant.
†$p < .05$.
‡$p < .01$.
§$p < .001$.
LS = least squares; CI = confidence interval.

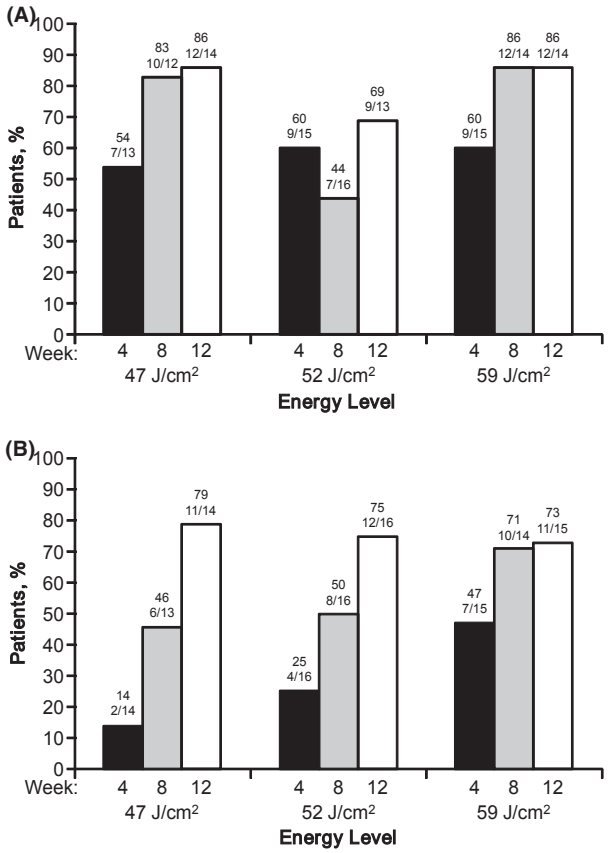

Figure 2. Global Aesthetic Improvement Scale ratings through week 12: percentage of patients rated improved or much improved according to self-report (A) and investigator rating (B).

satisfied with the flatness of the abdomen (69–85%), were likely to return for additional treatment if necessary to achieve the best effects (69–92%), and felt that the results met most or all expectations or exceeded expectations (60–77%).

Safety

In all three treatment groups, the mean rating of worst pain experienced during treatment was mild (5–44 mm) (47 J/cm^2: LS mean 17.1 mm, 95% CI = 4.33–29.81 mm; 52 J/cm^2: 24.6 mm, 95% CI = 12.24–36.95 mm; 59 J/cm^2: 30.9 mm, 95% CI = 18.71–43.17 mm). The worst pain reported was none (0–4 mm) or mild (5–44 mm) in the majority of patients in the 47-J/cm^2 (n = 12/14; 85.7%), 52-J/cm^2 (n = 13/16; 81.3%), and 59-J/cm^2 (n = 10/15; 66.7%) groups. Only two patients (1 premedicated, 1 unmedicated) reported severe pain (75–100 mm): one in each of the 52- and 59-J/cm^2 treatment group. Moderate pain was reported by 27% of patients with 59 J/cm^2, versus 13% to 14% of patients receiving 47 or 52 J/cm^2. Data suggested an increase in discomfort with increasing energy level, but this was not statistically analyzed.

Preprocedure analgesia with one to two tablets of 5 mg oxycodone per 325 mg acetaminophen was administered to all but four patients, of whom two were given two tablets of 30 mg codeine/30 mg caffeine/325 mg acetaminophen and two received no opioid premedication. Only two patients received pain medication during treatment: one patient treated with 52 J/cm^2 HIFU received 30 mg codeine/30 mg caffeine/325 mg acetaminophen, and one patient treated with 59 J/cm^2 HIFU received 5 mg oxycodone/325 mg acetaminophen. The quantity of analgesia administered to all patients was not considered likely to cause any postprocedure impairment.

Analgesic use was similar across groups, with most patients using an analgesic (5 mg oxycodone/325 mg acetaminophen × 2 or 300 mg acetaminophen/30 mg codeine) before treatment (47 J/cm^2, 86%, n = 12/14; 52 J/cm^2, 88%, n = 14/16; 59 J/cm^2, 93%, n = 14/15) and only two patients (1 each 52 and 59 J/cm^2) receiving pain medication during treatment. A few patients also received lorazepam as a premedication to reduce anxiety (47 J/cm^2, 14%, n = 2/14; 52 J/cm^2, 6%, n = 1/15; 59 J/cm^2, 13%, n = 2/15) or dimenhydrinate to counteract nausea from oxycodone-acetaminophen or codeine-acetaminophen (47 J/cm^2, 14%, n = 2/14; 52 J/cm^2, 6%, n = 1/15; 59 J/cm^2, 13%, n = 2/15).

A majority of patients reported mild or transient abdominal bruising or redness. There were no serious AEs or unanticipated adverse device effects.

Physical examinations produced no remarkable findings.

Discussion

Noninvasive ablation of abdominal SAT with HIFU at different energy levels and multiple tissue depths significantly reduced waist circumference as assessed using objective and subjective measures and was generally well tolerated. Statistical significance was achieved on the primary assessment—CBWC at week 12 measured at the HIC with all treatment groups combined—as well as within each treatment group. Discomfort was mild overall, and the most common AEs were mild, transient abdominal bruising and redness.

When combining the treatment groups, we observed a mean CBWC at the HIC of 2.51 cm at 12 weeks. This is meaningful given that treatment was applied to the abdomen only and did not include the flanks, as in previous studies.[2,8] There may have been an advantage to multiple passes at three different depths, whereas in previous studies each pass was done at one depth.

Statistically significant CBWC was observed at week 4 in the 59-J/cm^2 group, but reductions were statistically significant in all groups starting at week 8 and appeared to increase somewhat further at week 12. The patient experience questionnaire and GAIS ratings were consistent with CBWC and all trended toward greatest improvement at week 12. Although mean CBWC with each energy level was less than 3 cm, reductions of 1 cm or more were correlated with patient and physician ratings of improved or very much improved. The observed similarity between the objective measure (CBWC) and subjective measure (GAIS) suggests both that CBWC is a reliable surrogate marker of aesthetic outcome, and that even small reductions in CBWC with a single treatment are associated with patient and physician satisfaction. It is important to note that body weight did not fluctuate substantially ($\leq$0.5 kg) during the study, which suggests that the CBWC observed was a product of treatment rather than diet.

The 47-J/cm^2 energy level produced the least discomfort, the 52-J/cm^2 treatment had the shortest treatment time, and the 59-J/cm^2 treatment appeared to have the quickest onset. There was a slight trend for greater CBWC (week 12) measured at the HIC with 52 J/cm^2. However, no statistically significant group differences in CBWC were observed at any time point. Thus, a high energy level may not be warranted to achieve better results. We believe the lack of improved effectiveness with increased energy suggests that all of the treatable tissue within the focused treatment area was ablated at the lower energy levels. This interpretation of the results would suggest that the focus of the device effectively limits the boundaries of the applied energy such that application of excessive energy (i.e., more than is necessary to ablate the focused area) does not overcome the focus parameters or permit extension of tissue destruction into surrounding areas.

Measurements obtained 2 cm above and below the umbilicus further confirmed the effectiveness of all three energy levels, although differences were generally smaller and emerged later than when using the iliac crest as the marker. The reason is unclear, but may be a consequence of individual variability in the location of the umbilicus relative to the iliac crest and in the distribution of abdominal fat. Generally most abdominal fat hangs below the umbilicus.

Change from baseline waist circumference assessed using the validated HIC method was selected as a quantitative and objective surrogate for aesthetic improvement. In most cases, subjective assessments were consistent with CBWC. Patients treated with 52 J/cm^2 had the lowest patient-reported GAIS score despite a trend toward the greatest CBWC at the iliac crest at 12 weeks, but this discrepancy was slight. The post hoc analysis demonstrated high agreement between waist circumference and

investigator and patient GAIS assessments, suggesting that CBWC is a clinically meaningful surrogate of aesthetic outcome.

Most patients (90%) received analgesic premedication and experienced minimal to mild discomfort during the study. Patients treated at 59 J/cm^2 experienced the greatest discomfort, although mean "worst pain" was still in the mild range. This group also had the smallest percentage of patients reporting that treatment met or exceeded expectations, suggesting that pain may have influenced certain subjective measures.

At 2 MHz, HIFU precisely ablates SAT, producing oblong lesions approximately 1 mm wide and 10 mm long.[4] At frequencies of 1 to 10 MHz, HIFU is also reported to elicit collagen contraction.[4] During the subsequent wound healing response, macrophages engulf cellular debris and free lipids and transport them from the treatment area, and the destroyed adipocytes are resorbed.[2] Safety data are consistent with this mechanism of action. There were no unanticipated AEs reported in the current study. In retrospective chart reviews of patients who received one HIFU treatment (total energy: 135–137 J/cm^2) with this device to the abdomen and flanks,[2,8] 12% to 14% of patients reported one or more AEs, including prolonged tenderness, pain during treatment, ecchymosis, hard lumps, and edema. Use of analgesia was not reported. No changes in plasma lipids have been observed following HIFU treatment.[5] Skin laxity was not observed or reported as an AE in the current study.

A limitation of this study is its short duration. Given limited follow-up, it was not possible to determine whether reductions in waist circumference were diminished, increased, or were maintained after 12 weeks. Furthermore, it is unclear whether repeated treatments might provide greater benefits. The absence of a control group is a second limitation of the study. Addition of a sham control would aid interpretation of subjective measures, whereas the primary assessment is an objective measure and is unlikely to be influenced by a placebo effect. Although the study was small, it was adequately powered. The observed CBWC is unlikely to reflect changes in diet and exercise because patients were required to refrain from such changes during the study, and mean weight fluctuated by 0.5 kg or less.

Conclusions

This HIFU device was effective and generally well tolerated for body sculpting by noninvasive ablation of abdominal SAT at each of three energy levels applied sequentially at three specified depths. HIFU administered at lower energy levels provided equal results with less discomfort compared with higher energy levels. An energy level of 59 J/cm^2, administered in three passes for a total energy dose of 177 J/cm^2, provided the most rapid results (significant CBWC at 4 weeks), but an energy level of 47 J/cm^2 (total dose: 141 J/cm^2) provided effectiveness equal to 52 J/cm^2 (total dose: 156 J/cm^2) and 59 J/cm^2 with the least degree of discomfort. Results, and trends toward greatest effectiveness at week 12, were similar across the objective and subjective efficacy assessments, and a post hoc analysis demonstrated a high level of agreement between CBWC and GAIS ratings. Further study will determine whether repeated treatments improve results.

References

1. Moreno-Moraga J, Valero-Altes T, Riquelme AM, Isarria-Marcosy MI, et al. Body contouring by non-invasive transdermal focused ultrasound. Lasers Surg Med 2007;39: 315–23.

2. Fatemi A. High-intensity focused ultrasound effectively reduces adipose tissue. Semin Cutan Med Surg 2009;28:257–62.

3. Haar GT, Coussios C. High intensity focused ultrasound: physical principles and devices. Int J Hyperthermia 2007;23:89–104.

4. Quistgaard JU, Desilets C, Martin P. High intensity focused ultrasound. The European Aesthetic Guide, Medical Insight, Inc.

Available from: http://digital.miinews.com/publication/?i=34631&page=1 Accessed July 12, 2010.

5. Fodor PB, Smoller BR, Stecco KA, Desilets CS. A noninvasive method for body sculpting: the use of high-intensity focused ultrasound. Presented at American Society for Aesthetic Plastic Surgery Annual Meeting 2006, April 21–25; Orlando, FL.
6. Garcia-Murray E, Adan Rivas O, Stecco K, Desilets C, et al. The use and mechanism of action of high intensity focused ultrasound for adipose tissue removal and noninvasive body sculpting. Presented at American Society of Plastic Surgeons Annual Meeting, E-Poster Session; 2005, September 23–27; Denver, CO.
7. Jensen MP, Chen C, Brugger AM. Interpretation of visual analog scale ratings and change scores: a reanalysis of two clinical trials of postoperative pain. J Pain 2003;4:407–14.
8. Fatemi A, Kane MA. High-intensity focused ultrasound effectively reduces waist circumference by ablating adipose tissue from the abdomen and flanks: a retrospective case series. Aesthetic Plast Surg 2010;34:577–82.

Address correspondence and reprint requests to: Nowell Solish, MD, FRCP (C), 66 Avenue Road, Suite 1, Toronto, ON M5R 3N8, Canada, or e-mail: n.solish@utoronto.ca