

A Multicenter, Randomized, Controlled Study to Evaluate the Contour I V3.1 System for Non-Invasive Reduction in Abdominal Circumference

W. Coleman, R. Weiss, J. Kenkel, D. Ad-El | FDA Study, 2013

METHODS

- The 22-week long study consisted of a device phase and a follow-up phase, in which 32 patients received a total of 3 treatments on the abdominal region that were performed at baseline and at week 2 and week 4 of the study, and were followed up at 6, 8, 10, 14, 18 and 22 weeks post-procedure.
- Patient weight, and abdominal circumferences recorded at the midline, 2 cm above the midline and 2 cm below the midline were measured at enrollment, baseline and at each following visit, and changes in circumferential reduction as well as safety and tolerability of treatment were assessed at the end of the clinical trial.
- Study participants also completed a questionnaire to help elucidate satisfaction of outcomes and as well as tolerability of treatment.

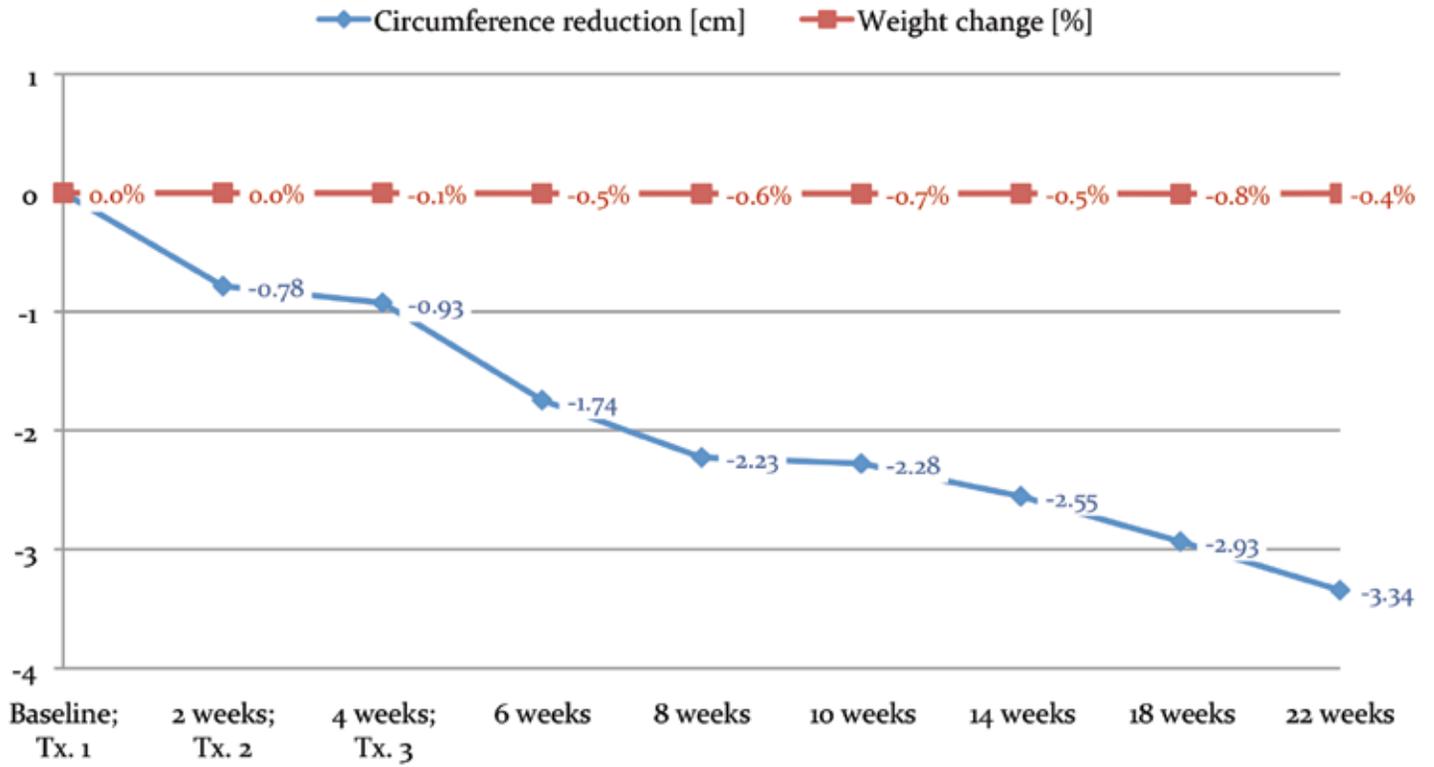
RESULTS

- Significant reductions in abdominal circumference could be achieved in all study participants, with results throughout the clinical trial showing a steady decrease in abdominal circumferences recorded at the midline, 2 cm above midline and 2 cm below midline.
- At the final follow-up assessment, data showed that from baseline, the average reductions in abdominal circumference at the midline, 2 cm above the midline and 2 cm below the midline were -3.5 cm, -3.7 cm and -3.0 cm, respectively.
- Adverse events recorded throughout the study period were mild and transient in nature, supporting a favorable safety profile for the UltraShape device. Study participants generally tolerated the treatments well, and patient satisfaction questionnaires revealed an overall satisfaction with device treatment during follow-up.

CONCLUSIONS

The clinical data presented here robustly support both the efficacy and safety of the UltraShape system used for the non-invasive reduction in abdominal circumference.

Circumference significantly reduced, while subjects' weight remained stable along the study course.



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

Teitelbaum et al. | *Plastic and Reconstructive Surgery*, 2007

OBJECTIVE

The authors describe a controlled, multicenter, clinical trial assessing the safety and efficacy of a focused therapeutic ultrasound device for non-invasive body contouring.

METHODS

One hundred sixty-four eligible healthy adult subjects participated in the study (137 subjects in the experimental group and 27 in the control, untreated group) at five sites. The experimental group received one treatment with the Contour I device 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

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.

CONCLUSIONS

The Contour I device provides a safe and effective non-invasive technology for body contouring.



SINGLE TREATMENT RESULTS

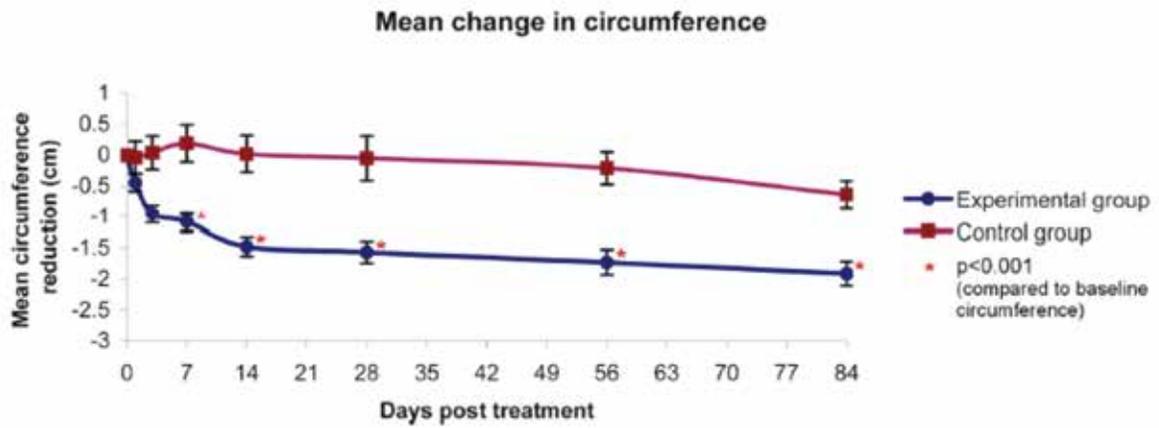


Figure 2. Mean circumference change from baseline in the experimental and control groups

Body Contouring by Non-Invasive Transdermal Focused Ultrasound

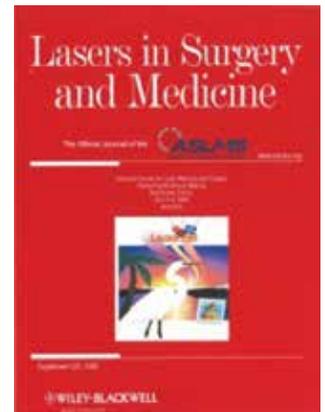
J. Moreno Moraga, M.D. | *Lasers in Surgery and Medicine*, 2007

OBJECTIVES

The aim of this study was to assess the efficacy and safety of a novel non-invasive focused ultrasound system (UltraShape Ltd., Tel Aviv, Israel) in reducing localized fat deposits to improve body contours.

METHODS

A prospective study was conducted on 30 (22 female, 8 male) healthy patients. All patients underwent three treatments, at 1-month intervals, and were followed for 1 month after the last treatment. Areas treated were the abdomen, inner and outer thighs, flanks, inner knees and breasts (males only). No other body contouring procedure was used during the study. Efficacy was determined by change in fat thickness, assessed by ultrasound measurements and by circumference measurements. Weight change was monitored to assess whether reduction in fat thickness or circumference was dependent on or independent of weight loss. Safety was determined by clinical findings, assays of serum triglycerides, and liver ultrasound evaluation for the presence of steatosis.



RESULTS

All patients showed significant reduction in subcutaneous fat thickness within the treated area. The mean reduction in fat thickness after three treatments was 2.28 ± 0.80 cm. Circumference was reduced by a mean of 3.95 ± 1.99 cm. Weight was unchanged during the treatment and follow-up period. No adverse effects were observed.

CONCLUSIONS

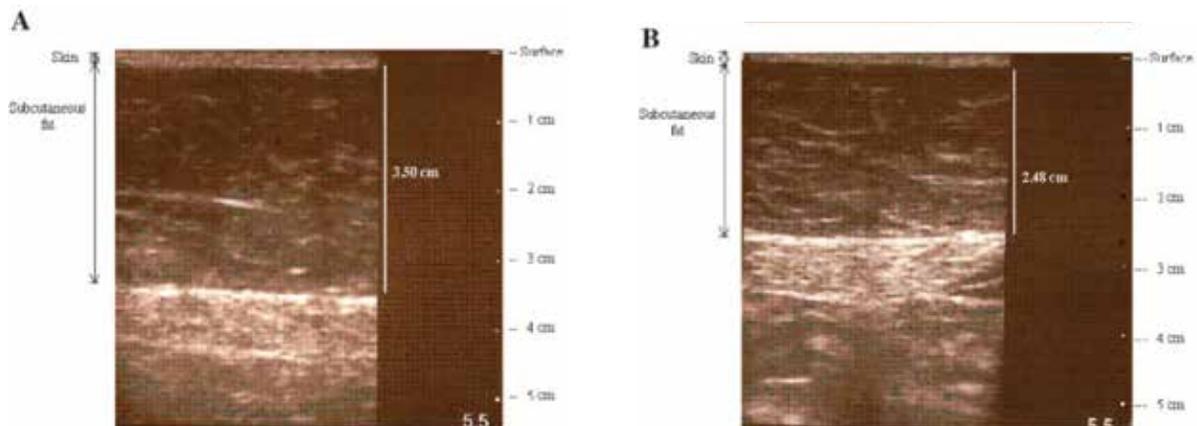
This study shows the efficacy and safety of focused ultrasound, using the UltraShape Contour I, as a non-invasive transdermal method for reducing unwanted fat deposits in the body. Multiple treatments combined with appropriate patient and treatment area selection can produce dramatic improvements in body contour.

TABLE 2. Fat Thickness Reduction by Treatment Area, After Three Sessions

Treatment area (n)	Final reduction (cm)	
	M ± SD	Range
Abdomen (10)	2.16 ± 0.63	1.02–3.36
Outer thighs (10)	3.02 ± 0.58	2.14–3.94
Flanks (3)	1.63 ± 0.15	1.46–1.73
Pseudo-gynecomastia (3)	1.88 ± 0.44	1.50–2.37
Inner knees (2)	2.06 ± 0.70	1.56–2.56
Inner thighs (2)	0.96 ± 0.40	0.68–1.24

TABLE 5. Baseline and Final Treatment Data for Fat Thickness, Weight, and Lipids

	Baseline (M ± SD)	After three sessions (M ± SD)	P
Fat thickness (cm)	4.44 ± 0.99	2.16 ± 0.44	<0.01
Weight (kg)	66.0 ± 12.1	65.3 ± 11.5	0.33
Total cholesterol (mg/dl)	205.1 ± 46.7	205.8 ± 46.7	0.09
Triglycerides (mg/dl)	85.1 ± 43.6	95.4 ± 45.3	<0.01



Lipotripsy: Non-invasive Ultrasonic Selective Destruction of Adipocytes Using UltraShape

Hector Leal-Silva, M.D. | Presented at IMCAS 2008 and ASLMS 2008

METHODS

Thirty six patients between 21 and 60 years old, 33 females and 3 males with diagnosis of lipodismorphism, were treated for localized adiposities in several parts of the body: abdomen, flanks or/and thighs in three sequenced sessions of approximately 1000 ultrasonic pulses each one, made one month apart. Diagnostic ultrasound to measure fat tissue thickness in the treatment areas were performed, photographic assessment, weight and measures were registered pre and post treatments in each one of the three procedures and also at the final follow up visit, three months after the last treatment. CT scan to precisely measure fat thickness was performed in a sample of six cases.



RESULTS

The study showed definitive, measurable results in 100 percent of patients including an average of two-inch (5 cm) reduction in circumference in the abdomen after a series of three treatments, one month apart. CT scans taken in a subset of study subjects showed objective quantifiable fat thickness reduction. Photographic assessment, weight and circumferential measures were evaluated before and after each treatment and one month after the last treatment. Visual contour improvement was seen in over 85% of patients as assessed by an independent panel of physicians. Ninety-four percent (94%) of patients were satisfied with the procedure. In addition, there were no adverse events reported.

CONCLUSIONS

“UltraShape has addressed a previously unmet patient need in my practice for a safe and effective non-invasive option for the reduction of localized fat deposits,” said Leal-Silva.

Reduced Pulse Duration (1.0 second) and Shorter Treatment Intervals Using UltraShape

Dean Ad-El, M.D. | Presented at IMCAS Asia, 2008

METHODS

The trial included 26 patients who were treated on the abdomen with 1 second pulse, 3 treatments at 2 week intervals. Follow-up was performed 56 days post last treatment.

RESULTS

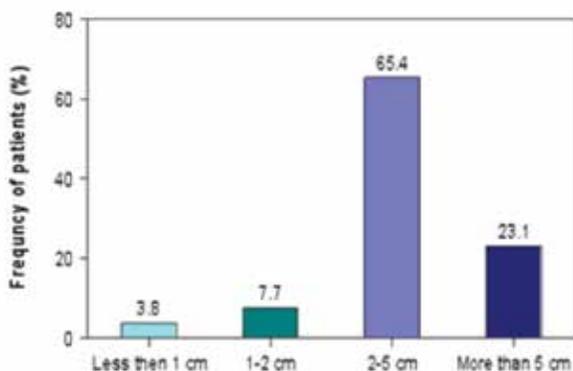
- 90% of patients experienced circumference reduction > 2.0 cm
- 3.95 cm average reduction in body circumference
- 1.6 kg average weight loss
- 3 mild skin effects – all resolved spontaneously same day

CONCLUSIONS

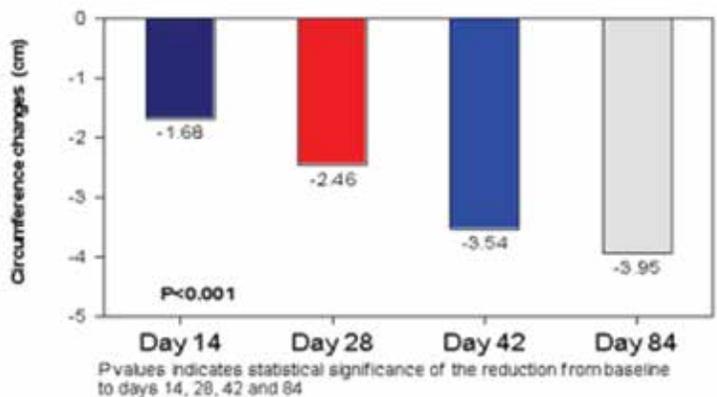
According to this study, treatment with 1.0 second pulse duration at two-week treatment intervals is safe and shows equivalent results when compared to published clinical studies using 3.0-second pulse duration at four week intervals.



Frequency (N, %) of Circumference (midline) changes from Follow up day 84 to baseline



- 90% of patients showed ≥ 2.0 cm circumference reduction
- 23% of patients showed ≥ 5.0 cm circumference reduction



- 3.95 cm avg. circumference reduction
- Equivalent results to published clinical data using 3.0 second pulse duration and 30 day treatment intervals

3.6 CM REDUCTION



Treatment 1 – Day 1



Treatment 3 – Day 28

Non-invasive Ultrasonic Selective Fat Cell Lysis and Body Contouring

Chris Inglefield, M.D. | Presented at ASPRS 2007

METHODS

- Study was conducted at London Bridge Plastic Surgery in London
- 118 women (n=86) and men (n=32) with a mean age of 38 years old, received a series of three treatments, one month apart
- Selected patients had a body mass index of less than 30, a healthy, motivated attitude toward exercise and diet, localized fat deposits and a desire for non-invasive fat-reduction and body contouring

RESULTS

- An average three-inch (7.5 cm) reduction in circumference for all body areas
- An average 2.5-inch (6.3 cm) reduction in circumference for the abdomen, hips and lateral thighs
- Ninety-three percent (93%) of patients described their results as either “good” or “excellent”
- No patient-related adverse events

CONCLUSIONS

“The excellent patient satisfaction that I’ve seen with the UltraShape procedure over the past two years confirms that this technology is safe and effective, and answers an unmet patient need for non-invasive fat reduction with no pain or downtime,” said Inglefield. “The convenient ‘walk-in, walk-out’ procedure allows patients to see measurable circumference reduction and body contouring without the hassle and risk associated with other, more invasive approaches—they literally receive the treatment and then immediately resume their daily routine.”

LOWER ABDOMEN – 3 TREATMENTS



Pre-treatment



1 month post treatment

Reduction: 6 cm

Photos courtesy of Dr. Chris Inglefield,
London, UK

Novel Technique for Non-invasive Destruction of Fat Cells: 3-dimensional Evaluation

Guilherme De Almeida, M.D. | Presented at WCD 2007

PURPOSE OF THE STUDY

Evaluate the efficacy of a novel technique for non-invasive destruction of adipose cell via focused ultrasound (UltraShape, Tel Aviv, Israel), using images from a three-dimensional photography system (Vectra 3D, Canfield) and pre and post treatment measurements.

METHODS

Ten patients with abdominal fat layer up to 3 cm in thickness and without contraindications for the device. They underwent 3 treatments at 1-month intervals. Three-dimensional images and circumference measurements with a special tape measure were performed pre and post treatment.

RESULTS

An average reduction in circumference of 2.5 cm per session was observed in all treatment areas. No adverse events were recorded throughout the study.

CONCLUSIONS

The focused ultrasound was effective, safe and painless for the body contouring, showing good results in 3D pictures as a non-invasive solution for fat reduction.



UltraShape New Advancements and Clinical Studies

Arie Benchetrit, M.D. | Presented at IMCAS Paris, 2010

METHODS

- 109 patients received 3 treatments on the abdomen, flanks thighs and/or back rolls
- 157 total treatment areas

RESULTS

- 96% of patients experienced measureable circumference reduction.
- 4.5 cm average circumference reduction
- Average weight change 0.6 kg



Pre-treatment



4 weeks post treatment

Reduction:
4.7 cm upper abdomen
5.4 cm lower abdomen

Using Focused Ultrasound to Treat Localized Fat

A. Niwa et al. | *Surgical & Cosmetic Dermatology*, 2010

METHODS

- 120 patients underwent 2 or 3 focused ultrasound sessions with 4-week intervals.
- The abdomen, hips, thighs, dorsum and infragluteal fold were the treated areas.

RESULTS

Average reduction of 4.95, 4.88 and 3 cm in the circumference of the abdomen, hips and thighs, respectively.

CONCLUSION

Focused ultrasound is a safe, effective and well tolerated procedure for remodeling areas of the body.



Table 1 – Average reduction in circumference per area treated

Treatment area	1 st session	2 nd session	3 rd session
Abdomen	1.76cm	2.54cm	4.95cm
Flanks	1.43cm	2.03cm	4.88cm
Trochanterica	1.84cm	2.75cm	3cm
Infragluteal	2.35cm	-	-
Dorsum	2.6cm	-	-

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

Benjamin Ascher, M.D. | *Aesthetic Surgery Journal*, 2010

OBJECTIVE

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

METHODS

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

RESULTS

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

CONCLUSIONS

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

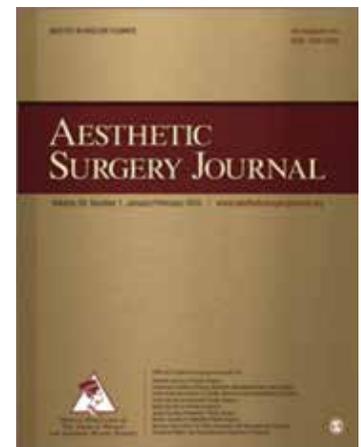


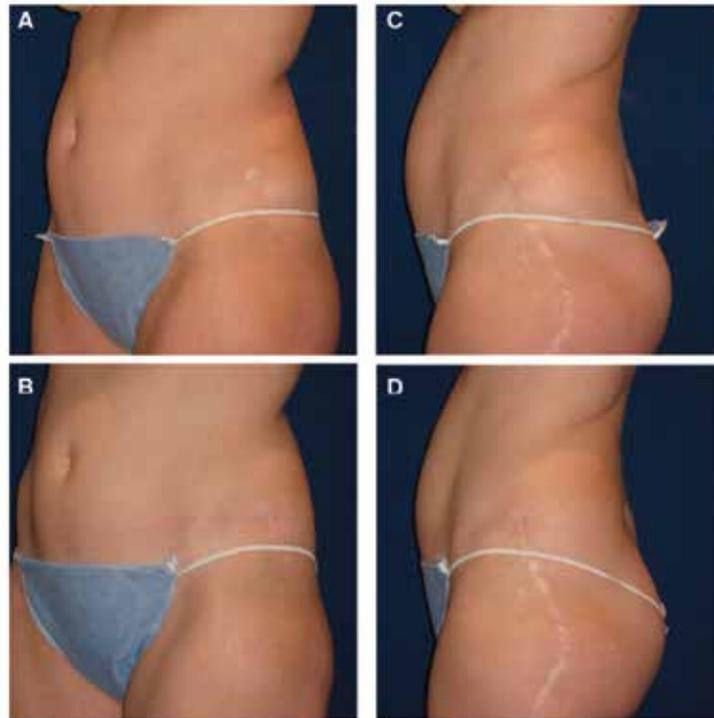
Table 2. Change in Circumference (2 cm Below Midline) From Baseline

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

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

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

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



7.5 cm reduction in waist circumference after 3 treatments

Combination Therapy of Focused Ultrasound and Radio Frequency for Non-invasive Body Contouring in Asians with MRI Photographic Documentation

Chang et al. | 2013

OBJECTIVE

This study aimed to assess the efficacy, safety, and pain and satisfaction levels of the combination therapy of focused ultrasound and radio frequency for improving body contours.

METHODS

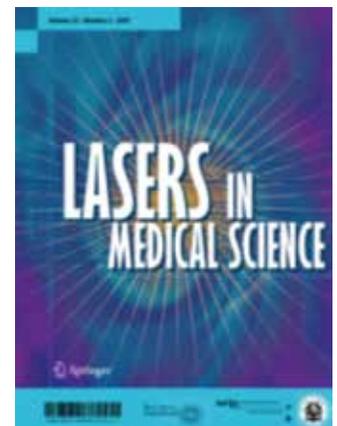
Thirty-two Asian patients received 3 sequential treatments every 2 weeks in the abdominal region. Safety parameters and adverse events were recorded. The subjects' pain and satisfaction levels were evaluated using a five-point Likert scale. Two patients underwent MRI study randomly.

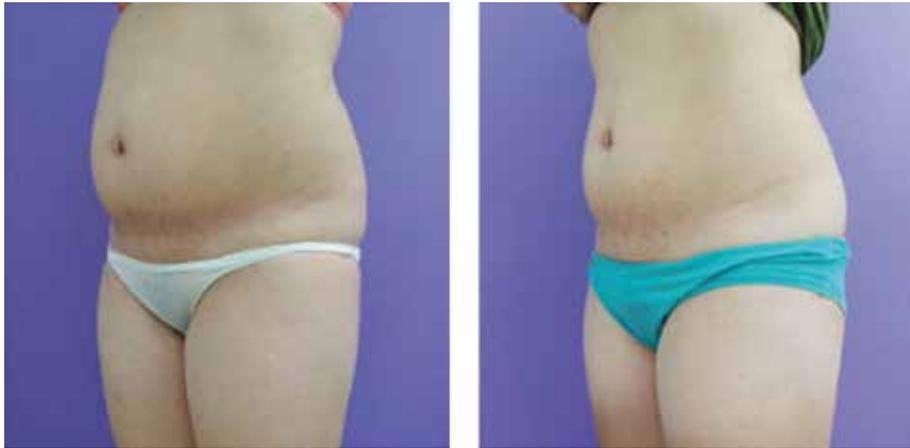
RESULTS

There was a mean reduction in circumference of 3.91 ± 1.8 cm ($p \leq 0.001$). In MRI measurement, the average in fat thickness reduction was 21.4 and 25% on the upper and lower abdomen, respectively. There were three mild and self-limited localized adverse events. The satisfaction survey showed that 71.9% was satisfied with the results, while pain level evaluation showed that 90.5% felt no pain.

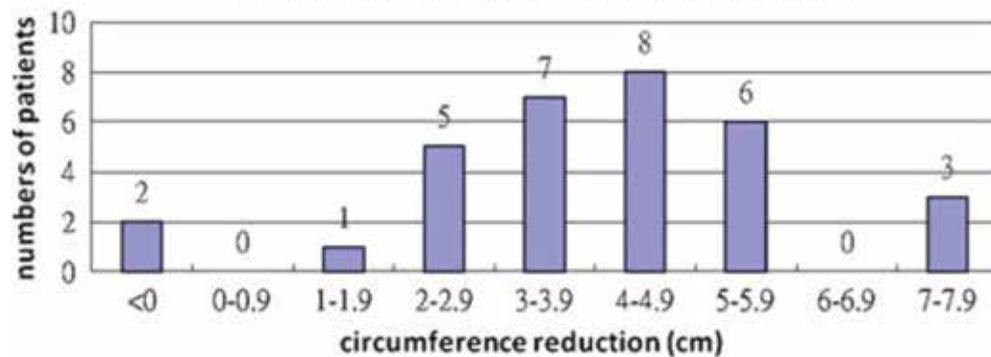
CONCLUSIONS

Combination therapy of focused ultrasound and radio frequency for non-invasive body contouring is an effective, safe, and painless procedure in Asians. Although the change is minor compared to traditional surgical procedure, it is real, definite and effective.



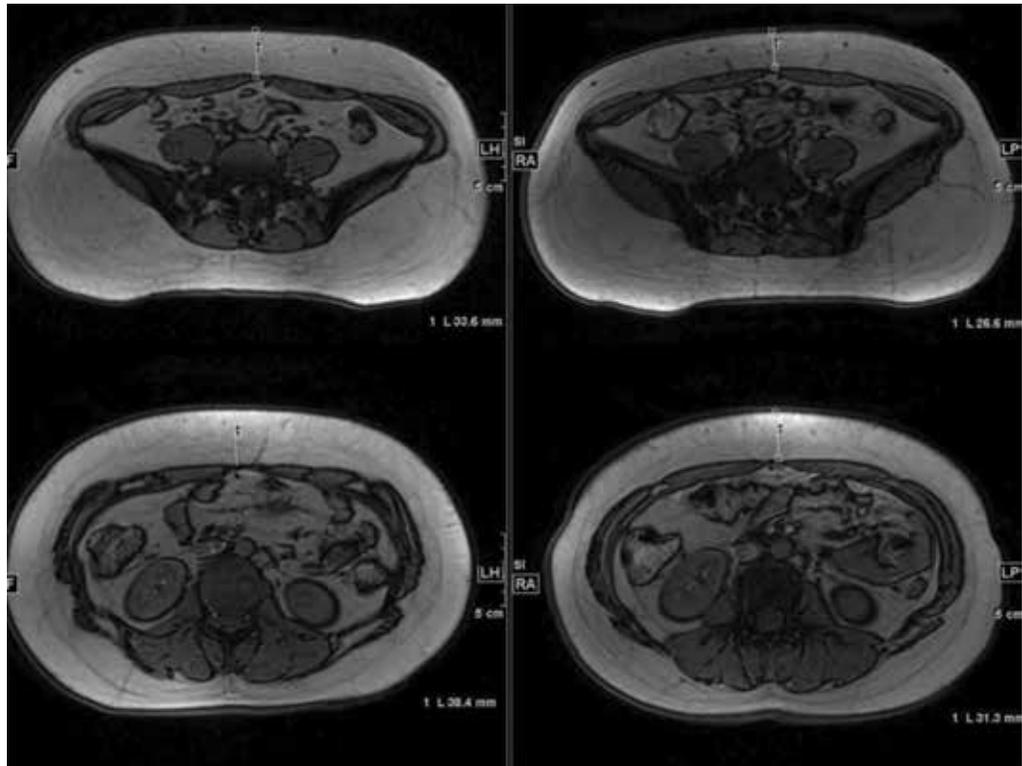


Abdominal circumference reduction



MRI FAT LAYER THICKNESS MEASUREMENTS

Lower Abdomen



Upper Abdomen

Table 1 Fat thickness reduction on the upper and lower abdomen by MRI measurement

	Age	BMI	Upper abdomen			Lower abdomen		
			Before treatment (mm)	After treatment (mm)	Fat thickness reduction (mm) (%)	Before treatment (mm)	After treatment (mm)	Fat thickness reduction (mm) (%)
Case 23	30	28.5	38.4	31.3	7.1 (18.5)	33.6	26.6	7 (20.8)
Case 24	42	24.2	22.7	17.2	5.5 (24.2)	18.8	13.3	5.5 (29.2)

