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Use of a novel combined radiofrequency and ultrasound device for lipolysis, skin tightening and cellulite treatment

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ABSTRACT

Introduction: Skin laxity and excessive subcutaneous fat are growing cosmetic concerns. The objective of this study is to evaluate the efficacy and safety of a novel radiofrequency and ultrasound workstation for lipolysis, circumference reduction, treatment of skin laxity and cellulite. **Materials and methods:** Two hundred seventy-five (235 women and 40 men) patients were enrolled into the study. Each patient received 3 treatment sessions, each session comprising Ultrasound and Radiofrequency treatments, at two-week intervals. Some received treatment for the abdomen, some for the thighs and some for both. Efficacy was assessed accordingly by measuring changes in abdominal circumference, thigh circumference and appearance of cellulite. Any adverse effect was noted. **Result:** Paired *t*-test between measurements at baseline and 4 weeks after 3rd session was significant amongst all the groups, showing that most patients showed improvement in abdominal and/or thigh circumferences. No significant adverse effects were noted during or after the treatment. **Conclusion:** A combination of alternating hot and cold module Ultrasound and Radiofrequency technologies is a safe and effective modality for lipolysis and to treat skin laxity and cellulite.

ARTICLE HISTORY

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KEYWORDS

Body contouring;
radiofrequency and
ultrasound; skin tightening

Introduction

Concerns about tissue laxity and localized subcutaneous fat deposition in the body are increasing amongst cosmetic patients. A wide range of technologies, both invasive and non-invasive, are available to perform body contouring. Currently available non-invasive tightening devices include laser, broadband light (including infrared), Radiofrequency (RF) and Ultrasound (ULS) (1,2).

Non-invasive methods of tissue tightening and body contouring involve application of energy to the skin surface, producing heat in the dermal and subcutaneous tissues, resulting in collagen denaturation, neocollagenesis and subsequent skin tightening (3). Although laser and light-based devices are able to reach up to deep dermal layers, light scattering and absorption of energy by chromophore melanin limit their thermal effects (4). Radiofrequency is electromagnetic energy in frequency range of 3 KHz to 1 MHz. Radiowaves are neither scattered nor absorbed by epidermal melanin; thus, they are suitable for treating all skin types. Radiowaves produce significant heat, without causing a hazardous effect on epidermal integrity. RF energy can be delivered in three different ways, including monopolar, unipolar and bipolar (5).

In recent years, ULS technology has gained popularity amongst aesthetic practitioners, as a non-invasive method for treatment of adiposis and for body contouring. There are two broad categories of ultrasound used for body contouring: low frequency non-thermal ultrasound and high-intensity focused ultrasound (2,6). Currently available ULS technologies are non-

selective, produce heat and are thus liable to cause epidermal injury. Thus, a ULS technology is needed, which will non-thermally and selectively disrupt/destroy adipocyte membrane integrity, without causing significant damage to the epidermis or to nearby cells in the adipose layer, such as blood vessels or nerves.

The efficacy and safety of a novel, combined radiofrequency and ultrasound workstation for lipolysis, circumference reduction, body shaping and the reduction of cellulite was evaluated in our study. The Ultrasound (ULS) module targets fat reduction and body contouring. The Unipolar Radiofrequency (RF) module with deep massager treats skin laxity, assists body contouring and enhances lymphatic drainage.

Mechanism of action

The ultrasound module provides “cold” mode and “hot” mode alternately. In cold mode, primarily shear ULS waves are delivered, while in hot mode, primarily compression waves are delivered (Figure 1). Compression waves pre-heat the tissue, before delivering the shear waves. Upon reaching the adipose tissue, the shear waves repeatedly stretch and relax adipocyte membrane, resulting in deformity and damage to the adipocyte, which triggers delayed cell death. In our study, 20-second cycle comprising alternating hot (up to 5 seconds) and cold (at least 15 seconds) ULS, was used. If the ultrasound module is set for 5 seconds of hot ULS, the module will continuously generate alternating blocks of 5-second hot ULS followed by 15-second cold ULS.

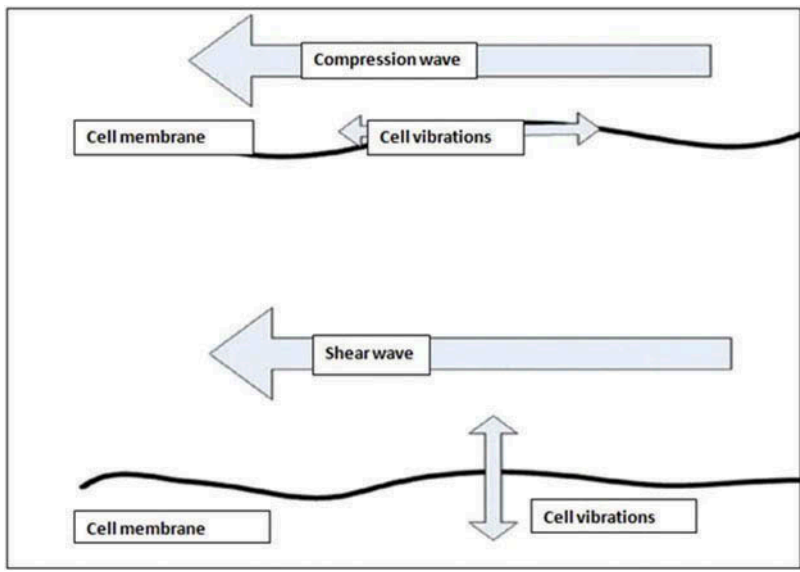


Figure 1. Direction of vibration and propagation of compression and transverse shear waves.

Table 1. Mechanism of action.

Technology	Mechanism of action
Hot ULS	Generates compressive sound waves Micro gas bubbles in tissue fluid contract and expand
Cold ULS	Cavitation in tissue Generates transverse waves Penetrates deeper
Unipolar RF application	Causes selective adipocyte membrane disruption Increases subcutaneous heat Increases local metabolism
Massager incorporated with the RF tip	Enhances microcirculation, facilitates drainage of trapped intracellular fluid and breaks down adhesions

Table 2. Difference between focused and selective ULS.

Limitation of focused ULS	Key feature of selective ULS
Slow	Visible damage to fat cells
Fixed focal depth-depend on tissue and patient position	Selective damage only to fat cells
Expensive and disposable transducers	Increase of connective tissue 2 weeks after treatment
NON SELECTIVE-can break blood vessels or nerves	Compacting of the fat cells layers
	No pain is generated

The unipolar Radiofrequency module increases local metabolism and induces thermal effect by progressively increasing subcutaneous heat, while the deep massager improves microcirculation, enhances lymphatic drainage and breaks down erythrocytic adhesions (Tables 1 and 2).

Materials and methods

Two hundred seventy-five patients (235 women/40 men), aged 29–66 years (average 38 years), with Fitzpatrick skin types 3–6, body mass index between 23 and 30 (average 26.5 kg/m²), desiring reduction of subcutaneous fat deposition on the abdomen and/or thighs or improvement of cellulite on thighs (grade 1–3), were enrolled in the study, after obtaining appropriate consent from them.

Each patient received 3 treatment sessions, each 2 weeks apart, each session comprising ULS and RF. Exclusion criteria included: Patients with existing or history of cancer, including skin malignancy; existing skin diseases; multi-systemic diseases (diabetes, hypertension, coronary artery disease, renal insufficiency, hyper-cholesterolemia); history of collagen or vascular disease; patients with implantable pacemaker, or automatic implantable defibrillator/cardioverter (AICD) or any other implantable electric device; any large metallic implant, i.e. artificial hip joint; history of hypertrophic scar or keloids formations; history of prior aesthetic surgery or treatment in the area to be treated within 3 months of study enrolment; use of any medication that can cause dermal hypersensitivity or affect skin characteristics within 30 days of study enrolment; use of isotretinoin within the past 6 months; women who are pregnant, lactating, or planning to get pregnant during the study period.

Weight and height of all patients were measured at baseline using standard equipment. Body standing circumference at 3 fixed reference points i.e. at umbilicus and 5 cm above and below it, was taken with a standard anthropometric measuring tape (Figure 2). Similarly, circumferential measurements at mid-thigh, and 5 cm above and below it were taken. For determining the midpoint on the thigh, the patients were asked to sit upright on a chair, and the distance from the inguinal groove to the proximal border of the patella was measured. Then, the midpoint of this length was marked, and the standing circumference of the thigh was taken at this point (Figure 3). Photographs to document contour and superficial changes using a high-resolution digital camera, with the patient standing and at rotating angles, using constant lighting and focal distance, in exhalation, and circumferential measurements of each area, at fixed reference points as mentioned above, were obtained prior to, after each treatment and 4 weeks after the last treatment, under same controlled conditions. A blinded trained physician assistant performed all the measurements and took an average of three readings.

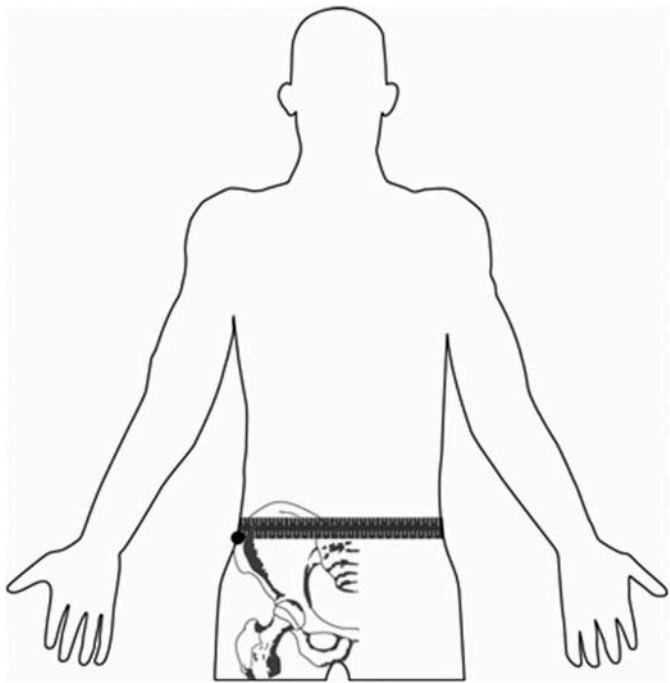


Figure 2. Measuring tape position for abdominal (waist) circumference, at umbilicus and 5 cm above and below it.

Body weight was assessed using a digital scale and measured to the nearest 0.1 kg.

Complete blood count, liver function test, renal function test and serum lipids were measured before and 4 weeks after the last treatment. Patients were monitored for the development of any local adverse effect such as bruising, pain, dyschromias, fat texture-nodule or irregularities. Subject's rating on comfort level and satisfaction were collected via questionnaires at every follow-up.

Bilateral 15 × 20 cm grids were drawn on each abdomen, with each grid further divided into 4 equal quadrants (Figure 4). Bilateral 10 × 20 cm grid was drawn on each flank; each grid was divided horizontally into 2 equal halves. On thighs, a circumferential grid was similarly taken, and each grid was divided

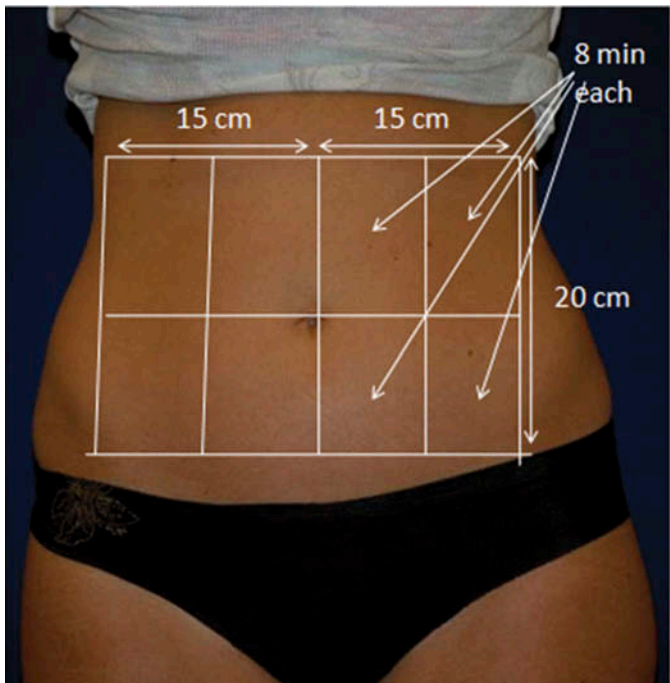


Figure 4. Abdominal treatment quadrants – front.

into 4 equal quadrants. Vaseline was applied as conducting medium. As the procedure is painless, no pre-treatment anaesthesia was required. Each quadrant received alternate hot and cold ULS, from the same handpiece, in the ratio of 1:3 (5:15 seconds respectively) for 8 minutes, holding the ULS hand piece perpendicular to the skin and in continuous semi-rotational motion within the quadrant. Mild erythema and warmth were noted during the process. After the completion of treatment on all quadrants, Vaseline was wiped off. The area was then prepared for treatment with unipolar RF.

A manufacturer-supplied medical grade and transducer-compatible oil was used to ensure optimal acoustic contact between the therapeutic transducer and the patient's skin, and

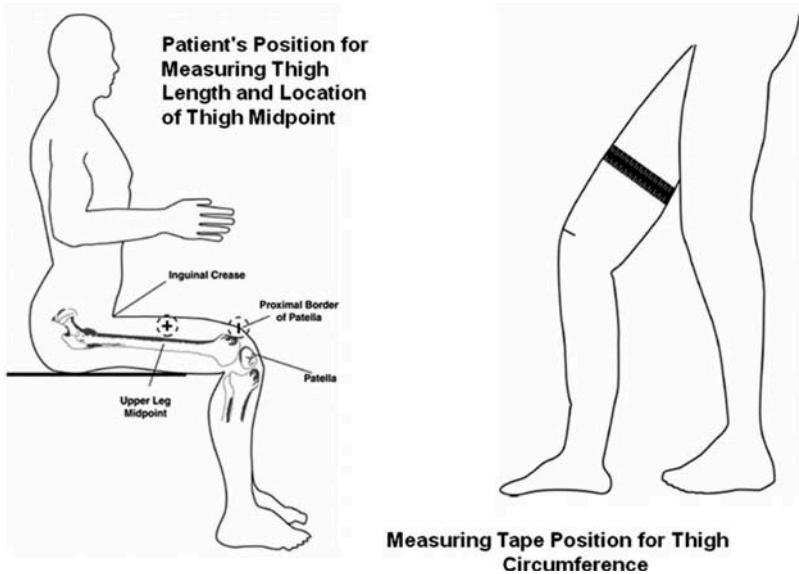


Figure 3. Circumferential measurements at mid-thigh, and 5 cm above and below it.

unipolar RF was delivered with the handpiece in motion. For this, the entire treatment area was divided into 2 quadrants, and each quadrant received 150–180 watts energy and thus 80–100 kJ of accumulated energy on the abdomen and 130–150 watts on the thighs with 60–80 kJ of accumulated energy. The energy levels were adjusted according to the patient's sensitivity, skin response and apparent subcutaneous thickness. The end point was reaching a recommended total energy (kJ) maintaining skin temperature between 40 and 43°C (Figure 5) measured with a laser thermometer. Sensation of heat during treatment and appearance of erythema were noticed (Figure 6). RF treatment required about 35 minutes of average treatment time for the abdomen and 25 minutes of that for the thigh.

Post treatment, plenty of water intake was advised. No other special care was advised. None of the patients underwent other slimming or aesthetical procedures (endermologie, mesotherapy, radiofrequency, etc.) during the study. However, they were instructed to maintain a healthy lifestyle with a balanced diet low in saturated fat. Weight change was monitored to assess whether the reduction in circumference was due to weight loss.

A total of 960 treatments sessions were performed on 220 abdomens and 100 pairs of thighs.

Statistical analysis

Statistical analysis was done using Minitab software. Within each treatment group (abdomen, right and left thighs), the test for equal variances with Bartlett's test at 95% confidence intervals was applied for testing differences between baseline (day 0) assessment and follow-up assessments for circumference reduction.

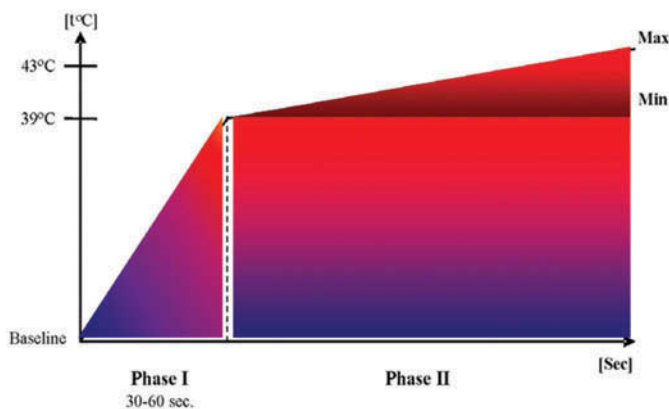


Figure 5. Unipolar RF treatment cycle.

Results

Demographics

250 patients (220 women and 30 men) completed the study. Their age ranged from 29 to 66 years (average 38 years) (Table 3). Delineation of subjects by Fitzpatrick Skin Type can be appreciated in Table 4. Their baseline characteristics are shown in Table 5.

Clinical results

Circumference reduction of the treated body areas was considered for analysis. The changes in the 'lower' i.e.: infra-umbilical circumferences were considered for final assessment. Presenting data of all the patients is not practically feasible. Thus, we are presenting the data of 22 abdomen and 10 pairs of thighs. The reduction in infra-umbilical measurements (cm) between assessments is given in detail in Table 6 and Graph 1.

The average infra-umbilical circumference for baseline (A), before 2nd (B) and 3rd (C) sessions and 4 weeks after 3rd session (D), were 85.73 ± 7.16 , 83.26 ± 7.65 , 80.28 ± 7.77 and 77.73 ± 7.99 cm, respectively. The average reduction in abdominal circumference between A and B, B and C, C and D, and A and D was 2.47 ± 1.13 , 2.98 ± 1.34 , 2.55 ± 1.31 , and 8.00 ± 2.89 cm, respectively. 140 of 220 (64%) cases showed a

Table 3. Demographics by age group.

Age group (years)	Number of Subjects (n = 250)
25–34	40
35–44	130
45–54	60
55–64	10
65–74	10

Table 4. Demographics by Fitzpatrick skin type.

Skin type	Thighs (%) (n = 100) +	Abdomen/flank (%) (n = 220)
III	10	9
IV	30	36.36
V	50	45.45
VI	10	9

Table 5. Baseline characteristics of patients enrolled in the study.

Baseline characteristic	Mean
Age (years)	38
Weight (kg)	60.5
Height (cm)	160.4
BMI (kg/m ²)	26.5

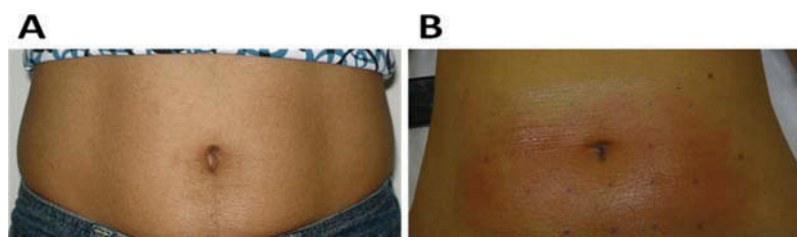


Figure 6. (A) Before treatment; (B) immediately after the treatment.

Table 6. Abdominal circumference measurement data before and after treatment (infraumbilical).

Patient no.	Before 1st session (cm): A	Before 2nd session (cm): B	Reduction (cm) between A and B	Before 3rd session (cm): C	Reduction (cm) between B and C	4 weeks after 3rd session (cm): D	Reduction (cm) between C and D	Reduction (cm) between A and D
1	91.0	89.5	1.5	88.2	1.3	86.0	2.2	5.0
2	97.0	95.4	1.6	92.0	3.4	88.5	3.5	8.5
3	80.0	76.2	3.8	73.0	3.2	70.0	3.0	10.0
4	77.6	74.0	3.6	71.6	2.4	67.2	4.4	10.4
5	79.6	76.4	3.2	72.6	3.8	69.1	3.5	10.5
6	83.2	81.0	2.2	78.2	2.8	75.0	3.2	8.2
7	90.2	85.7	4.5	82.0	3.7	80.6	1.4	9.6
8	72.3	66.8	5.5	62.3	4.5	60.3	2.0	12.0
9	88.9	86.6	2.3	82.4	4.2	78.0	4.4	10.9
10	91.2	89.3	1.9	84.0	5.3	80.6	3.4	10.6
11	88.0	85.7	2.3	83.3	2.4	79.9	3.4	8.1
12	96.0	94.1	1.9	90.1	4.0	88.3	1.8	7.7
13	79.2	76.2	3.0	72.3	3.9	68.2	4.1	11.0
14	96.6	94.5	2.1	91.7	2.8	87.0	4.7	9.6
15	90.2	88.6	1.6	88.0	0.6	87.8	0.2	2.4
16	85.0	83.0	2.0	79.2	3.8	76.5	2.7	8.5
17	92.6	89.3	3.3	87.2	2.1	86.2	1.0	6.4
18	79.9	78.0	1.9	75.8	2.2	74.0	1.8	5.9
19	77.2	74.8	2.4	71.4	3.4	69.0	2.4	8.2
20	81.0	80.0	1.0	79.6	0.4	78.7	0.9	2.3
21	90.6	88.6	2.0	84.1	4.5	82.6	1.5	8.0
22	78.8	78.0	0.8	77.2	0.8	76.6	0.6	2.2

reduction in abdominal circumference above the mean ranging from 8.1 to 12 cm.

The mean final circumference reduction for abdomen at 3 reference points has been shown in Chart 1. The average reduction in final circumference for abdomen at 3 individual reference points was 7.7, 7.8 and 8.0 cm for upper, middle and lower reference points, respectively.

Detailed data of measurements of thighs before and after the treatment

The reduction in the thigh measurements (cm) between assessments is given in detail in Tables 7 and 8 and Graphs 2 and 3. The average right thigh circumference for baseline (A), before 2nd (B), 3rd (C), sessions, and 4 weeks after 3rd session (D) was 52.34 ± 3.14 , 51.49 ± 3.36 , 50.37 ± 3.20 , and 49.16 ± 3.37 cm, respectively.

The average reduction in right thigh circumference between A and B, B and C, C and D, and A and D was 0.85 ± 0.63 , 1.12 ± 0.55 , 1.21 ± 0.77 cm, and 3.18 ± 1.33 cm, respectively. 50% cases showed a reduction in right thigh circumference above the mean ranging from 3.5 to 5.5 cm.

The average left thigh circumference for baseline (A), before 2nd (B) and 3rd (C) sessions, and 4 weeks after 3rd session (D) was 52.07 ± 2.67 , 51.45 ± 2.92 , 50.34 ± 2.97 , and 49.21 ± 3.21 cm, respectively.

The average reduction in left thigh circumference between A and B, B and C, C and D, and A&D was 0.62 ± 0.43 , 1.11 ± 0.80 , 1.13 ± 0.69 , and 2.86 ± 1.39 cm, respectively. 50% cases showed a reduction in right thigh circumference above the mean ranging from 3.0 to 5.7 cm.

Visually, A–D is different with the rest 3 having similar variances amongst all the groups. After excluding A–D, one-way analysis of variance was applied, which showed that the reduction in circumferences of abdomen, right and left thighs is not statistically different between A and B, B and C, and C and D sessions. Paired *t*-test between baseline (A) and 4 weeks after 3rd session (D) is highly significant amongst all the groups ($p \leq 0.0001$), showing that all patients showed improvement in abdominal and thigh circumferences.

Another parameter assessed, by a dermatologist not involved in performing the treatment, was improvement in appearance of cellulite. 40 subjects were evaluated for change in appearance of cellulite on thighs. The score of cellulite improvement was evaluated on a quartile grading scale: Score 1 = $\leq 25\%$, Score 2 = 26–50%, Score 3 = 51–75% and Score 4 = $>75\%$. Up to 25% improvement in skin texture and cellulite was seen in all subjects. Ten subjects scored 3, and none scored 4 (Chart 2).

All skin types tolerated treatments well. In 40 patients, the output RF power was lowered than in others during treatment

Table 7. Right thigh measurement data before and after treatment.

Patient no.	Before 1st session (cm): A	Before 2nd session (cm): B	A–B (cm): RT	Before 3rd session (cm): C	B–C (cm): RT	4 weeks after 3rd session (cm): D	C–D (cm): RT	A–D (cm): RT
1	50.0	50.0	0.0	49.3	0.7	49.0	0.3	1.0
2	55.0	54.2	0.8	53.6	0.6	53.0	0.6	2.0
3	49.5	48.2	1.3	46.8	1.4	46.0	0.8	3.5
4	52.3	51.8	0.5	51.0	0.8	50.0	1.0	2.3
5	48.5	47.0	1.5	46.5	0.5	45.5	1.0	3.0
6	51.6	51.0	0.6	48.9	2.1	47.5	1.4	4.1
7	55.5	53.8	1.7	52.2	1.6	50.0	2.2	5.5
8	58.2	57.9	0.3	56.4	1.5	56.0	0.4	2.2
9	49.6	48.0	1.6	47.4	0.6	45.5	1.9	4.1
10	53.2	53.0	0.2	51.6	1.4	49.1	2.5	4.1

Table 8. Left thigh measurement data before and after treatment.

Patient no.	Before 1st session (cm): A	Before 2nd session (cm): B	A-B (cm): LT	Before 3rd session (cm): C	B-C (cm): LT	4 weeks after 3rd session (cm): D	C-D (cm): LT	A-D (cm): LT
1	52.0	51.8	0.2	51.6	0.2	51.0	0.6	1.0
2	53.5	53.0	0.5	52.0	1.0	51.5	0.5	2.0
3	50.0	49.2	0.8	48.3	0.9	47.0	1.3	3.0
4	52.2	52.0	0.2	52.0	0.0	50.0	2.0	2.2
5	48.5	47.0	1.5	46.5	0.5	45.5	1.0	3.0
6	51.2	50.8	0.4	48.6	2.2	47.0	1.6	4.2
7	54.6	53.6	1.0	51.2	2.4	48.9	2.3	5.7
8	57.5	57.3	0.2	56.4	0.9	56.0	0.4	1.5
9	49.2	48.3	0.9	46.8	1.5	45.5	1.3	3.7
10	52.0	51.5	0.5	50.0	1.5	49.7	0.3	2.3

due to thermal discomfort. In pain level evaluation of the entire procedure, the results showed that 92 % felt no sensation or some sensation but no pain, 7 % felt minimal pain, 1 % felt pain, and none felt very extreme pain. The reduction in circumference in men and women was not significantly different. Patient weight largely remained constant over the 3 months of treatment and observation. Pre-procedure and post-procedure photographs demonstrating improvement in body shape in the treated areas and appearance of cellulite are shown in Figures 7–9. The results of test for equal variances for C5 for abdomen, right thigh and left thigh are shown in Figures 10–12, respectively.

The patient's reports of treatment satisfaction were greater in the abdomen and flank-treated group as opposed to the thigh-treated group, although both groups objectively had statistically significant results. There were no adverse effects noted throughout the study.

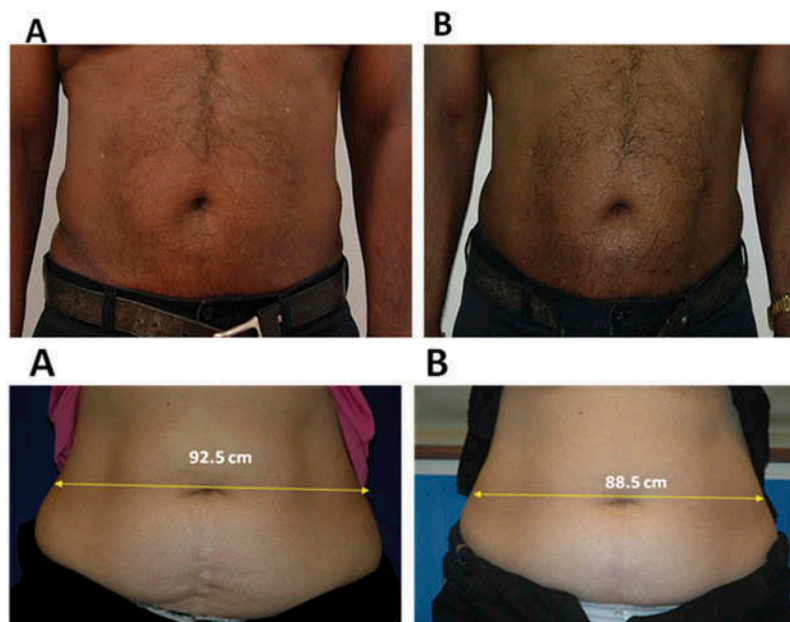
Discussion

Use of ULS for body contouring has rapidly grown recently. Available focused ULS technologies are non-selective, produce high amount of heat and are thus liable to cause epidermal injury. ULS energy can cause selective lipolysis when transmitted subcutaneously. The ideal method for selective lipolysis should

be non-invasive, destroying the fat cells, while maintaining the integrity of epidermis, dermis, blood vessels and nerves; and generate minimal pain and heat.

The significant circumference reduction may be justified due to the combination of ULS and RF, producing synergistic effects. The unipolar RF with its deep heating reaches hypodermis and adipocytes increasing heat in subcutaneous fat, facilitating contraction of collagen fibres and together with the deep massager improves blood and lymphatic circulation. All these result in shrinkage of subcutaneous layer, smoother appearing skin and overall improved contour.

Studies using only one modality such as ULS for body contouring and treatment of cellulite have shown good results, but overall reduction in circumferences was less than that using combined modalities (7,8). Modalities using a combination of the techniques of computerized massage, vacuum suction and continuous sinusoidal pulse employing ULS, have been assessed to find out their effectiveness in reducing thigh and abdominal circumference, and have shown good results. (9). The only study with the combination of focused ultrasound and radiofrequency by Chang et al. in 2014 (10) shows a statistically significant reduction in mean abdomen circumference of 3.91 cm at 1-month follow-up after the last of three consecutive treatments with 2-week intervals. The minimal and insignificant body weight change and the visible reduction only in treated areas support the

**Figure 7.** (A) Before treatment; (B) after 3 treatments.

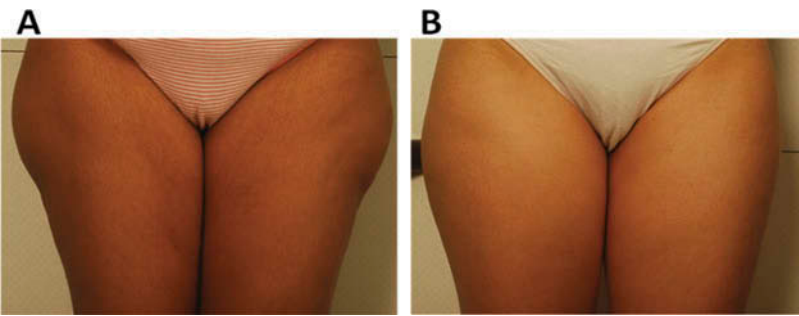


Figure 8. (A) Before treatment; (B) after 3 treatments.

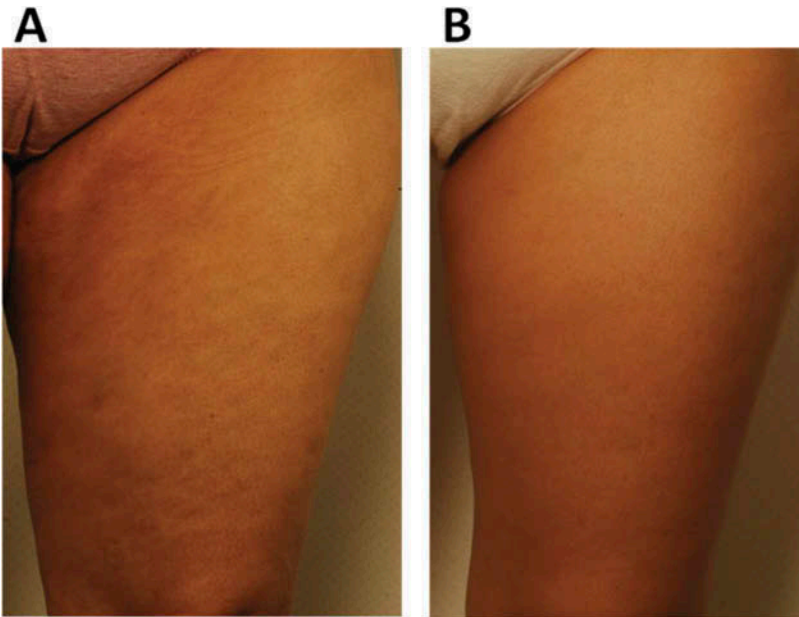


Figure 9. Appearance of cellulite (A) before treatment; (B) after 3 sessions.

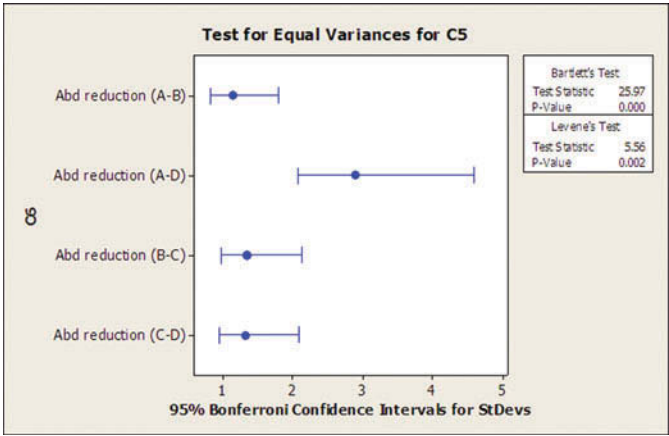


Figure 10. Test for equal variances for reduction in abdominal circumference.

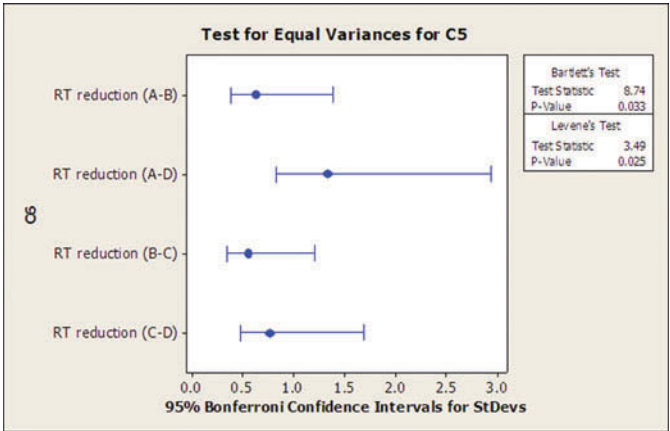


Figure 11. Test for equal variances for reduction in right thigh circumference.

benefit of focused ultrasound procedure. Their result is consistent with previous reports of an average of 3.51 cm loss after three successive treatments in the abdomen by Ascher (11), an average of 3.95 cm loss after three successive treatments at 1-month intervals by Moreno-Moraga et al. (7), and a 2.3-cm loss after

single treatment by Teitelbaum et al. (8) all of these having used focused ultrasound only. The average circumference reduction in our study is higher compared to those in all the above studies. There is no downtime after this treatment. Compared to liposuction, laser-assisted lipolysis or other non-invasive body

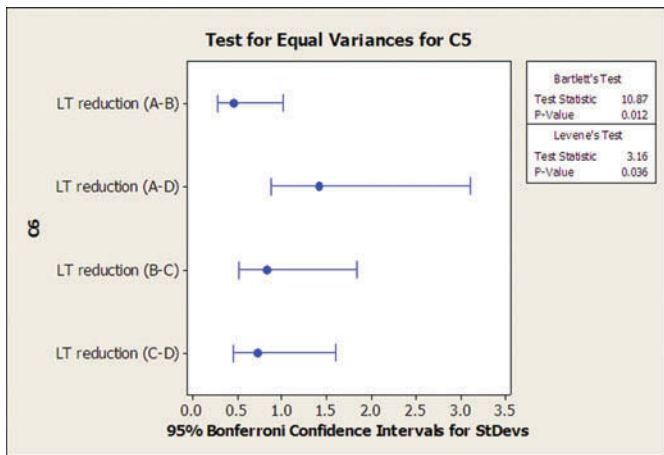


Figure 12. Test for equal variances for reduction in left thigh circumference.

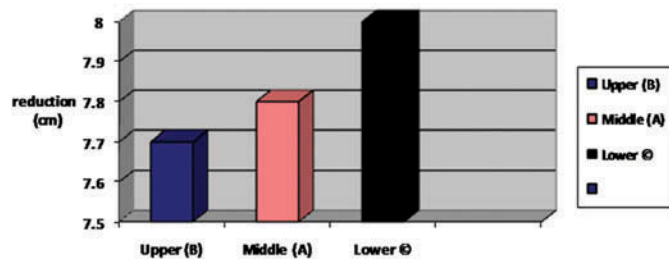


Chart 1. Mean final circumference reduction for abdomen at the 3 individual reference points.

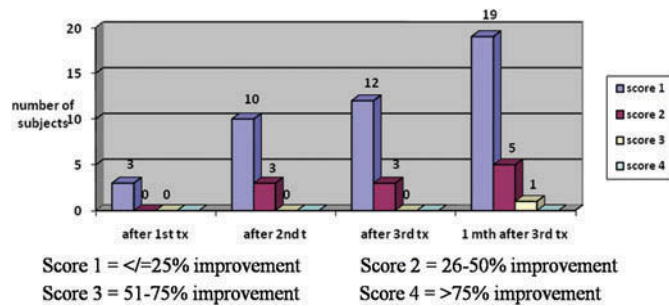
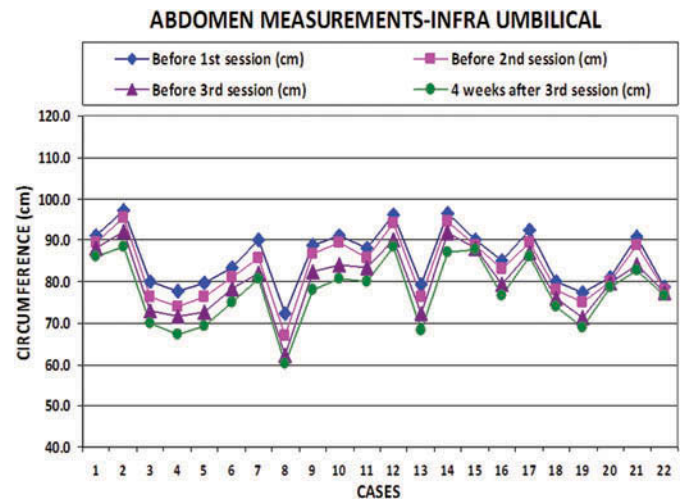


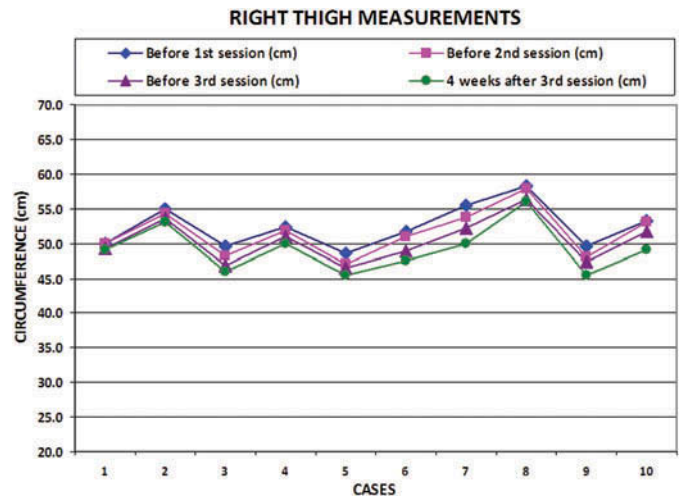
Chart 2. Cellulite improvement score based on the quartile grading scale.

contouring procedures, this procedure allows patients to resume their normal activities and exercises immediately after because there is no need to wear compression garment, no puncture or operation wound, and no skin texture change, irregularity, discoloration, ecchymosis, bruising, oedema, and paraesthesia. Patients can wear summer clothes and swimsuits immediately after the treatment.

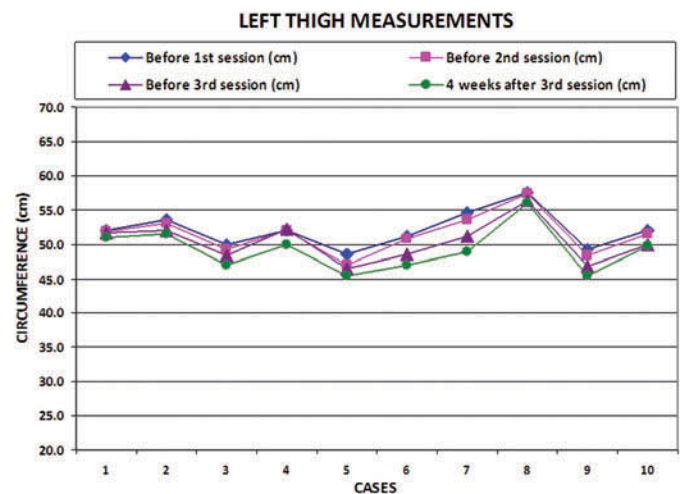
Limitations of this study include less number of sessions, lack of extended follow-up evaluations and untreated control group, and the inherent human errors while taking measurements. Even after taking every precaution while taking measurement, a slightest change in the tension of measuring tape can affect the data to some degree. While measuring the abdomen, the measurement needs to be taken in the same phase of respiratory cycle. Some women have complaints of bloating during pre-menstrual phase, which may affect



Graph 1. Reduction in infra-umbilical measurement.



Graph 2. Reduction in right thigh measurement.



Graph 3. reduction in left thigh measurement.

circumference measurement data. Large meals or fluid volumes taken immediately before measurement may also affect the result. Grading of skin surface irregularities is a

complicated subject, and photography alone may not be enough to evaluate; rating by patient is needed. 3D ultrasound and MRI (10) though expensive may be ideal for objectively quantifying skin surface irregularities.

However, although minor compared to that of traditional surgical procedures, change is real, definite and effective. The non-invasive nature and painless process, without downtime, makes it an alternative choice for patients and physicians, seeking non-surgical lipolysis, skin tightening and body contouring, without surgery.

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Conflict of interests

The authors do not have any financial interest in the materials and methods used in the study. The authors state no conflict of interests.

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