The Use of Focused Ultrasound for Non-Invasive Body Contouring in Asians

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Introduction: Previous studies demonstrated that multiple treatments using focused ultrasound can be effective as an non-invasive method for reducing unwanted localized fat deposits. The objective of the study is to investigate the safety and efficacy of this focused ultrasound device in body contouring in Asians.
Method: Fifty-three (51 females and 2 males) patients were enrolled into the study. Subjects had up to three treatment sessions with approximately 1-month interval in between treatment. Efficacy was assessed by changes in abdominal circumference, ultrasound fat thickness, and caliper fat thickness. Weight change was monitored to distinguish weight loss induced changes in these measurements. Patient questionnaire was completed after each treatment. The level of pain or discomfort, improvement in body contour and overall satisfaction were graded with a score of 1–5 (1 being the least). Any adverse effects such as erythema, pain during treatment or blistering were recorded.
Result: The overall satisfaction amongst subjects was poor. Objective measurements by ultrasound, abdominal circumference, and caliper did not show significant difference after treatment. There is a negative correlation between the abdominal fat thickness and number of shots per treatment session.
Conclusion: Focused ultrasound is not effective for non-invasive body contouring among Southern Asians as compared with Caucasian. Such observation is likely due to smaller body figures. Design modifications can overcome this problem and in doing so, improve clinical outcome. Lasers Surg. Med. 41:751–759, 2009.

Key words: focused ultrasound; body contouring; fat

INTRODUCTION

In the recent years, a lot of attention has been focused on aesthetic medicine. The population does not only demand a youthful appearance but they also want to maintain a favorable physique. This has led to the development of new techniques and devices for improving body contour.

The conventional method of improving body contour is by removing local fat through liposuction. This is an invasive approach which carries multiple risks such as complications from the surgical procedure and anesthesia. Patients would experience pain and a long post-operative recovery period [1–2]. All these factors contribute to the hesitancy in undergoing such procedure. More recently, laser assisted lipolysis has been introduced as an alternative to liposuction. It involves the introduction of a small fiber optic through a small incision into the subcutaneous fat. Laser emitted through the fiber optic leads to fat damage which is then removed through the small incision. While the potential complication rate is smaller than traditional liposuction, it is nonetheless, an invasive procedure.

Focused ultrasound (*Contour I*, UltraShape, Ltd, Tel Aviv, Israel) is a new device that has been reported to be capable of removing stored fat with the same efficacy as liposuction but without the invasive component and complications associated to it. Previous studies demonstrated that multiple treatments using this device can be effective as an non-invasive method for reducing unwanted fat deposits [3,4].

The concept of focused ultrasound is to generate primary mechanical effect and in doing so, rupture the adipocyte membrane with minimal damage to neighboring blood vessels, nerves and connective tissue. No discomfort during or after treatment and no complications have been reported [3,4].

The objective of the study is to investigate the safety and efficacy of this focused ultrasound device in body contouring in Asians.

MATERIALS AND METHODS

All subjects were informed of the aim of the study and received explanation about the technique. After reading the patient information sheet, an informed consent was signed.

The investigator carried out physical examination on each individual. This includes using the standard caliper,

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Skyndex (Caldwell Justiss, Fayetteville, USA), for measuring abdominal fat thickness. Those with less than 1.5 cm measured from the skin surface to the subcutaneous fat were excluded because the focused ultrasound has target depth of 1.5 cm. Inclusion and exclusion criteria are listed in (Fig. 1). Complete blood count, liver and renal function tests and lipid profile were performed prior to treatment and only those with normal findings were included into the study.

Before treatment, the weight (kg) and height (cm) were taken. The abdominal fat thickness was measured with a caliper (mm). The abdominal circumference was measured

Fig. 1: The list of participant's inclusion/exclusion criteria

Participant's Inclusion Criteria
1. Healthy Individuals of any race or either gender between the age of 18 and 65 Years.
2. Hairless skin over the areas to be treated (the area will be shaved prior to treatment if needed).
3. Fat thickness of at least 1.5 cm in the areas to be treated.
4. Participant who signed the informed consent letter for this protocol and have furnished the principal investigator with a signed medical statement regarding their medical state by their family physician (or GP).

Participant's Exclusion Criteria
1. Previous medical history including chronic diseases especially like hyper trigliceridemia or any metabolic disease whether treated medically or not, congenital problems, and other health problems that may interfere to the trial protocol, as judged by the investigator.
2. HIV positive or any non-A hepatitis.
3. Cardiac pacemaker.
4. Abdominal wall hernias if in the region of the treatment.
5. Clinically significant abnormal laboratory results, as judged by the investigator.
6. Medical/pharmaceutical treatment, within the last 30 days, that might interfere with the study as judged by the investigator especially by drugs that are fat-soluble (oral contraceptives not included).
7. Chronic treatment with aspirin or any Non-Steroidal-Anti- Inflammatory Drugs (NSAID) or within the last 10 days before the planned treatment.
8. Treatment with homeopathic drugs.
9. History of blood coagulation problems (excessive menstrual bleeding, excessive bleeding in minor trauma/lacerations).
10. History of organophosphate and/or herbicides and /or pesticides exposure.
11. Pregnancy or female patients of childbearing potential who do not intend to practice acceptable methods as indicated in the informed consent letter. Two contraceptive methods are needed to be used currently.

Fig. 1. The list of participant's inclusion/exclusion criteria.

at a fixed distance from the ground, using a special tape provided by the company (UltraShape, Ltd), so the same tension is applied every time. All subjects had caliper reading and abdominal circumference measured. A control circumference was also taken in the abdomen or the thigh where no treatment was to be performed. In 82 out of 140 treatment sessions (28 subjects), ultrasound measurement to measure abdominal fat thickness were performed. This is because we introduced the ultrasound system after we have started the study as we wanted to improve the accuracy of the study, therefore, not all subjects had ultrasound imaging done. All measurements were taken on the same location with the same pressure. The attempt of achieving the same pressure is to apply the minimal pressure that would allow a clear ultrasound image.

The investigator examined the subjects and marked the treatment area which included all the abdomen and in some cases, the flank. For the abdomen, a circular pattern that was treated and bony areas were avoided (Fig. 2). Digital photography was taken using the Canfield System® (Fairfield, NJ). The same settings (focal length), same lighting and rotating angles were used each time. All the measurements mentioned above are carried out before every treatment and on 1, 3 months post-treatment follow-up visits.

Fig. 2. The treatment area in a circular pattern.

The subject lied on the bed with the video tracking and guiding system over the patient. The operator moved the transducer over the targeted area, guided by the computerized system. The system operated at fixed parameters of frequency 200 ± 30 kHz, acoustic output intensity 17.5 W/cm^2. Each session lasted 2–3 hours. No anesthetic cream was applied. A manufacturer-supplied oil was used as a coupling agent during the treatment. Subjects had up to three treatment sessions with approximately 1-month interval. The patients were not allowed to undergo other slimming or aesthetic procedures during the study period. The first 30 subjects had a second blood test 1 month after the first treatment in order to identify any abnormality particularly in the lipid profile.

Efficacy was assessed by changes in abdominal circumference, ultrasound fat thickness, and caliper fat thickness. Weight change was monitored to distinguish weight loss induced changes in these measurements. Patient questionnaire was completed after each treatment. The level of pain or discomfort, improvement in body contour and overall satisfaction were graded with a score of 1–5 (1 being the least). Any adverse effects such as erythema, pain during treatment or blistering were recorded.

Statistical analysis of data was performed using SPSS 13.0 software. Due to the small sample size, non-parametric tests were used. Wilcoxon signed ranks test was used to compare the measurement of pre- and post-treatment. Also, the Spearman's rho correlation coefficient was used to test the potential relation between variables.

The number of sets of data decreased due to a high drop out rate by the 3rd month follow-up. Eleven subjects had ultrasound measurement and 18 had caliper measurement. These subjects do overlap, that is, the 11 subjects who had ultrasound measurement did have caliper measurement as well. We tested the correlation between the two measurements (subjects who had both ultrasound and abdominal circumference measured) with Spearman's rho coefficient. There is a positive relationship between them at baseline and second treatment but not the rest of the visits. We also tested the correlation between the variation in weight and abdominal circumference with Spearman's rho coefficient and show a positive relationship between the fluctuation in weight and abdominal circumference after second treatment and at 3 months follow-up.

RESULTS

Fifty-three patients were enrolled (51 were females and 2 were males). The median age was 40 years old (range 26–69 years). Areas treated include the abdomen (53 patients) and flanks (33 patients). Based on the abdominal circumference measured, the mean measurement at baseline was 96.6 cm and the mean measurement at 3-month follow-up was 96.2 cm. The mean reduction of fat measured by caliper measurement was 0.13 cm (range 0.76 to +0.68 cm) (Table 1). After three treatment sessions, the mean abdominal circumference increased by 2.03 cm

TABLE 1. The Mean Reduction of Fat Post-Treatment

	Descriptive statistics—caliper (cm)				
	N	Minimum	Maximum	Mean	Standard deviation
Reduction after 1st Tx	41	−0.50	−0.96	0.0598	0.24394
Reduction after 2nd Tx	37	−0.55	1.13	0.1408	0.37682
Reduction after 3rd Tx	23	−0.55	0.75	0.1000	0.34512
Reduction after 3rd month follow up	14	−0.68	0.76	0.1293	0.36180

TABLE 2. The Mean Abdominal Circumference Post-Treatment

	Descriptive statistics—abdominal (cm)				
	N	Mean	Standard deviation	Minimum	Maximum
Baseline	53	91.6491	7.07818	77.90	109.50
After 1st Tx	48	91.1250	6.90176	77.50	107.50
After 2nd Tx	39	92.2949	7.19503	76.00	108.00
After 3rd Tx	25	93.9160	6.67375	81.50	108.00
3rd month follow up	18	93.6833	6.20477	81.50	103.00

(Table 2). Whereas the ultrasound measurement remained approximately the same after three treatments (Table 3). The different results from each method of measurement look incomprehensible. This raises an issue of accuracy. Which method is the best for analyzing a change in body contouring? Potentially, operator error is possible in all three methods and we have tried to be consistent in order to eliminate it. For abdominal circumference, it also depends on how lax or tense the subject's abdomen is at the time. The difference in measurement can be great between a lax and tense abdomen.

According to the measurement from abdominal circumference and caliper, about 22% of the subjects were responsive after one treatment (Table 4). The most striking improvement observed was a 3.80 cm reduction in abdominal circumference 1 month after first treatment (Table 5). The most impressive contouring detected by ultrasound was 1.08 cm reduction after three treatments and 1.13 cm reduction by caliper after second treatment (Table 6).

We tested the correlation between reduction in ultrasound measurement, reduction in abdominal circumference and reduction in caliper measurement at each

TABLE 3. The Mean Abdominal Fat Thickness Measured by Ultrasound Scanner

	Descriptive statistics—USG (cm)				
	N	Mean	Standard deviation	Minimum	Maximum
Baseline	28	2.2452	0.61542	1.51	3.82
After 1st Tx	28	2.2743	0.58326	1.53	3.59
After 2nd Tx	26	2.5915	0.73897	1.26	4.33
After 3rd Tx	16	2.5225	0.53317	1.57	3.45
3rd month follow up	11	2.3909	0.65981	1.56	3.68

TABLE 4. The Change in Abdominal Circumference and Fat Thickness Post-Treatment

	Abdominal, n (%)			Caliper, n (%)		
	Decrease	No change	Increase	Decrease	No change	Increase
After 1st Tx	21 (43.8)	3 (6.3)	24 (50.0)	23 (56.1)	0 (0)	18 (43.9)
After 2nd Tx	13 (33.3)	6 (15.4)	20 (51.3)	24 (64.9)	1 (2.7)	12 (32.4)
After 3rd Tx	12 (48.0)	1 (4.0)	12 (48.0)	14 (60.9)	0 (0)	9 (39.1)
3rd month follow up	4 (22.2)	1 (5.6)	13 (72.2)	10 (71.4)	0 (0)	4 (28.6)

TABLE 5. The Mean Reduction of Abdominal Circumference Post-Treatment

	Descriptive statistics—abdominal (cm)			
	Minimum	Maximum	Mean	Standard deviation
Reduction after 1st Tx	−2.70	3.80	0.0417	1.58031
Reduction after 2nd Tx	−4.50	3.00	−0.2949	1.81760
Reduction after 3rd Tx	−6.00	2.50	−0.2000	2.00624
Reduction after 3rd month follow up	−4.50	2.00	−1.1056	1.83863

TABLE 6. The Reduction of Ultrasound Abdominal Fat Thickness Measurement Post-Treatment

	Descriptive statistics—USG (cm)			
	Minimum	Maximum	Mean	Standard deviation
Reduction after 1st Tx	−1.50	0.91	−0.0885	0.47143
Reduction after 2nd Tx	−1.93	0.93	−0.4276	0.75942
Reduction after 3rd Tx	−1.15	1.08	−0.2427	0.61585
Reduction after 3rd month follow up	−1.10	1.06	−0.2769	0.80775

follow-up with BMI, age, baseline weight, and number of shots per treatment. Based on the data collected after the first treatment, there is a correlation between the reduction in abdominal fat thickness measured by ultrasound and the number of shots per treatment session. The *P*-value is 0.041 (Table 7).

One subject lost 4.3 kg over the treatment period. The rest of the subjects' weights remained constant. Visual improvement in body contour was appreciated in a few subjects (Fig. 3).

Cholesterol and triglyceride levels remained in normal ranges. There is one case of adverse event reported. A female patient, age 28, developed blisters after second treatment. The blisters were located bilaterally, close to the iliac crest. The subject defaulted follow-up as she had to go aboard. Upon returned, she was found to have an ulceration. Skin swab for culture and sensitivity was performed. She was instructed to have daily wound cleansing and dressing. Topical fusidic acid and oral cefuroxime was prescribed. Culture came back to be negative. She was subsequently treated with four sessions of pulse dye laser and kenacort+fluorouracil injection for scarring (Fig. 4). Three subjects had mild erythema after treatment which subsided spontaneously after 30 minutes to an hour. No other adverse effects were recorded.

TABLE 7. The Correlation Between the Reduction in USG and the Risk Factors

Correlation	Correlation coefficient (*P*-value)
Reduction in USG after 1st Tx	
BMI	0.065 (0.763)
Age	−0.178 (0.405)
Weight (baseline)	0.278 (0.189)
Shots (1st Tx)	0.421 (0.041)
Caliper (baseline)	0.378 (0.076)

Subjects rated the immediate pain level, improvement in body contour and overall satisfaction with a score of 1–5, 1 being least painful or effective. On average, 76.5% scored 1–2 for pain and 2.5% scored 5 (Fig. 5). In terms of improvement in body contour, 69.3% thought there was no improvement. No subject scored 4 or 5 throughout the study (Fig. 6). Majority of the subjects reported mild satisfaction with a score of 1–2 only (Fig. 7).

DISCUSSION

Various techniques have been invented for the purpose of improving body that ranged from massage device to a combination of light source or bipolar radiofrequency with message [5–7] While these devices improve cellulite, there is limited data to suggest they can be effective in the removal of localized fat.

The use of focused ultrasound to non-invasively remove localized fat involved mechanical disruption of the adipocytes. Cell debris and fat content, comprised of 80–90% triglycerides, are released into the interstitial space after adipocyte breaks down. It has been suggested that the fat and debris clearance follow the normal physiological pathways following such procedure [8]. Each triglyceride molecule is enzymatically metabolized by endogenous lipases to glycerol and three molecules of free fatty acid. The glycerol, which is water-soluble, is absorbed by the circulatory system and recycled for energy. The fatty acids, which are hydrophobic, are carried by transport proteins or chaperones, predominantly albumin, and trafficked to the

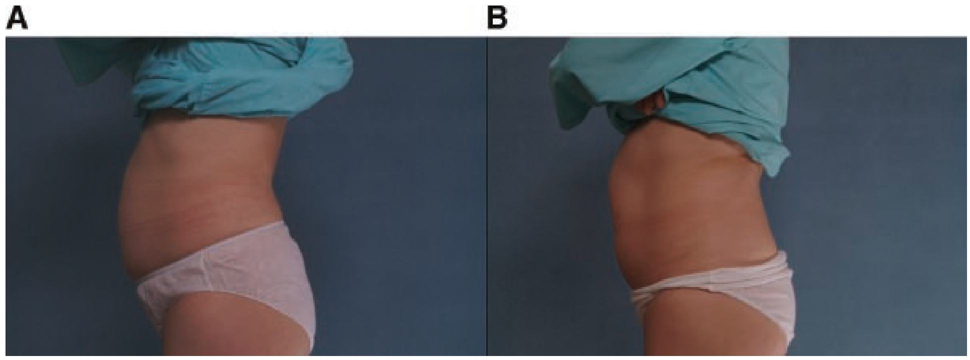

Fig. 3. (**A**) Baseline; (**B**) 1-month post-2nd treatment.

liver, where they are processed as any other fatty acid. Therefore, unlike liposuction or laser assisted lipolysis, the fat destroyed by this non-invasive procedure, is recycled in the body. This is an important issue as unless the treated subjects undergo other measures such as dietary restriction or physical exercise to reduce this recycled fat, the fat will be recycled to other areas ranging from other body part to even the cardiovascular system.

It is worthwhile to point out that ours and others did not find any evidence of systemic abnormalities such as changes in liver function or lipid profile. Nor were there evidences of fat re-distribution as indicated by increase circumference in control areas. However, any change can be too subtle or too transient to be detected by current methods. The implication is that for such non-invasive technique for localized fat removal to be used, other measures including dietary restriction, must be taken to reduce the potential risk of fat recycling.

Only a few subjects had appreciable improvement in contour. Other than one subject, the weights of all subjects remained constant. Our findings differ significantly from previous reports. Interestingly, although the caliper showed some degree of improvement, other measurements showed no improvement. It has been known that the caliper is not the most accurate way of measuring body fat [9]. This is why we took ultrasound measurements as well as the abdominal circumference in this study. Most importantly, the subjects' satisfaction was low and the treatments were given free of charge. This is the major reason for the high drop out rate in our study. The second reason the subjects refused to return for further treatments is that the time required for one treatment session is too long. They are not

Fig. 4. Blister developed post-2nd treatment.

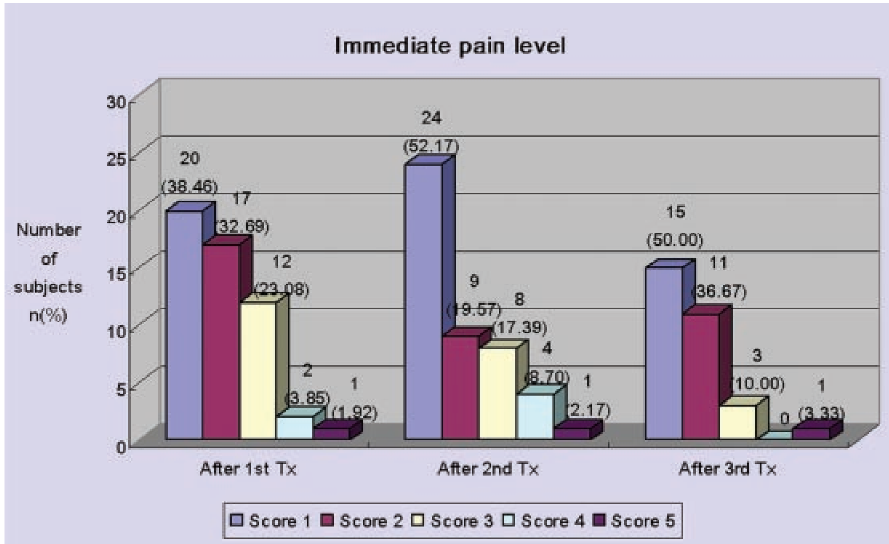

Fig. 5. Subjective assessment of immediate pain level.

satisfied with the result given the amount of time they have invested.

A study conducted in Spain by Moreno-Moraga et al. [3] recruited 30 patients. Each patient undergone three treatments at 1-month intervals. They found that the mean reduction in fat thickness after three treatments was 2.28 ± 0.80 cm while the circumference was reduced by a mean of 3.95 ± 1.99 cm. Another multi-center study [4] (two centers in the United States, one in the United Kingdom, two in Japan) recruited 137 patients who had undergone one treatment. They reported a single contour treatment produced a mean reduction or approximately 2 cm in treatment area circumference and approximately 2.9 mm in skin fat thickness. A possible explanation for such differences in result is the variation of body size. The larger frame and surface area in Caucasians allowed a larger target area to be treated. Even among Asians, there is known variation with northern Asians have bigger body size as compared with southern. With a much smaller body figures, bony areas such as the rib cage and pelvic prominence prevented further treatment. It is therefore likely that threshold existed whereby at least certain percentage of subcutaneous fat needed to be treated before clinical improvement become apparent. Indeed, our study did indicate the greater the number of shots per treatment, the more significant the reduction in ultrasound measurement. Alteration of the device design such as smaller transducer should be able to overcome such issue. Another

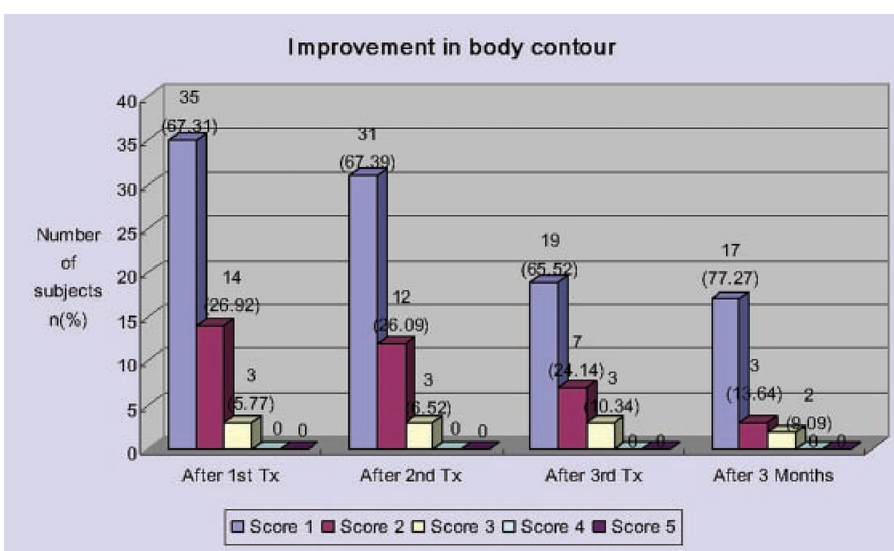

Fig. 6. Subjective assessment of improvement in body contour.

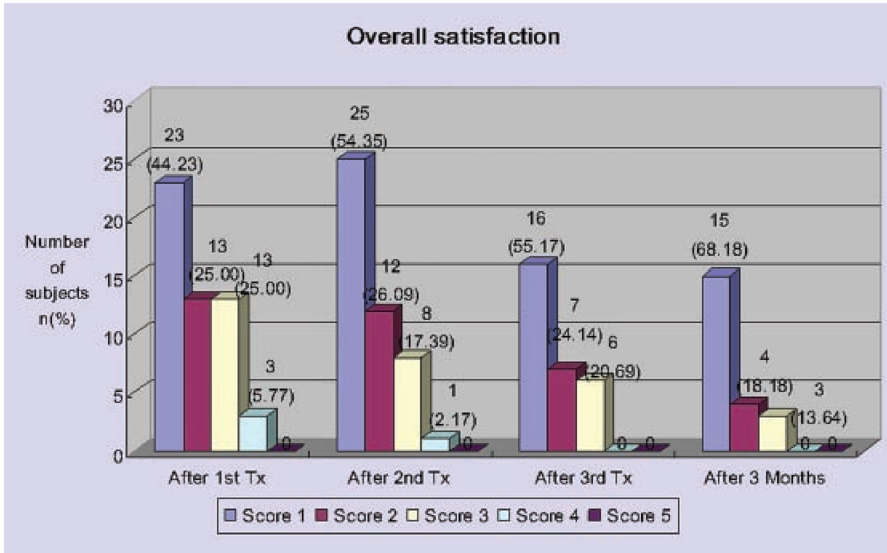

Fig. 7. Subjective assessment of overall satisfaction.

explanation can be that if the fat cells have a greater load of triglycerides at the 1.5 cm energy liberation point, a greater reduction in volume is produced than in the cases with less voluminous adipocytes. If our subjects have less voluminous adipocytes compared to those recruited by Moreno-Moraga et al., this can also explain the lesser volume reduction in our study.

One of the major disadvantages of focused ultrasound is wave reflection. Ultrasound waves are created by compression and rarefaction. The speed of ultrasound does not depend on its frequency. Ultrasound travels faster in dense materials and slower in compressible materials. Ultrasound is reflected at the boundaries between different materials. Ultrasound reflects very well wherever soft tissue meets air, or soft tissue meets bone, or where bone meets air [10,11]. This is why sufficient coupling agent is required to ensure efficient energy delivery into the target area. This also explains why bony areas such as the hip must be avoided. If the transducer is tilted or when patient's positioning lead to alternation of the skin marking, the ultrasound waves can hit a bony surface at an angle leading to wave reflection. This is the likely cause of skin ulceration in our patient with wave reflection form the iliac crest leading to skin injury. Focused ultrasound is safe when delivered to the target area, however wave reflection is not because once reflection occurs, it becomes non-selective. Potential serious issues can occur as if the wave reflection injury other structures rather than the skin. Skin burn due to alterations in the transducer contact membrane is also possible but if this is the case, we would expect to see more lesions as the same transducer was used for the entire abdomen treated.

In conclusion, our study indicated focused ultrasound to be less effective for non-invasive body contouring among Southern Asians. Smaller body figure is a possible explanation. Design modification can overcome this problem and improve clinical outcome. Wave reflection leading to non-selective tissue injury can be an issue. Operators have to take this into consideration and must take all necessary precautions to avoid potential complication.

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