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Body Contouring by Non-Invasive Transdermal Focused Ultrasound

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Background and Objectives: The risks of currently available invasive procedures in body contouring motivate a need for safer, non-invasive technologies for improving the appearance of body silhouette. A new device has been developed that uses focused therapeutic ultrasound to reduce adipose tissue non-invasively. 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.

Study Design/Patients and Methods: A prospective study was conducted on 30 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. Lasers Surg. Med. 39:315–323, 2007. © 2007 Wiley-Liss, Inc.

Key words: body contouring; focused ultrasound; non-invasive lipolysis

INTRODUCTION

Greater demand in body aesthetic medicine for non-invasive procedures has motivated researchers to develop new techniques to replace traditional treatments for body contouring. In the past, the only way to achieve dramatic improvement in body silhouette was by removing local fat deposits through liposuction or other surgical procedures. These surgical approaches have drawbacks for patients (hospitalization, general or tumescent anesthesia, pain, post-operative bruising and swelling, long post-operative recovery, and other risks inherent to surgical procedures) and create technical challenges for surgeons [1–4]. Such drawbacks prompted the development of a new device (*Contour I*, UltraShape Ltd, Tel Aviv, Israel) to reduce subcutaneous fat volume in areas that would normally be treated by liposuction, and to provide significant improvement in the contour of these areas while avoiding invasive techniques and their associated disadvantages.

Ultrasound can be used in medicine as a diagnostic method, when used in imaging, or as a therapeutic modality. The UltraShape™ system applies ultrasound in a therapeutic manner. The system emits focused ultrasound waves to deliver concentrated energy into a focal volume at a precise depth in the subcutaneous tissue. This system was designed to use mechanical (non-thermal) energy to disrupt fat cells and without damaging neighboring structures (skin, blood, and lymph vessels, muscles, and nerves), due to their differential susceptibility to mechanical stresses induced by the ultrasound.

The approach of using non-invasive focused ultrasound for tissue disruption differs from other therapeutic ultrasound devices in important ways (Fig. 1). The first and most obvious distinction is between invasive therapeutic ultrasound, such as is used in internal ultrasound assisted liposuction (UAL), and external therapeutic ultrasound of various types. Among external ultrasound treatments, the approach of tissue or substance destruction should be distinguished from tissue warming. As a rough generalization of currently marketed systems (which are

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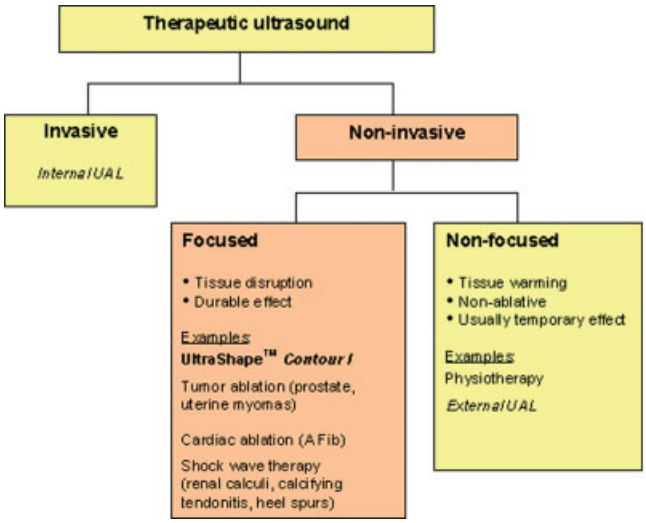

Fig. 1. Therapeutic ultrasound approaches and characteristics. UAL-ultrasound assisted liposuction; A Fib–atrial fibrillation.

predominantly for non-aesthetic applications), most non-invasive destructive or disruptive ultrasound devices use focused ultrasound, whereas devices that warm the tissue are non-focused. For example, shock wave treatments (extracorporeal lithotripsy for renal calculi, orthopedic treatments for calcifying tendonitis and heel spurs) operate by focusing single, very intense pulses of ultrasound energy onto their target and deliver mechanical (rather than thermal) action. They can be very painful and require sedation and/or anesthesia, but their effect (destruction of a substance) is long lasting. In contrast, thermal treatments, which are very commonly used in physiotherapy, are very well tolerated. Such thermal treatments induce temporary vasodilation and increase blood flow, and this mechanism has been proposed to explain their beneficial effects in temporary relief or muscle and joint pain.

A non-ablative thermal treatment would not be expected to have a significant or durable effect on fat. In fact, external non-focused therapeutic ultrasound has been applied to body contouring but was found to be effective only as an adjunct to liposuction, where it is postulated that treatment with external ultrasound after infiltration with tumescent solution improves tissue hydration and distribution of the tumescent solution [5]. Other devices currently marketed for body aesthetics claims (such as temporary cellulite improvement), which act by heating, require numerous treatments (six or more) and generally have short-term effects. In the context of the benefits and drawbacks of previously available therapeutic ultrasound approaches described above, the UltraShape^{TM} system was designed to be non-invasive (to improve upon the risks of UAL) and focused (to provide a fat-disruptive effect, with an expected long-lasting effect), but well-tolerated, for office-based use without the need for any sedation or anesthesia, downtime or recovery period.

Previous clinical studies in Israel, Europe, Japan, and the United States (UltraShape, personal communication) showed that ultrasound lipolysis by UltraShape^{TM} is a safe, painless, non-invasive technique for body contouring of the abdomen, thighs, and flanks, and that it delivers definite measurable results in a single treatment. Our work describes the results obtained on the first patients treated at Instituto Medico Laser with non-invasive focused ultrasound, and evaluates safety and efficacy of multiple treatments with this system.

MATERIALS AND METHODS

Patients

Patients who presented to the clinic during a 2-month period for treatment of localized fat deposits were asked to participate in the study with the UltraShape^{TM} *Contour I*. Thirty patients agreed to participate. Prior to assessment and treatment, all patients received explanations about the technique and read and signed an informed consent. All patients underwent a screening visit including physical examination and blood tests. Areas for treatment were those desired by patients, with at least 2 cm fat thickness measured by caliper. Skin areas with large tattoos or scars were excluded. Fat thickness in the treatment area was assessed with a standard for skin fold caliper and measured to the nearest millimeter. Treated areas were measured with a standard measuring tape. Blood tests included complete blood count and basic chemistry, liver function (transaminases, alkaline phosphatase, and bilirubin), and serum lipids (total cholesterol, LDL, HDL, and triglycerides). Patients with active illness, known malignant or other terminal disease, severe liver disease, or severe hyperlipidemia (defined as total cholesterol $\geq$300 mg/dl or triglycerides $\geq$500 mg/dl) were absolute contraindications for the UltraShape^{TM} procedure.

Patient Preparation and Treatment

Prior to treatment, the region of interest was photographed by a digital camera with the patient standing and at rotating angles, using constant lightning and focal distance. The area to be treated was then marked with a skin-marking pen. Special care was applied to the topographical design of the targeted areas, so that each treatment area represented the target localized fat deposit, as done in standard surgical liposuction procedures (Fig. 2). Before each treatment, fat thickness in the treated area was assessed by a portable ultrasound device and measured to the nearest millimeter, to confirm the minimal fat thickness for treatment of 2 cm and to record pre-treatment fat thickness. The patient was then placed on the treatment bed and positioned carefully to avoid areas that might be under tension due to the prominence of bony structures (mainly on the thighs), as

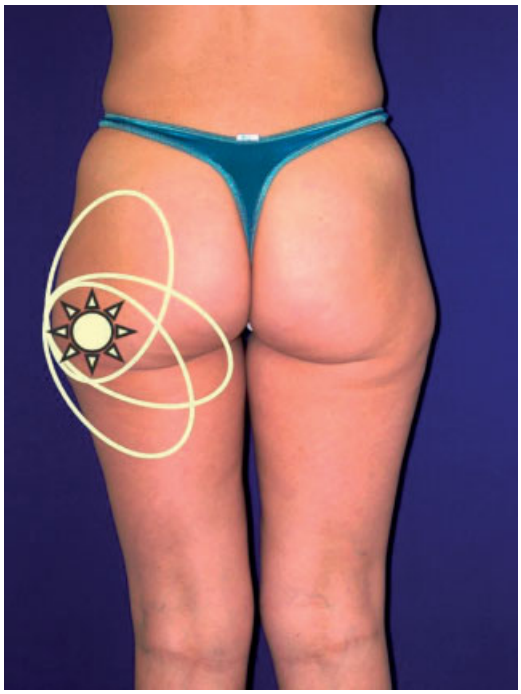

Fig. 2. Marking of treatment areas. Oval areas are marked, covering the fat deposit as an anatomical unit. Each oval drawn represents one treatment session. The resulting overlap leads to greatest effect in the area of greatest fat deposit, with improvement of silhouette of the entire region.

such tension would reduce the fat thickness within the targeted treatment area.

Treatment was then commenced and performed according to the manufacturer's instructions. In areas except the abdomen, patients were treated bilaterally in the same session. The system operated at fixed parameters of frequency 200 ± 30 kHz, acoustic output intensity 17.5 W/cm^2. 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. Treatment was guided by the UltraShape^{TM} *Contour I* real-time video treatment tracking and guidance system. This system guides the operator's movement of the ultrasound transducer over the treatment area, per the pre-programmed treatment algorithm. The system ensures that each spot is treated only once and that each pulse of energy is delivered immediately adjacent to the prior pulse, ensuring even and complete coverage of the treatment area. The tracking system notifies the operator when the treatment area has been completely covered. The area is treated a single time at each session.

At the conclusion of each treatment session, patients were photographed under the same controlled conditions. Post-treatment ultrasound fat measurements were performed by the same ultrasonographer and at the same skin

TABLE 1. Fat Thickness Reduction, Measured by Ultrasound, After Each Session and Cumulative

	Mean (cm)	SD (cm)	Range (cm)
Reduction after 1st session	1.28	0.54	0.40–2.42
Reduction after 2nd	0.56	0.29	0.20–1.80
Reduction after 3rd session	0.44	0.24	0.14–0.99
Cumulative reduction (three sessions)	2.28	0.80	0.68–3.94

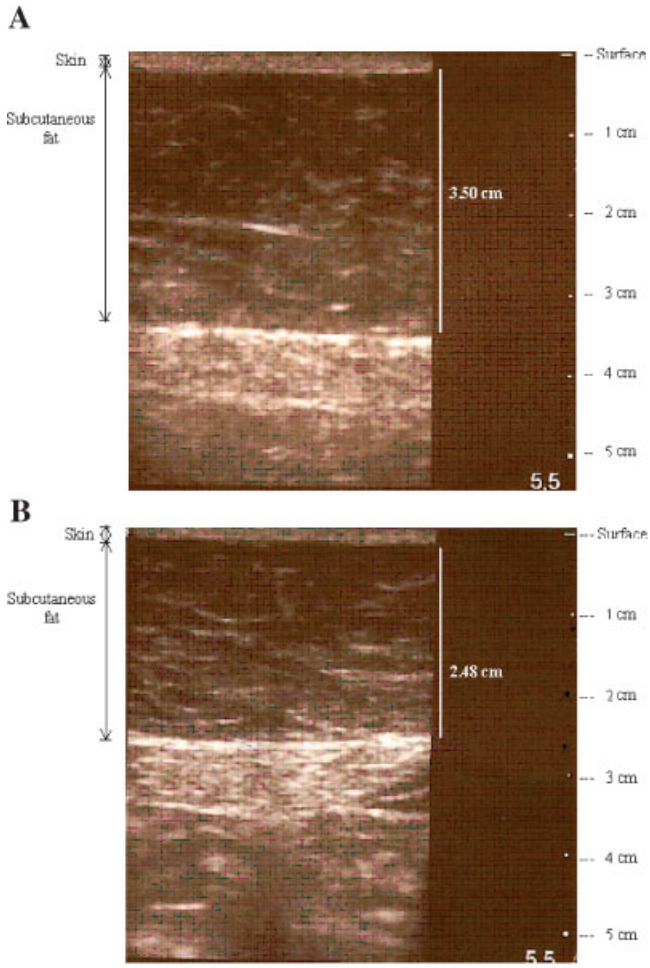

Fig. 3. Fat thickness assessment by ultrasound (**A**) before treatment and (**B**) after treatment.

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

	Final reduction (cm)	
Treatment area (n)	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

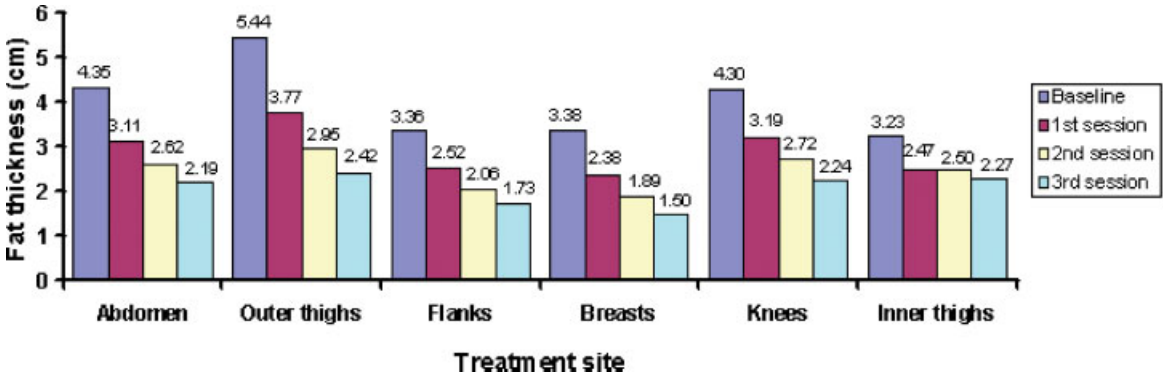

Fig. 4. Fat thickness change by treatment area incremental fat thickness reduction was seen in all treatment sites with multiple treatments. Mean fat thickness at each site is presented.

location at which the pre-treatment assessment was conducted and under constant pressure.

All patients underwent three treatment sessions at 1-month intervals. 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. Patients returned 30 days after the last treatment for an additional circumference measurement and photography.

Efficacy and Safety Parameters

Efficacy was assessed by changes in ultrasound fat thickness and circumference measurements. Weight change was monitored to distinguish weight loss-induced changes in body contour from UltraShape™ *Contour I* procedure-induced improvements in body contour. Body weight was assessed using a digital scale and measured to the nearest 0.1 kg. Safety assessments included clinical signs (adverse effects to skin, pain, etc.) as well as monitoring of liver function and serum lipid levels 1 month after treatment. Liver ultrasound was performed after the third treatment session.

Statistical analysis of data was performed using G-Stat 2.0 ® software (GlaxoSmithKlein, UK). Due to the small size of the sample, the non-normal distribution of the data, and the heterogeneity of the groups, non-parametric tests were used: the Mann–Whitney–Wilcoxon test for comparing two paired variables, the Friedman test for comparisons between three or more measurements, and Kruskal–Wallis for differences between groups. The Wilcoxon test was used for post hoc comparisons, adjusting the critical alpha value using the Bonferroni's inequality ($\alpha' = \alpha/k$, where k is the number of tests undertaken). Results are expressed as the mean and standard deviation ($M \pm SD$), and range. Potential relation between variables was tested using the Spearman's rho correlation coefficient (r_s). Statistical significance was defined as $P < 0.05$.

RESULTS

Thirty patients were enrolled and all completed the study. The group was comprised of 22 females and 8 males, with a median age of 36.5 ± 11.7 years old (range 18–62 years). Areas treated included the abdomen (10 patients), outer thighs (saddlebags, 10 patients), flanks (love handles, 3 patients), inner thighs (2 patients), inner knees (2 patients), and pseudo-gynecomastia (3 patients). Patients who were treated on non-abdomen areas had bilateral treatments at each session length, with re-positioning for each treatment area. All patients were able to resume normal activities upon completion of the session.

The mean pre-treatment fat thickness, as assessed by ultrasound, was 4.44 ± 0.99 cm (Table 1). After one treatment session, the mean fat thickness was reduced by approximately 1.3 to 3.16 ± 0.59 cm ($P < 0.01$). After the second treatment session, an additional reduction of 0.56 to 2.60 ± 0.45 cm ($P < 0.01$), and a third treatment session yielded an additional reduction of 0.4 to 2.16 ± 0.44 cm ($P < 0.01$), for a total mean reduction in fat thickness of approximately 2.28 ± 0.80 cm. A representative ultrasound image pair, showing fat thickness before and after treatment of the abdomen, with a reduction of 1.02 cm, is shown in Figure 3. The greatest reductions were observed in the outer thighs, followed by the abdomen, while the inner thighs exhibited the lowest reductions, but this trend was not statistically significant (Table 2 and Fig. 4). Final reduction of fat thickness correlated positively with baseline fat measurement ($r_s = 0.88$, $P < 0.01$).

After three treatment sessions, the mean circumference reduction was 3.95 ± 1.99 cm (Table 3). The change in circumference was significant relative to baseline ($P < 0.01$).

TABLE 3. Circumference Reduction After Each Session and Cumulative

	Mean (cm)	SD (cm)	Range (cm)
Reduction after 1st session	1.88	1.40	0–5.50
Reduction after 2nd	1.07	0.93	−1.00 to 4.00
Reduction after 3rd session	1.05	0.64	0–2.50
Cumulative reduction (three sessions)	3.95	1.99	1.50–10.00

In addition, the change following each treatment session was significant when compared to the measurement prior to that treatment ($P < 0.01$). The response of different treatment areas is shown in Table 4. There was no statistical difference between circumference change across treatment areas. The reduction in men and women was not significantly different.

Patient weight remained constant over the 3 months of treatment and observation (Table 2). The reduction in treatment area fat thickness without a concomitant reduction in weight strongly suggests that the fat thickness reduction is due to treatment.

Improvements in body contour were visibly appreciable in all patients after three procedures. Patients who had visible improvements after the first treatment had continued improvement after additional treatments, as reflected by the additional reductions in fat thickness reduction and circumference presented in Tables 1–4. In this study, a series of three procedures was pre-determined and was continued, since the fat thickness in the treatment area was not less than 2 cm. In clinical practice, where the aesthetic outcome is the endpoint, the provider and patient will mutually decide when the desired aesthetic improvement is achieved. Pre-procedure and post-procedure photographs, demonstrating significant improvement in body shape in the treated areas, are shown in Figures 5–8. Of note, the untreated areas do not show changes in contours, again supporting the role of the focused ultrasound procedure rather than weight loss in causing the improvement of body contours in the treated areas.

No severe adverse events were reported during and after the completion of the procedure. Two patients reported transient pain during the treatment. One of these patients, who had insufficient acoustic contact oil within the treatment area, developed a few blisters, which resolved fully within 3 weeks. No paresthesias, hematomas, ecchymoses, or edema were noted or reported.

Cholesterol levels remained unchanged during the UltraShape™ procedure (Table 5). Triglyceride levels were mildly increased, and although the change was statistically significant, levels remained within normal limits (Table 3). Liver ultrasound, performed 1 month after the 1st session, was normal in all patients, suggesting that triglycerides released as a result of treatment do no pose a systemic burden that cause fat deposition in the liver.

DISCUSSION

The UltraShape™ focused ultrasound system was designed to apply non-invasive therapeutic focused ultrasound to produce a disruptive mechanical effect on adipocytes in the subcutaneous layer, in order to reduce and improve the contour of localized fat deposits. In our hands, three treatments resulted in a mean reduction of approximately 2.3 cm in fat thickness, as assessed by ultrasound. All of our patients experienced fat volume reductions with noticeable aesthetic results after three sessions. We attribute the local fat thickness reduction and the aesthetic improvement to the UltraShape™ procedure

TABLE 4. Circumference Reduction by Treatment Area

Treatment area (n)	Baseline (cm) M ± SD (range)	Reduction (cm) M ± SD (range)			
		1st session	2nd session	3rd session	Cumulative
Abdomen (10)	96.10 ± 10.35 (80.00–115.00)	2.05 ± 0.95 (0.50–4.00)	1.20 ± 1.16 (0.00–4.00)	0.90 ± 0.66 (0.00–2.00)	4.15 ± 2.30 (2.50–10.00)
Flanks (3)	93.33 ± 4.93 (90.00–99.00)	1.00 ± 0.50 (0.50–1.50)	1.17 ± 0.58 (0.50–1.50)	0.50 ± 0.50 (0.00–1.00)	2.67 ± 0.58 (2.00–3.00)
Outer thighs (10)	102.15 ± 4.63 (96.00–108.00)	2.20 ± 1.49 (0.00–5.50)	0.90 ± 0.99 (−1.00–2.50)	1.50 ± 0.62 (0.50–2.50)	4.60 ± 2.12 (2.00–8.50)
Inner thighs (2)	60.25 ± 3.18 (58.00–62.50)	1.00 ± 0.71 (0.50–1.50)	0.25 ± 0.35 (0.00–0.50)	0.75 ± 0.35 (0.50–1.00)	2.00 ± 0.71 (1.50–2.50)
Inner knees (2)	44.50 ± 2.12 (43.00–46.00)	0.75 ± 0.35 (0.50–1.00)	1.00 ± 0.70 (0.50–1.50)	1.00 ± 0.03 (0.50–1.00)	2.75 ± 1.06 (2.00–3.50)
Pseudo-gynecomastia (2)	112.83 ± 5.01 (109.00–118.50)	2.00 ± 0.50 (1.50–2.50)	1.67 ± 0.29 (1.50–2.00)	0.83 ± 0.58 (0.50–1.50)	4.50 ± 1.32 (3.50–6.00)
Total (30)		1.88 ± 1.40 (0.00–5.50)	1.07 ± 0.93 (−1.00–4.00)	1.05 ± 0.64 (0.00–2.50)	3.95 ± 1.99 (1.50–10.00)

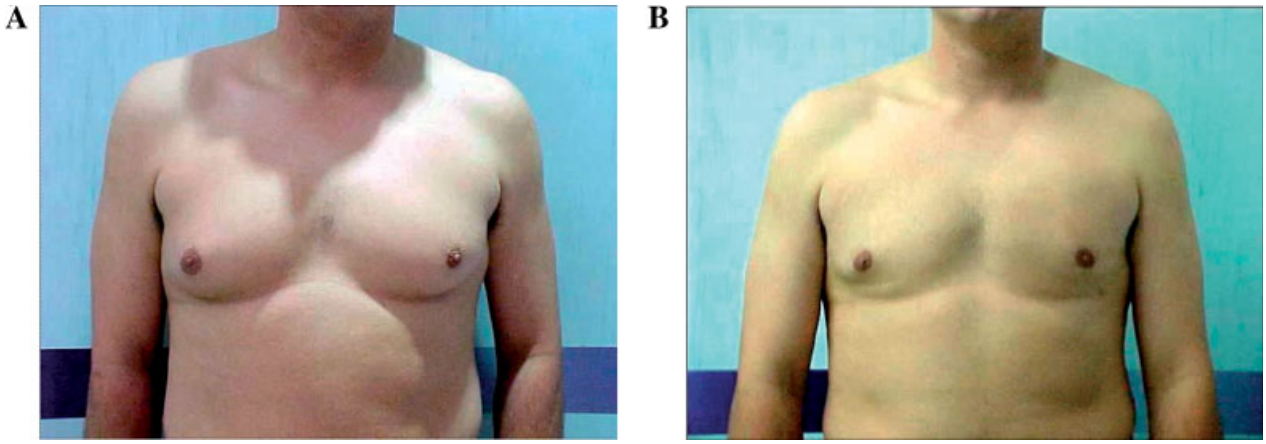

Fig. 5. Pseudo-gynecomastia (**A**) before treatment and (**B**) after treatment.

since there was no statistically significant change in patient weight.

Treatment methodology is critical for achieving good results and assuring that the procedure is well tolerated. A generous layer of the acoustic contact oil must be maintained over the treatment area at all times to ensure safe and efficient energy delivery into and through the skin and to prevent discomfort. In addition, since at least 2 cm of fat must be present in the treatment areas, and since bony protrusions (such as the hip) must be avoided, we recommend strict attention to patient positioning, and suggest the use of cushioned positioning blocks to raise dependent fat areas to the treatment plane and to reduce the convexity of tissue over areas such as the hip.

The size of the treatment area is dictated by the fat deformity and the fat thickness. We marked the treatment area while the patient was standing, so that we could best assess the topography and mark the boundaries of the fat deformity. Using a pinch test, we confirmed that the fat thickness in the entire area was at least 2 cm. The marked area became the treatment area that the tracking system recognized once the patient was positioned on the treatment table. We treated the entire area at each session.

The non-invasive focused ultrasound procedure demonstrated good tolerability and clinical safety. Adverse skin effects were rare (a single instance of blisters, in one of 30 patients and in only one treatment). The absence of seromas and hematomas suggests that the procedure did

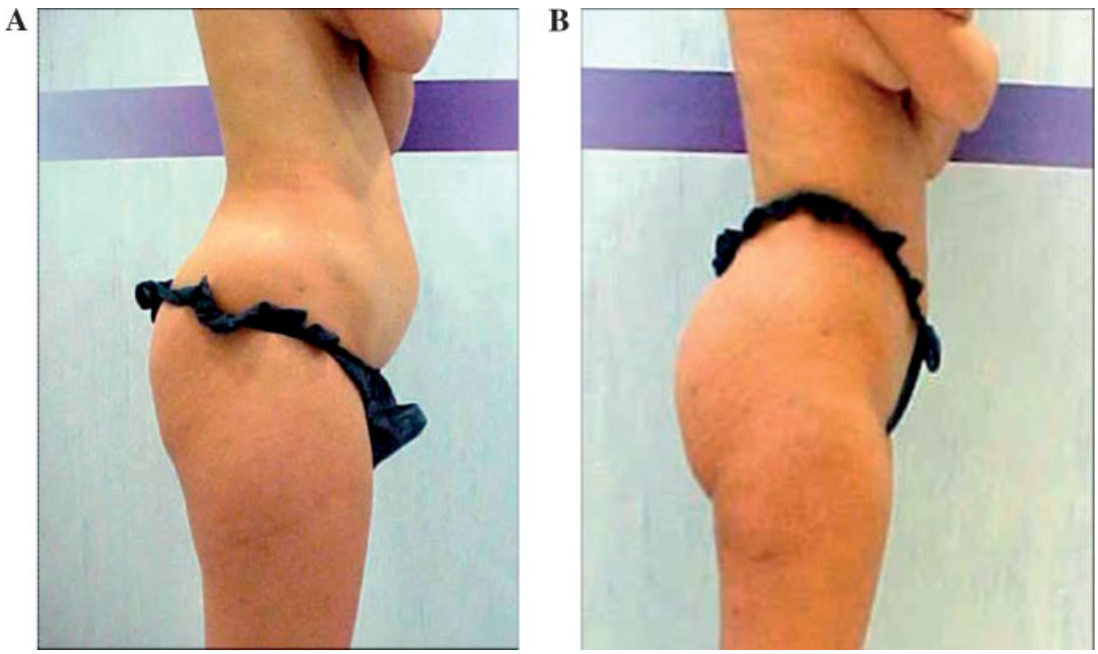

Fig. 6. Abdomen (**A**) before treatment and (**B**) after treatment.

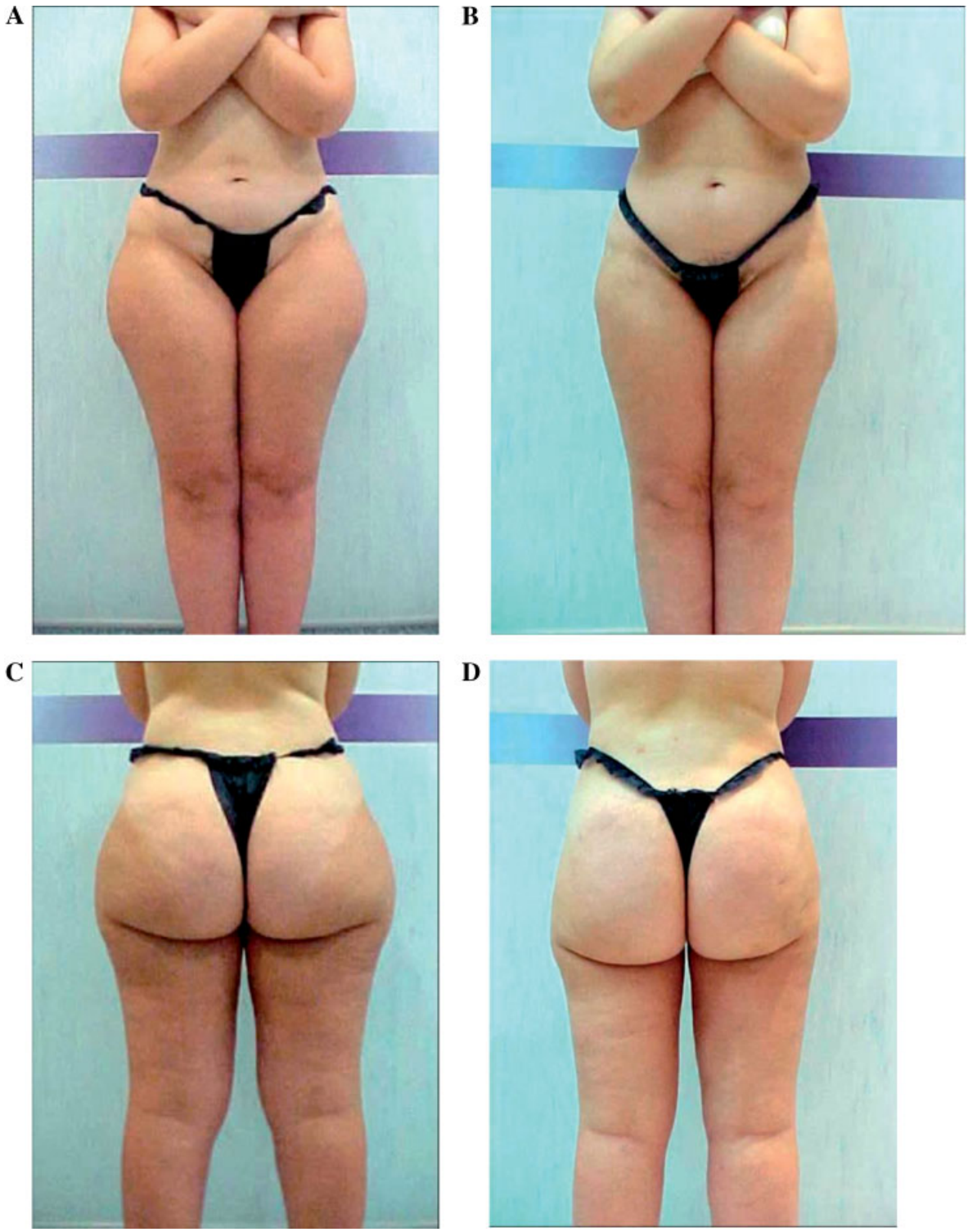

Fig. 7. Outer thighs (**A**,**C**) before treatment and (**B**,**D**) after treatment.

not harm vessels. Serum cholesterol was unchanged. Serum triglycerides were slightly elevated; we consider this result clinically non-significant, as final levels are maintained within normal limits [6]. Importantly, no liver steatosis was detected by post-treatment ultrasound. The stability of lipid profiles during treatment and the absence of fatty liver changes suggest that the UltraShape™ procedure is a safe technique with no detectable adverse

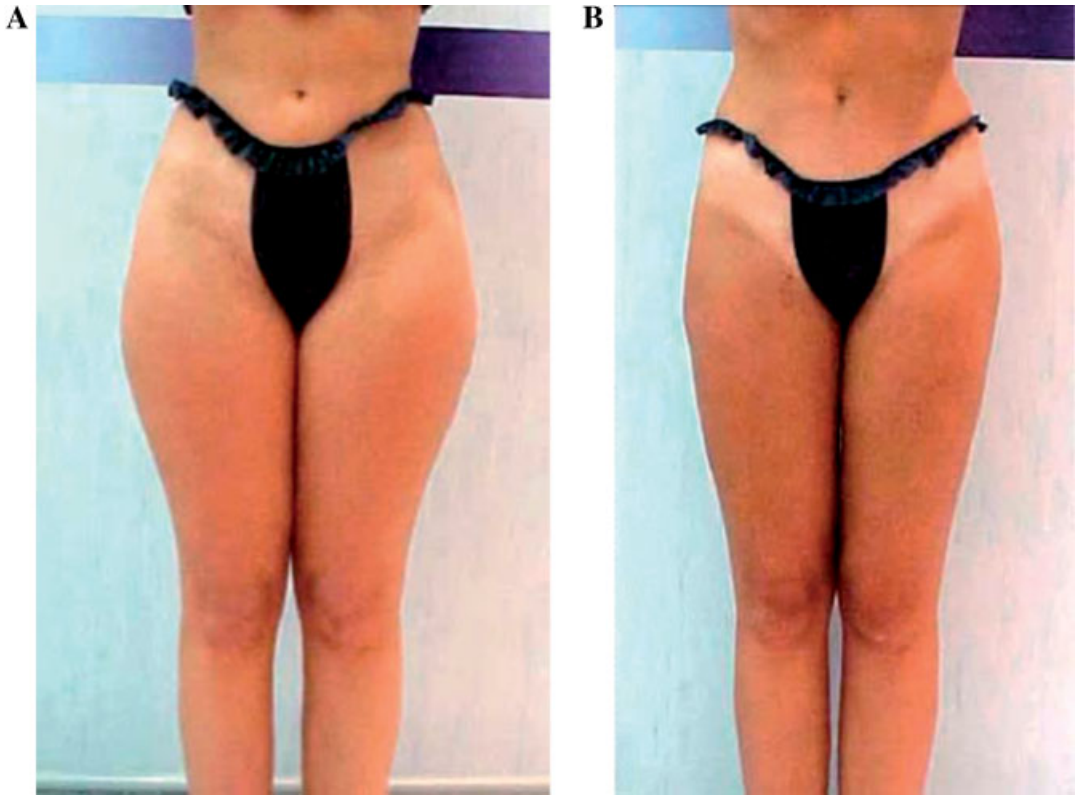

Fig. 8. Outer thighs (**A**) before treatment and (**B**) after treatment.

physiological effects. Fat released from treated areas is cleared by the natural fat metabolism pathways.

We have treated approximately 400 patients with the UltraShape^{TM} system outside of this clinical study, with a total of approximately 1,000 procedures. Most patients desire treatment in multiple treatment areas, and we often treat multiple treatment areas in a single session. While effects are seen after a single session, we do find incremental improvement with additional treatments, as demonstrated in this study. No patients have had severe adverse events. We tailor the size of the treatment area and the number of procedures to the individual patient.

We found in our non-obese patient group (mean weight 66 kg) that there was a positive correlation between fat thickness reduction and baseline fat thickness. However, we do not wish to extrapolate from this that heavier patients are better candidates. Based on our overall experience in the practice, we find the technique very effective for thin individuals who desire treatment of local fat deposits. We do not see the UltraShape device as a treatment for obesity, but rather for improving body contour. We therefore instruct all our patients to maintain a healthy lifestyle in order to retain the effects of treatment.

We conclude that the use of non-invasive focused ultrasound, using the UltraShape^{TM} *Contour I*, is a safe, effective, and well-tolerated non-invasive technique for body contouring, and that it may be considered a non-invasive alternative to conventional liposuction for patients who decline or are not suitable for surgical approaches to body contouring. We suggest three treatment sessions to achieve enhanced results and high patient satisfaction.

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

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