# Non Invasive Ultrasonic Body Contouring – Initial Experience

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## INTRODUCTION

Currently, the only way to induce long term body contouring is by the destruction of fat cells, involving some form of invasive surgery. Surgical removal of fat cells by means of liposuction is becoming an increasingly attractive option for men and women.

The complexity of liposuction procedures, accompanied by the inconvenience to patients, a relatively long recuperation period (contrary to advertisments for a "lunch hour" procedure) and a variety of hidden dangers[1] highlight the pressing need for a method that combines the simplicity and safety of non-surgical methods of body shaping, with the effectiveness of the surgical techniques that ensure effective body contouring.

A novel device for non-invasive destruction of fat cells by focused ultrasound has been developed by UltraShape Ltd. (Tel Aviv, Israel) and is currently being used in clinical trials. The treatment procedure developed by UltraShape is painless and is performed using a topical analgesic cream. These qualities enable carrying out the procedure in an office environment. The treatment is not associated with a period of recovery.

The result is selective fat lysis by breaking the adipocyte membranes with no damage to neighboring structures like skin, blood vessels and peripheral nerves. The fat clearance is performed by the physiological pathways, i.e. the lymphatic, venous and immune systems: the triglycerides from the broken cells are released into the interstitial fluid where they are gradually transported through the lymphatic or venous system to the liver, where they are utilized through the physiologic metabolic pathways, in a process lasting between several hours to days. The capacity of the body to carry away triglyceride molecules is much larger than the amount of triglycerides that are liberated as a result of the treatment. The broken-cells debris is cleared by the normal inflammatory response, i.e., phagocytosis. Both of these breakdown products are transferred safely through the blood.

The safety of the UltraShape™ ***Contour I*** treatment was demonstrated in Bioethical Committee approved studies performed in Israel. The safety - and later on the efficacy - of the ***Contour I*** system were tested on 60 women, who were subjected to abdominoplasty surgery at different intervals, post UltraShape treatment. Histological specimens showed destruction of fat tissue with no damage to adjacent skin, connective tissue, blood vessels or nerves. Clinical observations did not reveal any hematomas or petechiae in the skin or subcutaneous tissues and there was no alteration in skin sensation.

## MATERIALS AND METHODS

Thirty four healthy individuals participated in the study which was performed at my clinic. The study protocol was approved by a local Ethics Committee (Ravenscourt Ethics Committee, London UK). According to the study protocol, only healthy volunteers with no underlying medical conditions and who were not on medication were enrolled to the study. Male to female ratio was 1:2 and there was no racial discrimination in the enrollment. All volunteers underwent a screening visit including medical history, physical examination, blood and urine analyses and liver ultrasonography.

The treatment was carried out on both women (n=16) and men (n=11). The body regions treated included the abdomen (n=13), external thighs ("saddle bags", n=5) and flanks ("love handles", n=9, total= 27). Patients' ages ranged between 18 and 57 (median 41) and their weight ranged between 52 and 110 Kg (median 70.5). EMLA topical anesthetic cream (AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA), was applied for 60 minutes prior to treatment. Castor oil (at room temperature) was applied as a coupling agent during the ***Contour I*** therapeutic session.

The UltraShape treatment lasted 1-2 hours. The treatment was directed by a video tracking & guidance system, an inherent feature of the ***Contour I*** device. The

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(1) Liposuction is associated with a statistical mortality rate of 19.1 per 100,000 procedures that exceeds that of automobile fatalities over a similar population, "Fatal Outcome from Liposuction: Census Survey of Cosmetic Surgeons", F.M.Grazer and R.H.de Jong, *Plast. Reconst. Surg.,* 105: 436-446, 2000.

tracking system records and synchronizes the body's position at which the treatment is to be performed in real-time, according to the pre-mapped calculation of the treatment area. The operator's interface is displayed on the system's LCD. Figure 1 shows the treatment area and the operator's interface, during a typical treatment of the abdomen.

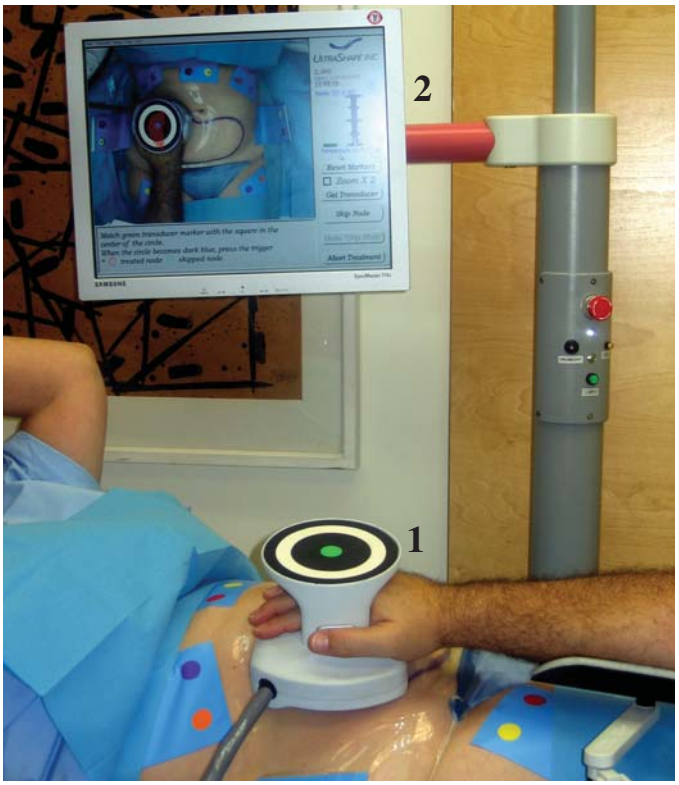


**Fig. 1**: System components: 1- the treatment transducer; 2- the user interface, showing the treatment area

The treatment efficacy measurements were a reduction in circumference of the treated area as demonstrated on days 1, 3, 7, 14, 21 and 28, post treatment. In addition, fat thickness in the treated and control areas was measured by Ultrasound at days 0 (before the treatment), as well as at days 14 and 28 post treatment.

### Treatment Efficacy Measurements

*Circumference measurements* - a special device was developed by UltraShape™ to eliminate any bias introduced by measuring methods due to different levels of pressure applied by the physician when determining the circumference. The measuring tape was placed horizontally, parallel to the floor at a constant height per participant. The circumference of all treated areas was measured at the mid-vertical height of the treated area.

Each patient served as his own control. The weight of the participant and the thighs' circumference in an untreated area were recorded at each follow-up visit. A reduction in the circumference of the treated area, as opposed to no change in the participant's weight and control-area circumference, suggested that the reduction was due to the ***Contour I*** treatment.

*Ultrasonography* - fat thickness in the treated areas was measured by a commercial ultrasound imaging device before treatment, at day 14 and at day 28. A special modification of the standard transducer allows performing the measurement under constant pressure, to assure that fat thickness measurements are not compromised by pressure during the ultrasonography scan.

*Weight measurements* - weight measurements served as an internal control, proving that the reduction in circumference was not due to weight loss.

*Photography* - photographs were taken under standardized distances and camera height, using a 35mm SLR camera positioned on a tripod with a fixed focal length lens. Distance –1.5 meters between the participant and the camera. Camera height was adjusted to the mid-vertical height of the participant's treated area, registered and used in all photography sessions for each participant. The patient was placed on a rotating podium and photographed at 45º increments.

### Treatment Safety Parameters

Blood and urine analysis were performed as part of the screening procedure, prior to the treatment at each follow-up visit during the one month immediate follow-up and the additional two months of post treatment surveillance. The tests included:

1. Blood hematology (complete blood count).
2. Blood biochemistry and endocrinology including: Cholesterol; HDL; LDL; LDH; CPK; Triglycerides – total; Alkaline phosphatase; AST; ALT; Bilirubin – total; Potassium; Urea; Sodium; Albumin; Creatinine and Calcium; Glycerol; ß-HCG; coagulation functions: PT/PTT/INR
3. Urine analysis.

## RESULTS

### Safety

The treatment involved minimal discomfort with no inconvenience reported after the treatment. All participants resumed normal daily activities immediately after the treatment. Only one out of 28 participants presented with a 5 mm blister towards the end of the treatment session, which disappeared spontaneously within 24 hours with no other sequelae.

Liver ultrasonography revealed no pathological changes during a one month follow-up post treatment.

All blood and urine tests were within normal ranges during the entire follow-up period.

### Efficacy

Reduction in circumference in the applicable treated anatomical sites was noted in all participants (Figure 2). There was no gender or racial difference or anatomical site predilection related to the efficacy of the treatment. All participants responded to the treatment as noted by reduction in circumference at the treated areas.

Reduction in fat thickness as measured by ultrasound examination was noted in all treated areas. The results are displayed in Figure 3.

## DISCUSSION

### Safety

No adverse events were encountered during and following the treatment. No sensation of discomfort was noted post treatment. There were no skin hyper/hypo-pigmentation changes post treatment. Subcutaneous fat remained smooth throughout the entire follow-up period. Physical examination during the follow-up was uneventful.

Blood and urine analysis of all participants stayed within normal ranges. Liver ultrasound showed no change in liver status before and at the end of the study, with no fatty infiltration. These tests prove that fat removed from the treatment area is cleared in the regular fat metabolism pathways, with no adverse physiological effects.

Treatment had no influence on participants' daily routine, which remained unaffected from immediately after treatment termination and during the entire follow-up period.

Participants stated satisfactory convenience during the follow-up period.

### Efficacy

Reduction in circumference was observed in all patients. The reduction can be attributed to the treatment since the participants did not lose weight nor did they have a reduction in circumference in the control areas during the entire follow-up period.

Fat thickness, as measured by ultrasonic imaging, showed a statistically significant reduction in fat thickness in the treated areas. There was no significant change in weight of the participants, proving that the measured changes in circumference and fat thickness can be attributed only to the effects of the ***Contour I*** treatment.

It may therefore be concluded that the ***Contour I*** treatment is a safe and efficient solution for non invasive body contouring.

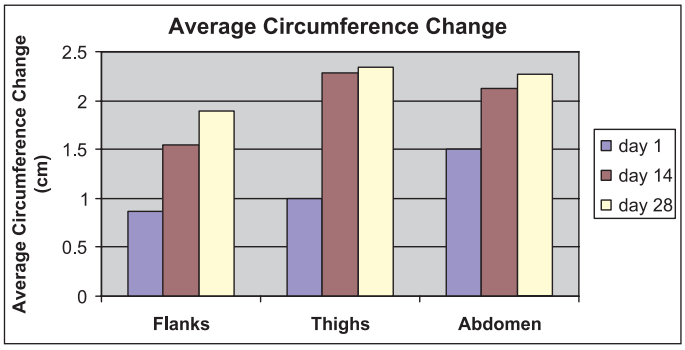


**Fig. 2**: Average circumference change over the follow-up period, for specific treatment zones. Circumferences of the treatment (and control) areas were performed using a specially designed, constant tension, measuring tape.

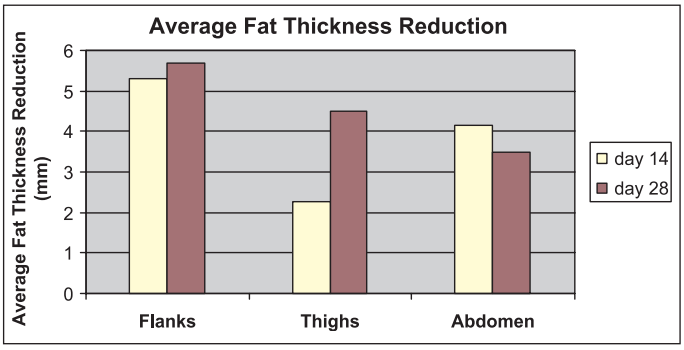


**Fig. 3**: Average changes in fat thickness in different treatment zones. Fat thickness was measured by ultrasound, using a modified transducer which restricts the pressure on the tissue during ultrasonography.

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