Non-Invasive Body Contouring by Focused Ultrasound: Safety and Efficacy of the Contour I™ Device in a Multi-Center Controlled Clinical Study

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MEETINGS AT WHICH THE WORK HAS BEEN PRESENTED

- BAD 85th Annual Meeting, Glasgow, Scotland (July 2005)

- IADC, Paris, France (July 2005)

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- Plastic Surgery, Paris, France (November 2005)

- International Master Course on Aging Skin, Paris, France (January 2006)

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RUNNING HEAD

Non-Invasive Body Contouring by Focused U/S

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PRODUCTS, DEVICES AND DRUGS USED IN THESE STUDIES

- Contour I™ (UltraShape Ltd., Israel)

- EMLA Cream (lidocaine 2.5% and prilocaine 2.5%; AstraZeneca)

- SAS software (SAS Institute, Cary, North Carolina)

ABSTRACT

Background: The removal of unwanted body fat using a non-invasive technique is desirable to patients and physicians. We describe a controlled multi-center clinical trial assessing the safety and efficacy of a focused therapeutic ultrasound device for non-invasive body contouring.

Methods: Eligible healthy adult subjects were enrolled to the experimental or the control group at five sites. The experimental group received one treatment with the Contour I™ device (UltraShape Ltd., Israel) 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 to the untreated group and to an untreated area (thigh) within the treated group. Safety monitoring included laboratory testing (including serum lipids), pulse oximetry, and liver ultrasound.

Results: One hundred and sixty four subjects participated in the study (137 subjects in the experimental group and 27 in the control (untreated) group. A single Contour I™ treatment was safe, well tolerated, and produced a mean reduction of ~2 cm in treatment area circumference and ~2.9 mm in skin fat thickness. The majority of the effect was achieved within two 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.

INTRODUCTION

Body contouring by liposuction is the most frequently performed cosmetic surgery procedure in the United States, with an estimated 455,000 cases in 2005.[1] This number represents less than 1% of the potential pool: 45 million Americans diet every year to improve health and enhance body contour, and even this is a small portion of the one hundred and thirty million Americans who are overweight.[2, 3] Liposuction methodology has evolved over several decades to yield a procedure that is safer, amenable to regional anesthesia or conscious sedation, and can be performed in an outpatient setting.[4-7] Despite the many advances in the liposuction technique, it retains risk and discomfort by virtue of its invasive nature, and post-procedure recovery may require extensive downtime and compression garments.[8] In addition, even when clinically well-tolerated, hemodynamic and metabolic changes occur in the immediate post-surgical days.[9-13]

Ultrasound-assisted liposuction (UAL) accounted for 21% of liposuction procedures in 2005.[1] Internally-applied ultrasound improves the liposuction technique by disrupting adipose tissue.[14-18] This advantage is offset to some degree by the increased technical skill required and the increased risk of injury to the skin at sites of direct contact between the probe and the skin, due to the thermal effects of the currently available ultrasonic probes.

Existing non-invasive and minimally-invasive technologies for improving the appearance of skin and subcutaneous fat appearance, such as deep body massage, radiofrequency, and light-based treatments, have gained popularity due to their minimal downtime, relative safety, and cosmetic benefit in temporary reduction in the appearance of cellulite.[19-22] However, they are suboptimal for body contouring as they provide only modest and temporary circumference reduction, require multiple treatments for effect, provide short-term results, and may require maintenance therapy. Their use is therefore limited to treatment of the superficial

subcutaneous layer for temporary reduction in the appearance of cellulite.[23-25] Furthermore, unlike liposuction, they do not aim to remove excess subcutaneous fat, but rather to tighten the overlying skin or to improve circulation, with theorized secondary effects of reducing edema and mobilizing intracellular fat by inducing biochemical lipolysis in intact adipocytes. There is a need for a technology that provides improved durability.

A method of delivering ultrasound to the fat without depositing significant ultrasound energy in the skin would provide the benefits of ultrasound disruption of fat with greater safety. Furthermore, an ideal non-invasive method of delivering energy would reduce periprocedural morbidity such as infection, scarring, anesthesia-related complications, and other risks associated with surgical procedures.

We describe here the pivotal clinical trial which demonstrates the safety and efficacy of the Contour I™ (UltraShape Ltd., Israel), a non-invasive device for body contouring. This device utilizes pulsed ultrasound at parameters designed to produce non-thermal effects in the subcutaneous fat.

MATERIALS AND METHODS

This pivotal phase II clinical trial, conducted at five centers (2 in the USA, 1 in the UK and 2 in Japan) between August 2004 and June 2005, was approved by the relevant institutional review boards/ethics committees for the protection of human subjects. All participants provided informed consent prior to their enrollment in the study.

Screening and Enrollment

One hundred and sixty four (164) healthy volunteers were enrolled in this prospective, multi-center, comparative study designed to assess safety and efficacy of a single treatment with the Contour I™ system (UltraShape Ltd., Israel) at different body areas (abdomen, thighs, or flanks). One hundred and thirty seven (137 total; 25-30 at each clinical site) participants were assigned to the experimental (treated) group and twenty seven (27; 5-6 at each clinical site) participants to the control (untreated) control group. The male-to-female participant ratio was 1:2. Participants were aged 18-65 years and had subcutaneous fat thickness of at least 1.5 cm in the area to be treated, as measured with a commercial pinch caliper. At the screening visit subjects underwent physical examination and liver ultrasound, and serum was isolated from whole blood via venipuncture for laboratory testing. Individuals with cardiac pacemakers, abdominal wall hernias, pregnancy, diabetes, hepatitis, HIV positivity, coagulation disorders or recent ingestion of anticoagulants, history of exposure to highly fat-soluble compounds, as well as subjects who failed the screening testing were excluded. Females of child-bearing potential were enrolled only if using two methods of contraception. Treatment area assignment was dictated by clinical assessment of each subject by the investigator.

Measurements

Immediately prior to the procedure (Day 0), the area to be treated (abdomen, thighs, or flanks) was marked and fat thickness in the marked area was confirmed by the investigator to be at least 1.5 cm with a pinch caliper. Each participant was weighed and measured for circumference (cm) at the treatment area and at the internal control area (thigh). Circumference was measured via a standardized measuring technique using a specially designed and validated apparatus that provides measurements at a constant height and under constant tension. Ultrasound assessment of fat thickness (mm) was performed with a specially-designed apparatus that held the diagnostic ultrasound transducer on the skin at a constant pressure. Photography was performed with a dedicated 35-mm camera, set at fixed focal length and under constant lighting.

Treatment with the Contour I™

Treatment with the Contour I™

A topical anesthetic (EMLA Cream - lidocaine 2.5% and prilocaine 2.5%; AstraZeneca) was applied under occlusion for 90 minutes before the procedure. The EMLA cream was removed and a skin-compatible treatment oil, provided by the manufacturer, was applied to serve as an acoustic coupling medium. Treatment was applied using a handpiece whose positioning was monitored and guided by the Contour I™ real-time video tracking and guidance system manufacturer's pre-set and unchangeable settings. Pulse oximetry was assessed throughout the procedure. (**Figure 1**).

The experimental group received a single Contour I™ treatment on Day 0. Control values were derived from subjects who were untreated but followed over the time of the protocol. No subject underwent a sham procedure. After treatment, participants were instructed to resume regular daily activities and eating habits to maintain baseline body weights. Follow-up visits for both experimental and control groups were scheduled on Days 1, 3, 7, 14, 28, 56, and 84.

Efficacy Assessments

At each follow-up visit, participants underwent photography, weighing, and measurement of the circumference of the treated and internal control areas. The untreated thigh was used as an internal control to indicate circumference changes that were unrelated to treatment, for example induced by weight loss. Change in circumference was assessed as the difference between circumferences measured at follow-up visits and the pre-treatment circumference. Ultrasound measurements of subcutaneous fat thickness were performed before treatment and on Days 14 and 28.

Safety Assessments

Safety assessments included laboratory testing, pulse oximetry, liver ultrasound, and adverse event monitoring. The laboratory evaluation included complete blood count, chemistry (sodium, potassium, creatinine, urea, calcium), fasting lipids (total cholesterol, HDL, LDL, and triglycerides), liver markers (ALT, AST, LDH, alkaline phosphatase, total bilirubin, albumin), as well as complete urinalysis at all study visits. Pulse oximetry was continuously monitored during treatment and was measured before and after treatment and on Day 1 to assess potential pulmonary adverse effects. Liver ultrasound was performed before treatment and at Day 14 and 28 to identify treatment-induced fatty infiltration of the liver. Two-point discrimination testing was performed at baseline and at Day 28.

Statistical Analysis

Circumference reduction and fat thickness reduction from the three treated body areas were combined for analysis. Data were analyzed using SAS software (SAS Institute, Cary, North Carolina). All tests applied were two-tailed, and a p-value of ≤ 0.050 was considered statistically significant. Within each group, the paired t-test was applied for testing differences between baseline (Day 0) assessment and follow-up assessments for quantitative parameters. The two-sample t-test was applied for testing differences between the treated and untreated study groups for quantitative parameters (fat thickness reduction and circumference reduction, participant demographics). The data were expressed as mean and standard error of the mean.

RESULTS

Subject Disposition and Baseline Demographic Characteristics

A total of 164 subjects participated in the study: 137 were treated and 27 were untreated. Overall, 96 females and 41 males received treatment, and 21 females and 6 males were untreated. No significant differences in subject baseline characteristics were observed among all study centers. The proportion of experimental and control subjects was similar across study centers. Assessments of demographic and baseline parameters (age, weight, height, BMI, and fat thickness by ultrasound) showed no statistically significant differences between the experimental and control groups (Table I). The distribution of participants across treatment area groups (abdomen, flanks and thighs) is summarized in Table II. Only females underwent treatment in the thigh area. The control group for thighs was composed only of women.

Efficacy of the Contour I™ in Circumference Reduction

A single treatment resulted in a mean circumference reduction of 1.9 cm at 12 weeks, with a response rate of 82% (Figure 2). In the experimental (treated) group the mean circumference reduction from baseline was significant at all time points except Day 1 ($p<0.001$ on Days 14, 28 and 84; $p=0.223$ Day 1). Approximately 77% of the observed circumference reduction occurred within 14 days of treatment. The response of the abdomen, thighs and flanks was comparable: there was no statistically significant difference in the mean circumference reduction at each of these treatment areas (Table III). The response of males and females was similar, with a mean circumference reduction of 1.8 cm in females and 2.2 cm in males on Day 84 ($p=0.368$). Responses across the five clinical sites were comparable ($p>0.100$ at all time points).

In the control group, circumference reductions were combined for comparative analyses to the experimental group. When compared to the control (untreated) group, the circumference reduction in the experimental group was significant at all time points, except Day 1 ($p<0.001$ on Day 14 and Day 28, and

$p<0.006$ on Day 84; $p=0.227$ on Day 1). Within the control group, no statistical differences were observed in the mean circumference reduction from baseline (Figure 2, $p=0.149$ at Day 84).

An untreated thigh area served as an internal control area for the treatment area in the same participant for both the treated and untreated group. This internal control was included to indicate circumference changes that were unrelated to treatment, for example induced by weight loss. No statistical differences were detected between the experimental and control groups for circumference reduction of the internal control area at all time points ($p=0.195$ at Day 84). As shown in **Figure 3**, in the experimental group, the treated area circumference was significantly reduced ($p<0.001$ at Day 84) relative to the internal control area circumference at all time points except Day 1. No statistically significant weight reduction was observed in the treated or untreated group ($p=0.288$ at Day 84).

Photographs of six participants are depicted in Figure 4. A post-treatment response in the lower abdomen of a male participant is shown in panel A. At Day 28, circumference at the abdomen was reduced by 4.5 cm from baseline measurement while his weight remained stable during the study time period. (+0.2 kg relative to baseline. A female participant experienced a reduction of 4.0 cm in circumference of the upper thighs at Day 28, with a small change in weight (-2.5 kg) (panel B). In panel C, the post-treatment flank contour of a male participant had a reduction of 3.5 cm in circumference, with a small increase in weight (+1.8 kg). Panel D demonstrates reduction in the flanks of a female participant, with a -2.6 cm reduction with a small weight loss of 1.8kg at Day 28. In panel E, a female had her abdomen treated and a 3.4 cm reduction was measured; she had a 2.1 kg weight loss during the 28 days. Panel F is of a male participant who had an abdominal reduction of 3.0 cm in circumference at Day 28, with a change in weight (-3.1 kg).

Fat Thickness Evaluation

In the experimental group the fat thickness was reduced from baseline by 2.6 mm on Day 14 and by 2.9 mm on Day 28 ($p<0.001$ for both Day 14 and Day 28; Figure 5). Approximately 85% of the reduction in fat thickness occurred within 14 days of treatment. **Figure** shows a representative sonogram, demonstrating a 4 mm reduction in fat thickness at Day 14. No statistical differences were observed in the control group ($p=0.368$ at Day 14 and $p=0.246$ at Day 28). Responses across the five clinical sites were comparable ($p=0.037$ at Day 14 and $p=0.068$ at Day 28).

Safety

The treatment is safe and well tolerated, and no clinically significant treatment-associated changes in laboratory values were observed. Notably, no treatment-induced elevations in serum lipids or lipoprotein levels were detected (data not shown). Pulse oximetry readings during the treatment and at Day 1 were within normal range (94-99% O_2 saturation). Analysis of liver ultrasounds showed no treatment-induced changes. No clinically significant changes in two-point discrimination were observed.

No serious adverse events were reported throughout the study. Seven localized adverse events were observed during the treatment session, and no further events were reported during the follow-up period. All adverse events were related to the treatment procedure and were anticipated. One participant reported a mild tingling sensation during treatment, which resolved immediately upon completion of treatment. Three participants were noted to have mild erythema, which resolved by the Day 1 follow-up visit. One participant developed sparse purpuric lesions which resolved by the Day 7 visit. Two participants developed small blisters. Of these, one resolved within three days; the other progressed to a dermal erosion and was treated with topical antibiotics. At the Day 84 visit, the erosion was healed with mild residual erythema.

DISCUSSION

Our clinical study shows that the Contour I™ as the first non-invasive focused ultrasound technology for body contouring is safe and effective. These results were consistent among five international clinical sites with a total of 164 subjects. The devices were preset with a single power setting and one treatment protocol, and all clinical sites had control subjects. All principle investigators were trained by the manufacturer prior to initiation of the study.

This focused ultrasound procedure reduced the circumference in the treated areas. Average reduction in the circumference was ~2 cm in the abdomen, thighs and flanks. The reduction in circumference was corroborated by a reduction in fat thickness, as assessed by ultrasound measurement. The majority of the effect – 77% of the circumference reduction and 85% of the fat thickness reduction – was seen within the first 14 days after treatment, and additional reduction was seen over the following weeks. The effect was maintained for at least the study period of 12 weeks after a single treatment. Neither the control group nor the internal control area exhibited significant reduction during the 12-week study follow-up. Reduction in circumference could not be correlated with weight loss, as no statistically significant weight reduction was observed in the experimental or control group.

The procedure was well tolerated. Ninety two percent of treated subjects reported that they experienced minimal or no discomfort during or after the procedure (data not shown). In the clinical studies, a topical anesthetic cream (EMLA) was applied 90 minutes prior to treatment. In post-trial experience, in countries where the device is commercially available, we have performed numerous treatments without EMLA and found it to be equally well tolerated. UltraShape has confirmed that pre-treatment with EMLA is not required.

Physical examination and laboratory assessments throughout the study period demonstrated no clinically significant changes. No subject withdrew from the study due to treatment-associated events at any study site.

Of importance, assessment of hepatic function revealed no changes in serum transaminases, LDH, alkaline phosphatase, bilirubin, albumin, PT/PTT, or plasma lipids. Liver ultrasound at Day 14 and Day 28 showed no increase in liver fat content. No hematomas, seromas, or ecchymoses were seen, and hematocrit and hemoglobin remained stable, suggesting no significant bleeding. No leukocytosis was observed. Pulse oximetry, performed during the procedure and one day after the procedure to assess potential pulmonary events, revealed normal oxygen saturation. There was no clinically significant change in two-point discrimination. No hyperpigmentation or hypopigmentation was reported. Fat texture in the treated area remained smooth, with no nodules or irregularities in texture reported.

No adverse and seven adverse events were observed during the treatment. These were mild and were anticipated as outlined in the consent form. One patient was treated on the thigh, where the subcutaneous fat over the greater trochanter was very thin, and where the ultrasound could potentially be reflected from the bone. Erythema, the most common event (three out of seven), was painless and resolved within hours.

This new technology from UltraShape utilizes focused ultrasound to deliver a finite amount of acoustic energy at a controlled distance from the ultrasound transducer in order to achieve non-invasive body contouring. Ultrasound energy is emitted from a hemispherical transducer (Figure 7). In this geometry, the energy is low near the transducer surface and is concentrated in an additive manner at a distant focus. The transducer is placed directly on the skin and focuses the energy at the depth of the subcutaneous fat. As a result, the energy can be delivered through the skin, with low energy density at the epidermis and dermis, and with a high energy density in the subcutaneous fat. The ultrasound energy is delivered in pulses, using parameters that provide a non-thermal effect. High levels of ultrasound energy within the subcutaneous fat can disrupt adipose tissue safely and effectively, as has been demonstrated in ultrasound-assisted liposuction.[14, 15]

A unique central tracking and guidance system provides a crucial element of safety and quality control. A real-time video image of the treatment area is displayed on the LCD monitor. The tracking component captures the region of interest and generates a treatment algorithm, such that each spot is treated once and only once. The tracking system does not allow a pulse of energy to be delivered outside the region that the physician marked prior to initiating the treatment, obviating the potential for accidental treatment in undesired areas.

All patients resume normal activities immediately after treatment, without downtime, pain, or compression garments. The procedure is performed as an office-based procedure, without the need for additional equipment, garments, or medication. The procedure time ranges from 60-120 minutes depending on the size of the treatment area. The ease of the device operation along with the real-time video tracking and guidance system make the procedure amenable to use by physicians or properly-trained medical staff, under medical supervision. Physician expertise is required, however, for patient selection and marking of treatment areas, as well as determination of medical eligibility for treatment.

There is a challenge in presenting an approximate change of a mean reduction of 2.3 cm for the abdomen, 1.8 cm for the flanks and 1.6 cm for the thighs with digital images. This post-treatment change represents a small change in the percentage of total body circumferences in these population groups. However, the change in circumferences after treatment was quantifiable and significant compared to the control group and to baseline values. In addition, the majority of subjects reported overall satisfaction with their results (data not shown).

A single treatment dose was used to show safety first and then efficacy. The response rate, as assessed by reduction in treatment area circumference, was 82%. The factors that may have contributed to non-response are not defined but may include weight fluctuation, body fluid levels, physical activity levels post-treatment, etc. Furthermore, one must note that the treated areas were not mapped out for maximal circumference

change. The treated areas were marked in the same fashion as used for lipoplasty. For example, if maximal abdominal circumference change was the endpoint, then the "fat handles" of an individual would have been treated. Multiple treatments could provide additional benefit for subjects with more excess fat (fat thickness greater than 1.5 cm).

What is actually happening to the fat released from the treated adipocyte? Where does it or the byproducts of its dissolution go? This clinical protocol was designed to monitor known metabolic pathways of fat metabolism (fatty liver, plasma triglycerides, lipoprotein lipid levels, and free fatty acid levels). In all of these parameters, no clinically significant level in any of these endpoints was observed after treatment. The body has a tremendous capacity to move water-insoluble fat as documented by fat-loading challenge tests. Future studies will examine the relative clearance rates of triglycerides and the hydrolytic products (water soluble glycerol and albumin-bound free fatty acid). There are no other metabolic pathways in which fat is handled by the body that are related to any known clinical problem.

CONCLUSIONS

This clinical study is the first assessment of the safety and efficacy of non-invasive focused ultrasound in an aesthetic application, to the best of our knowledge. Focused ultrasonic body contouring is an ideal procedure for patients who would require small or moderate amounts of adipose tissue removal over time using single or multiple treatments or who otherwise would not be considered for large volume liposuction procedures.. Future clinical studies will provide insights into whether greater fat reduction can be achieved through various treatment algorithms, in conjunction with weight loss strategies or other aesthetic technologies to treat obesity related fat depots.

Greater application of this technology in body contouring will be achieved by performing clinical trials to assess whether serial treatments produce incremental fat reduction. Future clinical studies will provide insights into whether greater fat reduction can be achieved through various treatment algorithms, in conjunction with weight loss strategies or other aesthetic technologies to treat obesity related fat depots.

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Figure Legends

Figure 1. Treatment area (abdomen) homogeneously covered by individual treatment nodes, as guided by the Contour I™ real-time video monitoring and guidance system. During treatment, a video camera captures the treatment area and the transducer in real time and guides the user, by means of graphic overlays displayed on the system monitor, to place the transducer on the next treatment spot ("node"). The nodes homogeneously cover the treatment area, which is detected by the system, without overlap and without extension beyond the marked boundaries of the treatment area. This image is a screen-shot of the treatment area as it appears at the completion of treatment, when the entire area has been evenly covered with individual nodes (red circles).

Figure 2. Mean circumference change from baseline in the experimental and control groups. The effect of a single Contour I™ treatment on circumference reduction from baseline at each study visit point (baseline and days 1, 3, 7, 14, 28, 56 and 84) for the treated and untreated groups is shown in this graph. The number of treated participants evaluated at each time point from Day 1 to 84 was: 133, 130, 132, 132, 127, 115, 118; the number of untreated participants evaluated at each time point from Day 1 to 84 was: 27, 26, 27, 26, 26, 25, 23. The mean circumference reduction in the treated group was 1.9 cm ±0.2 at Day 84 (12 weeks). In the treated group, the circumference reduction from baseline was significant at all time points, except Day 1 ($p<0.001$ on Days 14, 28 and 84). There were no statistical differences in circumference reduction from baseline in the untreated group. Overall, there were statistical differences between the treated and untreated group at all time points, except Day 1 ($p<0.001$ on Day 14 and Day 28, and $p<0.006$ on Day 84).

Figure 3. Changes in control parameters: internal control area and weight – Mean circumference change of the treated area vs. mean circumference change of the internal control area (thigh). Circumference changes from baseline at the treated area and the internal control area, within the same subject, in the treated group is depicted in this graph. The circumference of the treated area was significantly

reduced relative to the internal control area at all time points except Day 1 ($p<0.001$ at Day 84). The circumference reduction of the treated area and internal control area were similar between baseline and Day 1 and therefore are shown on the same line.

Figure 4. Response to a single Contour I™ treatment of the abdomen. Panel A. Male, treatment area: abdomen; Panel B. Female, treatment area: thigh; Panel C. Male, treatment area: flanks; Panel D. Female, treatment area: flanks; Panel E. Female, treatment area: abdomen;

Figure 5. Fat thickness reduction: Mean fat thickness reduction from baseline, assessed by ultrasound, in the experimental and control group. Change from baseline of fat thickness, as measured by ultrasound, at Days 14 and 28, in the treated and untreated group is depicted in this graph. In the treated group, fat thickness was statistically reduced by 2.6 mm on Day 14 ($p<0.001$) and by 2.9 mm on Day 28 ($p<0.001$) relative to the baseline measurement. No statistical differences were observed in the untreated group ($p=0.368$ at Day 14 and $p=0.246$ at Day 28).

Figure 6. Fat thickness reduction: Sonogram of representative fat thickness assessment. Fat thickness at baseline and 14 days after treatment shows thinning of the subcutaneous fat layer from 17 mm to 13 mm (reduction of 4 mm). This participant was treated on the flanks.

Figure 7. Cross-section of the Contour I™ transducer. (Courtesy of UltraShape Ltd.)

TABLES

Table I. Subject baseline characteristics by study group for age, weight, height, BMI, and fat thickness

	Treated			Untreated			
Baseline Characteristic	**N**	**Mean**	**SEM**	**N**	**Mean**	**SEM**	**p value**
Age (years)	27	41.3	2.02	137	40.1	0.95	0.587
Weight (kg)	27	66.5	3.44	137	68.3	1.48	0.609
Height (cm)	15	160.4	1.42	84	163.9	0.93	0.129
BMI (kg/m^2)	15	22.3	1.11	84	23.8	0.42	0.195
Fat thickness (mm)	23	24.5	1.83	111	24.7	0.88	0.936

Participant baseline characteristics by study group for age, weight, height, BMI, and fat thickness (by ultrasound). These characteristics were not statistically different between treated and untreated groups. SEM – standard error of the mean.

Table II. Distribution of study groups by treatment area

	Treatment Area			All
	Abdomen	Flank	Thigh	
Experimental	56 (80%)	47 (85%)	34 (87%)	137 (84%)
Control	14 (20%)	8 (15%)	5 (13%)	27 (16%)
Total	**70 (100%)**	**55 (100%)**	**39 (100%)**	**164 (100%)**

Study group distribution by treatment area. The participant distribution across treatment areas in the experimental group was: 41% abdomen, 34% flank and 25% thigh. Only females underwent Contour I™ treatment in the thigh area. The participant distribution across treatment areas in the untreated group was: 52% abdomen, 30% flank and 18% thigh. Only females had thigh measurements.

Table III. Circumference change by body site treated

Treatment Area	Circumference Change (cm)	SEM
Abdomen	-2.3	0.32
Flanks	-1.8	0.31
Thighs	-1.6	0.39

Circumference change in each of the treatment areas at Day 84. The difference between treatment sites was not significant (p=0.366). SEM – standard error of the mean.

Figure 1

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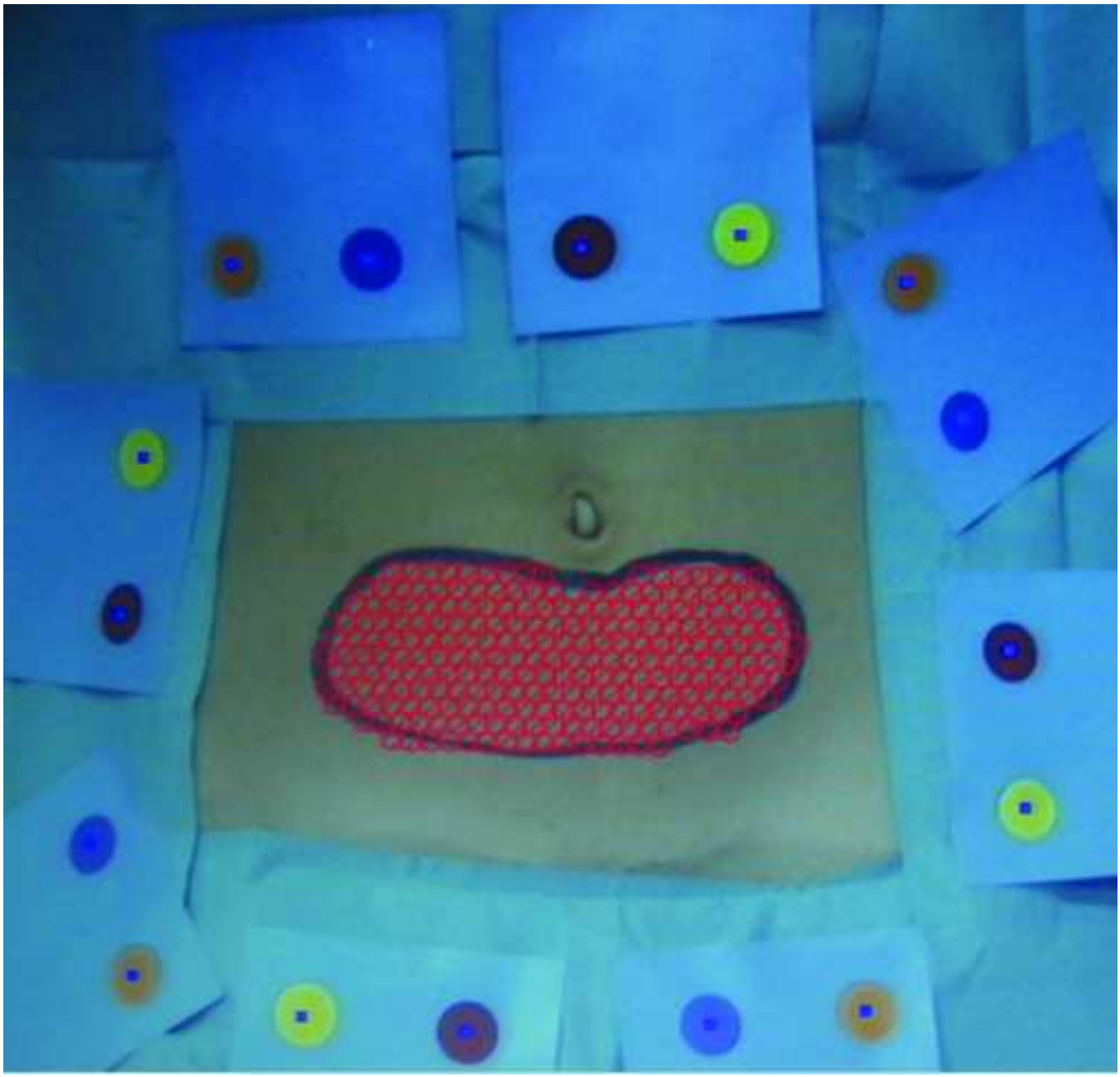

Figure 2

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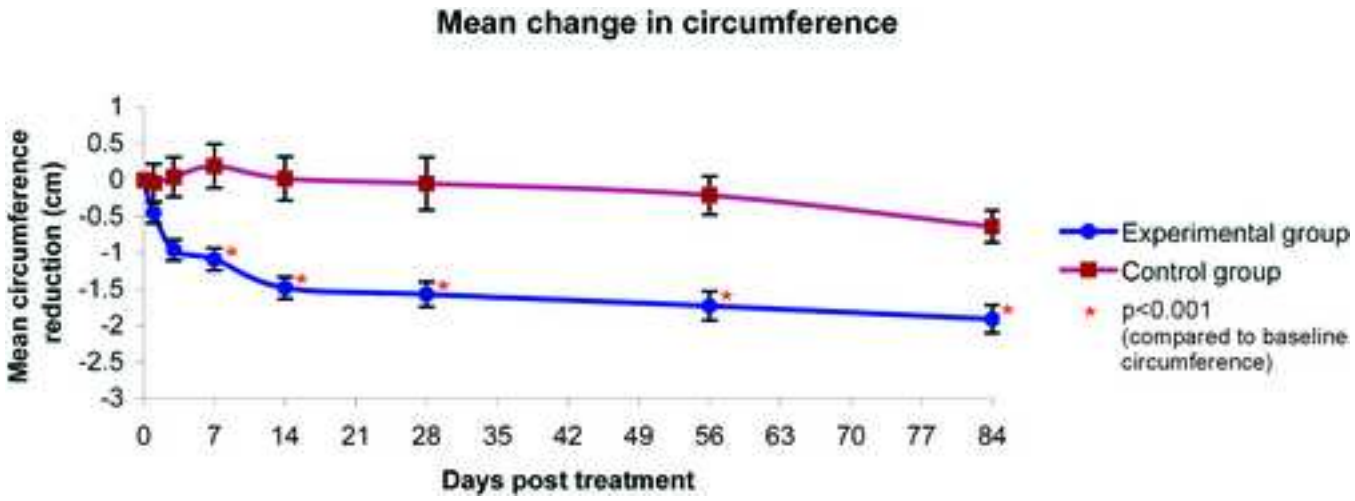

Figure 3

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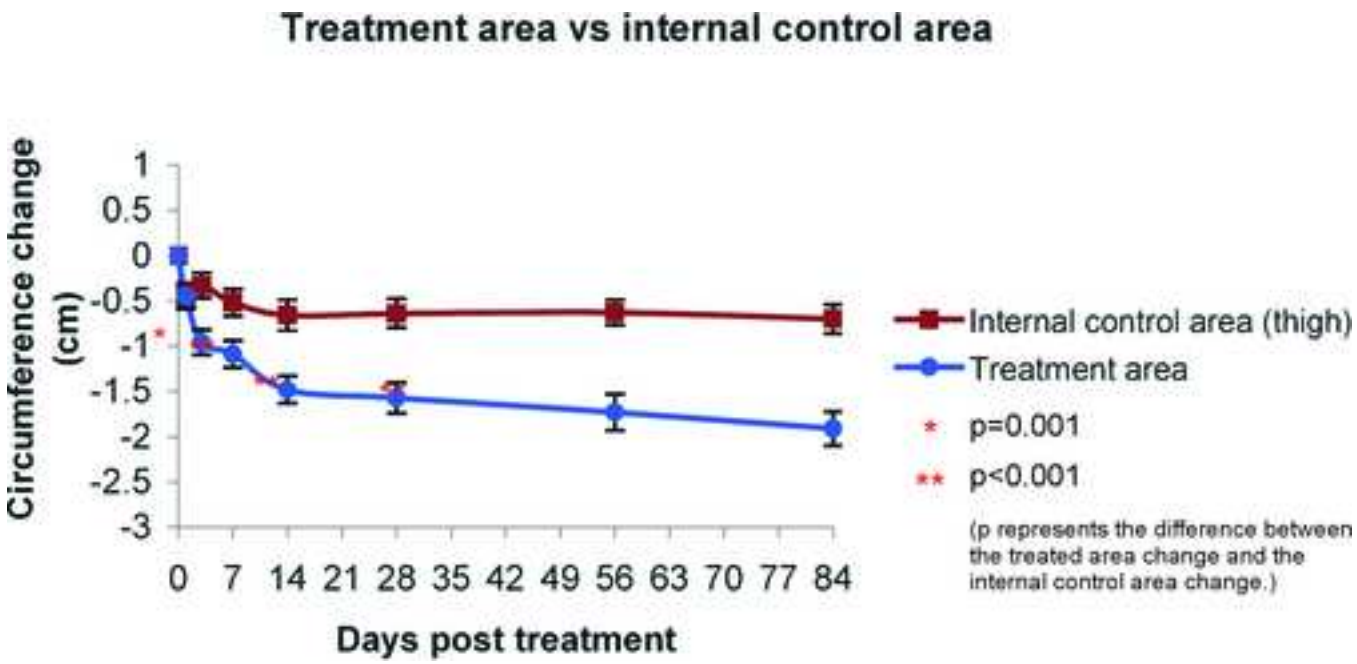

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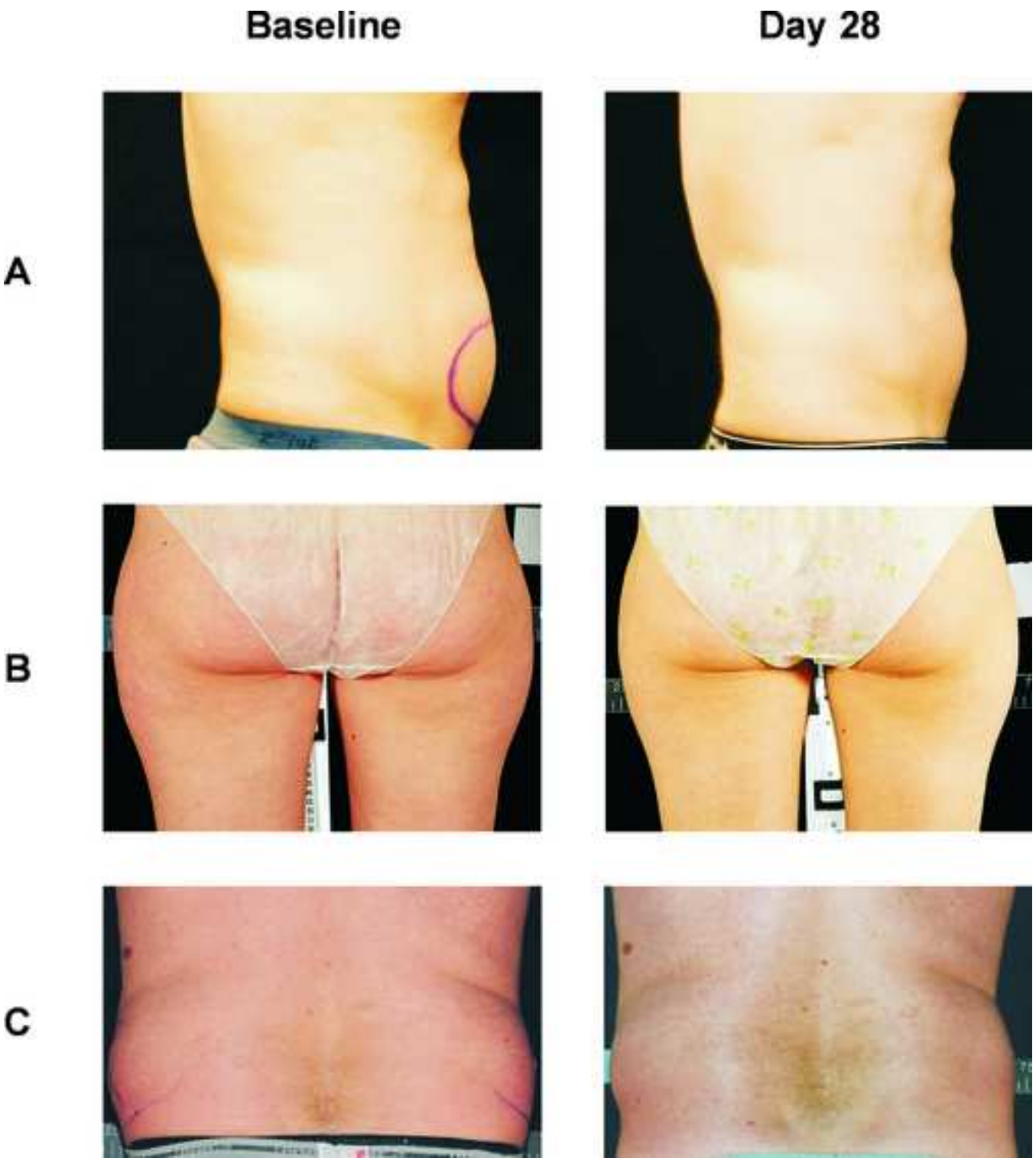

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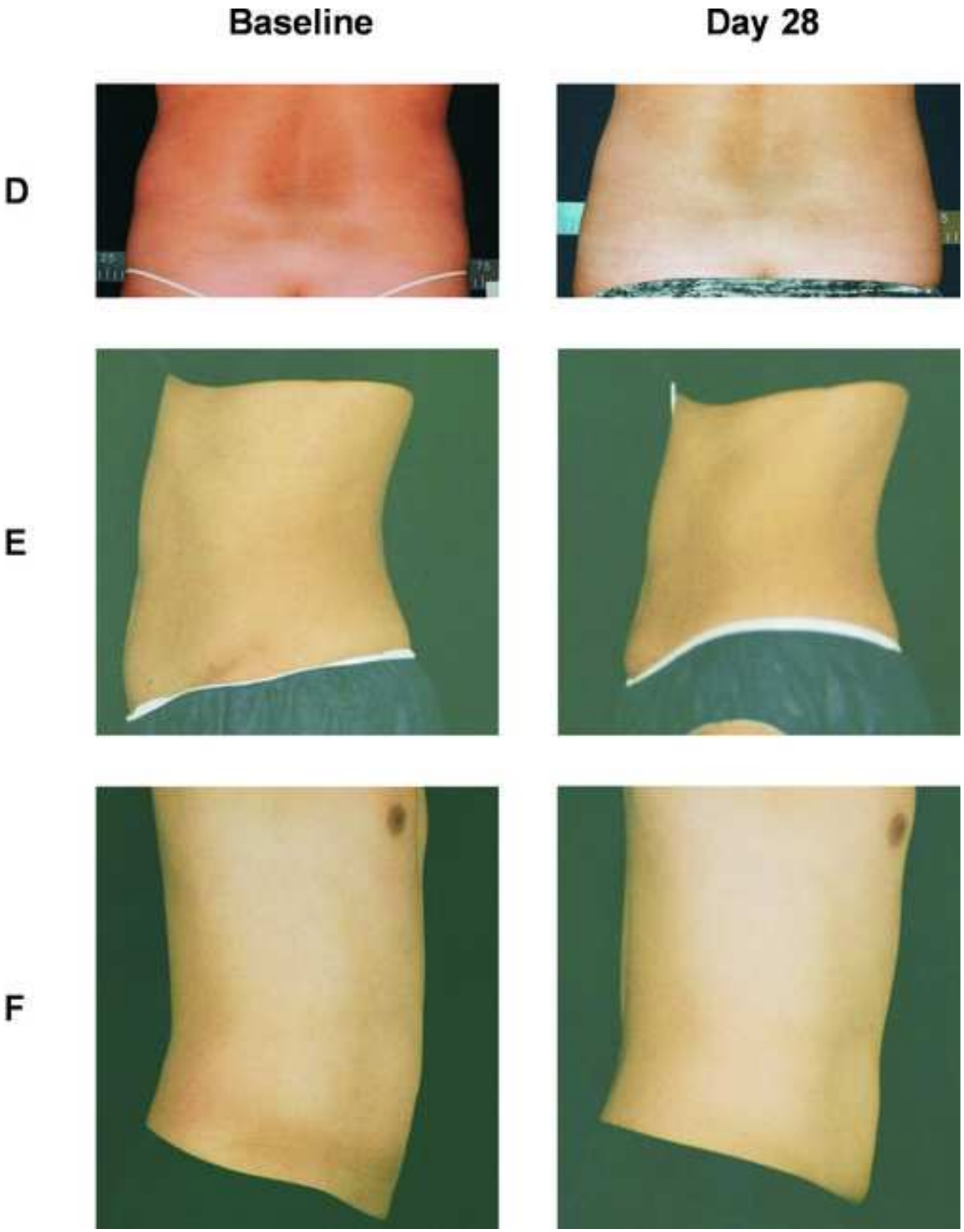

Figure 5

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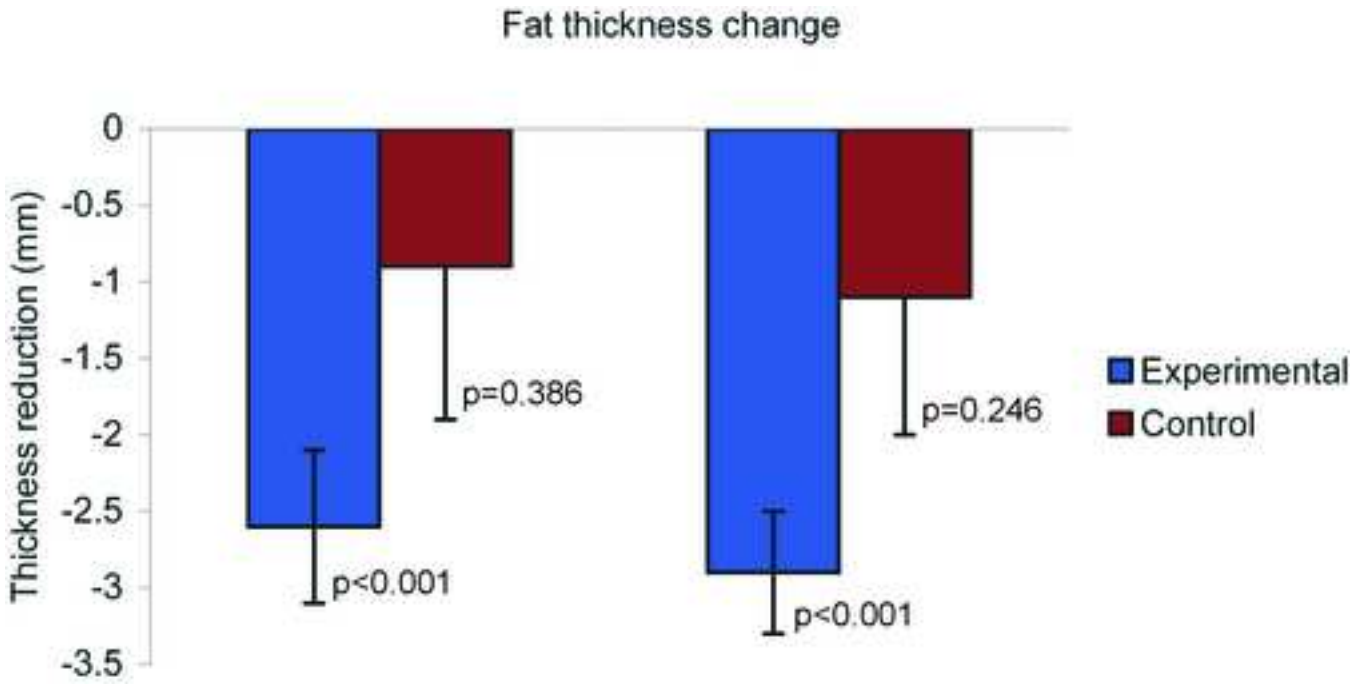

Figure 6

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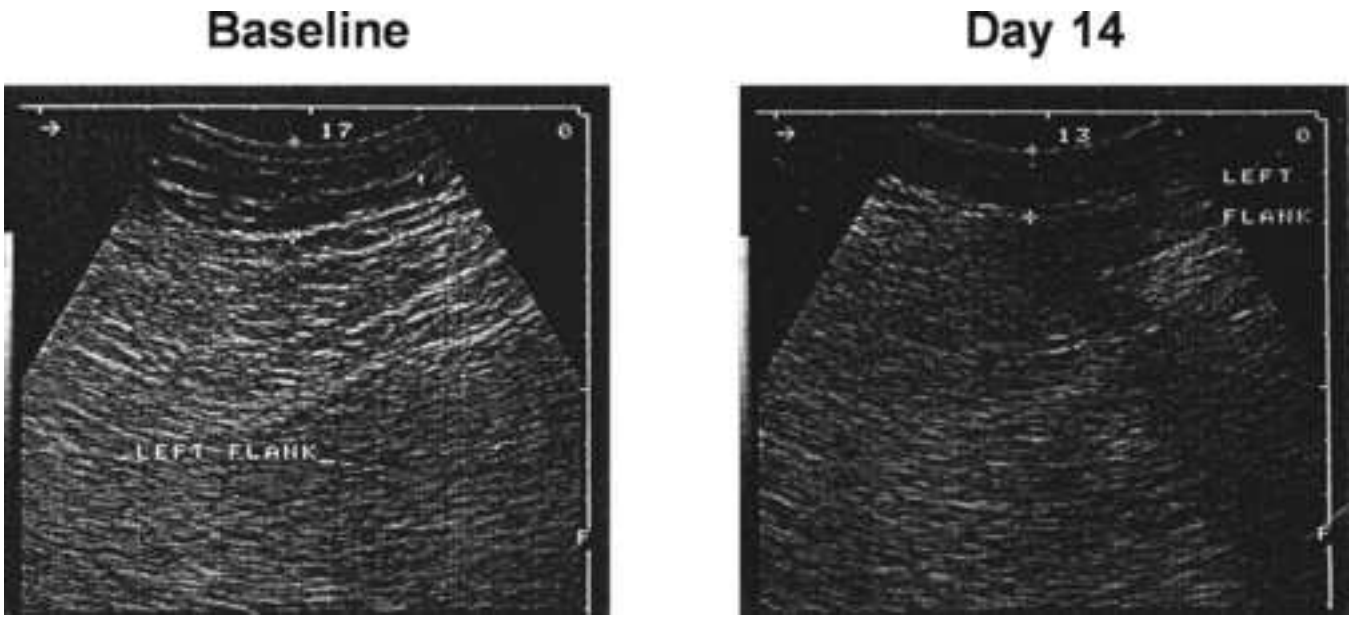

Figure 7

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