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BACKGROUND: The removal of unwanted body fat using a noninvasive technique is desirable to patients and physicians. The authors describe a controlled, multicenter, clinical trial assessing the safety and efficacy of a focused therapeutic ultrasound device for noninvasive body contouring. **METHODS:** Eligible healthy adult subjects were enrolled to the experimental group or the control group at five sites. The experimental group received one treatment with the Contour I device (UltraShape Ltd., Tel Aviv, 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 with the untreated group and with an untreated area (thigh) within the treated group. Safety monitoring included laboratory testing (including serum lipids), pulse oximetry, and liver ultrasound. **RESULTS:** One hundred 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 and well tolerated and produced a mean reduction of approximately 2 cm in treatment area circumference and approximately 2.9 mm in skin fat thickness. The majority of the effect was achieved within 2 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. **CONCLUSION:** The Contour I device provides a safe and effective noninvasive technology for body contouring.

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