

High-Intensity Focused Ultrasound Slims Waists, Study Finds

BY MIRIAM E. TUCKER

FROM THE ANNUAL MEETING OF
THE AMERICAN SOCIETY FOR
LASER MEDICINE AND SURGERY

GRAPEVINE, TEX. – High-intensity focused ultrasound body contouring was both objectively and subjectively superior to sham treatment for reducing waist circumference in a randomized controlled trial of 180 adults who sought removal of excess abdominal fat.

“High-intensity focused ultrasound is a noninvasive, effective, and well-tolerated option for body contouring,” said Dr. Jeremy B. Green of Skin Care Physicians, Chestnut Hill, Mass.

The patients were enrolled at nine clinical sites. They were aged 18-65 years, with subcutaneous abdominal adipose tissue depth of 2.5 cm or greater but with body mass indexes no greater than 30 kg/m².

The majority (80%) were white women, with an average

weight of 70 kg and BMI of approximately 25 kg/m². They were randomized to one of three groups: a “low-energy” HIFU dose of 141 J/cm² (three passes of 47 J/cm²), a “high-energy” dose of 177 J/cm² (three passes of 59 J/cm²), or a sham control using three passes with 0 J/cm².

The primary outcome was mean change from baseline waist circumference at 12 weeks post treatment.

In the per protocol population of 168 patients, there were significantly greater least squares mean reductions of 2.5 cm with the high-energy treatment and 2.1 cm with the low-energy treatment, compared with a drop of 1.2 cm in the sham group. (Subjects had agreed not to change their diet or exercise.)

There were also significantly greater waist circumference reductions for the high-energy HIFU at 4 weeks (1.8 cm vs. 0.2

VITALS

Major Finding: In the per protocol population of 168 patients, there was a significantly greater least squares mean drop of 2.5 cm with the high-energy treatment, compared with a drop of just 1.2 cm in the sham group.

Data Source: A randomized controlled trial of 180 adults with excess abdominal fat.

Disclosures: The study was funded by Medicis Technologies, which manufactures the HIFU device called Liposonix.

cm with sham) and for both energy levels at week 8 (2.6 cm with high-energy and 2.6 cm with low-energy vs. 0.9 cm with sham).

Significance was achieved for the primary outcome with the high-energy treatment and some of the secondary outcomes in the intent-to-treat population of all 180 enrolled patients, he noted.

Subjective aesthetic assessments by both investigators and patients were consistent with the primary outcome measure. Investigator Global Aesthetic Improvement Scale (GAIS) rat-

ings were significantly improved compared with sham treatments for both energy levels at weeks 4-8.

At 8 weeks, investigators deemed two-thirds of the patients as “much improved” or “improved” with both high- and low-energy HIFU, compared with just 19% for sham treatment, Dr. Green reported.

On patient satisfaction questionnaires, 58% treated with the low-energy and 67% with high-energy HIFU reported being “satisfied” or “very satisfied” at week 12, compared with 48% of those who received sham treat-

ment. The difference was statistically significant for the high-energy HIFU.

Adverse events included pain during and after the procedure, ecchymosis, and edema. Six of the 180 enrolled patients did not complete the treatment because of pain. However, more than two-thirds of each group reported just mild or no pain, and all resolved by 16 days. Half of the active treatment patients had mild bruising, all of which resolved in 10-14 days. There were no unanticipated adverse events. Clinical laboratory tests did not reveal any abnormalities or fluctuations with regard to lipid profiles, markers of inflammation, coagulation, hepatic or renal function, hematologic assessments, or blood chemistry, he reported.

Patients were compliant in maintaining their pretreatment diet and exercise habits, and there were minimal weight fluctuations during the study. ■