Discussion: Randomized Sham-Controlled Trial to Evaluate the Safety and Effectiveness of a High-Intensity Focused Ultrasound Device for Noninvasive Body Sculpting

Jennifer M. Capla, M.D.
J. Peter Rubin, M.D.
Pittsburgh, Pa.

Will liposuction become obsolete? Fueled by the success of effective minimally invasive and noninvasive treatments for aesthetic management of the face, the quest for effective nonsurgical body contouring technology continues at a robust pace. To date, no noninvasive body contouring treatment has assumed a prominent role in plastic surgery practice. Jewell et al. present data from a randomized controlled trial to demonstrate the efficacy of a high-intensity focused ultrasound device for reducing subcutaneous fat deposits. This study is a thorough investigation of the LipoSonix high-intensity focused ultrasound technology (Medicis Technologies Corp., Scottsdale, Ariz.), demonstrating both safety and efficacy in a blinded prospective trial. The authors are to be commended for collecting well-controlled data to test the effect of this device.

According to the 2010 report of plastic surgery statistics from the American Society of Plastic Surgeons, the number of patients seeking cosmetic minimally invasive procedures has increased from 5,500,446 in 2000 to 11,561,449 in 2010.[1] This 110 percent increase is indicative of patients seeking the "quick fix" that allows them to improve areas of concern with decreased downtime and minimal risk. At 203,106 cases, liposuction is still one of the top five cosmetic surgical procedures performed in 2010, and while it is touted as "minimally invasive," many technologies have been explored in an effort to improve body contour and tighten skin with less recovery and risk.

In Jewell et al.'s article, we see data from a multicenter, randomized, sham-controlled, single-blinded trial of 180 patients designed to determine the effectiveness of high-intensity focused ultrasound on trunk aesthetics. The primary outcome measure was reduction in waist circumference at 12 weeks. In patients treated at the highest energy level (59 J/cm^2) in the "per protocol" group, in which maximal effect was seen, there was a statistically significant decrease in waist circumference of 2.52 cm compared with a decrease in the sham control group of 1.21 cm. One potential source of error in this study is the use of a standard measuring tape to determine waist circumference.[2] Other modalities, such as three-dimensional photography or magnetic resonance imaging assessment, may be considered for future studies.[3] In particular, magnetic resonance imaging will show precise changes in the thickness of the abdominal subcutaneous tissues after treatment. A major challenge in the evaluation of noninvasive body contouring treatments is establishing standard methods of assessment that can provide accurate and reproducible results. One other variable that may affect the results presented in this article is that the patients in this study population did not respond as well as other patients might have. Indeed, a prior high-intensity focused ultrasound study of 282 patients by Fatemi, one of the current authors, revealed an average circumference reduction in the abdomen and waist of 4 to 5 cm.[4]

While effective, the change in waist circumference induced by high-intensity focused ultrasound is relatively small compared with that in the sham-treated patients. This leads to two important questions. First, why does the sham group have a waist reduction of 1.21 cm? Second, how does high-intensity focused ultrasound fit into our aesthetic armamentarium?

With regard to the changes in the sham group, the authors stated that patients agreed to maintain their current diet and exercise regimens without any changes during the study period. In their Discussion, the authors do suggest that this decrease in waist circumference in control subjects may be

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related to unintended consequences of asking patients to pay attention to their diet and exercise habits. Despite our best efforts in asking our patients to comply with requests *not* to change their lifestyle, the placebo effect may be strong enough to induce subconscious changes in activity that favor tightening of the trunk muscles. It may have become a self-fulfilling prophecy that our patients, once treated with a device intended to improve their waistline, will adjust their lifestyle in accordance with the image they desire. Although it is impossible to regulate a patient's lifestyle changes during a study period of 12 weeks, a diary of diet and exercise habits implemented both before and after treatment might have provided some insights into the changes seen in the sham group.

How high-intensity focused ultrasound fits into our aesthetic practice depends on whether patients will consider that it is worthwhile to undergo a safe 45-minute office treatment, followed by 7 to 10 days of mild discomfort and up to 16 days of edema and bruising, to achieve a decrease in waist circumference of a little more than a centimeter. The authors performed a patient satisfaction survey at week 12 that revealed interesting points. In evaluating the change in abdominal contour in the group that received the higher-energy LipoSonix treatment, 68.4 percent rated an improved or much improved score, compared with 23.4 percent of the sham group subjects. Clearly, patients within the treatment group noticed a change, but only 50 percent of this treatment group reported being satisfied with the results. Although not evaluated in this study, it is possible that repeated treatment with this device may lead to further improvement.

This technology, in its current form, will not make liposuction obsolete. It may, however, meet the demands of well-selected patients seeking less invasive procedures that can help with their "trouble spots." Rather than take away from the pool of patients undergoing liposuction, this technology may bring a new group of patients to the plastic surgeon's office who would not ordinarily have presented for evaluation and treatment. Because many patients presenting with a request for high-intensity focused ultrasound may be candidates for liposuction (even after their initial ultrasound treatment), it is imperative that board-certified plastic surgeons embrace noninvasive body contouring technology. Most assuredly, noncore aesthetic practitioners will be interested in this technology and may use this as a gateway to offering more invasive body contouring procedures.

J. Peter Rubin, M.D.
University of Pittsburgh
Suite 682, Scaiffe Hall, Plastic Surgery
3550 Terrace Street
Pittsburgh, Pa. 15261
rubinjp@upmc.edu

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