Fat Removal Alternatives Can Be Disappointing

BY DIANA MAHONEY

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BOSTON — Noninvasive fat removal is now technically possible, but media hype of new devices may lead to unrealistic expectations.

"We can absolutely remove fat without breaking the stratum corneum [using the new devices], but it's important to put context to this," Dr. Mathew M. Avram said at the American Academy of Dermatology's Academy 2009 meeting.

"While [the devices] are effective, the technology is truly limited at this point. There is a long and deserved reputation of snake oil salesmanship in the field of fat, so it is essential that we assess the new tools critically," said Dr. Avram of Harvard Medical School and Massachusetts General Hospital, Boston.

Focused ultrasound, high-intensity focused ultrasound, radiofrequency, and,

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most recently, cryolipolysis have shown promise as nonsurgical options for trimming fat from the hips, thighs, abdomen, and buttocks, but they are limited in what they can achieve, said Dr. Avram.

Focused ultrasound, for example, uses mechanical energy to target subcutaneous adipose tissue and break up fat cells, which are then flushed out through the liver, he said.

Clinical studies of patients treated with focused ultrasound, which has not yet received FDA approval for this indication, have demonstrated circumference reductions of 2-3 cm at the thighs, flanks, and abdomen with no associated lipid or liver function abnormalities after three treatments.

"The findings are limited, however, because none of the studies used an untreated control group for comparison and all relied on change in circumference as an outcome measure, which is an imprecise measure of improvement. To truly show a reduction in the fat layer, you really need to use MRI, which is expensive, or high-resolution ultrasound—neither of which were done in these studies." The commercial device that uses this technology is used around the world except in the United States, he said.

High-intensity focused ultrasound devices similarly target and ablate subcutaneous fat while leaving the epidermis, dermis, and surrounding tissue unharmed, but they do so by inducing thermal versus mechanical fat injury, said Dr. Avram.

The efficacy of this method of body contouring, which has also not yet received FDA approval, has yet to be demonstrated in clinical studies.

Unipolar and bipolar radiofrequen-

cy-based, nonsurgical skin tightening devices, which many clinicians use for "nonsurgical facelift," are also being used to remove localized fat deposits. These devices, which are cleared by the FDA, deliver radiofrequency energy, and sometimes infrared light energy, into fat deposits over multiple weeks to destroy the fat cell membranes and release the fatty acids for removal through the liver, said Dr. Avram. Although the devices are being used and marketed for fat removal, "at this point we're still awaiting studies to determine the efficacy of the technology."

The latest contender to enter the fatremoval ring is a concept known as cryolipolysis, developed at Massachusetts General Hospital, which cools fat to selectively cause cell breakdown without damaging the surrounding tissue ("Cryolipolysis on Track to Become First Cool Way to Remove Cellulite," April 2009, p. 11).

"The technology is based on the concept of cold panniculitis, or popsicle panniculitis, through which cold exposure causes clinically [and histologically] evident inflammation in fat. The inflammation peaks several days or weeks after the exposure with subsequent focal lipoatrophy," said Dr. Avram.

"What we believe is happening is a se-

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lective crystallization in lipids in fat cells at temperatures above freezing-in other words there is a different melting point for fat cells than for the [surrounding tissue]-and there is fat cell apoptosis, followed by slow dissolution of the cell with gradual release of lipids over a period of 2-6 weeks," he said.

The technology, which has not received FDA clearance, has shown promise in an initial human study, said Dr. Avram.

The multicenter investigation included 32 male and female subjects with visible fat on the flank (love handles) or

back. The patients were treated using a prototype cryolipolysis device on one side with exposure times ranging from 30 to 45 minutes, while the contralateral side served as the untreated control. Outcome measures included fat-layer reduction as measured by ultrasound, comparison of pre- and posttreatment photographs, and physician assessment.

"At 4 months post treatment, a visible contour change was observed in most of the subjects," said Dr. Avram. Specifically, he noted, ultrasound measurements taken on a subset of 10 subjects demonstrated a fat layer reduction in all; the average reduction was 22.4%. Among the treatment-related side ef-

fects, some of the patients experienced redness at the treatment site that lasted for minutes to hours, as well as bruising and dulling of sensation in the treatment area that resolved within 1-8 weeks, Dr. Avram said, noting that "there were no pigmentary changes, nor were there any lab abnormalities suggesting systemic side effects."

Further studies are needed to establish optimal treatment parameters, but these early results suggest that cryolipolysis will likely be best suited for localized fat

removal in areas that are particularly resistant to exercise, he said.

Despite the apparent promise of the new technologies, Dr. Avram was quick to stress that the "clear but limited noninvasive fat removal achieved with these devices is in no way, shape, or form a competitor for liposuction." They are noninvasive alternatives that can achieve certain results, which should be made clear to patients.

Dr. Avram has conducted research for Candela Corp. and owns stock options in Zeltiq Aesthetics, which holds the cryolipolysis patent.

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