

SKIN & AGING™

PRACTICAL AND CLINICAL ISSUES FOR TODAY'S DERMATOLOGIST

The Fat-Busting BOOM

A growing array of non-invasive procedures, and novel techniques and devices, aim to give traditional liposuction a run for its money.

Psoriasis Review

Locker Room Dermatoses

Leadership in Dermatology:
Creating Effective Employee
Incentives and Rewards

BOARD REVIEW
In this Issue
on page 13

The Fat-Busting BOOM

A growing array of non-invasive procedures, and novel techniques and devices, aim to give traditional liposuction a run for its money.

BONNIE DARVES, CONTRIBUTING EDITOR

Tumescent liposuction may still be the gold standard for getting rid of moderate pockets of unwanted fat effectively and expediently. But in the quest for less invasive ways to whittle the waist or hone the hips, alternative treatment modalities are gaining ground.

Laser, radiofrequency, ultrasound and, of late, devices that employ cooling to break down fat cells, are proving a viable option for patients who don't want the downtime or discomfort associated with liposuction and are amenable to less dramatic results. (See sidebar on page 26.) The technologies and devices range from the laser-driven CoolLipo, SmoothShapes and SLIMLipo, to the radiofrequency-boosted Thermage and Exilis, to the recently FDA-approved cryolipolysis-based Zeltiq. And all are sparking intensifying patient interest in cosmetic dermatologists' offices these days.

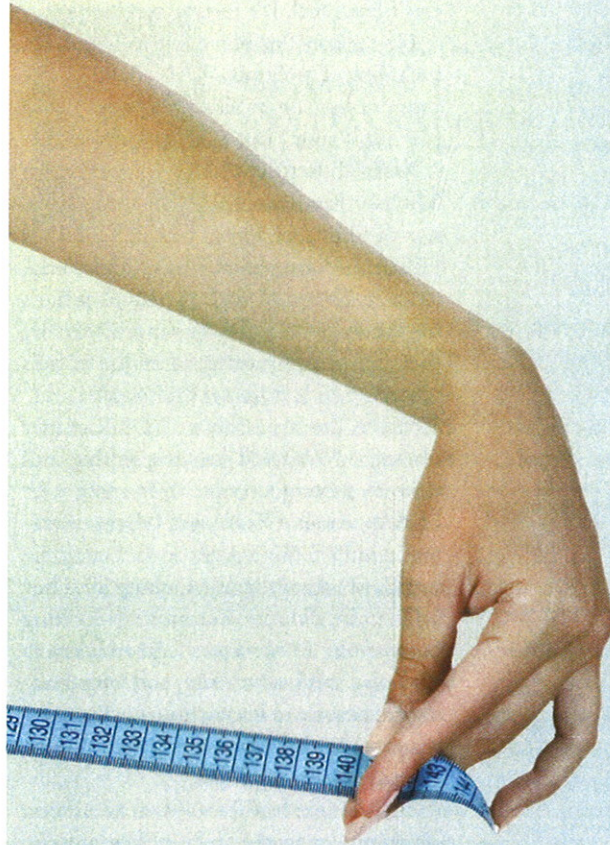
"Patient interest has been incredible, and I personally get asked about fat-reduction procedures and Zeltiq about 5 times a day," reports Robert Weiss, MD, of Maryland Laser, Skin, & Vein Institute, LLC, in Hunt Valley, MD. "The idea of doing something that's relatively painless but actually works sounds too good to be true — and usually is. But things are changing, if patients are willing to wait longer for results."

To find out what patients might expect, Dr. Weiss recently became his own guinea pig in a personal "mini-trial." He tried out Zeltiq, whose CoolSculpting procedure grabs, chills and then kills fat cells without damaging the skin, on himself, on one flank only.

"For the last 20 minutes of the procedure I was sitting there responding to e-mail," he says. "For me it was completely painless, though some patients report a tingling sensation as the area gets cooled down. The area felt a little sore to the touch for a week or two, but I found that a minor annoyance."

The results weren't rapid but instead occurred along the lines of what the manufacturer claims: gradual reduction starting at about 6 to 8 weeks. "At 6 weeks I thought it wasn't working. Then at the 2-month point I started to see the fat going away," he recalls. "I guess I'm impatient just like other people are. But it did work, and my patients are getting good results, too."

Dr. Weiss also has used SmoothShapes, and has participated in trials for two products awaiting FDA approval, UltraShape and LipoSonix. He thinks that the emerging technologies and procedures, for patients with reasonable expectations and relatively small fat pockets, could become the treatments of choice as techniques improve and use in body areas beyond the belly expands.



What's Out There Now

The last few years have brought a range of new tools, techniques and technologies to the fast-evolving area of fat removal, noninvasive approaches intended to either complement or potentially replace traditional liposuction. The offerings, described briefly below, are sparking an upsurge in patient interest — especially among men who've not previously sought cosmetic procedures, dermatologists report.

CoolLipo. This CoolTouch system uses a 1320 nm laser system designed for fat removal in small areas — the neck and chin, in particular — by ablating tissue. The procedure is usually performed under a local anesthetic.

Exilis. FDA cleared last spring for treatment of wrinkles and rhytids, Exilis uses controlled heating and ultrasound. Combining radiofrequency energy and mechanical waves, the device is intended for body contouring and skin tightening.

LipoLite. This Syneron device, FDA-approved for laser lipolysis, employs a liposculpture system that enables users to control pulse energy, pulse length and repetition rate, to tailor treatment.

ProLipo Plus. This Sciton device is designed for laser liposculpture of the chin, neck, upper arms, abdomen, flanks, buttocks and upper thighs.

SLIMLipo. This Palomar device (SLIM stands for Selective Laser Induced Melting) uses laser lipolysis with the objective of melting and dissolving fat, which can subsequently be removed by suction.

Smart Lipo. This device, from Cynosure, uses laser energy to break up and dissolve fatty tissue trapped beneath the skin and also encourages the development of collagen.

SmoothShapes. This Elemé Medical technology-assisted procedure that targets cellulite combines laser and light energy, vacuum massage and a patented roller system to increase collagen production, circulation and lymphatic drainage.

Thermage. This radiofrequency device, intended for body contouring, uses monopolar heating to penetrate tissue, with the intent of tightening existing collagen and stimulating new collagen growth.

VelaShape. This Syneron device uses a combination of bi-polar radiofrequency (RF), infrared light energy, and vacuum and mechanical massage to treat upper skin layers and deeper tissue.

Zeltiq. The most recent entrant — Zeltiq received FDA approval in August — employs cryolipolysis in a procedure it calls CoolSculpting, with the objective of breaking down fat cells without damaging the skin.

Zerona. The device uses laser technology to “flatten” fat cells to reduce inches temporarily or semi-permanently. The treatment targets the waist and thighs, and is provided in a series of low-level laser procedures.

On the horizon: LipoSonix and UltraShape contouring devices. Both products, which use ultrasound to target fat through ablation or fatcell disruption, are awaiting FDA approval but have been used widely abroad. An injectable fat melter is under investigation.

So does Kenneth Beer, MD, a co-founder of The Cosmetic Bootcamp. “The state of the state with fat reduction, I think, is that we're getting there — and these noninvasive procedures are getting closer,” says the West Palm Beach, FL, dermatologist, who has

conducted trials in many devices and procedures (Dr. Beer is a speaker and trainer for Elemé Medical, maker of SmoothShapes). “I think that Zeltiq and SmoothShapes are pretty good. I also think there's movement toward rethinking how liposuction is done

and that we may start to see it getting better,” Dr. Beer said. “SmoothShapes, which I think is good for patients who want cellulite [appearance] improvement — but not weight loss or sculpting — you can't even feel. It's just very relaxing.”

He concurs that emerging technologies, including LipoSonix, “may hold some promise but are awaiting more data and [dermatologists'] hands-on experience.”

Massachusetts cosmetic dermatologist Michael Kaminer, MD, managing partner of SkinCare Physicians in Chestnut Hill and editor of the field's “bible,” the *Atlas of Cosmetic Surgery*, gauges what's on the horizon in fat-busting in part by the increasing number of requests he's receiving to lecture on the topic.

“Fat is the new frontier,” Dr. Kaminer observes. “We're all looking at this, and now it's starting to come to fruition, with FDA approval of Zeltiq and other companies' products. We're starting to scratch the surface of what patients are asking for: They want to be slimmer and more fit-looking but want to avoid surgery.” In addition to his recent work with Zeltiq and longstanding experience in liposuction, Dr. Kaminer is known for his expertise in laser- and ultrasound-assisted lipolysis.

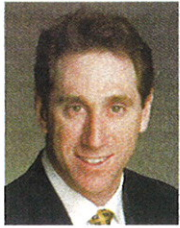
Dr. Kaminer has observed an interesting development in the wake of noninvasive fat-reduction procedures: growing interest among men. “Men rarely come in for cosmetic surgery, but they're coming here in droves for nonsurgical treatment of their ‘love handles,’” he says.

MORE, BETTER RESEARCH NEEDED

While Dr. Beer concedes that the growing array of fat-reduction treatment options are promising overall, he cautions that given the limited quality of research to date, much more patient-experience data is needed before the noninvasive modalities can be deemed liposuction competitors. “The research has been very varied, ranging from anecdotal reports to true clinical trials with histology and MRIs. The problem for dermatologists is that it's difficult to sort out the good, the bad and the ugly,” he contends.

Dr. Beer's preference is for trials that involve at least 24 participants and that use standardized photography and objective measurements — and ideally are double-

blinded. But that's been a hard-to-find combination. "With fat, it's a challenge because the lighting varies, patients and investigators want to see differences, and bias enters into the equation even for investi-



"Fat is the new frontier. We're all looking at this, and now it's starting to come to fruition, with FDA approval of Zeltiq and other companies' products."

~Michael Kaminer, MD, Chestnut Hill, MA

gators who don't want it to," he says.

For Seattle dermatologist Jennifer Reichel, MD, whose practice is split roughly 50-50 between Mohs surgery and cosmetic procedures, liposuction remains the standard, and the most requested treatment among her patients. She has tried some of the alternative procedures and products, however, and thinks that over time, the non-invasive-technologies realm will improve.

"I think it still holds true that traditional tumescent liposuction, under general or local anesthetic, remains the most proven and effective way to remove small- to moderate-sized excess fatty tissue in the body," says Dr. Reichel, a liposuction specialist who teaches dermatologic surgery at the University of Washington and the SeattleVA Hospital. "However, I think that there's some promise to the laser-assisted, ultrasound-assisted or cryo-assisted procedures. The issue, of course, is that devices can be approved regardless of proven effectiveness — and are used on- or off-label." As such, dermatologists are relegated to waiting several years to see which modalities "stick," Dr. Reichel adds.

She says the jury's still out on the benefits of add-on laser or ultrasound in liposuction. "We know from pretty decent trials that laser doesn't really decrease large or moderate fat [deposits], but that with small volume [deposits] patients do show improvements," she says, adding that the skin-tightening effects of laser — by virtue of possible collagen remodeling — is a promising area. "It's certainly more attractive from a risk-profile perspective, for patients willing to gain less improvement for less risk."

What apparently doesn't work and may be harmful, at least according to the FDA, are procedures involving drug in-

jections intended to dissolve and remove small pockets of fat. Earlier this year, in April, the agency published a warning stating that procedures being marketed as lipodissolve, mesotherapy, lipozap,

lipotherapy or injection lipolysis are not backed by "any credible scientific evidence that supports [their] effectiveness" and hadn't been evaluated by the FDA.

The most commonly injected drugs, phosphatidylcholine and deoxycholate, are in some cases mixed with vitamins, minerals or herbal extracts. Some entities marketing the treatments had claimed that the procedures were superior to other fat-loss procedures, including liposuction. Janet Woodcock, MD, who directs the FDA's Center for Drug Evaluation and Research, cited concerns that companies promoting the procedures were misleading consumers. The agency also received reports of procedure-associated adverse events, including permanent scarring.

MANAGING PATIENTS' EXPECTATIONS

Patients who are looking for a miracle or quick results in the newer noninvasive procedures that have been FDA-approved, are

"Most studies have focused on the abdomen, and we haven't really had the appropriate applicators for the thighs or the face," Dr. Weiss says. "But these areas are definitely on the radar screen. I think we'll see some good noninvasive devices for the face and neck in the future."

~Robert Weiss, MD, Hunt Valley, MD



likely to be disappointed. That's because results, when they occur, may be modest with an initial procedure or treatment series, and may take awhile — up to a few months — to appear. In addition, it's challenging to predict which patients will require more treatments than others to achieve visible results. In most cases, patients with moderate to large amounts of unwanted fat are un-

likely to obtain dramatic results without simultaneously engaging actively in losing weight and improving physical fitness, all sources concurred.

As such, managing patients' expectations from the outset is crucially important, Dr. Beer maintains, especially if patients are hoping for liposuction-like results. "Managing expectations is tough. One needs to educate the patient that with these [noninvasive] procedures, it is not possible to project what their waist or hips will look like," he says. "I try to explain this but some patients hear what they want to hear. So we also put as much detail as we can into the consent form so that people see it in black and white."

In his experience with SmoothShapes, for example, patients may start seeing results within a month, after eight brief visits. "For the other procedures, improvements may be faster but might require visits that are longer," Dr. Beer adds, or more intensive.

In Dr. Kaminer's experience with Zeltiq, between 80% and 95% of patients with small pockets of fat experience improvement, but the timeframe for that benefit varies. "We've surveyed a lot of our patients, and have found that it takes about 2 months — 4 months on the outside — to see results from the CoolSculpting procedure," he observes, noting that he has treated several hundred patients in the last year. "On average, each treatment will eliminate about 20% of the fat in the area."

Dr. Weiss notes that about half of his patients go on to receive a second treatment with Zeltiq, and that the practice recommends patients wait at least 2 months before scheduling subsequent treatments.

Overall, sources concurred, patients can expect long-term effects from non- or minimally invasive procedures comparable to liposuction in one key area:

The fat cells that are removed or destroyed do not return, at least not in the area treated. “Typically, if patients gain weight the fat will choose another area,” Dr. Weiss explains. “The idea with all of



“I think it still holds true that traditional tumescent liposuction, under general or local anesthetic, remains the most proven and effective way to remove small- to moderate-sized excess fatty tissue in the body. However, I do think there’s some promise to the laser-assisted, ultrasound-assisted or cryo-assisted procedures.”

~Jennifer Reichel, MD, Seattle, WA

these [procedures] is that results would pretty much last indefinitely if patients’ weight remained the same.”

All sources also emphasized the importance of training in performing the procedures, as even minor variations from recommended processes or equipment placement could reduce treatment efficacy. “In all of these procedures the operator’s skill is important,” Dr. Weiss stresses. “Even something that looks as simple to use as Thermage might lead to poor results if the operator hasn’t been adequately trained.” With Zeltiq, he adds, the individual performing the procedure has to ensure that the device is sufficiently sealed onto the skin so that the fatty tissue is “grabbed uniformly into the applicator.”

PATIENT-SELECTION ISSUES

Because the emerging fat-reduction procedures are generally noninvasive, patient selection isn’t as pressing an issue as it is with traditional liposuction. However, there are important medical considerations with some of the procedures, and patients for whom any fat-reduction treatment would be contraindicated. The latter includes patients with moderate to morbid obesity, severe chronic illness such as brittle diabetes, renal failure or certain autoimmune diseases — or any condition that might interfere with normal reprocessing of body fat.

With procedures that employ chilling, Dr. Weiss explains, patients with autoimmune disorders that create cryoglobulins could, theoretically at least, have an increased risk of skin necrosis. “I haven’t seen this yet, but as these procedures are done more widely, I

expect this could be a complication that develops inadvertently or unexpectedly,” he says. Dr. Kaminer mentions that cold urticaria would also be a contraindication for procedures such as Zeltiq.

Dr. Weiss also cautions that men who want their abdomen treated but who have visceral fat — fat under the abdominal-wall muscle — aren’t likely to benefit from noninvasive fat removal procedures.

On the psychological end of the spectrum, Dr. Beer advises against treating individuals with obvious or suspected body dysmorphic disorder, or those whose expectations are clearly unreasonable. “Poor candidates are patients who say they ‘want an area gone’ and ones who don’t under-

“Managing expectations is tough. One needs to educate the patient that with these [noninvasive] procedures, it is not possible to project what their waist or hips will look like.”

~Kenneth Beer, MD, West Palm Beach, FL



stand the risk/reward ratio with fat reduction,” he cautions.

The ideal patient for any of the noninvasive procedures, all sources agreed, is an individual who is close to normal weight, reasonably fit and is seeking reduction of relatively small, contained pockets of fat. Patients who seek treatment but aren’t good candidates because of weight or fitness issues should be encouraged to make lifestyle changes and then return, Dr. Kaminer suggests. “One byproduct of these noninvasive treatments is that there are people who wouldn’t have asked about liposuction, coming in now,” he observes. “There is a group of patients we’ve seen in the last year since we started offering Zeltiq who we never saw before but have been able to give some good health advice to.”

LOOKING AHEAD

Dermatologists interviewed for this article agreed that while the new noninvasive procedures and associated technologies are promising, more experience, especially with larger fat deposits and hard-to-treat areas, is needed. “Most studies have focused on the abdomen, and we haven’t really had the appropriate applicators for the thighs or the face,” Dr. Weiss says. “But these areas are definitely on the radar screen, and I do think we’ll see some good noninvasive devices for the face and neck in the future.”

Most sources noted that cryolipolysis and external-beam ultrasound body shaping are likely to gain ground if positive patient experiences become more widely reported, and agreed that the outer thighs, face and neck have proved difficult to address with existing noninvasive procedures.

The other issue that device makers should address with future products or procedure enhancements, Dr. Beer adds, is consistency. “Some of the devices are very inconsistent — you get great results on some people and nothing on others — even if the patients ‘look’ comparable. We need to be able to tell patients

‘you’ll get a 5%, 10% or 20% improvement,’ and have more reliability,” he says. When manufacturers can make results reliable, predictable and effective, he maintains, they’ll have good products that will capture an increasing share of the fat-reduction marketplace.

Dr. Kaminer concurs. “Liposuction is the most common cosmetic procedure performed in the United States, and that’s because it works. It’s the standard by which all of these other noninvasive treatments are being judged,” he says, “so if there’s a procedure that works some of the time but not all, patients aren’t happy about that.” ■

Disclosure: Drs. Beer, Kaminer and Weiss all have served as paid investigators for one or more of the devices mentioned in this article.