



Lipodissolve injections are some of the latest weapons against body fat. Viscose jersey dress by Versace. Jeweled pumps by Christian Louboutin. Sterling-silver-and-gold cuff by Caroline Carlisle. Sunglasses by Vogue. These pages: Hair, Yannick d'Is of the Cutler Salon; makeup, Mark Carrasquillo; manicure, Sheril Bailey. Prop stylist: Tom Bell. Model: Elisaveta Stoilova. Fashion editor: Paul Cavaco. Details, see Credits page.

# FAT Chance

**The new fat melters are seductive. But are they worth a shot? By Joan Kron**

**D**etox diet? Protein shakes? Hoodia? A tabloid recently reported that a certain music star had gone “from flab to fab” not with any of these methods, but with injections. The photographs are riveting. In the before picture, the diva’s exposed midriff looks soft; in the after image, her abs are washboard flat. This was all accomplished, readers are informed, by a series of shots to the stomach and thighs with “Hollywood’s hottest new ‘must-have’ procedure”: lipodissolve—a “revolutionary” micro-injection process that rids the body of fat. “Like most stars,” the article proclaims, the singer “is always searching for the next big thing to make her look better.”

So are plenty of other women. And there is no question that the next big thing in cosmetic procedures is fat melting. Nonsurgical fat-reducing treatments are increasingly available and popular; they include lipodissolve (sometimes marketed as Lipostabil and generically referred to as injection lipolysis), which involves shots of a chemical cocktail to rupture fat cells; and two devices, UltraShape and LipoSonix, which employ ultrasound waves to destroy the fat. Novel eradicators of fat are also being developed by scientists at Harvard Medical School and Georgetown University Medical Center, among others.

“There are 8 million women who would like to lose fat but would never consider liposuction because they fear surgery and anesthesia,” says Gary Jonas, founder and CEO of MedSculpt, a



PHOTOGRAPHED BY MICHAEL THOMPSON

lipodissolve clinic that has two locations in the greater Washington, D.C., area and plans to open more throughout the Northeast. Having frequent, small procedures instead of one big one not only is less invasive, but also can be less expensive. (Prices around the country vary, but at MedSculpt, three sessions of lipodissolve on one body area cost between \$1,800 and \$2,400; the average fee for liposuction in the United States is \$2,868, which doesn't include operating-room charges.) Industry experts predict lipodissolve could become a bigger moneymaker than Botox, and scores of physicians—including medical practitioners such as dentists as well as plastic surgeons—are signing up for weekend training courses. One physician who was approached to join a lipodissolve clinic recalls being told by the recruiter, "American women will spend anything to get rid of fat." And nothing—not warnings from doctors nor complaints on the Internet from lipodissolve patients detailing pain and complications—will stop them.

So far, UltraShape and LipoSonic have not raised any significant safety concerns, although neither is yet available in the United States. UltraShape is already approved in 48 countries including Canada, and 40,000 treatments have been performed with no reported serious side effects. Three treatments per area, at one-month intervals, is the recommended regimen; the company is now seeking FDA clearance. LipoSonic will be offered in Europe and Asia by the end of this year. In both procedures, the doctor guides an ultrasound wand across the target areas to destroy fat cells. The released fat is then carried by the lymphatic system to the liver, where it can be broken down and burned as energy. Fat loss and skin shrinkage is gradual—in a LipoSonic trial, peak results were visible between 8 and 12 weeks after one treatment, though additional sessions may be required. The two procedures have never been directly compared, but both seem to produce losses of one to three inches per body part within three treatments, according to Lisa Kellett, a dermatologist in Toronto who offers UltraShape, and Mark Jewell, a plastic surgeon in Eugene, Oregon, who has studied LipoSonic. Side effects for both

most commonly involve slight redness. LipoSonic may also temporarily cause bruising or numbness; mild burns (with no scarring) have occurred rarely with UltraShape. Currently, these procedures can be done only on the waist, hips, abdomen, or outer thighs; the arms,

during her course of treatment, the fat can potentially be stored in the body's remaining fat cells—so patients are advised to avoid excessive calorie intake.

Despite tabloid hype about weight loss from the procedure, lipodissolve is a method of shrinking small pockets

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inner thighs, knees, back, and neck are off-limits until the ultrasound wands can be made smaller. Teresa\*, 37, an education teacher in Laguna Beach, California, says that after three painless UltraShape sessions in Tijuana, she lost five inches in her waist.

**S**uzanne, a real-estate manager in Virginia, hopes to lose an inch from each upper arm with lipodissolve injections. In one of MedSculpt's treatment rooms, she lies back on an inclined examination table, her arms raised above her head, for one of three sessions, spaced eight weeks apart. The underside of each upper arm has been marked with a grid of dots in blue ink. Two nurses, one on each side, inject each dot with the lipodissolve formula—a blend of a soy derivative called phosphatidylcholine (PC) and salt from the bile of sheep or cows called sodium deoxycholate (DC). The rhythmic whoosh-smack of the pneumatic injection devices sounds like a carpenter's nail gun. The nurse on the right counts 93 shots; the one on the left, 107 shots. With .4 cc's of the formula in each injection, the total PC content is well within the limit of 2,500 milligrams that lipodissolve practitioners believe the body can tolerate safely at one time. Fat cells in the injected area break apart, and their fat content can then be burned off. Still, if the person takes in more calories than she expends

of fat, not shedding pounds. The most appropriate patient is within 10 or 15 percent of her ideal weight, with a fat deposit no larger than a soda can, says Diane Duncan, a plastic surgeon in Fort Collins, Colorado, who trains all MedSculpt personnel and is considered an expert on lipodissolve. "The larger the area, the less percentage of visual change." Many clinics, she laments, are "selling the American Dream to people who weigh 180 pounds and think they'll go down two dress sizes." In fact, MedSculpt (which also offers a weight-loss program) will accommodate those 30 percent above a healthy weight.

Maria, a saleswoman at another lipodissolve clinic who quit her job, says she was dismayed that staffers cared more about sales quotas than whether patients were well-suited for treatment (or well-informed). "They were just selling it to anybody—and didn't care what they weighed," she says. "There are still people that I remember.... I feel absolutely horrible that I sold them this."

Patients generally sign a consent form that lists several side effects, which may include soreness, itching, redness, blisters, hives, swelling, nausea, diarrhea, malaise, a Jell-O-like feel to the tissue under the skin, and pea-size lumps that may not be visible but could last for days or weeks. (These are clusters of dead fat cells in the process of breaking down, says Leroy Young, a plastic surgeon in St. Louis who is leading a scientific investigation of the procedure.) MedSculpt has

**\*Some patients' names have been changed.**

adjusted its formula twice to incorporate a numbing agent “after patients complained of terrible pain,” Jonas says.

**C**ristina, 32, a sales executive in Dallas, received lipodissolve injections at a local clinic that does not add a painkiller to its solution. Withstanding the treatment, she wrote on the website realself.com, is comparable to giving birth without an epidural. Despite feeling “foolish and vain” for wanting a flatter belly, she decided to continue. She says now that the dozens of shots from hip to hip were “the easiest part,” akin to tiny pinpricks. “But soon there is tingling that grows in intensity till it’s almost unbearable...like an itch you can’t scratch,” she says. Her abdomen felt heavy and began to swell. She drove home, she says, but had difficulty getting out of her car. Then came sharp abdominal pains, and her skin was blotchy and hot. She went to work the next day in an Empire dress to hide her engorged midsection; three days later, the discomfort had lessened, but her belly was still distended and tender. “They told me there would be pain,” she says, but “I don’t know if I understood [how much].”

Even lipodissolve’s practitioners don’t claim to understand everything about the procedure. They haven’t done the exhaustive studies that UltraShape has completed for FDA review; in other words, no one can assume that the injected chemicals are harmless. Almost every medical article on the subject concludes that more research is required. “Fat is an organ like the liver and the brain,” says Mathew Avram, a dermatologist and director of the Massachusetts General Hospital Laser and Cosmetic Center, which is developing a fat-melting laser. “As we remove fat, we need to study what, if any, medical consequences there are” from each method, he says.

The laser has been tested on animal and human tissue from abdominoplasties, and clinical trials could begin within a year. Heat from the device harmlessly penetrates the skin and destroys fat cells. “We expect the body will safely metabolize the treated fat,” Avram says, but “if you gain weight, fat might end

up accumulating in other places.” The researchers believe the laser will also smooth cellulite and destroy some sebaceous glands that cause acne.

Other fat-melting research is focused on a protein in the human body called NPY, which appears to regulate fat storage by activating receptors in fat tissue. When mice received injections of a blocker for these receptors, they lost 40 to 50 percent of their body fat in two weeks, says Stephen Baker, associate professor of plastic surgery at Georgetown University. (The researchers were also able to stimulate NPY receptors to generate body fat, which Baker says could someday prove useful for growing new breast tissue or filling out wrinkles.) The shots caused nothing comparable to the side effects of lipodissolve injections.

Fat-melting shots were pioneered when a Brazilian dermatologist injected Lipostabil, a drug intended to melt blood clots intravenously, into the undereye bags of 30 patients in the late 1990s. That makes lipodissolve “one of the few treatments that has been tried

are basically a blend of PC and DC, numerous variations exist with different additives in different amounts. And that means that preparations may also vary in efficacy and sterility, critics say.

Although the injections’ ingredients have no FDA clearance, many clinics imply otherwise or say that PC and DC are approved for other medical uses and therefore are appropriate for pharmacists to formulate into drugs as prescribed by a doctor. The website for Blue MedSpa in Atlanta, for example, states that the injection ingredients are mixtures of “homeopathic agents and FDA-approved medications.” An FDA spokesman, however, says, “There is no drug for injection under the skin approved for fat melting in the United States,” and furthermore, neither PC nor DC “is approved individually for any use.” They are components of other medications, but “when mixed together or combined with painkillers, preservatives, vitamins, and artery dilators, it seems to us that the mixture constitutes a new unapproved drug,” the official says. Two studies are testing

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on human beings before it has been tested in a lab or on animals,” Duncan says. Essentially, lipodissolve clinics are practicing “human experimentation, due to the lack of significant data to support the claims to the consumer,” says Rod Rohrich, chief of plastic surgery at the University of Texas, Southwest Medical Center. Injection lipolysis is “scientifically unproven, lacking any objective data on safety and efficacy,” the American Society for Aesthetic Plastic Surgery (ASAPS) cautioned in an advisory last May. Franz Hasenschwandtner, an Austrian physician and cofounder of Network-Lipolysis, a group of doctors who practice fat-melting injections, says: “Our God is beauty and not the FDA.”

Though all lipodissolve formulas

a drug code-named ATX-101, with the active ingredient of DC, for its ability to reduce fat under the chin and destroy lipomas—benign masses of fatty tissue—but the approval process could take years.

The first placebo-controlled, independent research of lipodissolve on humans (led by Young and overseen by a branch of ASAPS) will begin this November in St. Louis, where 20 patients will receive the shots, every four weeks, in one side of their abdomen and a placebo in the other. They will be tracked for 46 weeks, and a report is expected by April 2008.

Until then, patients, doctors, and state health officials must draw their own conclusions. In August, after several patient complaints, the Kansas State Board of Healing Arts (*continued on page 206*)

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voted to outlaw lipodissolve treatments, except for approved drug trials, citing “business practices” (insiders believe that refers to reneged money-back guarantees) and “reported side effects.” A court judge then blocked the ruling from taking effect in response to legal action from a lipodissolve chain, Fig; a trial is pending. (Brazil and Canada have banned lipodissolve; England has prohibited advertising it, and doctors’ insurance there no longer covers the procedure for malpractice.)

Practitioners of lipodissolve have risen to its defense. In the *Kansas City Star*, Matt Taranto, owner of a lipodissolve center in Leawood, Kansas, commented, “I have yet to hear of a serious reaction or side effect from lipodissolve.” When questioned by *Allure* about serious patient complications, Gary Jonas of MedSculpt said he is unaware of any. “Have you ever seen a problem from this?” he asks.

Actually, yes—more than one. Several doctors and patients contacted by *Allure* reported complications, calls to 911, hospital admissions, and surgeries as a result of lipodissolve treatments.

A Canadian woman developed open wounds and loss of skin under her eyes when trying to have the fat bags reduced with lipodissolve injections, according to Alistair Carruthers, a dermatologist in Vancouver, who did not do the damage but is trying to repair it.

A lipodissolve patient in California lost a piece of skin larger than a paper-back from her underarm and needed a burn specialist to graft new skin.

Angie, a 33-year-old photographer in Kansas, developed hives twice after treatments, even though she does not have an allergy to the soy in the formula. After her fifth session, she broke out in fiery welts from her ears to her knees and ended up in the hospital. She still has swelling nine months after the last round of injections—and she says she has lost not one centimeter of fat.

Alison, a mother of two, underwent lipodissolve in Las Vegas. According to her husband, Chris, as well as an investigator at NBC’s affiliate in Las Vegas, she developed abdominal abscesses the size of golf balls. She was hospitalized to have them drained surgically and endured three months of wound care.

Amy, 33, is a facialist and makeup artist near Atlanta who was offered a discount on lipodissolve from the spa where she works. Friends of hers had tried it elsewhere with no problem, so Amy (who is five foot seven and 135 pounds) signed up, hoping to reduce her hips and thighs. On a Saturday afternoon she got shots on all four sides of each thigh, though Duncan warns that treating wider surface areas and delivering higher doses in a single session can cause enough inflammation to impede blood flow. Amy noticed swelling immediately and felt dizzy, nauseated, and listless, she says. By dinner, her chest felt numb, she was having trouble breathing—and her father called 911. When the paramedics arrived, she says, they gave her oxygen and lowered her heart rate with medication, but she refused to go to the hospital because she didn’t have health insurance. That night she was in convulsions and vomiting; on Monday, she still felt sick and had headaches. The clinic doctor, her boss, said she must have had an overdose and advised her to drink three gallons of fluids a day. She swelled from a size 4 to a 16. “I had elephant legs!” she says. Her boss assured her that her next injections would contain a lower dose. “There won’t be a next time,” Amy says. The nurse who gave her the shots, she adds, apparently never took a course, but was instructed on the phone by the pharmacy that supplied the formula. Says Amy, ruefully, “She was practicing on me.”

In fact, many people who have suffered ill effects from lipodissolve say they were never examined by a doctor and dealt only with nurses, who are not as qualified to treat possible complications. Renee, a 42-year-old in Northern California, never saw a lipodissolve clinic physician before, during, or after her disaster. Following her third treatment to lose abdominal fat, she developed a lump the size of a grapefruit. The clinic phoned in a prescription for pain medication; a week later, her stomach was blistered and inflamed. Stumped, the nurses at the clinic suggested Renee go to the hospital emergency room. Once there, she was rushed into surgery. The diagnosis was cellulitis—massive tissue decay—and a raging staph infection. The surgeon said that she had barely survived. Renee spent five days in quarantine and eight weeks at home healing. She says

her stomach is now disfigured by a scar, discoloration, and five dimples, each one inch long, which require reconstructive surgery—hardly the abdominal trimming she’d had in mind.

Suzanne, though, is a success story, at least so far. Besides her arm injections, she has had three lower-back treatments, and her jeans size has dropped from a 14 to a 12. She is midway through a series on her upper back and also plans to treat her stomach and thighs; when she has finished, she will have invested 10 to 12 months and nearly \$10,000, plus Capital One finance charges.

One night in June, MedSculpt hosted a seminar for prospective patients in its corporate office in Vienna, Virginia. Considering the stormy weather, the turnout was respectable—33 people, including a magazine art director, attracted by a radio ad. Rick Hatch, MedSculpt’s vice president of marketing, gave a persuasive explanation of the procedure. He referred to the lack of FDA approval for fat removal but said that PC is used to treat other conditions, and he claimed that the shots have a safe track record. “We don’t know of any hospitalizations,” he told the audience. He also made the case that lipodissolve is less risky than liposuction by saying, “You could die from liposuction.”

The art director seemed convinced. “Liposuction scares me,” she remarked. Hatch announced, “You’ll get 100 dollars off procedures in the future if you sign up.” Seven people did.

With obesity and slim-beauty ideals on the rise, fat melting’s appeal is unmistakable. Several patients at the clinic where Maria worked cashed in their savings to get the shots, she says. “The ones that were really desperate weren’t the extremely overweight people,” she adds. “They were the people that wanted to lose that last ten pounds.”

Maria was not only a lipodissolve saleswoman, but also a patient. She contends that her treatment was ineffective, and that months later, she still has broken veins and bruise-like discoloration, which she fears will never go away. Despite her initial excitement, she no longer believes the procedure is worthwhile. “I don’t think anyone should be injecting that,” she says. “Hopefully it doesn’t hurt anyone. Who knows?” ♦