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Shots that claim to melt fat also inject fears

As lipolysis gains popularity in U.S., critics warn of risks

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After giving birth to three children, Julie Ohnsorg couldn't get rid of that last bit of post-baby belly bulge.

"I had this pouch there," says Ohnsorg, who weighs 136 pounds and is 5 feet 4 inches tall.

Frustrated, the 38-year-old customer-service supervisor tried creatively camouflaging with clothes, but not always with success in this era of low-rise jeans. She considered liposuction but was put off by the expense, the recovery time and the pain. "I thought, 'Oh my God, there is no way I can do this.'"



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Instead, Ohnsorg turned to injection lipolysis, a relatively new and increasingly popular treatment in the U.S. that's being touted as a nonsurgical solution to stubborn, localized fat. Injection lipolysis, sometimes loosely referred to by the trademark name "Lipodissolve," is said to melt away fat through a series of injections offered at specialty clinics and doctors' offices.

But critics are quick to caution that too little is known about the efficacy and long-term effects of the procedure. Consumers, they say, could be wasting their money and putting themselves at risk.

Patients who undergo injection lipolysis receive a series of shots in their bellies, thighs, neck, upper arms and other fatty areas they want to shrink. Depending on the target area and the clinic's method, patients may require six visits, often spaced two to four weeks apart, where they get between five and 25 shots. Costs often run between \$1,000 to \$3,000 per area for a complete series of injections. While practitioners of lipolysis say the shots feel similar to bee stings, some patients say that's a serious understatement.

Reports of infection, tissue death

A study published in the Aesthetic Surgery Journal in 2006 found that 75 doctors who treated more than 17,000 patients worldwide noted that about 12 percent of patients expressed disappointment with the results of injection lipolysis. The best treatment areas, with the greatest number of physicians reporting good results, were the abdomen, the flanks and under the chin.

But for some, those results can come with serious complications.

Angie Ross says she regrets having injection lipolysis. The 33-year-old photographer began visiting a Kansas branch of the national specialty clinic chain Fig last November to treat a small amount of stubborn fat in her abdomen. Ross says she developed minor allergic reactions a week or so after each of her first four sessions, but never connected them to the procedure. She stopped the treatment after her fifth session, she says, when a substantial reaction sent her to the emergency room. "Within an hour, I had hives head to toe."

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to the emergency room. Within an hour, I had nives head to toe," says Ross. "I was completely covered — even inside my ear."

But Fig says it has treated more than 11,000 patients and that allergic reactions are rare. Doctors or [nurse practitioners](#) at the clinics administer the shots. "Most allergic reactions are minor in nature and have been resolved with supportive treatment," says Fig in a written statement. "Our medical professionals are trained to help patients identify and manage such reactions. Patients are informed of this possible reaction prior to opting for the procedure."

Fig points to success stories such as Ohnsorg, who recently completed her ninth round of injections at a Fig clinic in Scottsdale, Ariz. After her sixth round, she says, she'd lost three inches in her abdomen.

In May, the American Society for Aesthetic Plastic Surgery (ASAPS) issued a warning against the use of injection fat-loss treatments, citing a need for further study. There were also reports of complications including infection, disfiguring masses of inflamed tissue and tissue death, especially when the procedure was performed by laypersons.

Where does the fat go?

How injection lipolysis works is a subject of some debate. Dr. Roger Friedman, a plastic surgeon and medical director of MedSculpt, an injection lipolysis clinic with two branches on the East Coast, says the injections cause an inflammatory response that breaks open and destroys fat cells. The breakdown materials, he says, are then carried to the liver, where they are processed before being excreted.

But critics say this hasn't been adequately proven and that most studies that support the procedure are done by parties that could financially benefit. They also dispute studies that proponents say prove the safety of injection lipolysis.

"There is no scientifically validated, peer-reviewed study that discusses the mode of action, the breakdown of the products of the fat, the safety, the efficacy," says Dr. Alan Gold, president-elect of ASAPS and president of the Aesthetic Surgery Education and Research Foundation (ASERF). "How are they metabolized? And how are they excreted? We don't understand if it's filtered in the liver, the kidneys [or] deposited in the blood vessels."

In other words, say critics, it's not clear where the fat goes.

The ingredient commonly used in injection lipolysis is known as PCDC, a mixture of phosphatidylcholine, a soybean derivative, and sodium deoxycholate, a bile salt. Mixed in compounding pharmacies, PCDC has not been approved by the [Food and Drug Administration](#) for spot-fat reduction — something critics are quick to cite. And how it's mixed and what it's mixed with varies.

Gold says there's not a regulated formula or dosing for the injections. "Everyone mixes something a little different with it."

Gold and ASERF have been working with [the FDA](#) to set up a 20-patient, 46-week, placebo-controlled pilot study that will examine the safety and efficacy of the most commonly used formulation of PCDC. Depending on the results, the study may be expanded.

Competing with liposuction?

Meanwhile, some who perform injection lipolysis say plastic surgeons are opposed to the procedure because it can be performed by nonsurgeons and would mean lost revenue from liposuction, which is more expensive.

"The people who are causing a fuss are the plastic surgeons, because it interferes with their business," says Dr. Raphael Nach, a Beverly Hills-based ear, nose and throat specialist who has performed the treatment to reduce fatty areas under the eyes.

But the surgeons fire back that the procedure, which they say seems to work best in smaller areas, is not likely to replace liposuction. And even proponents of injection lipolysis are careful to distinguish between the two.

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"It will not take away pounds, but inches," says MedSculpt's Friedman. "If there's a liter of fat in each flank," he says, "that person is better off doing liposuction."

Friedman describes injection lipolysis as a contouring tool — something that will remove just enough fat to smooth out a shelf over a C-section scar, for example, or that little bit of flab that hangs over the waistband of jeans. He says the ideal candidate is someone who is not overweight overall and has a specific area to deal with.

According to MedSculpt's Web site, the fat cells removed by injection lipolysis are gone for good — but the fat cells that remain in the area will expand to accommodate food intake. In other words, your results won't last unless you maintain a healthy lifestyle.

Friedman notes injection lipolysis has been done outside the U.S. for years. According to one study, it first appeared in Italy in 1980. But it's considered by some to be a form of mesotherapy, which was developed in France more than 50 years ago and has also raised some controversy. With mesotherapy, a range of substances such as

vitamins, antibiotics and hormones are injected to treat a variety of disorders, from chronic pain to psoriasis.

"There have been well over 100,000 [injection lipolysis] treatments in Europe," says Friedman, "with no major side effects."

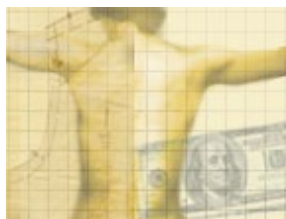
Critics are careful to say that they haven't ruled injection lipolysis out. However, until more is known, especially with respect to the procedure's long-term effects, they encourage both patients and doctors to take a wait-and-see approach.

"This [procedure] may turn out to be good," says Gold. But, he adds, "we shouldn't be experimenting on patients."

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Source: American Society for Aesthetic Plastic Surgery

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