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SKIN DEEP

Feel Pudgy? There's a Shot for That

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CONTROVERSIAL new procedures in cosmetic medicine, like genital rejuvenation or buttock implant surgery, tend to take hold on the West or East Coasts and then move inland. But, during the last two years, a procedure called lipodissolve, which uses injections of a drug compound to target unwanted fat deposits, has captured the attention of thousands of cosmetic patients in Missouri and Kansas.

"Two years ago, nobody in St. Louis had heard of it," said Laurie Calzada, a petite blond self-help author who last year completed a series of anti-fat shots on her outer thighs and abdomen. "But now lipodissolve is practically a household word."

Anti-fat injections are one of the most hotly debated procedures in cosmetic medicine because they are spreading faster than the science behind them. Unlike mesotherapy, a process that entails superficially injecting [vitamins](#) and other substances into the skin, lipodissolve involves deeper injections of a compound drug that is supposed to break down cells in the fatty layer under skin.

But the [Food and Drug Administration](#) has not approved any drug to be used cosmetically in anti-fat injections. Neither the drug formula used in lipodissolve nor the method of treatment is standardized. And researchers disagree whether the shots eliminate fat cells, or merely liquefy fat so that it shifts around in the body, raising the possibility of long-term consequences such as the aggravation of heart disease.

Still, Ms. Calzada, who heard about the procedure from her gynecologist who tried it for his love handles, said that she did not mind being an early adopter. Ms. Calzada went to a medical office in St. Louis, then called the Advanced LipoDissolve Center, which specializes in the injections. She was so pleased with the results that she spread the word to at least 50 friends and acquaintances, she said.

But some regulators and local doctors have issued warnings about lipodissolve, arguing that such anti-fat shots lack the kind of rigorous prospective clinical research that would prove their safety and efficacy. In an effort to collect some hard data, Dr. V. Leroy Young, a plastic surgeon here, said he had just received permission from the F.D.A. to conduct a small clinical study of one of the drug mixtures. In Kansas, the board of medicine last month tried to ban injections of the same drug compound after receiving complaints from consumers, but a judge last week stayed the restrictions after a petition from lipodissolve providers.

"These are unapproved drugs for unapproved uses and we can't guarantee consumers' safety," said Karen Riley, an F.D.A. spokeswoman.

But the agency does permit doctors on an individual-patient basis to prescribe a compounded drug, formulated with ingredients from approved drugs and made by a licensed compounding pharmacy. That is how providers of lipodissolve obtain their mixtures.

Doctors said anti-fat shots often contain a compound of approved drug ingredients known as PCDC, which includes a phospholipid called phosphatidylcholine and a bile acid called deoxycholate. A drug containing PCDC called Lipostabil is approved in Germany as an intravenous medication to treat blood vessels blocked by fat embolisms. In Britain, where the drug is not licensed, it has been marketed for cosmetic anti-fat injections under the name Flabjab.

The fight over lipodissolve raging in Missouri and Kansas represents one small skirmish in the battle among regulators, doctors and medical entrepreneurs to control the explosive growth of cosmetic medicine and to set standards for scientific proof of efficacy and safety.

“Cosmetic medicine is an incredibly frightening and unregulated frontier right now,” said Dr. Audrey G. Kunin, a dermatologist who lives in Mission Hills, Kan., who said she has been discouraging fellow Kansans from getting lipodissolve treatments.

The Advanced LipoDissolve Center opened its first office here in September 2005. The company, which recently changed its name to Fig. (short for figure), heavily promoted the procedure on television, radio and in magazines. Because the shots target small areas of unwanted fat deposits, the company positioned the injections as a less invasive alternative to liposuction surgery. Soon after, more than a dozen spas and doctors offices, including surgeons whose liposuction business had diminished, began to offer similar treatments.

Now Fig., whose motto is “dissolve to your beautiful shape,” has 15 centers across seven states, including three clinics in St. Louis. In the last two years, Fig. offices have performed more than 100,000 lipodissolve treatments, said Chris Dornfeld, the company’s chief development officer.

“There were people on both coasts doing this, but we made lipodissolve visible in the marketplace,” Mr. Dornfeld said.

Fig. has now expanded its services, but lipodissolve remains its most popular procedure, he said. Treatments typically cost \$2,000 per body part and require a series of six injection sessions, spaced two weeks apart. Women most frequently request treatment on their abdomens and thighs while men choose love handles and jaw lines. A typical client signs up for two or three body parts. Doctors and [nurse practitioners](#) who administer the treatments advise clients that the shots can cause stinging, swelling, redness and bumps and that the inflammation indicates the medication is working.

Dr. David A. Caplin, a plastic surgeon who offers lipodissolve in his private practice and serves as Fig.’s national medical adviser, said results can be hard to measure.

“The decrease is variable and hard to quantify, but when you look at the before and after photos, the fat mass is not there,” he said. “The best measure is patient satisfaction.”

Rob Semaan, the chief executive of Fig., said that lipodissolve is safe, and that doctors, who have performed the procedure worldwide, had not reported any deaths or other serious consequences.

And yet, in an effort to warn consumers in 2005, the British health authority reported that it had received complaints about side effects.

Even a few doctors here who offered themselves as guinea pigs for the procedure experienced problems.

Last year, when Dr. Young, the plastic surgeon, was considering offering the shots at his office, he asked an instructor at a lipodissolve course to inject his right flank. Thirty minutes later, he felt like he had been stung by 50 bees and his skin turned black, he said. "It looked like I had been hit with a garden hose," Dr. Young said. "I thought, I am going to lose some skin and I am going to have to ask one of my colleagues to do a skin graft."

A plastic surgeon in his office named Dr. C. B. Boswell, and their nurse, Holly Foelsch, also injected each other with PCDC. Dr. Boswell said that his stomach became so enlarged that he looked six months pregnant. Ms. Foelsch said that her thighs became so swollen with liquid that she wore panty hose to keep them from jiggling.

All three reported that the side effects dissipated after two weeks but none of them experienced any cosmetic benefit. "Missouri is the show-me state," Dr. Boswell said. "But no one has shown me that this stuff works."

Dr. Caplin, the medical adviser to Fig., said serious side effects had not occurred from treatments at its centers. "Certain techniques that use higher volumes than we do can get massive swelling," said Dr. Caplin, who added that the occasional patient at Fig. had experienced skin blistering.

Dr. Young's practice decided not to offer the shots to patients. But now he is about to start a pilot study of lipodissolve on 10 volunteers who will have PCDC shots on one side of their abdomens and a placebo on the other.

Patients will also have [M.R.I.](#) scans to see if their fat mass changes and blood tests to see if liquefied fat impacts their [cholesterol](#). Such a small study will not provide definitive data, Dr. Young said, but it should establish whether the procedure warrants further research or is the kind of sham that the writer Damon Runyon called the "phonus bolonus."

"It would be good if this turns out to work, but if it doesn't work and all these people are wasting their money, we need to say that too," Dr. Young said.

Across state lines in Kansas, where lipodissolve has attracted clients, Dr. Kunin, the dermatologist, applauded the Kansas medical board for trying to regulate shots of PCDC. But she argued that the proposed ban should go further.

"If they ban one drug, people will just start offering injections of a different drug cocktail," Dr. Kunin said. "I would have liked to have seen a more comprehensive ban that outlawed the injection of any type of agent into the body that claims to reduce or eliminate fat."

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