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From the Los Angeles Times

Weighing in on lipolysis

Lipodissolve, mesotherapy 'lunchtime lipo.' The injectable surgical alternative has many names, many patients -- and many critics.

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COME in on your lunch hour, have a few injections and melt away those stubborn bulges of fat. That promise has made injection lipolysis -- also called lipodissolve and mesotherapy -- one of the fastest-growing cosmetic procedures in the country, with centers sprouting up almost as fast as Starbucks stores. Nevermind that neither the procedure nor the drug cocktail used has FDA approval. Nevermind that Kansas and Nebraska are trying to ban the procedure. Nevermind that the American Society of Plastic Surgeons and the American Society for Aesthetic Plastic Surgery do not condone the procedure. Nevermind that the procedure has been banned in Brazil, Canada and England.

People want a better body *now*.

Driving the demand for a fat-dissolving miracle is the insatiable quest for thinner-ness, a rise in noninvasive cosmetic procedures -- specifically injectables such as Botox and Restylane -- and doctors who want to capitalize on both. ASAPS members reported performing injection lipolysis on nearly 29,000 patients in 2006, six times more than in 2005. Members of this group represent only a small fraction of those doing the procedure, so the numbers are actually much higher. Fig, the largest national provider of lipodissolve, has performed more than 170,000 treatments on 50,000 patients since opening its first center in September 2005. The company now operates 17 body-shaping centers in eight states according to Fig chief development officer Chris Dornfeld. Its newest center, and its first in California, opened in August in Costa Mesa and is adding more than 200 patients each month, he said.

When performing the procedure, doctors -- or, more often, nurses, assistants or aestheticians -- inject PCDC, a mixture of phosphatidylcholine (a chemical found in soybeans) and sodium deoxycholate (derived from cattle bile) into the fat layer under the skin to break it down. They say it's not for the obese but, rather, for normal-weight men and women who want to resolve diet-resistant pockets of fat. Treatments involve a series of six to nine injections every few weeks to the same area, commonly the abdomen, love handles, chin and thighs. Most centers, including Fig, charge around \$1,500 per treatment area.

The idea behind injection lipolysis arose in the 1950s in France, where doctors began practicing what was known as mesotherapy, a broad term for injecting substances under the skin. They weren't targeting fat but were injecting different vitamins to treat a variety of ailments. In the late 1960s, doctors in Germany started using PCDC, marketed under the name Lipostabil, intravenously to dissolve fat or lipids in blood, and the drug was approved in Europe for that use but never in the United States.

"PC helps the body carry away fat that's already in the blood," said Keith Leonard, president of Kythera, a biopharmaceutical company researching and developing a PC-free fat-dissolving substance. "There's a lot of legitimate science behind that. We might use PCDC today to lower blood lipid, but we have statins, which work so much better." DC, he said, was added to PC as an organic stabilizer. In the 1980s, doctors in Austria and Italy combined mesotherapy and PCDC and reasoned that if it worked on fat in blood, it might work under the skin. The procedure spread from Europe to Brazil and a few years ago landed in the United States.

But not to universal acclaim.

"The doctors doing this are driving ahead of their headlights," said Los Angeles plastic surgeon Brian Kinney, immediate past president of the Plastic Surgery Educational Foundation of the United States and clinical assistant professor of plastic surgery at USC. "They are practicing way outside the bounds of science, which is why some of us are uncomfortable. There's a lot we don't know about these chemicals, including how they affect nerves, tissue and blood vessels. We don't know what happens to the fat once it's dissolved, whether it enters the bloodstream or the lymphatic system."

Terry Dubrow, a board-certified plastic surgeon and medical director for the Costa Mesa Fig center, said the fat doesn't wind up in the bloodstream, that it and the drug are excreted through "normal metabolic pathways."

Richard D'Amico, assistant clinical professor of plastic surgery at the Mount Sinai School of Medicine in New York City and president of the ASPS, agrees with Kinney. "This is another example of hype and marketing getting ahead of science. Patient safety is at risk." The ASPS doesn't recommend patients undergo these treatments until the drugs' safety and efficacy have been proven, he said.

"That's a very safe, conservative and appropriate position, and exactly the position they should take," said Dubrow, who nonetheless says injection lipolysis offers patients a lot of benefits. "When it comes to body shaping, the best treatment is diet and exercise. For people who have diet-resistant areas, liposuction works really well. But surgery and anesthesia have inherent risks, which is why the trend for the past several years has been toward less-invasive techniques," he said. "The goal is to go from invasive, to less invasive to noninvasive and get the same or better result. This is the way we're heading with lipodissolve. This is the new frontier. The demand is incredibly high."

Addressing the FDA issue, Dornfeld said, "Not all drugs or devices have received, require or are used with FDA approval. Botox, for example, was criticized by the FDA as an egregious example of off-label use before it was officially approved for cosmetic procedures in 2002. Last year it was the top nonsurgical [cosmetic] procedure in the United States." Nonsurgical procedures have increased 749% in the last decade, according to the ASPS. Another driving factor, he added, is the fact that more doctors are looking to tap into aesthetic areas of medicine.

Some interpret the trend as the point where patient vanity meets physician greed. "It saddens me that physicians would place patient safety in jeopardy for the sake of making a profit," said Joel Schlessinger, president of the American Society of Cosmetic Dermatology and Aesthetic Surgery. He says he has seen half a dozen cases of patients asking him for help after they've gotten botched treatments elsewhere. "They come in with pain, swelling, bruising and bloating in the treatment areas, irregular dimpling and divots in the skin. Some complain of feeling ill and have nausea, diarrhea and fatigue." Because a judge overturned the ban on the procedure in Kansas, Schlessinger is working with his local state senator to introduce a bill to the Legislature that would outlaw the use of PCDC until it is FDA approved.

"Some things women do in the name of beauty are really frightening," said Linda Wells, editor in chief of Allure magazine, which recently ran an article critical of injection lipolysis. "Everyone is in a dramatic hurry to look better, younger and thinner. That accelerated drive, combined with the profit motive of some healthcare professionals, can be [a] very dangerous combination. Lipolysis falls under that heading. Women think lipolysis is easy. Skipping dessert and wearing Spanx is easier, risk-free and completely safe." If patients want a proven solution to get rid of fat, we have one: liposuction," D'Amico said. "Unlike lipolysis injections, which require multiple visits for minimal results, liposuction is over in two hours, has predictable outcomes and a proven safety record."

But the thought of doctors using a cannula to surgically suction out fat is a turnoff to many. Plus, liposuction involves recovery time, whereas after lipodissolve, patients can go back to work and routine tasks that same day. That's what appealed to Sheila Yee, 45, of Riverbank, Calif., outside Modesto.

'Lunchtime lipo'

A third-degree black belt and martial-arts instructor, Yee works out six days a week. At 5 feet 4 inches and 120 pounds, she didn't need to lose weight, but she wanted to get rid of some "stubborn areas" left over from two pregnancies. She first heard about lipodissolve from a newspaper ad, then noticed that an Advanced Lipo & Wellness Center had opened inside her local spa. It offered the procedure, billing it as "lunchtime lipo." She paid \$3,200 to have a series of six sets of injections in her stomach and love handles. She had her first injections last May, and her second a month later.

"Each time, I got lightheaded and nauseated," she said. Her stomach swelled so much that she couldn't button her pants. However, she continued with her treatment plan, because, she said, "they told me results usually don't show up until after the fourth visit. I'd paid my money and figured I just had to suck it up."

A week after her third treatment last July, Yee said, she went back to show the staff a lump about the size of a tennis ball that had formed in her abdomen. By her account, the nurse there assured her that the lump was a sign the treatment was working and advised her to drink water and massage the lump. When the lump grew to the size of a grapefruit, she went back again. That time, the office offered to pay for her to go to the local emergency room to have it checked. There doctors diagnosed an acute staph infection and the next day performed surgery to remove a 9-inch abscess and necrotic (dead) tissue. Yee stayed in the hospital for a week on intravenous antibiotics to resolve the infection.

"I completely underestimated how serious this procedure was," she said. "I thought, 'This is a spa. They wouldn't do anything to hurt me in a spa.' " Today, her stomach has a hollow spot where the lump once was, an area that doesn't match the other side of her stomach. Meanwhile, her love handles showed no change.

The Advanced Lipo & Wellness Center fully refunded her \$3,200. (Her insurance covered her other medical costs.) The company, which has three centers in central California, notes on its website that "to date, over 350,000 procedures have been performed with no serious side effects being reported."

"We've never seen or heard of a complaint," said Christie Snows, director of operations for the Advanced Lipo Wellness Center. When asked about Yee's case, Snows said, "That wasn't a complaint; she never complained. When we see a complication, we follow procedure and in this case sent her for care." The center granted her a full refund, she said, "out of good customer service, out of empathy. She'd been through a lot. It was unfortunate that this happened, and I feel for the patient, but an infection can come from anywhere. A person can pick up an infection after leaving the clinic."

However, curious consumers don't have to look far to find complaints. On Realself.com, a website on which patients who've had cosmetic procedures describe their experiences and then report whether the procedure was worth it, out of 130 injection lipolysis reviews, 58% said it was not worth it. Many said it was far worse than not worth it and reported acute pain, allergic reactions, swelling, diarrhea, vomiting and more than a few trips to the emergency room in addition to no improvement.

Of the 42% who reported positive results, many were found to be employees of Fig, or MedSculpt, another large lipodissolve provider, according to an internal audit of reviewers' Internet provider addresses.

Little medical oversight

Critics as well as some people performing injection lipolysis worry about clinics operating with no physician on site. In some medspas, nurses or nurse practitioners administer the injections, and the overseeing physician might be many miles away. At the Fig center in Costa Mesa, Dubrow, who has a private practice across town, doesn't inject patients. "My job at Fig is to be sure the medical protocol is good," he said. However, a Fig spokesperson says that, in general at the centers, physicians, physicians' assistants and nurse practitioners perform lipodissolve procedures.

"Problems happen in clinics that have non-physicians doing this procedure," said Ronald Moy, clinical professor of dermatology at the David Geffen School of Medicine at UCLA, and a dermatologist in private practice in Westlake Village. "You need to know about drug reactions and who can tolerate the chemicals. This isn't a job for flunky aestheticians."

When Moy first became aware of the procedure about a year ago, he looked into it, thought it appeared "safe and reasonable" and got some training through courses and by working alongside fellow dermatologists and one plastic surgeon in Kansas City and New York who perform the procedure. About six months ago, he started performing injection lipolysis in his office. "I see that it reduces inches, causes no complications and patients are happy." However, he agrees that the procedure can involve a lot of time and money for areas better addressed with liposuction, which he also performs. "But that's not what patients want. Patients want anything but surgery."

Although he's aware of the controversy surrounding injection lipolysis, and that it's not FDA approved, he said, "I've talked to enough colleagues and seen enough people doing it and having it done that I decided to give it a try. A year ago, most patients had never heard of this; now they're all asking."

Physician administration is no guarantee the procedure won't go awry. Michelle, of Anaheim, who asked that her last name not be used, had injection lipolysis in her torso from a physician and called the whole experience "horrible." She knew the procedure wasn't FDA approved. After seeing an ad in her local paper in June, the mother of five went with her husband to visit a doctor who was doing the injections in an office behind a nearby beauty salon. "I should have seen the red flags because when we walked in it was a total sales job. But I knew that most people doing this weren't doctors. He was a doctor, so I trusted him."

After a brief medical exam, the doctor said they could start right then. Though the procedure was painful and made her feel sick, she went back for

her next appointment three weeks later, at which time the doctor asked for full payment of \$4,000, which included treatment for her husband too. Again, she had pain, swelling, bruising and nausea. After her third visit, last July, she ended up so ill, with vomiting, a fever and diarrhea that she went to the emergency room. There, doctors determined she was having a severe allergic reaction to the drug compound used in the procedure. They put her on an intravenous medication to stabilize her. When her husband called the doctor for a refund, he refused. They're disputing his payment through their credit card company. After all that, she says, neither she nor her husband saw any improvement. "I wish the FDA would step in and tell doctors not to do it."

Off-label use

It's not illegal for doctors to administer drugs that are not FDA-approved for a specific procedure. In what's known as off-label use, doctors may administer drugs that the FDA has approved for other uses. Though PCDC is not approved for any use in the United States, doctors administer it under another FDA provision that does allow doctors, on an individual-patient basis, to prescribe compounded drugs -- a blend of approved drugs, made by a licensed compounding pharmacy.

The FDA has just approved the first clinical trial for injection lipolysis. The study, which begins this month in St. Louis, will follow 20 patients for 46 weeks and assess reactions and long-term complications.

Kythera, the biopharmaceutical company based in Calabasas, is developing a PCDC-like chemical compound to reduce fat by injection. The company plans to get prospective data on 1,500 patients, study the chemical and procedure over three years and invest \$100 million to get FDA approval and bring the drug to market, said Leonard, Kythera's president. The company has FDA approval to conduct clinically controlled trials in the United States, Australia, Canada and Britain. Those trials are underway.

"There is a lot of patient demand, but there's a right way and a wrong way to go about this," Leonard says.

"Right now we're seeing rampant human experimentation without oversight in uncontrolled settings instead of approved clinical trials that fastidiously extend knowledge piece by piece," he said. "There is no standard formula for dosing, frequency of treatment or chemical strength. No one has determined the affect this might have on pregnancy or whether it could cause birth defects. That is not the right way to practice medicine."

And if Kythera's drug never wins FDA approval? "This is business," he said. "We take risks, but with money, not with patients."

Injection's outlook

Even critics remain optimistic that an injection method of body contouring will someday be approved. "It's quite possible that eventually this drug and treatment will be OK if it's manufactured and administered correctly," said Schlessinger. "I would love to have something like this available to patients. Administering it responsibly will only enhance our profession."

D'Amico agrees: "In the next few years we may have a nonsurgical method of fat removal, but we're not there yet."

While science sorts this out, many, such as Dreena Bryant, 31, of Irvine, prefer not to wait. Bryant first heard about injection lipolysis in a tabloid discussing celebrities who had had the procedure. After her divorce two years ago, Bryant gained about 30 pounds, mostly in her thighs, she said. "I wanted something quick that didn't involve surgery." An entrepreneur who works in the fashion industry, Bryant didn't want liposuction because it involves too much down time. She went to the closest Fig center, saw a video and started that day.

"It's a little painful and itchy afterward," she said of her treatments, "but it's nothing I can't endure." She likes the fact she can have a 15-minute treatment and hop on a plane. She feels some nodules that have formed in the injected areas but expects them to go away in four to six weeks. She just finished her third treatment on her inner thighs and abdomen and says she sees results. "I'm seeing a good 1 1/2 -inch reduction in the circumference of each thigh." She expects she'll need six to nine treatments in each area. The total cost will be \$3,000.

Is she worried about the controversy? "I haven't heard of any horror stories, and wouldn't want to because that won't be my experience. I trust my intuition," she said. "You're talking to a risk taker."

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