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## Procedure melts away fat

BY SUSAN JENKS  
FLORIDA TODAY

Responding to a recent ad, Tammy Conner decided to try lipodissolve, an increasingly popular and controversial fat-melting technique, on her stomach.

"At first, my husband thought I was crazy," Conner said, referring to the cosmetic nonsurgical treatment, which lacks approval from the U.S. Food and Drug Administration. "Now, he's happy."

The 34-year-old Port St. John resident, who also had the flab under her arms treated, said she has lost 21/2 inches and one pants size, and hopes to lose several more before completing the injections -- usually six of them, three weeks apart.

"What women will do for beauty," she said, laughing.

Lipodissolve injections, which commonly contain at least two compounds -- phosphatidylcholine and sodium deoxycholate or PCDC -- are proprietary formulations of a soy-based product and cow-derived bile, marketed for their ability to break apart fat cells through inflammation and swelling.

Critics contend there is insufficient safety data, especially over the long haul, for patients seeking out a relatively quick way of ridding themselves of small areas of "diet- and exercise-resistant fat."

But practitioners cite the lengthy process and cost of a clinical trial, as well as few adverse side effects, so far, in appropriate patients -- described as generally healthy individuals between 35 and 55 years of age.

"This is not meant as a procedure to lose weight," stressed Dr. Mukesh Aggarwal, a local ophthalmologist, who began offering lipodissolve in August. "It's meant to remove small amounts of stubborn fat. The cells swell and burst," and then are excreted naturally by the body.

So far, Aggarwal said, he has treated about seven patients in the county, including Conner, all of whom are "seeing some improvement."

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**Melting away fat.** Dr. Mukesh Aggarwal injects lipodissolve into the upper arm of patient Tammy Conner of Port St. John. Tim Shortt, FLORIDA TODAY

### About lipodissolve

- **What it is:** An umbrella term for a cosmetic procedure for treating "troubled" areas of fat through a series of injections, using proprietary compounds
- **Injection components:** Major injection components include small amounts of chemicals from a soy-based product, which is mixed with cow-derived bile.
- **What it does:** Proponents say the compound reduces small fat pockets by breaking apart fat cells, which are then excreted by the body naturally.
- **Lacks FDA approval:** The U.S. Food and Drug Administration cautions "buyer beware," because of a lack of long-term safety data.
- **Estimated cost:** \$2,000 to \$2,500, usually for six treatments -- generally not covered by insurance

### Dr. Aggarwal's medical record

Florida's Board of Medicine fined Dr. Mukesh Aggarwal \$5,000 and 50 hours of community service in August to settle an administrative complaint that he failed to properly diagnose a patient's eye condition in 2000. Practicing medicine since 1980, Aggarwal said, this is only action taken against him in 27 years.

### Controversial procedure

Lipodissolve has been used outside the United States for cosmetic purposes for more than a decade. Proponents of lipodissolve say it is a medical treatment, rather than a drug or medical device -- so U.S. Food and Drug Administration

Aneeta Kumar, a Viera resident, is one of them.

Midway through her six-course treatment, she said, she is "pleased with the procedure, and sees results already" in her abdomen, where she has lost 3 inches of fat.

Like Conner, she said, she experienced some initial discomfort -- a burning sensation that rapidly dissipated -- and swelling.

That the treatments lacked federal regulatory approval failed to bother or deter her, Kumar said, because Aggarwal is "a competent physician."

approval is not required. The FDA, however, takes the position that the injection of lipodissolve mixtures for fat removal are "unapproved drugs for unapproved uses," and requires further evaluation and investigation. But the agency offers no timetable for future action. And physicians are allowed on an individual patient basis to prescribe a compounded drug licensed by compounding pharmacies, which are monitored by state and federal agencies. As a board-certified physician, Dr. Mukesh Aggarwal offers the procedure locally, although his certification is in ophthalmology, not plastic surgery. But Aggarwal said he is a fellow of the American Academy of Cosmetic Surgery, and underwent a two-day intensive training course before using lipodissolve on patients.

--Susan Jenks, FLORIDA TODAY

### Sixfold increase

The American Society for Aesthetic Plastic Surgery estimates that 28,901 Americans underwent injection lipolysis -- an umbrella term for lipodissolve -- to eliminate or reduce unwanted fat pockets in 2006. That was six times the number of procedures performed the previous year.

The plastic surgery group announced in September that it soon would begin conducting a clinical trial under federal supervision, to evaluate how well the treatment works and to gather information on any long-term complications.

"This study is long overdue," Dr. V. Leroy Young, the study's chief investigator, said in a prepared statement, citing a lack of consistency in chemical formulations, which are compounded by licensed pharmacists and tailored to individuals.

"It will go a long way toward developing more standardized protocols and ultimately improving patient safety," Young said.

From Dr. Joel Schlessinger's perspective, however, such studies should have been done long ago.

Schlessinger, president of the American Society of Cosmetic Dermatology and Aesthetic Surgery and a past president of the Nebraska Dermatology Society, said the "drug was rushed to market, and not thoroughly examined before being introduced to the public."

"It's like having a Chinese toy with lead in it, but nobody cares," he said, adding his group has "seen countless people with injuries" from lipodissolve, including abscesses, and even "deformities where too much fat went away."

So, he advises consumers to be wary.

"People think the government is looking out for them, and if something is not safe, it will be taken off the market," he said. "That's not the case."

But the FDA's Karen Riley said the government is aware of lipodissolve and is looking into its use.

"It's not approved for any medical use," she said.

### Surgeons cautious

Although less harsh in their comments, several local plastic surgeons took the long view, while a spokeswoman for the lead manufacturer of a trademark product called Advanced LipoDissolve said the company supports an initiative in Kansas to regulate the product more closely.

"We've marketed our specific compound for the past several years," said Katie Rees, speaking on behalf of St. Louis-based Fig, which has 15 Fig Centers in eight states.

"What's going in Kansas is a continuing situation, and I'm not at liberty to discuss it," she said. "But we support the original decision by the Kansas Board of Healing Arts," to restrict its use to qualified health care providers -- the first state to attempt to do so.

Of the more than 28,000 patients treated in 2006, Rees said, Fig centers have treated 20,000 of them -- by far the greatest number of individuals nationwide.

Its proprietary compounds, which are prepared by FDA-registered suppliers, she said, were developed by the company's "leading plastic surgeons and

medical staff."

Dr. Ross Clevens, a Melbourne-based plastic surgeon specializing in the face, described lipodissolve as a "hot topic" among his colleagues at the American Academy of Facial and Plastic Surgeons.

But while lipodissolve "does seem to have promise for body-sculpting," he said, its value in the head and neck is "a little controversial," because when the face ages several processes occur, and lipodissolve addresses only one of them.

"It does nothing for the weakening of the muscle or the droopiness in the skin," Clevens said. "And that puts you at risk to fail."

Dr. Maurice Castellon, another Melbourne plastic surgeon, also expressed reservations about lipodissolve.

"I'm not a big fan of experimental treatments," he said. "If it causes a problem eventually -- such as a subcutaneous tumor there's no way to defend yourself against that."

Plus, he said, "we should have at least five years of scientific data and we're not there yet."

### \$2,000 'per zone'

During her recent flab-busting treatment, Conner chewed gum to calm her nerves, while Aggarwal swabbed each arm with an antiseptic, before jabbing a tiny needle into the fat areas underneath.


As the procedure continued, and the needle jabs picked up in number, Conner began to visibly flinch.

"It does get hot afterwards," she said, recalling her earlier experience with abdominal treatments. "It's kind of like having a fever."

Still, to rid her body of "troubled fat," she said, the cost -- \$2,000 to \$2,500 "per zone" or area treated -- the swelling and the pain all seem worth it.

"It's part of my Christmas present to myself," she said, "even though I know it's a little early."

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😬 OMG!! A 2 day intense course?? And someone would put their trust in THAT??????? Come on people! We go to Drs that have had several YEARS of training in specific fields of medicine, and still sometimes get a "quack"... what the heck makes you think that this Dr knows all that needs to be known, by going to a 2 day course? Hmm, seems awfully desparate to me. (Not to mention the fact that he is an ophthamologist, now practicing plastic surgery procedures). Wonders never cease....  
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Posted by: **grandma-ma** on Sat Nov 24, 2007 9:57 am

Too bad that is an employee in the article and picture. Show a real patient. Please do your homework before going to this "Dr"

Posted by: **axman3** on Sat Nov 24, 2007 9:56 am

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