

Injection Lipolysis Is Both Defended, Criticized

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Recent months have had a raft of bad news about injection lipolysis. Two prominent medical spas whose business was providing the popular treatments abruptly closed their doors, leaving patients in the lurch. Then, the Kansas Board of Healing Arts took action to strictly control the practice, a few months after trying to ban it.

Dr. Joel Schlessinger, immediate past president of the American Society of Cosmetic Dermatology and Aesthetic Surgery, warned the society that lipolysis might be neither effective nor safe, and he urged society members not to practice lipolysis until the ingredients used in the injections become Food and Drug Administration approved.

Recent news articles about this increasingly practiced treatment, popularly known as Lipodissolve, have tended to focus on individuals who complain of having permanent nodules or indentations from the procedure or who tell of rushing to the emergency department.

On the Web site www.realself.com, where consumers rate cosmetic procedures, it was reported as of Feb. 18 that 62% of the individuals who posted comments about their own Lipodissolve procedures said they were dissatisfied.

The Web site reported that an analysis of the IP addresses of the reviewers showed that many of the positive reviews came from one of the two now-defunct companies, Go Fig Inc., without the authors identifying themselves, and some came from MedSculpt (both companies are now out of business).

But while agreeing that better regulation might be a good idea, physicians who perform the procedure think that their experience and studies suggest the risks of complications are quite low and the results, in properly selected patients, generally good.

Support for Mesotherapy

"Injection lipolysis is not without risk, but it is pretty darn safe," said Dr. Thomas Wright, an internist who has a cosmetic practice in suburban St. Louis. He has been collecting reports of cases and complications from members of the American Society of Nonsurgical Aesthetics.

In reviewing about 200,000 treatment cases either reported to him or that he has sought out, he has found only 2 definite cases in which there was a serious complication. Both were cases of skin ulceration at or near sites of injection that needed skin graft repair. Overall, he said that he has found about 20 cases of skin breakdown or a pigment change, though some

of those were extremely small, a millimeter in size.

He reported having recorded no other confirmed complications.

"We've been using injection lipolysis in my clinic for 2 years now and getting excellent results," said Dr. Charles E. Crutchfield III, a dermatologist who practices in Minneapolis.

Dr. Crutchfield said the only serious complications he has seen or heard of are cases of skin ulceration. It is thought ulceration happens because of injections placed too superficially.

Dr. Crutchfield is a member of the medical advisory board of the American Society of Aesthetic Lipodissolve, a professional organization that owns a copyright on the term Lipodissolve and provides training in the procedure. Dr. Wright is also a medical advisory board member with the group.

Reports of Complications Conflict

Andrew Noel, a photographer from Las Vegas, had treatments at a Go Fig spa, and he said that 4 months after his last treatment, he still has welts "the size of 50-cent pieces" on his abdomen where he received the injections.

Lipolysis may be neither safe nor effective, and shouldn't be used until approved by the FDA.

DR. SCHLESSINGER

two patients who had complications presumed to be from Lipodissolve treatments, the first in a woman who was injected in her lower eyelids and the second in a woman injected in her thighs.

The second woman developed significant ulceration that caused scarring, Dr. Carruthers said.

Dr. Elizabeth Tanzi, a dermatologist in practice in Washington, has seen four patients with complications from Lipodissolve treatment, two with "an unnatural firmness" that resolved only slowly, one with a vascular pattern over the treated area that lasted for a year and required laser treatment, and another patient who had a draining nodule.

But surveys, like Dr. Wright's, of physicians who practice injection lipolysis suggest that the procedure—while sometimes causing discomfort and leaving temporary nodules in treated areas that resolve over time—only rarely has complications.

And another survey of 75 practitioners reported that among 17,376 patients treated there were no hospitalizations, no deaths, and no cases of skin necrosis (*Aesthetic Surg. J.* 2006;26:575-85). Moreover, less than 1% of patients reported to their physicians pain that lasted beyond 2 weeks, and the most common complaint of patients was a less than desired result, reported for 12% of patients. Nineteen of the practitioners reported having seen hy-

perpigmentation, but in the majority of cases this resolved within 3 months.

Safety Concerns

Another of the concerns with lipolysis treatment is whether there might be long-term effects from phosphatidylcholine or sodium deoxycholate, or acute problems from exposure to those ingredients or from the release of so much fat at once.

The substances are both naturally present in the human body already, and used the way they are to reduce fat, have only "relatively benign, localized effects," said Dr. Adam Rotunda, a physician who now works as a medical director of research and development at Allergan Inc., but who conducted research on injection lipolysis as a dermatology resident at the University of California, Los Angeles.

Dr. Rotunda has a patent for a formulation of sodium deoxycholate (licensed to Kythera Biopharmaceuticals Inc.) alone for injection lipolysis, which he claims might be as effective as the phosphatidylcholine/sodium deoxycholate combination. That formulation is at present in clinical trials. Dr. Rotunda has no financial interest in the product, though he has received consulting fees from Kythera. The licensing fees are paid to the University of California, Los Angeles, he disclosed.

A Flawed Business Plan?

Dr. Wright said he is very familiar with one of the now-defunct companies, Fig, which was based in the St. Louis area. He is not only well acquainted with the former principals in the company, but he has treated about 30 former Fig patients. And he suggests that many of the complaints and complications being reported about injection lipolysis come from Fig clients, who were guaranteed results or a refund.

The company often had no physician onsite at its locations and many sometimes used doses too high and treated inappropriate patients. Dr. Wright recalled one patient who went to a Fig location every month for a year to be treated and never once saw a physician.

"The company was selling to inappropriate candidates and overselling," he said.

Many Fig patients that Dr. Wright said he treated were extremely overweight, and the proper candidate for lipolysis is one who is not overweight but simply has a localized area with a small amount of fat they would like to be rid of. Fig—which had 18 locations in various states—ceased its operations in December and filed for chapter 11 bankruptcy in January. The other prominent company that recently closed was MedSculpt, a firm with locations in Rockville, Md., and Fairfax, Va., which went into receivership in January.

Officials from both companies were unavailable for comment, and physicians connected with the companies either declined to comment or did not return calls

and e-mails. However, in statements, Fig representatives said their investors pulled funding, and blamed the situation in part on a downturn in customers and bad press. MedSculpt needed a cash infusion and had investors lined up, but when Fig closed those investors balked, the representatives claim.

Recent Studies

Two studies have looked at whether the treatment has any identifiable systemic effects, and neither found any, said Dr. Rotunda. "We don't have the quality of data we need, but what we do have is pretty reassuring."

Brazilian investigators treated 30 patients with a series of four sessions of abdominal injections of sodium deoxycholate and looked at the local and systemic effects. At different time periods—ranging from 2 hours after an injection to 12 weeks—they measured lipids and kidney and liver function and found no significant changes (*Dermatol. Surg.* 2007;33:178-89).

In his own work, Dr. Rotunda has found that injecting phosphatidylcholine and sodium deoxycholate can produce changes in muscle architecture but the substances have to be injected directly into the muscles (*Dermatol. Surg.* 2004;30:1001-8).

Patients can experience nausea from the procedure, but that appears to be a cholinergic effect that occurs when too high a dose is used, he said.

Currently the evidence of the efficacy of injection lipolysis is anecdotal. But in November, a clinical trial of the combination solution got underway, sponsored by the Aesthetic Surgery Education and Research Foundation, run by Dr. V. Leroy Young, a former professor of plastic and reconstructive surgery at Washington University, St. Louis, who is now in private practice. The trial will enroll 20 subjects, who will be followed for 46 weeks.

In the meantime, both Dr. Crutchfield and Dr. Wright said they would have no problem if the FDA or some other agency came to regulate lipolysis procedures or the compounded ingredients used.

But Dr. Crutchfield also noted that injection lipolysis is not the first cosmetic product to be used off-label, and he cited Botox as an example. Botox was used cosmetically before its approval and currently is used in locations where it is not approved.

"If you are going to talk about this lacking FDA approval as a reason physicians should not be doing it, you are going to have to point the finger at everybody who does Botox," Dr. Crutchfield said.

Lipolysis has grown in popularity, while at the same time, a number of groups have expressed concern that it has no Food and Drug Administration approval, and have issued warnings about the procedure, saying there is no good clinical trial data to affirm benefit from the procedure and safety is not established. ■



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DR. CARRUTHERS