

## In Depth

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# Fat Treatments Draw Scrutiny

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by Rima Bedevian



Advances in nonsurgical body-contouring procedures have allowed physicians to offer alternatives to liposuction with no anesthesia or downtime. But are they safe?

The American Society for Aesthetic Plastic Surgery (ASAPS) has released a warning against the use of these injection fat-destroying treatments. Plastic surgeons are advised to avoid conducting these procedures, known as lipodissolve, mesotherapy, and endermologie.

Although they are marketed as fat-loss treatments, they have not been scientifically proven to reduce fat, and they lack objective data on safety and efficacy. More importantly, the injection formulations have not yet received FDA

approval.

### Lipodissolve

Lipodissolve is marketed as a nonsurgical alternative to liposuction. The treatment involves a series of injected medications that dissolve unwanted small, localized areas of fat deposits that are not affected by diet or exercise.

Lipodissolve claims to treat fat-related problems in the upper and lower abdomen, thighs, upper arms, and "saddlebags"; as well as fat pads under the eyes and chin, cellulite, stretch marks, scars, and residual fat deposits postliposuction. The treatment may also improve skin tone and elasticity, and increase collagen production that is impeded during the natural aging process.

Lipodissolve does not stop the aging process. Fat can appear again throughout a patient's lifetime.

"I have not performed lipodissolve treatments on any of my patients," says Andrew A. Jacono, MD, FACS, who practices in Great Neck, NY, and New York City. "These treatments, often referred to as 'mesotherapy' have no standardized composition or dosage of treatment, and have not been FDA-approved for removal of unwanted fat.

"Because I am a facial plastic and reconstructive surgeon," he continues, "I would only potentially use this on unwanted fat deposits on the face, for example in the submental region or jowls. I have seen many patients who have had mesotherapy with granulomas and localized fat necrosis, which results in contour irregularities that require surgery to correct. With more study, mesotherapy may or may not be an effective alternative to suction-assisted lipoplasty, but it is not the standard of care."

The ingredients used in lipodissolve vary depending on the physician and the area being treated. The ingredients may include phosphatidylcholine (PPC), sodium deoxycholate (DC), multivitamins, alpha lipid acid, enzymes, and plant extracts. Other agents such as nonsteroidal anti-inflammatory medications, antibiotics, and hormones may also be used.

During the treatment, the medication is injected into the fat layers and connective tissue using thin needles. The injection is relatively painless, with no need for anesthesia. The fat that is released is then naturally and permanently metabolized by the body.

Benefits from each injection should be evident within 3 weeks of the treatment. Several treatments, 4 to 6 weeks apart, are often required to produce a fully satisfactory result.

Complications from the injections are considered minimal—slight bruising, infection, swelling, or allergic reaction—and they can be treated by the physician. However, the long-term effects of lipodissolve have not been determined.

Lipodissolve should not be used on pregnant women, nursing mothers, obese patients, or people with diabetes, autoimmune diseases, vascular complications, or infections of any kind. It is important to note that lipodissolve is not an appropriate treatment for large areas of fat. In addition, it is recommended that all lipodissolve candidates participate in

a proper diet and regular exercise program to maintain the results.

### **Mesotherapy**

Mesotherapy is a minimally invasive procedure that is used to eliminate cellulite and localized fat deposits, and to provide antiaging benefits. During a mesotherapy treatment, tiny "medicinal bullets" are delivered directly into the mesoderm to treat the condition.

"I have not performed the treatment yet. As with most aesthetic procedures, I prefer to have solid evidence of safety and efficacy prior to implementing them in my practice," says Loren S. Schechter, MD, FACS, a plastic surgeon in Morton Grove, Ill.

"Although mesotherapy may work, the safety and efficacy have not been demonstrated in scientific studies. Concerning cosmetic procedures, it is my feeling that when a reasonable alternative exists (liposuction, diet, and exercise) we should be cautious in implementing untested modalities. After all, we are not talking about a lifesaving cancer drug."

Mesotherapy can eliminate cellulite on the legs and buttocks, breaking down the orange-peel appearance of skin, and producing a smooth contour. The average patient eliminates all visible cellulite in 10 to 25 sessions. Some patients require additional treatments if their cellulite is severe.

Mesotherapy is also used to reduce, eliminate, and contour specific undesired fat pockets. The method targets the receptors on fat cells that produce lipogenesis (fat production) and lipolysis (fat breakdown). Receptors that break down fat are known as beta receptors; those that create fat are alpha receptors.

Alpha receptors are stimulated to produce fat from food that contains carbohydrates, fat, amino acids, hormones, or alcohol. The physician selects a formula containing medications that block alpha receptors and stimulate beta receptors.

Once injected into the skin, the formula slowly diffuses into the fat and breaks it down. The number of weight-loss and body-sculpting treatments required varies from patient to patient. Mesotherapy is promoted as a safe alternative to invasive aesthetic procedures. The Mesolift process delivers vitamins, minerals, and amino acids directly into the skin to nourish and rejuvenate, promote production of collagen and elastin, and stimulate metabolism.

### **Endermologie**

Endermologie is a noninvasive technique that flushes out loose flat globules, tightens loose skin, smoothens wrinkles, and reduces the appearance of cellulite. Cellulite often shows up as dimpling on the skin and does not diminish with weight loss.

"Endermologie represents a deep massage technique that promotes circulation and leads to gradual improvement in the treated area," says David J. Goldberg, MD, JD, a dermatologist in New York City. "Anywhere from 14 to 18 treatments (often weekly or twice weekly) are performed. The improvement disappears once treatment has stopped.

"Over the last 2 years, two medical devices have been shown to produce better results, but still up to 16 treatments performed twice per week are required. We recently completed a study on a newly FDA-approved machine in which only six biweekly treatments were required, and the results lasted more than 6 months. This study has been accepted for publication in the journal *Dermatologic Surgery*.

"Because cellulite is not a disease, but a normal manifestation in women's skin, there will never be any 'true cure,' " he continues. "Maintenance treatments will be required."

Endermologie uses rollers that often feel like a deep-tissue massage over the problem areas of the skin. At the same time, suction is used to redistribute the skin and remove the dimpling. Patients usually need about 14 to 28 45-minute sessions to see results. Additional monthly treatments are needed to maintain the results.

Endermologie works best on patients who are fit. Those who do not regularly exercise may see only temporary results, and those who are 30 pounds or more overweight do not benefit from the procedure. Side effects are minimal and may include bruising or soreness in the areas treated.

### **What to Believe?**

Despite media and advertising claims that the fat-destroying procedures are safe, a placebo-controlled study sponsored by the Aesthetic Surgery Education & Research Foundation is currently under way to determine the safety and efficacy of the procedures. The formula that will be used for injection in this 20-patient study—PPC-DC—has shown the most promise in small, published trials.

The study, which will be conducted under FDA supervision, will follow patients for 46 weeks to evaluate the efficacy of PPC-DC for injection lipolysis and to collect data on local and systemic reactions and any long-term complications. Currently, neither drug under study in this trial is FDA-approved for subcutaneous injection for any purpose. Once completed, the results will be published in the *Aesthetic Surgery Journal* and presented at an ASAPS annual meeting.

### **ASAL Responds to ASAPS Regarding Lipodissolve Scrutiny by ASAL Medical Advisors**

The American Society of Aesthetic Lipodissolve (ASAL) objects to the inclusion of lipodissolve in the recent warning against injection therapy (mesotherapy) for localized fat reduction issued by the American Society for Aesthetic Plastic Surgery (ASAPS). Lipodissolve was introduced by the founders of ASAL in 2001 as distinct from mesotherapy. The ASAL included ingredients that were safe and whose mechanisms were understood. The ASAL limited training only to physicians and their nurses to perform the procedure. The ASAL and its original cohort, Network Lypolysis, have trained more than 300 physicians in Europe, and so far, more than 200 physicians in the United States.

ASAPS is incorrect in stating that there are no data relative to the effectiveness and safety of the lipodissolve procedure. More than 50,000 treatments have been reported in European and American peer-reviewed journals demonstrating objective evidence of improvement, based on actual measurements and images and a paucity of serious side effects.<sup>1-6</sup>

Serious side effects reported with liposuction such as death, fluid overload, epinephrine and lidocaine toxicity, thrombosis, fat embolism, and complications of general anesthesia have not been reported with lipodissolve therapy.<sup>7</sup>

The main ingredient in the lipodissolve formula is a lipid called phosphatidylcholine (PC), which is dissolved in a bile salt, called deoxycholate. When injected into the unwanted superficial body fat, deoxycholate helps break down the ingested fat cells and digests fat on a daily basis, as it does naturally in proximal duodenum. In the subcutaneous area, the dead fat cells are gradually removed by the body's physiologic repair mechanisms, the same way as after any trauma or liposuction, which leaves dead fat cells in the area to be removed by similar physiologic processes.

PC along with other phospholipids are significant dietary sources of essential fatty acids. Mammalian cell membranes are primarily composed of PC and other phospholipids that are mixed with cholesterol esters and salts to maintain fluidity. In other words, it is not a foreign or toxic substance.

ASAPS's statement that this procedure is not FDA approved is misleading. FDA approves drugs and devices, not procedures. ASAL maintains that there is no FDA approval requirement relative to phosphatidylcholine for two reasons:

- 1) It is a supplement that has been used for years for liver health, cholesterol, and other benefits. Supplements do not require FDA approval and can be administered by injection.
- 2) In lipodissolve, the ingredients are mixed by a compounding pharmacist upon a physician's order for specific patients, which does not require FDA approval (FDA Modernization Act Section 503a Compounding Pharmacy).

Lipodissolve is not a surgical procedure. Accordingly, ASAL has compiled an advisory board that includes credentialed physicians with diverse but relevant backgrounds in the fields of dermatology, aesthetic surgery, and internal medicine. These individuals are experienced clinicians, speakers, writers, researchers, and teachers, who provide advice regarding the procedure and its evolution. They conduct training workshops for other physicians in the United States. Thus far, the North American advisers have performed more than 2,000 lipodissolve procedures with satisfactory results in more than 90% of patients without any serious side effects. The ASAL has an ongoing monitoring process to record all lipodissolve procedures.

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