
Safety and Efficacy Report

Mesotherapy for Body Contouring

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DATA Committee

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There has been significant interest recently in the technique of mesotherapy as a method of “melting fat” for body contouring. Dr. Michel Pistor¹ is credited with having developed the technique of mesotherapy in France in 1952 for the treatment of vascular and lymphatic disorders. In 1987 mesotherapy was recognized by the French Academy of Medicine as a medical specialty. Mesotherapy has been used for several years in Europe and South America for body contouring. Its introduction and application in the United States are relatively recent. The public’s interest in mesotherapy has been piqued by a series of media reports in the lay press. In the lay press, “Thin-Jection” and “Lipo-Dissolve” are names that have been applied to mesotherapy for body contouring using phosphatidylcholine.

In mesotherapy, medications and other substances are injected into the mesoderm (the layer of fat and connective tissue under the skin). Mesotherapy using different substances is advocated by some to treat an assortment of conditions as varied as chronic pain, psoriasis, cellulite, weight loss, and spot weight loss. Moreover, mesotherapy has been advocated as a nonsurgical alternative to liposuction. The medications and plant extracts injected vary among practitioners and according to the condition being treated. They include vasodilators, nonsteroidal anti-inflammatory medications, enzymes, nutrients, antibiotics, hormones, and calcitonin.² One of the most frequently performed mesotherapy treatments utilizes phosphatidylcholine (lecithin), a naturally occurring phospholipid, for body contouring.

Phosphatidylcholine is the product most often referred to by the lay press.^{3–5} Plant extracts are sometimes used in combination with medications. Dietary modification, hormone replacement therapy, exercise, and nutritional supplements are often used in conjunction with mesotherapy.

The use of mesotherapy for body contouring, spot weight loss, and overall weight reduction typically involves multiple injections of phosphatidylcholine (lecithin) into the area selected for contouring. The methods of mesotherapy for weight loss and body contouring have not been published in the English-language literature. Injections are administered using a handheld device that has a syringe and needle attached; the depth and volume of injections can vary. Injection devices can be obtained through USA Meso, in West Orange, N.J. (973-325-1525; www.usameso.com). An informal inquiry of several practitioners in the United States revealed the following information:

A topical anesthetic cream is applied to the skin of the area to be treated. The compound is administered by multiple injections with a 27- or 30-gauge needle. The number of injections varies according to the size of the treatment area. When phosphatidylcholine is used for body contouring, a “typical” dosage is 100 mg per 5 × 5-cm area.⁶ The product can be obtained from compounding pharmacies (Pharmacy Creations, Randolph, N.J.; 973-328-8756), the Internet, or overseas (Mesoesthetic, Ltd., Barcelona, Spain, 00 34 93 325 30 30; in the United States, Sherman Oaks, Calif., 818-

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783-6881). Physicians using phosphatidylcholine recommend three to six treatments; treatments are often administered 2 weeks apart. The treated area may become swollen, tender, and bruised. The per-area charge ranges from \$1000 to \$1500 per treatment.

Information on mesotherapy in the English-language medical literature is scant. There are few publications in the English-language medical literature regarding the safety, efficacy, and mechanism of action of mesotherapy as a treatment modality. Information on formulations, technique, dosages, and toxicology is not available. Recently, two plastic surgeons performed a clinical study to evaluate the use of mesotherapy for body contouring and cellulite treatment.⁷ Forty patients were enrolled in the double-blind, prospective study; a single body region was treated by mesotherapy on a weekly basis for 5 weeks, followed by monthly maintenance therapy. The patients were separated into four groups: group I ($n = 10$) received mesotherapy treatments unilaterally; group II ($n = 10$) received treatments bilaterally; group III ($n = 10$) received mesotherapy in association with dietary modification and exercise; and group IV ($n = 10$) received saline placebo injections. Patients were surveyed by questionnaire and evaluated by a physician who was blind to the group assignments. Objective evaluations included circumference measurements and pinch tests. The majority of patients treated with mesotherapy reported a noticeable difference in the treated area (groups I and III, 18 of 20 subjects; group II, seven of 10 subjects). Circumference measurements decreased in the majority of treated patients. The average decrease in circumference was 2.6 cm at the waist and 1.8 cm at the thigh; the greatest circumference decrease was 3.8 cm at the waist and 2.5 cm at the thigh. In all the treated groups, the appearance of cellulite was dramatically reduced. No major complications occurred, but several minor complications were observed, including transient erythema of the treated area in six patients, localized infection at an injection site in one patient, minimal ecchymosis in five patients, and significant ecchymosis in one patient. Although this study demonstrated an improvement in the appearance of cellulite after mesotherapy, the possible mechanism of action remains unclear. A recent publication in the plastic surgery literature elucidates the architecture and biochemistry of cellulite; microdialysis assays in this

study showed no correlation between lipolysis and cellulite.⁸

Scientific literature describing the use of specific substances in mesotherapy is limited. Phosphatidylcholine injections have been reported to reduce cholesterol and triglyceride levels in the blood.^{9,10} Although these studies address issues possibly related to mesotherapy as a method of body contouring, they do not address the use of phosphatidylcholine in mesotherapy.

One clinical article describing the use of phosphatidylcholine has been published in the English-language literature.¹¹ A Brazilian physician reported in the American dermatologic literature on the use of injected phosphatidylcholine to reduce the size of infraorbital fat pads. Thirty patients were studied. The longest follow-up was 2 years. Twenty milligrams of phosphatidylcholine was injected into the central, medial, and lateral fat pads; the distribution per fat pad varied according to the patient's needs. The patients received additional treatments at 15-day intervals if bulging fat pads persisted after the first treatment. Two patients received four treatments, five patients received three treatments, 12 patients received two treatments, and 11 patients received one treatment. Improvement was noted by observation, and cosmetic improvement was seen in all patients. Patients noted mild burning that lasted 15 minutes after treatment. Edema of the entire lower eyelid lasted approximately 72 hours. There were no reported recurrences.

Another medication advocated for use in mesotherapy is isoproterenol. The use of subcutaneous injections of isoproterenol to study lipolysis is documented in the obesity research literature. Several publications describe enhanced lipolysis in adipose tissue perfused with isoproterenol, as measured in microdialysis studies.^{12,13} Two clinical studies report reduced thigh girth in subjects treated by subcutaneous injection of isoproterenol into the thigh.^{14,15}

Most of the reports on mesotherapy are published in the French, Italian, and Spanish literature. The *Tratado de Mesoterapia*¹⁶ is a Spanish handbook describing the various applications of mesotherapy, the active agents used, and the recommended protocols. It includes an extensive bibliography and is available through Laboratories Mesoesthetic, Ltd., a company based in Spain that manufactures products used in mesotherapy. At this time, an English translation is not available. In addition, several Russian

publications describe the effect of phosphatidylcholine in reducing serum lipid levels.¹⁷⁻²⁰

The medical literature contains several reports of infection after mesotherapy.²¹⁻²³ In all cases, the reported pathogens were mycobacteria. Multidrug treatment regimens and, in some cases, surgical excision were necessary to successfully treat the infection.

Collagenase, although not promulgated for mesotherapy, has also been studied for its effect on the size of lipomas.²⁴ In a U.S. Food and Drug Administration–approved study, lipomas on the body that were 5.0 cm or smaller were injected once with collagenase. Lipomas in the head, neck, and breast regions were excluded from the study. The collagenase dose was 1000 IU per centimeter diameter of the lipoma. The follow-up period was 6 months. By observation, a majority of lipomas were significantly reduced in size.

MECHANISMS OF LIPOLYSIS

Lipolysis of fat stored in adipocytes is regulated by alpha-2- and beta-adrenoreceptors on the adipocyte cell surface. Lipolysis is affected by hormones, including estrogen. Beta-receptor activity increases lipolysis. Alpha-2-receptor activity inhibits beta-receptors. So, beta-adrenergic activation and alpha-2-adrenergic inhibition increase lipolysis in fat cells. Compounds that promote beta activation and alpha-2 inhibition may therefore increase rates of lipolysis. The number and ratio of alpha-2- and beta-receptors on the adipocytes vary in different areas of the body. Adipocytes in the hip and thigh regions contain more alpha-2-receptors, so fat in these areas is more resistant to lipolysis.

Isoproterenol is a known beta-receptor stimulator. In the case of its use in mesotherapy for overall and spot weight reduction, the mechanism of action may be stimulation of the adipocyte beta-adrenergic receptor and a resultant increase in lipolysis.

Phosphatidylcholine is a naturally occurring phospholipid. It has three important functions: (1) it emulsifies dietary fat, thereby playing a vital role in the digestion of dietary fat; (2) it is an essential component of the apolipoproteins that regulate cholesterol metabolism; and (3) it is an essential component of cell membranes.

To understand its possible mechanism of action in body contouring, it is important to understand the role of phosphatidylcholine in

the emulsification of dietary fat.²⁵⁻²⁸ Phosphatidylcholine is found in bile and acts to promote the emulsification of dietary fat. A necessary step in the digestion of dietary fat occurs when fat globules, which are insoluble in water, are broken down into smaller sizes so that water-soluble digestive enzymes can act on the surface of the fat globule. The phosphatidylcholine molecule has both a polar (water-soluble) moiety and a nonpolar (fat-soluble) moiety. The fat-soluble portion of the phosphatidylcholine dissolves in the surface layer of the fat globule, with the polar portion projecting outward into the aqueous environment. Since the polar portion of the phosphatidylcholine is very soluble in the aqueous fluid, the interfacial tension of the fat globule is decreased and the fat globule can be broken up into minute particles by the normal agitation that occurs during peristalsis of the intestine. In the digestion of fats, this emulsification of fat can increase the total surface area of dietary fat by 1000 times. Thus, intestinal lipases can act upon a much larger surface area than would be available without emulsification.

The mechanism by which injectable phosphatidylcholine may result in decreased localized fat collections to improve body contour is not well understood. One hypothesis is that concentrated amounts of phosphatidylcholine injected subcutaneously would emulsify fat, allowing tissue lipases to hydrolyze fat and producing glycerol and free fatty acids. Alternatively, phosphatidylcholine may act to stimulate beta-receptors or inhibit alpha-2-receptors, thus producing increased lipolysis activity.

CONCLUSIONS

Localized deposits of excess adipose tissue and indeed obesity can be medically dangerous and psychologically distressing to patients. With respect to mesotherapy as a method of body contouring, more studies are necessary before we can advocate this therapy as a safe and effective treatment. It is possible that the mechanism of action involves enhancing lipase activity and thereby lipolysis; subsequent lipolytic activity may result in increased levels of free fatty acids and glycerol. To ensure some level of safety before using phosphatidylcholine in mesotherapy, it would be prudent to know the products of dissolution, whether or not free fatty acids are released into the patient's bloodstream, whether the injected

chemical is absorbed into the bloodstream, the effects on the liver and other organs, the appropriate dose, and so on. Moreover, although the intracellular contents of the adipocyte can be reduced, the fate of the adipose cell membrane and how that may affect recurrence are unknown. Similar questions remain regarding the safety and efficacy of using a known beta-agonist such as isoproterenol in mesotherapy.

No pharmaceutical drug is approved by the U.S. Food and Drug Administration for use in mesotherapy for body contouring. Injectable phosphatidylcholine is not approved in the United States for any use. Injectable phosphatidylcholine is manufactured by Aventis Pharmaceuticals (Paris, France) and marketed under the trade name Lipostabil. It is available in several countries outside the United States and can be obtained via the Internet. Isoproterenol (injectable) is approved by the U.S. Food and Drug Administration for the treatment of asthma, shock, and pulmonary hypertension and for the temporary control of hemodynamically significant bradycardia. Collagenase is approved in the United States for débriding chronic dermal ulcers and severely burned areas. Use of any of these agents for nonapproved indications, such as localized fat reduction, may place the practitioner at some risk.^{29,30}

When body-contouring procedures are skillfully applied to the appropriate patient, the results are pleasing to both the plastic surgeon and the patient. The promise of a simple, permanent method of weight loss, spot weight reduction, or cellulite improvement is obviously very appealing. In view of our cultural attitudes, which value a trim physique and youthful appearance, and the rise in the number of overweight individuals in our society, it is likely that the demand will increase for body-contouring procedures, including liposuction and other potential methods, such as mesotherapy.

Currently, support for the use of mesotherapy for body contouring in the English-language medical literature is limited to a few clinical trials. Consequently, controlled in vitro and in vivo experiments to determine the effects of agents used in mesotherapy, including phosphatidylcholine and isoproterenol, are needed before use of this technique can be endorsed.

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