Data Validate Some Lipolysis, but Not Mesotherapy

BY DAMIAN MCNAMARA Miami Bureau

LAS VEGAS — There are not enough data to recommend mesotherapy to patients, although some evidence supports a specific form—injected lipolysis—for localized fat reduction, according to two presentations at an international symposium on cosmetic and laser surgery.

Mesotherapy is touted for many indications worldwide, including cellulite reduction and pain management. Confusion abounds, however, because people often refer to mesotherapy and injected lipolysis interchangeably, said Dr. Paul T. Rose of Tampa.

"Oftentimes I am asked: Does mesotherapy work?" said Dr. Adam M. Rotunda of the division of dermatology at the University of California, Los Angeles. "We cannot say it works or does not work—it is such a general term."

An injected combination of the soy-derived phospholipid phosphatidylcholine (PC) and the solvent sodium deoxycholate (DC) "is well proven" for localized fat lysis, Dr. Rose said. He and colleague Dr. Michael Morgan assessed punch biopsies from a patient after PC/DC injections, and histology showed destruction of fat (J. Cosmet. Laser Ther. 2005;7:17-9). "There is a profound inflammatory response with neutrophils, plasma cells, and hopefully, macrophages to eat up the fat," he said.

Another study of 30 patients demonstrated some benefit of this combination for correction of lower eyelid bulging (Dermatol. Surg. 2001;27:391-2), Dr. Rotunda said. An open-label study of 43 patients who received a "pretty aggressive" regimen of up to 100 mL PC/DC per treatment session demonstrated some improvements in abdominal fat, he said.

"I'm not impressed with the abdomen you need a significant amount. I am impressed with jowl-area results," Dr. Rotunda said. Other commonly treated areas include inferior orbital fat, chins, arms, flanks, lateral and medial thighs, and knees.

Even with this evidence, more research is needed. "Most of these studies are unblinded, open case series. But we are moving in the direction of having peer review literature," Dr. Rotunda said. For example, Dr. David Goldberg and his associates conducted a study in 10 patients who received four monthly injections of multivitamin and conjugated hyaluronic acid

BRIEF SUMMARY OF PRESCRIBING INFORMATION



For Topical Dermatological Use Only

Rx only

826801-0905

Indication For Use

MimyX Cream is indicated to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. MimyX Cream helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Contraindications

MimyX Cream is contraindicated in persons with a known hypersensitivity to any of the components of the formulation.

Warnings

In radiation therapy, MimyX Cream may be applied as indicated by the treating Radiation Oncologist. Do not apply 4 hours prior to a radiation session.

Precautions and Observations - MimvX Cream is for external use only.

- WIITIYA Creatit is for external use only.

- MimyX Cream does not contain a sunscreen and should not be used prior to extended exposure to the sun.
 If clinical signs of infection are present, appropriate treatment should be initiated; use of MimyX Cream
- may be continued during the anti-infective therapy.
- If the condition does not improve within 10-14 days, consult a physician.
- Keep this and other similar products out of the reach of children.
- MimyX Cream may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

HOW SUPPLIED

MimyX[™] Cream is available in a 70 gram tube, NDC 0145-4200-01. Store at 15°C to 30°C (59°F to 86°F). Do not freeze. Stiefel Laboratories. Inc.

Coral Gables, FL 33134

REFERENCES: 1. Del Rosso JO, Bikowski J, Hawkes S, Sanglay L. Use of a palmitoylethanolamide-containing non-steroidal cream for the treatment of atopic dermatitis: impact on the duration of and time between flares. Presented at: 2006 Meeting of the American Academy of Dermatology; July 2006; San Diego, Calif. Poster 505. 2. Data on file. ITTF clinical results and protocoll. August C. Stiefer Research Institute, Inc.

Rx only - Prescription Medical Device: Federal Law restricts this

device to sale by or on the order of a physician.

MimyX is a registered trademark of Stiefel Laboratories, Inc., and Research in Dermatology is also a trademark of Stiefel Laboratories, Inc.



Mesotherapy Is a No Go for Cellulite

Not enough evidence of efficacy exists to recommend mesotherapy for treatment of cellulite.

Although some evidence supports a form of mesotherapy for local fat lysis, "I am far more skeptical about this area, it's more sketchy. Objective data

are lacking for cellulite," said Dr. Rose. Proponents of mesotherapy for cellulite say connective tissue dissolution can degrade and smooth out skin, Dr. Rotunda said, "but there are no published data that demonstrate improvements of 'skin dimpling.' "

"There is a lack of controlled studies

for facial rejuvenation (Dermatol. Surg., in press). Although thickened collagen fibers were noted, "no clinical benefits were seen," Dr. Rotunda said.

Intravenous PC can lower blood lipids, and a similar mechanism of action might lyse subcutaneous fat. "In our lab, however, phosphatidylcholine has not demonstrated any antifat property. Sodium deoxycholate, however, is a detergent known to lyse fat [Dermatol. Surg. 2004;30:1001-8]. So could this solvent actually be the active ingredient?" Dr. Rotunda asked.

"We are working on a double-blind study of PC vs. DC [for submental fat] to see if you need PC at all," Dr. Rotunda said. He disclosed a relationship with Kythera Biopharmaceuticals Inc., codeveloper of a patent-pending process owned by the University of California, Los Angeles, for the use of detergent in treating fat. Dr. Rose had no relevant disclosure. or histologic studies [but] there are people doing this," Dr. Rose said. "Unscrupulous individuals are ad-

ministering this," agreed Dr. Rotunda.

"Until further studies are performed, patients considering mesotherapy for cellulite must be aware that the substances currently being injected to treat this cosmetically disturbing, but medically benign, condition have not been thoroughly evaluated for safety or efficacy," Dr. Rotunda and his colleagues said in a review article on injectables used for cellulite (J. Cosmet. Laser Ther. 2005;7:147-54).

Injected lipolysis is contraindicated in patients on blood thinners or those with severe hypertension or cardiac disease, HIV, severe renal disease, allergies to medication, or unrealistic expectations, Dr. Rose said. "This is not a procedure for profound weight loss. If I have a patient come in and they are markedly obese, I tell them mesotherapy is not an option." The therapy can be an adjunct to liposuction or other procedures, he added.

Patients can receive the treatment every 2- 4 weeks at up to four areas at a time. "It is not magic. It can be four or five treatments," Dr. Rose noted. It is important to inform patients that they can get significant swelling and that bruising almost always occurs, he said.

Other effects, such as erythema, burning, tenderness, a jelly-like edema post injection, and nodularity, will go away within weeks, Dr. Rotunda said.

Ultrasound Breaks Up Subcutaneous Fat; May Be Liposuction Alternative

PALM DESERT, CALIF. — An ultrasound machine does appear to reduce waist size without changing a person's weight, Dr. Karyn L. Grossman said at the annual meeting of the American Society of Dermatologic Surgery.

The treatment produced an average 2cm reduction in circumference of thighs or abdomens treated and a 3-mm reduction in the fat layer of treated areas, relative to controls, reported Dr. Grossman, who practices in Santa Monica, Calif.

"This is probably a safe alternative to low-volume liposuction," she said.

The device used was the UltraShape Contour I (UltraShape Inc., Tel Aviv). The study enrolled 162 patients who received a single treatment of the abdomen or thighs at one of five centers, two of which were in the United States. Those patients were compared with control patients.

The reduction in circumference of the treated patients became noticeable at 7 days in some patients and was measurable in the overall group by 28 days. In the patients who had a single thigh treated, the average reduction observed in the treated thigh was 2 cm relative to the untreated

thigh at 21 days. That reduction persisted throughout the 84 days of the trial.

"I really can't imagine that after 84 days the fat is going to grow back," Dr. Grossman said.

There was a measurable reduction in circumference of the treatment areas in 82% of the treated patients, and 76% of patients expressed moderate to excellent satisfaction with the procedure. Neither the treated patients nor the controls lost any weight as groups during the trial, she added.

Safety evaluation to detect nerve damage or blood vessel destruction was conducted rigorously, and there were no abnormalities observed in any patient. The only adverse events occurred in two patients who experienced burns when treated over the trochanter, probably because the area did not have enough fat, Dr. Grossman said.

The device is not approved in the United States, but it is available in other countries. Dr. Grossman said that she has no financial connections with UltraShape Inc., but her partner in practice is a paid consultant to the company.