

# Sculptra Tips: Preparing Both Product and Patient

BY DAMIAN McNAMARA  
Miami Bureau

MIAMI BEACH — Although most U.S. dermatologists have limited experience with poly-L-lactic acid, this filler can be used successfully to correct lipoatrophy, Susan H. Weinkle, M.D., said at a seminar sponsored by the Skin Disease and Education Foundation.

Proper reconstitution, technique, and patient education were among the practical tips Dr. Weinkle presented for preparation of both the product and the patient.

Poly-L-lactic acid (Sculptra, Dermik Laboratories), which is indicated for restoration and/or correction of lipoatrophy in people with human immunodeficiency virus, was fast-tracked and approved by the Food and Drug Administration in August. Some physicians have been using the filler off label to restore volume to the aging face.

“Both the HIV and aging patients develop lipodystrophy, a loss of fat and a loss of volume. Our colleagues in plastic surgery think the way to deal with this is to pull and stretch. We want to volumize and fill,” said Dr. Weinkle, a dermatologist

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in private practice in Bradenton, Fla., who is on the advisory boards for Galderma, Procter & Gamble, and Dermik.

Poly-L-lactic acid (PLLA) is not a site-specific wrinkle filler; it’s a “global volume sculptor,” Dr. Weinkle said. It returns desired contours by smoothing wrinkles and folds from the inside out. The product stimulates a patient’s own fibroblasts to produce collagen. “We’re not just filling a wrinkle, we’re revolumizing from within,” she said during a live patient demonstration.

The filler material is freeze dried. Reconstitution with 5 mL sterile water or 4 mL sterile water and 1 mL lidocaine with epinephrine is recommended. Reconstitution with only 3 mL is possible, but this formulation should be reserved for experienced injectors who are treating the most severe cases, Dr. Weinkle said.

Do not shake the vial during or immediately after reconstitution. Set it aside for at least 2 hours. “I like to hydrate it the night before,” she added. Shake firmly just prior to injection.

Unlike some fillers, PLLA does not require an allergic skin test, and refrigeration is not needed. But because it has only a limited shelf life once reconstituted, PLLA can be a costly option if patients cancel or miss an appointment. Some physicians are requiring patients to prepay the estimated \$800-\$1,000 for each vial.

“The cost across the U.S. varies a lot. If the patient does not show up, you have 72 hours to use it. If you have some left, give it to your office staff, if suitable. Your of-

fice staff is your best marketer,” she said.

Prepare the area with a topical anesthetic such as Betacaine Plus. Injections should be deeper than the dermis and placed 0.5 to 1 cm apart. Inject 0.1 mL to 0.2 mL at each site. Dr. Weinkle suggested using an 18G BD Luer Lock 1-cc syringe. She injects bevel up and massages the area after every three to four injections.

It is important to undercorrect rather than overcorrect, she noted. “I usually inject a half cc on either side of the face to

start and have them return in a month.”

Patients must be told to expect little immediate gratification, Dr. Weinkle said. “Think of this as a staged procedure, like Mohs surgery. It typically takes three to five monthly treatment sessions to yield desired results. Uninformed patients are likely to call a few days after the initial session—once the swelling has gone down—and say, ‘I paid you so much and I have nothing,’ ” she said.

Dr. Weinkle likes to see patients every

4 weeks, which allows adequate time to gauge the results. “Then you can fine-tune it,” she said. “As a physician you need an aesthetic eye. Next time I may think I need some more volumizing in a different area to get a little more lift.”

The effect lasts 18-24 months, and PLLA is not permanent. Other fillers last 4-6 months.

Unlike collagen, injection of PLLA should stop as the needle is withdrawn, before the needle tip returns to the skin’s sur-

## Topicort® (Desoximetasone)

LP Cream 0.05%, Gel 0.05%, and Cream and Ointment 0.25%

**For topical use only. Not for ophthalmic use.**

**Rx only**

### DESCRIPTION

Topicort® LP (desoximetasone) Cream 0.05%; Topicort® (desoximetasone) Cream 0.25%; Topicort® (desoximetasone) Gel 0.05%; and Topicort® (desoximetasone) Ointment 0.25% contain the active synthetic corticosteroid desoximetasone. The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

Each gram of TOPICORT LP Cream 0.05% contains 0.5 mg of desoximetasone in an emollient cream base consisting of white petrolatum, purified water, isopropyl myristate, lanolin alcohols, mineral oil, cetostearyl alcohol, and edetate disodium.

Each gram of TOPICORT Cream 0.25% contains 2.5 mg of desoximetasone in an emollient cream base consisting of white petrolatum, purified water, isopropyl myristate, lanolin alcohols, mineral oil, and cetostearyl alcohol.

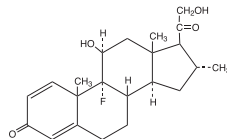
Each gram of TOPICORT Gel 0.05% contains 0.5 mg of desoximetasone in a gel base consisting of purified water, docusate sodium, edetate disodium, isopropyl myristate, carbomer 940, triethylamine, and SDAG-1B 95% alcohol.

Each gram of TOPICORT Ointment 0.25% contains 2.5 mg of desoximetasone in an ointment base consisting of white petrolatum and fractionated coconut oil.

The chemical name of desoximetasone is Pregna-1, 4-diene-3, 20-dione, 9-fluoro-11, 21-dihydroxy-16-methyl-, (11S, 16S)-.

Desoximetasone has the molecular formula C<sub>22</sub>H<sub>29</sub>FO<sub>4</sub> and a molecular weight of 376.47. The CAS Registry Number is 382-67-2.

The structural formula is:



### CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

### Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

Pharmacokinetic studies in men with Topicort® (desoximetasone) Cream 0.25% with tagged desoximetasone showed a total of 5.2% ± 2.9% excretion in urine (4.1% ± 2.3%) and feces (1.1% ± 0.6%) and no detectable level (limit of sensitivity: 0.005 µg/mL) in the blood when it was applied topically on the back followed by occlusion for 24 hours. Seven days after application, no further radioactivity was detected in urine or feces. The half-life of the material was 15 ± 2 hours (for urine) and 17 ± 2 hours (for feces) between the third and fifth trial day.

Pharmacokinetic studies in men with Topicort® (desoximetasone) Ointment 0.25% with tagged desoximetasone showed no detectable level (limit of sensitivity: 0.003 µg/mL) in 1 subject and 0.004 and 0.006 µg/mL in the remaining 2 subjects in the blood when it was applied topically on the back followed by occlusion for 24 hours. The extent of absorption for the ointment was 7% based on radioactivity recovered from urine and feces. Seven days after application, no further radioactivity was detected in urine or feces. Studies with other similarly structured steroids have shown that predominant metabolite reaction occurs through conjugation to form the glucuronide and sulfate ester.

### INDICATIONS AND USAGE

Topicort® LP (desoximetasone) Cream 0.05%; Topicort® (desoximetasone) Cream 0.25%; Topicort® (desoximetasone) Gel 0.05%; and Topicort® (desoximetasone) Ointment 0.25% are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

### CONTRAINDICATIONS

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

### WARNINGS

Topicort® LP (desoximetasone) Cream 0.05%; Topicort® (desoximetasone) Cream 0.25%; Topicort® (desoximetasone) Gel 0.05%; and Topicort® (desoximetasone) Ointment 0.25% are not for ophthalmic use.

**Keep out of reach of children.**

### PRECAUTIONS

#### General

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Pediatric patients may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (See **PRECAUTIONS - Pediatric Use**). If irritation develops, topical cortico-steroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

#### Information for the Patient

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions, especially under occlusive dressings.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

### Laboratory Tests

The following tests may be helpful in evaluating the hypothalamic-pituitary-adrenal (HPA) axis suppression:

- Urinary free cortisol test
- ACTH stimulation test

### Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results. Desoximetasone did not show potential for mutagenic activity in vitro in the Ames microbial mutagen test with or without metabolic activation.

### Pregnancy, Teratogenic Effects, Pregnancy Category C

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. Desoximetasone has been shown to be teratogenic and embryotoxic in mice, rats, and rabbits when given by subcutaneous or dermal routes of administration in doses 3 to 30 times the human dose of Topicort® (desoximetasone) Cream 0.25% or Topicort® (desoximetasone) Ointment 0.25% and 15 to 150 times the human dose of Topicort® LP (desoximetasone) Cream 0.05% or Topicort® (desoximetasone) Gel 0.05%. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, TOPICORT LP Cream 0.05%, TOPICORT Cream 0.25%, TOPICORT Gel 0.05%, and TOPICORT Ointment 0.25% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

### Nursing Mothers

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

### Pediatric Use

**Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.**

HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients. Safety and effectiveness of TOPICORT Ointment in pediatric patients below the age of 10 have not been established.

### ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

- |              |                             |                        |
|--------------|-----------------------------|------------------------|
| Burning      | Hypertrichosis              | Maceration of the skin |
| Itching      | Acneiform eruptions         | Secondary infection    |
| Irritation   | Hypopigmentation            | Skin atrophy           |
| Dryness      | Perioral dermatitis         | Skin atrophy           |
| Folliculitis | Allergic contact dermatitis | Miliaria               |

In controlled clinical studies the incidence of adverse reactions was low (0.8%) for Topicort® (desoximetasone) Cream 0.25% and included burning, folliculitis, and folliculo-pustular lesions. The incidence of adverse reactions was also 0.8% for Topicort® LP (desoximetasone) Cream 0.05% and included pruritus, erythema, vesiculation, and burning sensation. The incidence of adverse reactions was low (0.3%) for Topicort® (desoximetasone) Ointment 0.25% and consisted of development of comedones at the site of application.

### OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**).

### DOSAGE AND ADMINISTRATION

Apply a thin film of Topicort® LP (desoximetasone) Cream 0.05%, Topicort® (desoximetasone) Cream 0.25%, Topicort® (desoximetasone) Gel 0.05%, and Topicort® (desoximetasone) Ointment 0.25% to the affected skin areas twice daily. Rub in gently.

### HOW SUPPLIED

Topicort® LP (desoximetasone) Cream 0.05% is supplied in 5 gram tubes for physician samples, 15 gram and 60 gram tubes.

Topicort® (desoximetasone) Cream 0.25% is supplied in 5 gram tubes for physician samples, 15 gram and 60 gram tubes.

Topicort® (desoximetasone) Gel 0.05% is supplied in 5 gram tubes for physician samples, 15 gram and 60 gram tubes.

Topicort® (desoximetasone) Ointment 0.25% is supplied in 5 gram tubes for physician samples, 15 gram and 60 gram tubes.

Store at controlled room temperature 15° - 30°C (59° - 86°F).

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Revised: June, 2003



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face. "I was injected myself 5 days ago, and I have some bruising from not using enough pressure," Dr. Weinkle said.

Another caveat is to inject PLLA rapidly to avoid clogging of the needle. If a clog does occur, it is necessary to change the needle. "There is a learning curve, but this is so easy," Dr. Weinkle said.

"Some patients will experience some minor discomfort and should be forewarned," Dr. Weinkle said. Most adverse events are technique dependent, such as the bruising. Also, if PLLA is injected too superficially, nodules can result.

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PLLA for lipodystrophy volumizes and fills, thus restoring volume to the aging face.



After three sessions and half a vial of PLLA, there is significant improvement in volume and decrease in the nasolabial fold.

PHOTOS COURTESY DR. SUSAN H. WEINKLE

## There's a lot of Flexibility in *Topicort*<sup>®</sup> (Desoximetasone)



*Topicort*<sup>®</sup> provides you with a choice of multiple potencies<sup>1,2</sup> and vehicles, giving you remarkable flexibility to treat a broad range of dermatoses. And when it comes to treating corticosteroid-responsive dermatoses, *Topicort*<sup>®</sup> gives you flexibility you can trust...with established efficacy and safety through decades of clinical use.



The most common adverse reactions include burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and milium. When used in large areas or under occlusive dressing, patients should be evaluated for HPA axis suppression. Before prescribing, please see complete prescribing information.

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1. Stoughton RB. Percutaneous Absorption of Drugs. *Annu Rev Pharmacol Toxicol*. 1989;29:55-69.  
2. Gilman AG, Hardman JG, Limbird LE. *Goodman & Gilman's The Pharmacological Basis of Therapeutics*. 10th ed. McGraw-Hill, 2001, pg. 1799.  
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In corticosteroid-responsive dermatoses prescribe...

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## Common Sense Liposuction Tips

ST. LOUIS — Beware of the patient who considers liposuction just another type of "extreme makeover," Richard L. Schloemer, M.D., said at the World Congress on Liposuction Surgery.

"You cannot stress enough that liposuction is a major operation, and that if not done right it can lead to deformity, major complications, and death," he said.

Liposuction is not for weight loss, though it can contribute to an overall weight loss plan. It's absolutely essential that patients lower their body mass index one level before surgery, and that they maintain a diet afterward, said Dr. Schloemer, a surgeon in private practice in Troy, Ala. "I recommend the 'no white diet.' If it's white, don't eat it—potatoes, bread, rice, dairy products," he said at the congress, sponsored by the American Academy of Cosmetic Surgery.

Informed consent is vital. "You can't give a person too much information, and even when you do, you'd be surprised at how little they retain," he said. For example, one of his patients ignored instructions and took a soapy whirlpool bath 4 hours post procedure, and then spent 3 days in the hospital with a soap burn.

Preventing hypothermia is another important consideration. A cold operating room, cold solutions, and sedation can contribute to severe shaking.

But never use electric heating pads, he said. That practice resulted in a third-degree burn requiring a skin graft in one of his patients. "A heating pad that may fluctuate to greater than 100° F, and a wet solution in a numb patient can be a terrible combination. You have to warm the room and the solutions even if it is uncomfortable for you," Dr. Schloemer said.

Given the availability of tumescent anesthesia and intravenous sedation, general anesthesia is simply not necessary for liposuction. It's generally advisable to keep the lidocaine dose at 50 mg/kg or below to prevent toxicity, however.

"At the end of the procedure, have the patient stand up so you can assess the effects of gravity and ensure symmetry," he said. "Finally, don't promise too much, and remember that liposuction isn't for everyone. Declining to operate often shows good judgment and gains patient respect," he said.

—Nancy Walsh