Injectable Silicone Called a Safe, Elegant Filler

BY NANCY MELVILLE Contributing Writer

ANAHEIM, CALIF. — Liquid injectable silicone can be a highly effective means of tissue augmentation, especially for acne scarring and HIV-related lipoatrophy, Derek Jones, M.D., said at a cosmetic dermatology seminar sponsored by the Skin Disease Education Foundation.

"This can be an ideal filler that is long lasting and cosmetically elegant," said Dr. Jones of the department of dermatology at the University of California, Los Angeles.

A "wealth of anecdotal data" indicates that liquid injectable silicone is safe and effective, but the following critical rules are key to its safe usage, he said:

▶ Use only pure, Food and Drug Administration-approved, injectable-grade liquid silicone; in the United States that means only Silikon-1000, made by Alcon Laboratories. The product has FDA approval for intraocular injection to treat retinal detachment, but it may be legally used off label, under the 1997 FDA modernization act that allowed medical devices

It's important to note, however, that the law prohibits advertisement of off-label uses, and malpractice insurance carriers have different policies regarding such uses. Adhere to a strict serial puncture microdroplet technique, defined as 0.01 cc iniected into the immediate subdermal plane or deeper at 2- to 4-mm intervals,

with no double pass in the same plane. Intradermal injection should be strongly avoided except among the most skilled

The technique is necessary to allow a fibroproliferative response that develops around each microdroplet between treatments, not only causing each droplet to become anchored and less likely to drift but contributing to further augmentation, Dr. Iones said.

This is an oil, and if you inject a lot all at once, it's like throwing olive oil on the floor—it's going to spread out and track tissue planes along the path of least resistance," he said. "But the microdroplet technique addresses this problem."

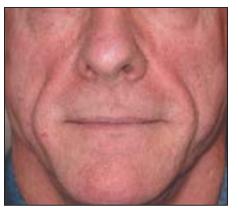
► Inject only small volumes—2 cc or less for lipoatrophy, or 0.5 cc or less for other indications. "Avoid the temptation to use larger volumes," Dr. Jones said, adding that injections should be spread out at intervals of at least 4 weeks.

In addition to these three critical rules, important considerations for silicone use include informing patients that liquid injectable silicone is permanent, and that its use is still investigational and likely to remain so for years. And, while patients can resume a normal routine immediately, they are advised to avoid activities that could predispose them to blunt trauma.

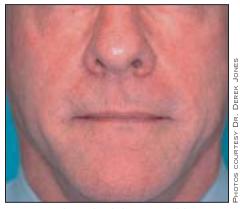
Dr. Jones demonstrated the injection technique on a patient with HIV-related facial lipoatrophy at the conference and said that most patients are highly pleased with the results.

Liquid silicone injections "really give an extraordinarily natural-appearing correction," he said. "When you touch the cheeks of these individuals, they feel nice, soft, and supple, and the injections really can restore subtle and refined facial contours."

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This HIV patient shows lipoatrophy before his silicone treatment.



Augmentation with injectable silicone gives a natural-appearing correction.

Luxíq® Konly

(betamethasone valerate) Foam, 0.12%

For Dermatologic Use Only Not for Ophthalmic Use

(Detamethasone valerate) Foam, 0.12%

BRIEF SUMMARY For Dermatologic Use Only Not for Ophthalmic Use

INDICATIONS AND USAGE

Luxíq is a medium potency topical corticosteroid indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp. CONTRAINDICATIONS

Luxíq is contraindicated in patients who are hypersensitive to betamethasone valerate, to other corticosteroids, or to any ingredient in this preparation. PRECAUTIONS

Generat's Systemic absorption of topical corticosteroids has caused reversible hypothalamic-pitultary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucostraic and also be produced in some patients by systemic absorption include the application of the more potential steroids, use over aligne surface areas, prolinged use, and the addition of occlusive dressings. Therefore, patients applying a topical steroid of a large surface area or to areas under occlusion of the more potential steroids, the overage produced in some patients of the produced in some patients and appropriate and appropriate in some patients and appropriate and appropria

Product	Total incidence	Maximum severity		
		Mild	Moderate	Severe
Luxíq Foam n=63	34 (54%)	28 (44%)	5 (8%)	1 (2%)
Betamethasone valerate lotion n=63	33 (52%)	26 (41%)	6 (10%)	1 (2%)
Placebo Foam n=32	24 (75%)	13 (41%)	7 (22%)	4 (12%)
Placebo Lotion n=30	20 (67%)	12 (40%)	5 (17%)	3 (10%)

other adverse events which were considered to be possibly, probably, of definitely related to Edxig occurred in 1 patient each; these were paresthesia, pruritus, acne, alopecia, and conjunctivitis. The following additional local adverse reactions have been reported with topical corticosteroids, and they may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximately decreasing order of occurrence: irritation; dryness; folliculitis; acneiform eruptions; hypopigmentation; perioral dermatitis; allergic contact dermatitis; secondary infection; skin atrophy; striae; and miliaria. Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pitultary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and elucesuria; in some nations. pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. **OVERDOSAGE** Topically applied Luxiq can be absorbed in sufficient amounts to produce systemic effects. (See **PRECAUTIONS**) **DOSAGE AND ADMINISTRATION** Note: For proper dispensing of foam, can must be inverted. For application to the scalp invert can and dispense a small amount of Luxiq onto a saucer or other cool surface. Do not dispense directly onto hands as foam will begin to melt immediately upon contact with warm skin. Pick up small amounts of foam with fingers and gently massage into affected area until foam disappears. Repeat until entire affected scalp area is treated. Apply twice daily, once in the morning and once at night. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary. Luxiq should not be used with occlusive dressings unless directed by a physician. **HOW SUPPLIED** Luxiq is supplied in 150 gram (NDC 63032-021-01), 100 gram (NDC 63032-021-00) and 50 gram (NDC 63032-021-50) aluminum cans. Store at controlled room temperature 68-77°F (20-25°C). **WARNING FLAMMABLE. AVOID FIRE, FLAME OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION.** Keep out of reach of children. Contents **DURING AND IMMEDIATELY FOLLOWING APPLICATION.** Keep out of reach of children. Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

Manufactured for: Connetics Corporation, Palo Alto, CA 94303 USA For additional information: 1-877-821-5337 or visit www.luxiq.com © 2005 Connetics Corporation PRM-LUXI-122-R1 5/05

OLUX® Foam, 0.05% (clobetasol propionate)

Ronly

(Clobetasol propionate)

BRIEF SUMMARY

For Dermatologic Use Only

Not for Ophthalmic Use

INDICATIONS AND USAGE

OLLX Form is a super-potent topical corticosteroid indicated for short-term topical

treatment of the inflammatory and prunitic mamifestations of moderate to severe corticosteroid-responsive dermatoses
of the scalp, and for short-term topical treatment of mild to moderate plaque-type positions of non-scalp regions

excluding the face and intentifying ous areas. Intendent beyond 2 consecutive weeks is not recommended and the total

designed should not exceed 50 g per week because of the potential for the drug is suppress the hypothalamic-pitularyadernal (PPA) acid, in a controlled pharmacokinetic study, some subjects experienced reversible suppression of the

adrenals following 14 days of OLLM Form therapy (See ADVERSE FEA/CTONS), Use in children under 12 years of age

is not recommended. ONTRAINDICATIONS OLLM Form is contrainedated in planters who are interpression of the

adrenals and 7.0 g of OLLM Form per day. Lessor amounts of OLLM Form bern of studied. Systemic

advantable and the position of the position of the preparation of the position of th on pregnant paramets, in large amounts, or tor protongee periods of urine. Nating Montares, "syletimically administered corticosteroids production, or cause other untoward effects, it is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Because many drugs are excreted in human milk, caution should be exercised when OLUX Foam is administered to a nursing woran. Pediatric Uses: Selfay and effectiveness of OLUX Foam in pediatric patients have not been established; therefore, use in children under 12 years of age is not recommended. Because of a higher ratio of skin surface area to body mass, pediatric judient of the site of a single period of the period of the

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