Microdroplets Provide Less Aggressive Brow Lift

BY JEFF EVANS

Senior Writer

VAIL, COLO. — The superficial injection of many botulinum toxin type A microdroplets may create a more naturallooking brow lift than more aggressive treatment of the central frontalis and nearby depressor muscles, Dr. Kenneth D. Steinsapir said at a symposium sponsored by the American Academy of Facial Plastic and Reconstructive Surgery.

In the area where Dr. Steinsapir practices, a common technique for raising the brow includes botulinum toxin type A (Botox) injections to the central forehead (leaving the lateral frontalis alone), aggressive treatment of the corrugator and procerus muscles, and "pretty aggressive treatment" in the crow's feet area, he said.

This technique creates a central depression and smoothing of the forehead and significant, unopposed elevation of the frontalis, which produces a taut, arching central brow. Extreme versions of this have been given the moniker "Klingon forehead," said Dr. Steinsapir, a cosmetic, eye, and facial plastic surgeon in private practice in Los Angeles.

These patients have smoother horizontal forehead lines, but often at the expense of brow position depression in which the eyebrows crowd into the eyes.

We have these treatment patterns because we're concerned that we'll get a ptosis after Botox treatment," he noted.

"Aesthetically, I think we can all agree that there is something not optimal about these faces," which are often seen in actresses, Dr. Steinsapir said. "This type of fakeness creates an impression in the public that Botox is a paralytic and undesirable at best.

"The key is, I think, to have a clearer picture of the anatomy and how these muscles interact," he continued.

"Brow position is really determined by the antagonists—the frontalis is really the only elevator in the brow. A substantial portion of the other muscles are brow depressors—the corrugators, the procerus, and the depressor supercilii," he said at the symposium, which was also sponsored by the American Society for Dermatologic Surgery and the American Society of Ophthalmic Plastic and Reconstructive Surgery.

To lessen the pronounced brow arch that occurs with that technique, Dr. Steinsapir developed his microdroplet technique, in which he aggressively treats the frontalis at and below the brow by injecting "smaller and smaller volumes of fluid in multiple locations." These microdroplets have volumes of 10-50 mcL of injectable saline; he has worked with microdroplets that contain 0.001-1 U Botox.

Dr. Steinsapir's currently preferred starting treatment is based on 100 U Botox and 3 mL of injectable saline, which equals about 0.33 U of Botox per 10 mcL.

He uses 32- and 33-gauge needles, which are more comfortable for the patient than a 30-gauge needle. He also uses magnification and subsurface illumination to see the subsurface vasculature "a little bit better," although he has not performed a study to determine if it reduces the rate of bruising, he said.

A typical treatment involves a total of about 100 microdroplets placed in double or triple rows just above, in, and below the brow, stopping around the level of the lowest brow cilia. The microdroplet injections are placed superficially about 1 mm into the skin to trap the Botox at the interface between the orbicularis oculi and the skin. For crow's feet, he will usually stop just before the midline of the lateral palpebral raphe. The glabellar area is also treated. The combination of these treatments produces a "uniform brow-lift effect," he said.

Dr. Steinsapir estimated that his starting treatment of about 100 microdroplets (about 33 U) works well for about 70% of women and about 50% of men. Of 75 consecutive patients (56 of them women) that he has treated with this technique, 61 returned at 3-week follow-up and had no ptosis, he said.

Caution should be used in performing this technique on patients who have had aggressive upper eyelid surgery, because their anatomy is slightly different and they may be at higher risk for ptosis, especially if their eyelids are thin, Dr. Steinsapir advised.

"If your patients are used to other techniques, it's a tough road because this is a very different treatment paradigm," he said.

Dr. Steinsapir has filed for a patent on the method and has asserted a trademark for the term microdroplet. "If you adopt it in your practice, you'll have to come up with a different name for it," he said.

Tretinoin Cream, USP (Emollient) 0.05%

Brief Summary of Full Prescribing Information

DESCRIPTION

Tretinoin is available as TRETINOIN CREAM, USP (EMOLLIENT) at a concentration of 0.05% w/w in a water in oil emulsion formulation consisting of light mineral oil, NF; sorbitol solution, USP; consisting of right mineral oil, Nr; sorbitol solution, OSF; hydroxyoctacosanyl hydroxystearate; methoxy PEG-22/dodecyl glycol copolymer; PEG-45/dodecyl glycol copolymer; stearoxytrimethylsilane and stearyl alcohol; dimethicone 50 cs; methylparaben, NF; edetate disodium, USP; quaternium-15; butylated hydroxytoluene, NF; citric acid monohydrate, USP; fragrance; and purified water USP. purified water, USP.

INDICATIONS AND USAGE

TRETINOIN CREAM, USP (EMOLLIENT) 0.05% is indicated as an adjunctive agent for use in the mitigation (palliation) of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin in patients who do not achieve such palliation using comprehensive skin care and sun avoidance programs alone (see bullet point 3 for populations in which effectiveness has not been established).

TRETINOIN CREAM, USP (EMOLLIENT) DOES NOT ELIMINATE WRINKLES, REPAIR SUN DAMAGED SKIN, REVERSE PHOTO-AGING, or RESTORE A MORE YOUTHFUL OR YOUNGER DERMAL HISTOLOGIC PATTERN.
TRETINOIN CREAM, USP (EMOLLIENT) should only be used under medical supervision as an adjunct to a comprehensive skin care and sun avoidance program that includes the use of effective sunscreens (minimum SPF of 15) and protective clothing when desired results on fine wrinkles, mottled hyperpigmentation, and roughness of facial skin have not been achieved with a comprehensive skin care and

facial skin have not been achieved with a comprehensive skin care a sun avoidance program alone.

Neither the safety nor the efficacy of using TRETINOIN CREAM, USP (EMOLLIENT) daily for greater than 48 weeks has been established, and daily use beyond 48 weeks has not been systematically and histologically investigated in adequate and well-controlled trials.

CONTRAINDICATIONS:

This drug is contraindicated in individuals with a history of sensitivity reactions to any of its components. It should be discontinued if hypersensitivity to any of its ingredients is noted.

TRETINOIN CREAM, USP (EMOLLIENT) is a dermal irritant, and the results of continued irritation of the skin for greater than 48 weeks in chronic, long term use are not known.

Safety and effectiveness of TRETINOIN CREAM, USP (EMOLLIENT) in individuals with moderately or heavily pigmented skin have not been established.

TRETINOIN CREAM, USP (EMOLLIENT) should not be

administered if the patient is also taking drugs known to be photosensitizers (e.g., thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulfonamides) because of the possibility of augmented

Because of heightened burning susceptibility, exposure to sunlight (including sunlamps) should be avoided or minimized during use of TRETINOIN CREAM, USP (EMOLLIENT). Patients must be warned to use sunscreens (minimum of SPF of 15) and protective clothing when using TRETINOIN CREAM, USP (EMOLLIENT). Patients with sunburn should be advised not to use until fully recovered. Patients who may have considerable sun exposure due to their occupation and who may have considerable sun exposure due to their occupation and those patients with inherent sensitivity to sunlight should exercise particular caution when using and assure that the precautions outlined in the Patient Package Insert are observed.

TRETINOIN CREAM, USP (EMOLLIENT) should be kept out of the

eyes, mouth, angles of the nose, and mucous membranes. Topical use may cause severe local erythema, pruritus, burning, stinging, and peeling at the site of application. If the degree of local irritation warrants, patients should be directed to use less medication, decrease the frequency of application, discontinue use temporarily or discontinue use altogether.

Tretinoin has been reported to cause severe irritation on eczematous skin and should be used only with utmost caution in patients with this

skin and should be used only with utmost caution in patients with this condition.

General: If a drug sensitivity, chemical irritation, or a systemic adverse reaction develops, use should be discontinued.

Drug Interactions: Concomitant topical medication, medicated or abrasive soaps, shampoos, cleansers, cosmetics with a strong drying effect, products with high concentration of alcohol, astringents, spices or lime, permanent wave solutions, electrolysis, hair depilatories or waxes, and products that may irritate the skin should be used with caution in patients being treated because they may increase irritation with use.

Tretinoin Cream USP (Emollient) should not be administered if the patient is also taking drugs known to be photosensitizers (e.g., thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulfonamides) because of the possibility of augmented phototoxicity.

Carcinogenesis, Mutagenesis, Impairment of Fertility

There was no evidence of carcinogenic potential when tretinoin was administered topically at a dose 5 times the average recommended human topical clinical dose. The mutagenic potential of tretinoin was evaluated in the Ames assay and in the in vivo mouse micronucleus assay, both of which were negative.

Pregnancy: Pregnancy Category C.

There are no adequate and well-controlled studies in pregnant women. TRETINOIN CREAM, USP (EMOLLIENT) **should not be used** during pregnancy.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, of be exercised when administered to a nursing women.

Pediatric Use: Safety and effectiveness in patients less than 18 years of

age have not been established.

Geriatric Use: Safety and effectiveness in individuals older than 50 years of age have not been established.

ADVERSE REACTIONS

(See WARNINGS and PRECAUTIONS sections.)

Local reactions such as peeling, dry skin, burning, stinging, erythema, and pruritus were reported by almost all subjects during therapy. These signs and symptoms were usually of mild to moderate severity and generally occurred early in therapy.

Application of larger amounts of medication than recommended has not been shown to lead to more rapid or better results, and marked redness, peeling, or discomfort may occur. Oral ingestion of the drug may lead to the same side effects as those associated with excessive oral intake of

DOSAGE AND ADMINISTRATION

TRETINOIN CREAM, USP (EMOLLIENT) should be applied to the face **once a day** before retiring using only enough to cover the entire affected area lightly. Patients should gently wash their face with a mild soap, pat the skin dry, and wait 20 to 30 minutes before applying. The

soap, pat the skin dry, and wait 20 to 30 minutes before applying. The patient should apply a pea-sized amount of cream to cover the entire face lightly. Special caution should be taken when applying the cream to avoid the eyes, ears, nostrils, and mouth.

With discontinuation of therapy, a majority of patients will lose most mitigating effects on fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin; however, the safety and effectiveness of using TRETINOIN CREAM, USP (EMOLLIENT) daily for greater than 48 weeks have not been established.

TRETINOIN CREAM, USP (EMOLLIENT) is available in these sizes: NDC 66530-24740 gram tube

NDC 66530-24760 gram tube

Storage: Store at 20-25° (68-77°F) [see USP Controlled Room Temperature]. DO NOT FREEZE.

Manufactured by DPT Laboratories, San Antonio, TX 78215 Distributed by Spear Dermatology Products, Randolph, NJ

