NEW & APPROVED

Sculptra Aesthetic

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Sculptra Aesthetic
(injectable poly-L-lactic acid, Sanofi-aventis)
Sculptra is an injectable filler containing microparticles of poly-L-lactic acid approved by the Food and Drug Administration in August for use in immune-competent people as a single regimen for the correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles "in which deep dermal grid pattern (cross-hatch) injection technique is appropriate," according to the manufacturer. The injectable was first approved in 2004 for correcting lipoatrophy in HIV patients.

► **Recommended Usage:** Injected into the deep dermis. Injection requirements for Sculptra Aesthetic are "unique," and include "a tunneling technique in a grid pattern that is medial to the nasolabial fold contour defect" being corrected, according to prescription information.

► **Special Considerations:** Contraindicated in patients with a hypersensitivity to any of the components of this product and those with a known history of keloid formation or hypertrophic scarring. The product has not been studied in the periorbital area, but use in this area has been associated with an increased risk of papules and nodules, according to reports in the literature. Side effects can include injection site discomfort, redness, bruising, bleeding, itching, and swelling, noted the manufacturer.

► **Comment:** Poly-L-lactic acid is a biodegradable synthetic polymer that has been widely used for years in dissolvable stitches, bone screws, and facial implants, according to the FDA. A randomized, multicenter, evaluator-blinded controlled study of 233 immune-competent mostly female patients (mean age 51 years) with previously untreated nasolabial fold wrinkles and wrinkle assessment scores of 2 (shallow) through 4 (deep) was conducted.

Patients were treated with bilateral injections of Sculptra Aesthetic (at 3-week intervals for up to four treatments) or with CosmoPlast (INAMED Aesthetics) for a maximum of four sessions over 9 weeks. At 13 months, those who received Sculptra had improvements in wrinkle assessment scores in correction of the contour deficiency of the nasolabial folds. Improvements were maintained among those patients followed for up to 25 months, according to the prescribing information. CosmoPlast results were maintained for up to 3 months.

In an interview, Dr. Leslie S. Baumann, director of cosmetic dermatology at the University of Miami, said that she has used Sculptra off-label for hundreds of patients since it was approved in 2004. It is not her first choice for nasolabial folds, but she likes to use it for improving cheek volume, which is similar to the HIV lipoatrophy indication.

The biggest issue with Sculptra is that patients need to have four to eight treatments before they see any improvement in cheek volume, which is more expensive initially than other treatments, she said. Also, it is difficult to predict how many treatments people will need.

Dr. Baumann tells patients that they will need four to eight treatments 1 month apart, and that they usually will not see changes until the third or fourth treatment. It is worth it, though, "because once you get them the way you want them to look, it lasts 2-3 years," she said.

The University of Miami was among the Sculptra Aesthetic study sites, and Dr. Baumann said she has been an investigator for Dermik Laboratories (the dermatology division of sanofi-aventis) and other major cosmetic filler manufacturers.

She described Sculptra as a "dermal stimulator" rather than a filler because it stimulates the dermis to make collagen. She cautioned that it should not be used in areas where there is a lot of movement, such as the corner of the mouth, because of the risk of developing hard lumps. "I've seen people with horrible lumps under their eyes and there's nothing you can do," she said.

Dr. Baumann stressed the need to be properly trained in how to inject Sculptra. When she trains residents, "this is the last thing I'll teach them, because they really have to get their skills down." ■

A consumer information page, with a link to the approval letter, is posted at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm176124.htm.