

Nasolabial Folds: Fewer Adverse Events With PLLA

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CHICAGO — Injectable poly-L-lactic acid used to treat nasolabial fold wrinkles produced significantly fewer overall product-related adverse events than human-derived collagen, study results have shown.

In a randomized multicenter trial of 233 patients with nasolabial fold wrinkles, the overall product-related adverse event rate was 21% with poly-L-lactic acid

(PLLA; Sculptra) and 36% with human collagen (Cosmoplast), resulting in a *P* value of less than .05.

Compared with the PLLA group, the collagen group had more injection-site erythema (26.5% vs. 2.6%) and pruritus (8% vs. 1%), Dr. Marta Rendon and the Cosmetic Study Trial Group reported in a poster at the American Academy of Dermatology's Academy 2008 meeting.

The PLLA group reported more injection-site pain (5.2% vs. 3.4%); more appli-

cation-site papules, defined as palpable elevations less than 5 mm in diameter (8.6% vs. 3.4%); and more application-site nodules, defined as lesions 5 mm or more in diameter (7% vs. 6%). The difference between the groups was statistically significant for nodules.

The papules and nodules were nonvisible, palpable, and mild or moderate in intensity; all but one event resolved spontaneously during the 13-month follow-up period.

The frequency of adverse events with injectable PLLA, including injection-site pain, papules, and nodules, was lower than reported in early published reports in patients with HIV-related facial lipoatrophy, reported Dr. Rendon, who is in private practice in Boca Raton, Fla., and her associates.

No product-related serious adverse events occurred during the study, which was sponsored by Sanofi-Aventis U.S., which markets Sculptra in the United States through its subsidiary, Dermik Laboratories.

Injectable PLLA is currently approved in the United States for HIV-related facial lipoatrophy and is under review for volume restoration and/or correction of facial wrinkles and folds.

Patients (mean age 51 years) in the study had scores of 2-4 on a 5-point photo-numeric wrinkle assessment scale (WAS) for both the right and left nasolabial fold.

They underwent bilateral injections of PLLA (maximum 5 mL of reconstituted product per session) or collagen (1-2 cc per session) at one to four treatment sessions at 3-week intervals until an optimal correction was achieved for both folds. Roughly 40% in each group were Fitzpatrick skin type III.

Both the PLLA and collagen groups had significant reductions from baseline in WAS scores 3 weeks after the last treatment, as assessed by three plastic surgeons/dermatologists blinded to treatment.

Comparisons between the two groups in the change from baseline in mean WAS scores at subsequent time points resulted in significant differences favoring PLLA at months 3, 6, 9, and 13, reported Dr. Rendon and her associates. ■

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1. Alora-Palli MB, Van Cott A, Kimball AB. Summer Academy Meeting 2008, American Academy of Dermatology, July 30–August 3, 2008, Chicago, IL; [†]Images show PSORENT-treated leg plaque; Dovonex (calcipotriol) is a registered trademark of Warner Chilcott Laboratories.; ^{*}Liquor carbonis distillate, equivalent to 2.3% coal tar. ^{††}86% of patients treated twice-daily with PSORENT for 12 weeks.

Radiesse Found Safe for Use In Skin Types IV-VI

CHICAGO — The first large-scale trial of calcium hydroxylapatite in patients with Fitzpatrick skin types IV-VI showed no keloid formation, hypertrophic scarring, or skin discoloration when used to treat nasolabial folds.

Although the reasons for scarring and keloids are not clear, anecdotally these side effects appear to present more in patients with darker skin types, lead investigator Dr. Ellen Marmur, chief of dermatologic surgery at Mount Sinai School of Medicine, New York, said in an interview.

"This study liberates many women and men with darker skin types to undergo cosmetic filler treatments with calcium hydroxylapatite," she said. "Past concerns about keloid scarring and discoloration now can be minimized, if not totally alleviated, for these patients.

"Their safety profiles matched those of the larger safety studies in lighter skin types showing this filler is safe to use in all skin types," she added.

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