

Nasolabial Folds: Fewer Adverse Events With PLLA

BY PATRICE WENDLING
Chicago Bureau

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.

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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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Maintain Lip Borders in Perioral Reconstruction

BY SHERRY BOSCHERT

San Francisco Bureau

SAN FRANCISCO — Respect the nasolabial folds, vermilion border, and mental crease to get the most natural-looking results from reconstructive surgery around the mouth.

Put linear surgical scars into those lines—not across them—to avoid a noticeable asymmetry that “gets very exaggerated during movement” of the mouth, Dr. Ken K. Lee said at the annual meeting of the Pacific Dermatologic Association. Even respecting the lines of current or future rhytids can help hide a scar.

Surgeons commonly used to use a transition flap from the cheek to repair surgical defects on the upper cutaneous lip, but this would blunt the entire nasolabial fold. “If the crease is completely gone, it looks unnatural,” so surgeons today shy away from that technique, said Dr. Lee, director of dermatologic and laser surgery at Oregon Health and Science University, Portland.

Perioral surgical defects on the upper lip tend to leave

indented scars unless the surgeon hypereverts the incision. “The natural tendency—the reason we get wrinkles in this area—is it wants to invert. So you really have to do an exaggerated eversion to prevent this type of indented scar,” he said. The creation of a little ridge when a defect is closed helps produce a nearly invisible scar instead of an indented one.

Closing in a linear fashion may not suffice for larger defects, but the surgeon still should respect the cosmetic lines when using other techniques for closure. Aligning the closure of a rotation flap with the nasolabial fold, rhytids, mental crease, or vermilion border will help hide a scar.

For larger defects, the island pedicle flap becomes the surgeon’s work horse, in all its variations. “It allows me to bring skin in from outside the lip unit to fill in larger defects in the lip,” Dr. Lee said.

He used a pedicle flap from outside the nasolabial fold

to help close a complex defect in the upper cutaneous lip, nose, and cheek in one patient, closing along the nasolabial fold and advancing the cheek. “Recreating all the cosmetic borders is important,” he said.

‘The natural tendency—the reason we get wrinkles in this area—is it wants to invert.’

DR. LEE

For a young woman in her 30s with little extra skin compared with older patients, it is difficult to repair a defect that takes up a large portion of the upper cutaneous lip just by using the skin inside of the nasolabial fold. It’s okay to tap the reservoir of cheek skin for an island pedicle flap to repair this, but “the important thing is that when you zip up the island pedicle—the defect behind it—that line needs to follow the nasolabial fold,” he said.

The downside of island pedicle flaps is potential “pincushioning,” he added, but if the incision has been adequately undermined and the edges everted, resulting in a good-looking scar, pincushioning will go away in time. ■



An island pedicle flap can utilize skin from outside the perioral borders to fill a defect in the upper lip, with closure along the nasolabial fold for a good cosmetic result as demonstrated in the patient above. The patient is shown before and after surgery (left and middle, respectively), and after the wound had healed (right).

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The open-label, multicenter, nonrandomized prospective trial enrolled 100 patients with moderate to severe nasolabial folds and Fitzpatrick skin types IV (24%), V (35%), and VI (41%). Calcium hydroxylapatite 0.6 mL-2.8 mL (mean 1.24 mL) was injected subdermally with a 25- to 27-gauge needle using a linear threading/fanning technique.

The mean patient age was 52 years and 94 were female; 85% were African American, 12% were Hispanic, 2% were Asian, and 1%, other.

Evaluation of 100 patients at 3 months and 98 patients at 6 months revealed no keloid formation, hypertrophic scarring, hypopigmentation, hyperpigmentation, or other clinically significant adverse events, Dr. Marmur and her associates reported in a poster at the American Academy of Dermatology’s Academy 2008 meeting.

The study did not objectively evaluate efficacy, but treatment benefit, based on physician assessment, persisted for up to 6 months. Radiesse contains calcium-based microspheres suspended in a water-based gel that absorbs in 2-4 weeks, and builds volume by stimulating collagen growth around the implanted material.

Calcium hydroxylapatite (Radiesse) is approved for HIV-associated facial lipoatrophy, and is used as a cosmetic dermal filler.

The study was sponsored by BioForm Medical Inc., the maker of Radiesse. Dr. Marmur is on the medical education faculty for BioForm.

—Patrice Wendling

Diamond Bilobed Flap Cuts Pincushion Risk

BY SHERRY BOSCHERT

San Francisco Bureau

SAN FRANCISCO — Three techniques can help make nasal reconstruction surgery easier while providing positive results.

Dr. Hayes B. Gladstone recommends using a more diamond-shaped bilobed flap instead of curved incisions, doing a shave contour instead of defatting a staged melolabial flap, and dividing a paramedian forehead flap after 1 week instead of 3 weeks.

The diamond bilobed flap results in less stress and tension during healing and may reduce the risk of pincushioning, also called trap-door deformity. A shave division of a staged melolabial flap is much easier than defatting, and patients seem pleased to shorten the time to division of a paramedian forehead flap, he said at the annual meeting of the Pacific Dermatologic Association.

► **Bilobed flap.** The original design for a bilobed flap was modified in 1989 to change the angles in order to reduce pincushioning, in which the flap raises up. “If you look in the literature, there is still about a 5%-10% risk” of pincushioning

with a bilobed flap, probably caused by wound contraction, said Dr. Gladstone of Stanford (Calif.) University.

By using more angular incision lines (instead of curved lines) to give the flap more of a diamond shape, only 2 mm of undermining is needed instead of the 3 mm needed with a conventional bilobed flap. “It’s more of an advancement flap in its angular design,” he said.

Computer modeling suggests that the diamond bilobed flap reduces strain on the closure points by 85%, compared with a conventional bilobed flap.

“With angles you’re going to get less compression and less contraction, and therefore you’re going to get less risk of pincushioning,” Dr. Gladstone said.

► **Melolabial flap.** He follows the conventional technique for most patients with thin, nonlobular alar rims who undergo a staged melolabial flap for nasal reconstruction, but after 3 weeks, instead of defatting the flap, he does a shave contour that takes around 3-4 minutes. He lets that heal by second intent.

“It seems a little counterintuitive, but it actually heals very well,” accompanied by closure of a small cheek defect when needed, he said.

The key to shave contouring the melolabial flap is to not be too aggressive, which can result in a divot or raising of the alar rim, he added.

► **Paramedian forehead flap.** Most patients dislike waiting 3 weeks to divide a paramedian forehead flap because the flap disrupts vision, making it difficult to read or drive; decreases quality of life; and can cause psychological stress.

One patient tore off his flap after 4 days but healed well. “That’s how I decided to start doing this” division earlier, Dr. Gladstone said.

He plans to submit for publication the results for 35 patients who underwent division of a paramedian forehead flap after 1 week.

A survey of the first 15 patients found that all preferred to have the procedure done after 1 week instead of 3 weeks. Tests showed good blood flow, and only three patients required small revisions, he said.

One 95-year-old patient with an active dating life was a prime candidate for the 1-week division of the paramedian forehead flap because “he wasn’t going to tolerate 3 weeks,” Dr. Gladstone said. The patient healed well. ■