A randomized study of the efficacy and safety of injectable poly-L-lactic acid versus human-based collagen implant in the treatment of nasolabial fold wrinkles

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Background: Injectable poly-L-lactic acid (PLLA) is a synthetic, biodegradable, biocompatible polymer device.

Objective: We sought to compare the efficacy and safety of injectable PLLA with human-derived collagen in treating nasolabial fold wrinkles.

Methods: In this randomized, evaluator-blinded, parallel-group, multicenter study, subjects received injectable PLLA (n = 116) or collagen (n = 117) injections (1-4 visits, 3-week intervals). Wrinkle Assessment Scale scores were calculated at screening; posttreatment week 3; months 3, 6, 9, and 13 (injectable PLLA or collagen groups); and months 19 and 25 (injectable PLLA group). Safety data were obtained from subject interviews and case report forms.

Results: Injectable PLLA significantly improved mean Wrinkle Assessment Scale scores (all time points, $P < .001$). Improvements (up to 25 months after last treatment) were significantly greater ($P < .001$) than with collagen for posttreatment months 3 to 13.

Limitations: Mostly white women and subjects with Fitzpatrick skin types II and III were included.

Conclusion: Injectable PLLA provides well-tolerated, effective, and long-lasting (up to 25 months) nasolabial fold wrinkle correction. (J Am Acad Dermatol 2010;62:448-62.)

Key words: aesthetic; dermal filler; injectable device; injectable poly-L-lactic acid; soft-tissue augmentation.

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Clinical trial registry: NCT00444210 (comparative study); NCT00444353 (long-term follow-up).

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According to the American Society of Plastic Surgeons, the use of soft-tissue fillers, including calcium hydroxylapatite, collagen, fat, and hyaluronic acid, for soft-tissue augmentation increased 133% from the year 2000 to 2007.[1] The increase in the popularity of soft-tissue fillers is understandable, particularly because they are noninvasive and are effective for restoring lost volume and for correcting contour deficiencies to the aging face. However, the duration of effect of these fillers is limited: a few months for autologous fat transfer and collagen (human or bovine derived), and approximately 12 months for hyaluronic acid preparations and calcium hydroxylapatite.[2-5] Therefore, it is desirable to identify injectable materials for soft-tissue augmentation that have a duration of effect that extends beyond what is currently available. One such category of injectable agents consists of poly-L-lactic acid (PLLA), which has a demonstrated use for medical devices.[6]

CAPSULE SUMMARY

- To our knowledge, this study is the first randomized, comparative clinical study to demonstrate the efficacy, safety, and tolerability of injectable poly-L-lactic acid for the treatment of nasolabial fold wrinkles in a healthy, immunocompetent population.
- This study establishes the extended duration of effect (25 months) of injectable poly-L-lactic acid for the treatment of nasolabial fold wrinkles.
- The results of this randomized, comparative study support the use of a novel injectable dermal filler for soft-tissue augmentation.

PLLA is a synthetic, biodegradable, biocompatible, and immunologically inert polymer device derived from the alpha-hydroxy-acid family, and it has a long history of safe use in numerous therapeutic applications.[7-16] Polylactides are used as resorbable suture materials in ophthalmologic, neurologic, and thoracoabdominal surgery; are widely used as support materials in maxillofacial surgery, periodontology, and stomatology; and are used as carriers for the prolonged delivery of several therapeutic agents.[7,10,11,17-19] More recently, PLLA has become the focus of attention by aesthetic dermatologists and plastic surgeons.

Injectable PLLA is marketed under the trade name Sculptra (Dermik Laboratories, a business of sanofi-aventis U.S. LLC, Bridgewater, NJ) and consists of a lyophilized preparation composed of PLLA microparticles, sodium carboxymethylcellulose, and nonpyrogenic mannitol.[20,21] Injectable PLLA is approved in the United States 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 injection technique is appropriate.[22] Injectable PLLA is also approved for the restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with HIV.[23]

The purpose of this randomized, controlled clinical study was to evaluate the efficacy and safety of injectable PLLA and to compare it with a commercially available human-derived collagen for the correction of mild to severe nasolabial fold wrinkles (NLFW) in immunocompetent subjects. The active comparator used in this study, highly purified human collagen (CosmoPlast, Allergan-Inamed, Irvine, CA), is chemically cross-linked using glutaraldehyde and suspended in phosphate-buffered physiologic saline containing 0.3% lidocaine. It is approved in both the European Union and the United States for the correction of soft-tissue contour deficiencies, such as wrinkles and acne scars.[24] It has been found to be immunologically inert, and subjects do not require a skin test before treatment.[25] The safety and efficacy of collagen products have largely been inferred from the safety and efficacy record of bovine-derived collagen.

The primary objective of this study was to evaluate the degree of correction attainable, using the mean change from baseline in Wrinkle Assessment Scale (WAS) scores, with injectable PLLA compared with human-based collagen in the treatment of NLFW at month 13 after the last injection of study treatment. Secondary objectives in the comparative 13-month study included global investigator and subject evaluations of treatment, subject treatment satisfaction scores, time to peak correction, and treatment success rate. This article reports the mean change from baseline in WAS scores. The results of the global investigator and subject evaluations of treatment, and subject treatment satisfaction scores will be presented in subsequent reports. The primary safety objective was the overall incidence of adverse events (AEs) reported during the 13-month follow-up period, regardless of severity, onset, duration, or relationship to study treatment. After the comparative treatment phase, subjects receiving injectable PLLA were followed up for an additional 12 months (the long-term surveillance phase) to collect safety and efficacy data. In the long-term surveillance phase, only subjects treated with injectable PLLA were scheduled to return for follow-up visits at months 19 and 25 after their final study treatment.

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