Safety and effectiveness of small and large gel-particle hyaluronic acid in the correction of perioral wrinkles

Fredric Brandt[1], Benjamin Bassichis, Michelle Bassichis, Christopher O'Connell, Xiaoming Lin
Affiliations expand

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Abstract

Background: FDA-approved for the correction of moderate-to-severe facial wrinkles and folds, small gel-particle hyaluronic acid (SGP-HA, Restylane, Medicis Aesthetics, Inc., Scottsdale, AZ) and large gel-particle hyaluronic acid (LGP-HA, Perlane, Medicis Aesthetics, Inc., Scottsdale, AZ) were studied to evaluate their safety for the correction of oral commissures, marionette lines, upper perioral rhytides and nasolabial folds (NLFs).

Objectives: The primary objective of this study was to investigate the safety of SGP-HA and LGP-HA in treating facial wrinkles and folds around the mouth; the secondary objective was to evaluate the effectiveness of these products.

Methods: This open-label, 4-week study at two US centers evaluated SGP-HA and LGP-HA in patients who intended to undergo intradermal injection for correction of of perioral wrinkles and folds. At screening, a 5-grade Wrinkle Severity Rating Scale (WSRS) was used to evaluate the baseline appearance of bilateral NLFs, and a 6-grade Wrinkle Severity (WS) scale was used to evaluate the appearance of bilateral oral commissures, marionette lines and upper perioral rhytides. To qualify, each patient must have had moderate-to-severe wrinkles at one pair of marionette lines and upper perioral rhytides. Each wrinkle was treated to optimal correction with either SGP-HA or LGP-HA at the discretion of the treating investigator. All reported local and systemic adverse events (AEs) were recorded. At two weeks after treatment or touch-up, the treating investigator and the patient assessed appearance using the Global Aesthetic Improvement Scale (GAIS).

Results: Twenty patients with a mean age of 59.6 years (range 49 to 65 years) were treated with an average of 5.58 plus minus 1.15 mL of HA for the entire perioral area. Treatment areas included NLFs, marionette lines, oral commissures and perioral rhytides. Eighteen of 20 patients received both SGP-HA and LGP-HA. Product was injected into the mid or deep dermis using primarily linear threading and multiple punctate pools.

Patients experienced a total of 66 treatment-emergent AEs (TEAEs); each patient experienced at least one TEAE. The reported events in decreasing order of occurrence were bruising, tenderness, swelling, redness, headache and discomfort. Bruising was more common in the NLFs and marionette lines than in the oral commissures and perioral rhytides. Tenderness occurred more often in the perioral rhytides than in the other areas. The maximum intensity of all TEAEs was considered mild. Most TEAEs resolved within seven days, with an average duration of four days. No serious TEAEs occurred during the study. One hundred percent of GAIS evaluations by both investigators and patients indicated improvement, regardless of filler used or area treated.

Conclusion: Both SGP-HA and LGP-HA were found to be safe and effective for the correction of perioral wrinkles and folds, with few differences among treatment areas Both investigator and patient GAIS evaluations indicated aesthetic improvement after SGP-HA and LGP-HA treatment in the perioral area.

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