

# Higher Dose Improves Filler's Safety, Efficacy

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ORLANDO — Patients getting an investigational hyaluronic acid gel filler for lip augmentation reported less pain and greater satisfaction with a 24-mg/mL dose than with a 20-mg/mL dose, interim study results have shown.

Patients who received the 24-mg/mL hyaluronic acid gel filler required fewer

touch-ups and trended toward less severe injection-site reactions than did patients treated with the 20-mg/mL dose, reported Dr. William Philip Werschler in a poster at the annual meeting of the American Society for Dermatologic Surgery.

Sponsored by Allergan Inc., the randomized, double-blind (to the patient and evaluator) parallel study included 30 women aged 30 years or older (mean

age, 51 years) whose lips were rated as 0 (none) or 1 (mild) on a fullness assessment scale by the treating investigator.

All participants had to agree not to undergo other antiwrinkle or augmentation procedures in the lower two-thirds of the face during the 6-month study, said Dr. Werschler of the University of Washington, Seattle. He coauthored the study with Dr. Steven Fagien, who is in private practice in Boca Raton, Fla.

A total of 12 patients were treated with the 24-mg/mL hyaluronic acid gel filler and received a mean injection volume of 0.88 mL in their upper lip and 0.78 mL in their lower lip. The 18 patients treated with the 20-mg/mL formulation received a mean injection volume of 0.97 mL in their upper lip and 0.85 mL in their lower lip.

Slight injection-site swelling occurred in 6 (50%) of the patients receiving the 24-mg/mL injection, compared with 10 (56%) of the patients receiving the 20-mg/mL dose. Two patients receiving the lower-dose treatment also had mild or severe swelling.

The patients returned for follow-up at weeks 1 and 2 and months 2, 4, and 6.



Patients who received a higher dose of the investigational hyaluronic acid gel required fewer touch-ups.

DR. WERSCHLER

Touch-up treatments were permitted at week 2 and were limited to half of the amount of the previous treatment.

Two (17%) of the patients treated with the 24-mg/mL hyaluronic acid gel filler received touch-up treatment, compared with 10 (56%) of the patients treated with the 20-mg/mL hyaluronic acid gel filler.

Two weeks after treatment, investigators and expert reviewers indicated that the 24-mg/mL hyaluronic acid gel filler was associated with a higher percentage of patients with no lines or shallow lines in the perioral area, Dr. Werschler said.

In addition, more investigators reported being "very satisfied" or "satisfied" with overall appearance, lip fullness, perioral or lipstick lines, curvature of the upper and lower lip, smile lines, and marionette lines associated with the 24-mg/mL hyaluronic acid gel filler.

Similarly, more patients receiving the higher dose reported that they were "satisfied" or "very satisfied," compared with those who received the 20-mg/mL hyaluronic acid gel filler.

The treatment effect lasted up to 216 days for patients receiving the 24-mg/mL injection (mean, 193 days) and for up to 178 days (mean, 158 days) for those receiving the 20-mg/mL dose.

Dr. Werschler said that full results of the study will be reported in late 2009.

Asked to comment on why the 24-mg/mL filler was superior, he cautioned that these are interim results. However, "the data points were clearly distinguished," he added. "Perhaps in the final results, this will be discussed further."

Dr. Werschler is a speaker, consultant, and clinical investigator for Allergan Inc. and Medicis Aesthetics Inc. Dr. Fagien is a consultant and clinical investigator for Allergan Inc. and Medicis Aesthetics. ■

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