Lip and Perioral Enhancement With HA Dermal Fillers in Individuals With Fitzpatrick Skin Types IV–VI

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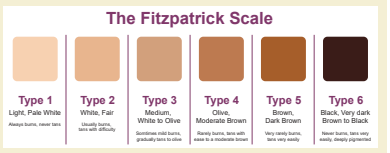
INTRODUCTION

- The number of surgical and nonsurgical cosmetic procedures performed in the United States increased by more than 25% between 2010 and 2015. Over that time period, the share of procedures performed in people with skin of color rose from 19% to 25%[1,2]
- Hyaluronic acid (HA) filler treatment is used to add volume to thin lips or restore volume and contour after age-related volume loss
- Individuals with skin of color request lip enhancement treatments, often to restore lip volume lost through aging,[3,4] as well as, in our experience, to further enlarge lips. However, there are minimal effectiveness or safety data for individuals with skin of color
- The safety and effectiveness of 2 HA dermal fillers for lip augmentation were previously assessed in 2 pivotal studies.[5,6] Both studies enrolled subjects of all Fitzpatrick skin types, including those with skin of color (Fitzpatrick skin types IV, V, or VI)
- The objective of this analysis was to examine the effectiveness and safety of HA fillers for lip and perioral treatment in subjects with Fitzpatrick skin types IV, V, or VI using data pooled from 2 pivotal clinical trials

METHODS

- Study design
  - Both studies included in the analysis were prospective, multicenter, randomized studies
  - Study 1 (clinicaltrials.gov identifier: NCT01197495)[5]
    - Treatment used for pooled analysis: HYC-24L HA injectable gel (24 mg/mL) with lidocaine (Juvéderm® Ultra XC; Allergan plc, Dublin, Ireland)
    - Optional touch-up treatments were given 14–30 days after initial treatment
    - Effectiveness assessments were made at 1, 3, 6, 7.5, 9, 10.5, and 12 months post-injection by blinded investigators
    - Repeat treatment with HYC-24L was allowed at least 6 weeks after the 6 month assessment, with repeat treatment assessments scheduled 1 and 3 months post-injection
  - Study 2 (clinicaltrials.gov identifier: NCT01998581)[6]
    - Treatment used for pooled analysis: VYC-15L HA injectable gel (15 mg/mL) with lidocaine (Juvéderm® Volbella® XC; Allergan plc)
    - Optional touch-up injections were given 30 days after initial treatment
    - Effectiveness assessments were made at 1, 3, 6, 9, and 12 months post-injection by blinded investigators
    - Repeat treatment with VYC-15L was allowed at the 12 month visit with a repeat treatment assessment scheduled 1 month post-injection
  - Time points included in the post hoc analysis: 1, 3, 6, 9, and 12 months post injection and 1 month after the repeat injection
- Subjects
  - Study 1 enrolled men and women (≥18 years) with, for subjects with Fitzpatrick skin types IV, V, or VI, a 5-point Allergan Lip Fullness Scale (LFS) score of "minimal" or "mild" for at least 1 lip at baseline
    - Exclusions: Facial plastic surgery, semi-permanent fillers or permanent facial implants anywhere in the face or neck, temporary dermal filler treatments or cosmetic facial procedures in the last 24 months, onabotulinumtoxinA injections in the lower face within the last 6 months, or lip tattoos, facial hair, scars, or dental devices that would interfere with study assessments
  - Study 2 enrolled men and women (≥22 years) with an LFS score of "minimal," "mild," or "moderate" desiring a ≥1-point improvement or, for subjects with Fitzpatrick skin types V or VI, an overall LFS score of 3 (marked) or 4 (very marked) desiring treatment to the vermilion body of 1 or both lips
    - Subjects who received treatment of perioral lines had an Allergan Perioral Lines Severity Scale (POLSS) score of moderate or severe
    - Exclusions: Lip tattoos, piercings, facial hair, or scars; oral surgery within 6 weeks before enrollment; permanent facial implants; semi-permanent dermal filler treatment within 24 months or temporary dermal filler treatment within 12 months in a facial region below the orbital rim; facial augmentation with fat or botulinum toxin injections below the orbital rim within 6 months; or cosmetic procedure of the face or neck within 6 months
  - Data from subjects with Fitzpatrick skin types IV, V, or VI (**Figure 1**) treated with HYC-24L (Study 1) or VYC-15L (Study 2) were pooled and included in the analysis

Figure 1. Fitzpatrick Skin Phototypes



- Assessments
  - Lip fullness was assessed using the validated 5-point LFS, scored as 1=minimal; 2=mild; 3=moderate; 4=marked; and 5=very marked
  - Severity of perioral lines at rest and oral commissures severity were assessed using the validated 4-point POLSS and Allergan Oral Commissures Severity Scale (OCSS), respectively, each scored as 0=none; 1=mild; 2=moderate; and 3=severe
  - Rates of response (defined as ≥1-point improvement from baseline) were determined for LFS, POLSS, and OCSS
  - Safety measures included rates of common injection site responses (ISRs; reported in daily subject diaries) and adverse events (AEs); ISRs with a duration >30 days were classified as AEs
- Statistical analysis
  - Changes from baseline in LFS, POLSS, and OCSS scores were summarized by visit using descriptive statistics
  - Responder rates based on LFS, POLSS, and OCSS were summarized by visit
  - ISRs were summarized by duration and severity

RESULTS

Subjects

- Seventy-two subjects with Fitzpatrick skin type IV, V, or VI who received treatment with HYC-24L or VYC-15L and had at least 1 post-baseline assessment in the 2 studies were combined and included in the analysis
  - Demographic and baseline characteristics for subjects are shown by study in **Table 1**

Table 1. Baseline Demographic and Characteristics, Subjects With Fitzpatrick Skin Type IV, V, or VI From Study 1 and Study 2

Characteristics		Study 1 (n=25)	Study 2 (n=47)	Pooled (N=72)
Age, median (range), years		49.0 (20, 79)	50.0 (22, 76)	49.5 (20, 79)
Sex, %	Female	96.0	95.7	95.8
	Male	4.0	4.3	4.2
Race/ethnicity, %	White/Caucasian	16.0	36.2	29.2
	Black/African American	52.0	31.9	38.9
	Hispanic/Latino	24.0	19.1	20.8
	Asian	0	4.3	2.8
	Other	8.0	8.5	8.3
Fitzpatrick skin type, %	IV	24.0	55.3	44.4
	V	64.0	23.4	37.5
	VI	12.0	21.3	18.1
Lip fullness, %	Minimal	12.0	6.4	8.3
	Mild	80.0	31.9	48.6
	Moderate	8.0	55.3	38.9
	Marked	0	6.4	4.2

Treatment Administration

- Median total HA volume injected (initial + touch-up treatment, all areas) for the pooled population was 1.85 mL (range, 0.30–5.30 mL)
  - Median initial treatment volume was 1.58 mL (range, 0.30–4.00 mL); 40/72 subjects received touch-up treatment (median volume, 0.80 mL; range, 0.10–2.65 mL)
  - Median volumes for each location are shown in **Table 2**

Table 2. Median (range) Injection Volumes, Pooled Population

	Volume Injected; median (range), mL	
Location	**Initial + Touch-up**	**Repeat***
Total	1.85 (0.30–5.30)	1.00 (0.30–3.60)
Upper lip	0.85 (0.10–2.00)	0.40 (0.10–1.30)
Lower lip	0.80 (0.20–2.00)	0.40 (0.10–1.40)
Oral commissures	0.40 (0.10–1.70)	0.38 (0.05–1.00)
Philtral columns	0.10 (0.03–0.75)	0.15 (0.10–0.30)
Perioral lines	0.35 (0.10–1.60)	0.30 (0.05–1.60)

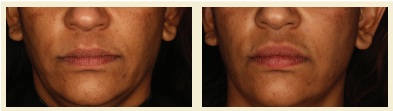
*Study 1 optional touch-up treatment was given 14–30 days after initial treatment; study 2 optional touch-up treatment was given 30 days after initial treatment.

Effectiveness

Lip Fullness

- After HA dermal filler treatment, mean (SD) lip fullness improved by 1.1 (0.63) points from baseline at 3 months post-injection and by 0.7 (0.81) points from baseline at 12 months
- Baseline and 3 month images for subjects treated in studies 1 and 2 are shown in **Figure 2**

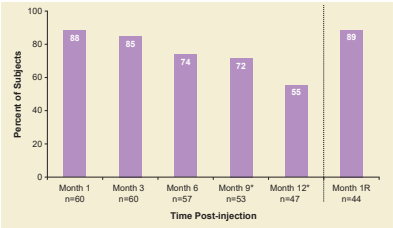
Figure 2. Lip Enhancement With HA Dermal Filler Treatment



This 47-year-old Asian female with Fitzpatrick skin type V received a total of 1.6 mL VYC-15L HA at initial + touch-up treatment in her upper and lower lips. Lip fullness was moderate (LFS=2) at baseline and marked (LFS=3) at month 3. HA, hyaluronic acid; LFS, Lip Fullness Scale.

- At 3 months, 51 of 60 (85.0%) subjects showed a response to lip enhancement treatment (≥1-point increase in LFS score; **Figure 3**)

Figure 3. Lip Fullness Scale Responder Rates, Pooled Population

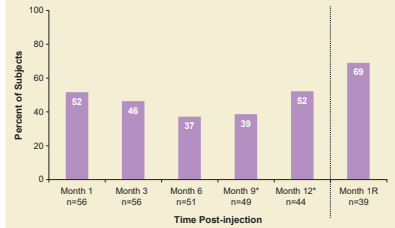


*Study 1 allowed repeat treatment prior to the 9 and 12 month assessments.
R, post-repeat injection.

Oral Commissures

- Mean (SD) OCSS score improved by 0.5 (0.71) points from baseline at 3 months post-injection, and by 0.5 (0.82) points from baseline at 12 months
- At 3 months, 26 of 56 (46.4%) subjects treated in the oral commissures were responders based on ≥1-point increase in OCSS score (**Figure 4**)

Figure 4. Oral Commissure Scale Responder Rates, Pooled Population

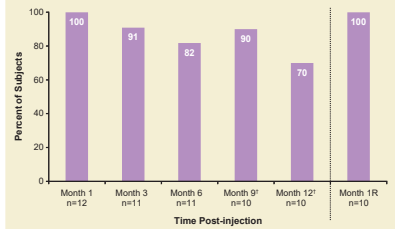


*Study 1 allowed repeat treatment prior to the 9 and 12 month assessments.
R, post-repeat injection.

Perioral Lines

- Among subjects with a baseline POLSS score of moderate or severe who received treatment, mean (SD) POLSS score improved by 1.1 (0.54) points from baseline at 3 months post-injection, and by 0.7 (0.48) points from baseline at 12 months
- Of the subjects with a baseline POLSS score of moderate or severe, 90.9% had clinically significant improvement at 3 months (**Figure 5**)

Figure 5. Perioral Lines Scale Responder Rates, Subjects With Baseline POLSS Score of Moderate or Severe*



*All subjects were from study 2; no study 1 subjects received perioral line treatment.
†Study 1 allowed repeat treatment prior to the 9 and 12 month assessments.
POLSS, Perioral Lines Severity Scale; R, post-repeat injection.

Safety

- For initial and touch-up injections, 63% of ISRs were mild or moderate in severity (**Table 3**)
- Most ISRs following the initial injection (68.4%) resolved within 2 weeks

Table 3. Injection Site Reactions, Initial and Touch-up Treatment

	Pooled Population
Any ISR, n/N (%)	59/62 (95.2)
Maximum severity, n/N (%)	
Mild	14/59 (23.7)
Moderate	23/59 (39.0)
Severe	22/59 (37.3)
ISRs in >30% of subjects, n/N (%)	
Swelling	55/62 (88.7)
Firmness	52/62 (83.9)
Tenderness	50/62 (80.6)
Lumps/bumps	49/62 (79.0)
Bruising	47/62 (75.8)
Pain	41/62 (66.1)
Redness	37/62 (59.7)
Discoloration (not redness or bruising)	21/62 (33.9)

ISR, injection site response.

- Thirty-three of 72 (45.8%) subjects reported AEs
  - The most common AEs, occurring in >5% of subjects, were injection site mass (19.4%), injection site bruising (12.5%), injection site pain (9.7%), injection site swelling (9.7%), injection site discoloration (5.6%), and injection site dryness (5.6%)

CONCLUSIONS

- This pooled analysis of HA dermal fillers for lip and perioral enhancement provides the first effectiveness and safety data in a cohort of subjects comprised exclusively of individuals with skin of color
- Responder rates were high for lip fullness and perioral lines at 3 months after treatment, with 85% and 91% of subjects showing at least a 1-point improvement on the LFS and POLSS, respectively
  - Responder rates for oral commissures were lower than responder rates for lip fullness, reflecting those observed in the overall population
- The low number of subjects who received POL treatment may indicate that darker skin types tend not to develop this type of wrinkle
- Treatment effects were maintained over time, with repeat treatment achieving similar or better improvements compared with initial and touch-up treatment
- Effectiveness of treatment for lip enhancement in subjects with Fitzpatrick skin types IV, V, or VI was similar to that reported for the overall populations in study 1[5] and study 2[6]
- HA injection was safe in subjects with skin of color, with most ISRs reported as mild or moderate in severity; the types and incidence of AEs were as expected for dermal filler treatment

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DISCLOSURES

Susan C. Taylor has served on advisory boards or as an investigator for Aclaris, Allergan, Alphaeon, Belersdorf, Evolus, Galderma, and Croma.
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Ava Shamban is an investigator for Allergan, Medicis, and Galderma, and a consultant for Allergan and Merz.
Julius Few serves on advisory boards for Allergan and Mentor; as a remunerated consultant for Allergan, Medicis, Palomar, Ulthera, and Venus Concepts; as a remunerated speaker for Allergan, Ulthera, and Venus Concepts; and has received research grants as an investigator for Allergan and Medicis.
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