**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 aesthetic procedures performed in the United States continues to increase by more than 30% between 2007 and 2016. Over the last decade, hyaluronic acid (HA) filler treatment is used to add volume to the lips to restore volume and contour with age-related volume loss. Individuals with skin of color require lip enhancement treatments, often to restore lip volume lost through aging, as well as as a cosmetic enhancement. However, there are minimal effectiveness or safety data with HA injection for lip enhancement in skin types IV–VI.

**METHODS**

- **Study design:** Both studies included in the analysis were prospective, multicenter, randomized trials. Study 1 (clinicaltrials.gov identifier NCT01810985) included treated subjects with Fitzpatrick skin type IV, V, or VI with 1 to 4 prior unsuccessful injections that demonstrated progression. Study 2 (NCT01810985) included treated subjects with Fitzpatrick skin type IV, V, or VI who had received no prior treatment in the study. Both studies enrolled subjects of all Fitzpatrick skin types, including those with skin of color. (Fitzpatrick skin type IV, V, or VI).

- **Study 1:** Subjects received treatment with 21G Softlift® HYC-24L or VYC-15L and had at least 1 post-baseline assessment in the 2 studies were included in the analysis. Randomization to treatment was stratified by injection site (lower vs upper lip) and by degree of Fitzpatrick skin type (IV, V, or VI). Subjects received repeat treatment with an equal volume at their repeat treatment visit. A total of 60 subjects received 2 treatments (10/60 at each site on each visit).

- **Study 2:** Subjects received treatment with 21G Softlift® HYC-24L or VYC-15L and had at least 1 post-baseline assessment in the 2 studies were included in the analysis. Randomization to treatment was stratified by injection site (lower vs upper lip) and by degree of Fitzpatrick skin type (IV, V, or VI). Subjects received repeat treatment with an equal volume at their repeat treatment visit. A total of 60 subjects received 2 treatments (10/60 at each site on each visit).

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- **Study 2:** Subjects received treatment with 21G Softlift® HYC-24L or VYC-15L and had at least 1 post-baseline assessment in the 2 studies were included in the analysis. Randomization to treatment was stratified by injection site (lower vs upper lip) and by degree of Fitzpatrick skin type (IV, V, or VI). Subjects received repeat treatment with an equal volume at their repeat treatment visit. A total of 60 subjects received 2 treatments (10/60 at each site on each visit).

**RESULTS**

- **Safety:** Severity by injection site and race/ethnicity is detailed in Table 1. The low number of subjects who received POL treatment may indicate that darker skin tones have not been studied adequately in the treatment of the face. There were no major adverse effects found with HA filler treatment. The most common treatment-related adverse effects were mild to moderate, with a maximum of 30% of subjects reporting redness. The number of surgical and nonsurgical cosmetic procedures performed in the United States continues to increase by more than 30% between 2007 and 2016. Over the last decade, hyaluronic acid (HA) filler treatment is used to add volume to the lips to restore volume and contour with age-related volume loss. Individuals with skin of color require lip enhancement treatments, often to restore lip volume lost through aging, as well as as a cosmetic enhancement. However, there are minimal effectiveness or safety data with HA injection for lip enhancement in skin types IV–VI.

- **Clinical endpoints:** The fewest endpoints reported were trained post-baseline assessments in the 2 months post-injection. There were no major adverse effects found with HA filler treatment. The most common treatment-related adverse effects were mild to moderate, with a maximum of 30% of subjects reporting redness. The number of surgical and nonsurgical cosmetic procedures performed in the United States continues to increase by more than 30% between 2007 and 2016. Over the last decade, hyaluronic acid (HA) filler treatment is used to add volume to the lips to restore volume and contour with age-related volume loss. Individuals with skin of color require lip enhancement treatments, often to restore lip volume lost through aging, as well as as a cosmetic enhancement. However, there are minimal effectiveness or safety data with HA injection for lip enhancement in skin types IV–VI.

- **Efficacy:** Improvement in face shape and volume was observed in the majority of subjects, as assessed by the Investigator Global Aesthetic Improvement Scale (IGR) and by the subjects themselves. The fewest endpoints reported were trained post-baseline assessments in the 2 months post-injection. There were no major adverse effects found with HA filler treatment. The most common treatment-related adverse effects were mild to moderate, with a maximum of 30% of subjects reporting redness. The number of surgical and nonsurgical cosmetic procedures performed in the United States continues to increase by more than 30% between 2007 and 2016. Over the last decade, hyaluronic acid (HA) filler treatment is used to add volume to the lips to restore volume and contour with age-related volume loss. Individuals with skin of color require lip enhancement treatments, often to restore lip volume lost through aging, as well as as a cosmetic enhancement. However, there are minimal effectiveness or safety data with HA injection for lip enhancement in skin types IV–VI.