VYC-17.5L Is Effective for the Treatment of Static and Dynamic Radial Cheek Lines: Results From the BEAM Study

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ABSTRACT

Background: Radial cheek lines are among the most difficult to treat by nonablative resurfacing therapies. VYC-17.5L (Juvéderm® Vycor; Allergan plc) is a new hyaluronic acid (HA) treatment with the latest generation of HA technology for improving the crosslinking efficiency of the HA chains, enabling a tighter crosslinked network that results in a significantly more stable and long-lasting correction of skin depressions. This study evaluated the safety and effectiveness of VYC-17.5L for improving static and dynamic radial cheek lines.

Methods: A total of 50 female subjects aged 18 to 68 years received VYC-17.5L treatment at the preauricular nose, nasolabial, and mandible nasion, or periorbital area (1.9 mL per injection site) on either side. Safety was assessed via instruments (20) and visual analog scales (VAS). Primary outcome measures of efficacy were satisfaction for treatment and improvement in radial cheek lines. This was assessed via independent lay panel reviews and instrument-assessed changes in roughness, amplitude, and texture of radial cheek lines while smiling. Secondary endpoints included objective measures of skin elasticity and firmness, roughness, and wrinkle depth.

Results: The median total injection volumes were 4.0 mL (range, 2.0–4.0) for initial treatment and 2.0 mL (range, 0.001 for all comparisons) for follow-up treatment. There were no subjects with Fitzpatrick skin phototypes I, V, and VI. Statistically significant improvements were observed in the lay panel reviews for the treatment effect and for reduction in roughness, amplitude, and texture of radial cheek lines while smiling (P < 0.05). Of those who viewed photographs of subjects at baseline and Day 45, 92% were unable to consciously discern treated vs untreated faces; 86% of women evaluators were more likely than men to view images after treatment as younger than before treatment (P < 0.05). Lay evaluator assessments of treatment noticeability during a review of videos of subjects smiling showed that 94% of subjects in photographs and videos were judged to look younger after VYC-17.5L; 70% of subjects in photographs and videos were judged to look younger after VYC-17.5L; and 82% of subjects in photographs and videos were judged to look younger after VYC-17.5L.

Conclusions: VYC-17.5L was effective for improving radial cheek lines, with 98% of subjects reporting that they believed their facial appearance had improved. Lay panelists were unable to consciously discern treated vs untreated faces; women were more likely to view images after treatment as younger than before treatment; and subjects believed that their facial appearance had improved. VYC-17.5L was generally well tolerated. There were no serious adverse events reported.

INTRODUCTION

Facial treatment, including serums containing retinoids, affects perception of a person’s age, health, and attractiveness. Perceived aging is often seen as the beginning of the ‘midlife crisis’. The skin’s appearance is significantly affected by visible skin depressions, such as ‘smile lines’ or radial cheek lines, which are seen when the perioral area is expressed. The skin’s structural integrity changes with age, with a decrease in skin thickness and elasticity and an increase in skin density and thickness, which can lead to wrinkles and other signs of aging. VYC-17.5L (Juvéderm® Vycor; Allergan plc) is a new hyaluronic acid (HA) treatment with the latest generation of HA technology for improving the crosslinking efficiency of the HA chains, enabling a tighter crosslinked network that results in a significantly more stable and long-lasting correction of skin depressions. The purpose of this study was to evaluate the effectiveness of VYC-17.5L treatment of dynamic and static radial cheek lines.

METHODS

Study Design

This was a prospective, open-label, single-site, single-arm study conducted at a single site in France and evaluated the effectiveness of VYC-17.5L in the treatment of dynamic and static radial cheek lines. This study compared VYC-17.5L (n=25) with the standard of care (SOC) (n=25). The study treatment group was assigned to subjects in both cheeks on Day 1, with additional treatment at Baseline day 14 and follow-up treatment on Day 45. Safety was assessed through analysis of changes in mean and median scores, and percentage change. The primary endpoints were satisfaction for treatment and improvement in radial cheek lines. The study was conducted from February 20, 2016, to June 30, 2016. Informed consent was obtained from all subjects. The study was approved by the Independent Ethics Committee for the study. Subjects were randomized to treatment on the basis of a computer-generated randomization schedule. The randomization code was provided by the sponsor. Subjects were eligible if they were aged 18 to 68 years and had Fitzpatrick skin phototypes II to IV. Subjects were also required to have static and dynamic radial cheek lines. The primary endpoint was satisfaction for treatment, measured by the Global Aesthetic Improvement Scale (GAIS) at Baseline day 14 and follow-up treatment on Day 45 after initial treatment. Lay panelist reviews were conducted on Day 14 and follow-up treatment on Day 45 after initial treatment. The study was performed at the Centre Chirurgical Niforos, Lyon, France; Allergan plc, Mallow, UK.

Subjects

- Total number of subjects: 50
- Gender: female
- Age: 18 to 68 years
- Fitzpatrick skin phototype: II to IV
- Radial cheek lines present on either side

RESULTS

- Safety: There were no serious adverse events reported.
- Efficacy: Statistically significant improvements were observed in the lay panel reviews for the treatment effect and for reduction in roughness, amplitude, and texture of radial cheek lines while smiling (P < 0.05). Of those who viewed photographs of subjects at baseline and Day 45, 92% were unable to consciously discern treated vs untreated faces; 86% of women evaluators were more likely than men to view images after treatment as younger than before treatment (P < 0.05). Lay evaluator assessments of treatment noticeability during a review of videos of subjects smiling showed that 94% of subjects in photographs and videos were judged to look younger after VYC-17.5L; 70% of subjects in photographs and videos were judged to look younger after VYC-17.5L; and 82% of subjects in photographs and videos were judged to look younger after VYC-17.5L.

Conclusions: VYC-17.5L was effective for improving radial cheek lines, with 98% of subjects reporting that they believed their facial appearance had improved. Lay panelists were unable to consciously discern treated vs untreated faces; women were more likely to view images after treatment as younger than before treatment; and subjects believed that their facial appearance had improved. VYC-17.5L was generally well tolerated. There were no serious adverse events reported.