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 lines in the cheek area can be associated with an older and less attractive appearance. In a prospective, open-label study (the BEAM study), we evaluated the effectiveness of Juvéderm® Volift® (VYC-17.5L)—a hyaluronic acid–based filler with lidocaine developed using Vycross® technology—for treating the deep skin depressions of dynamic radial cheek lines. The study combined objective clinical effectiveness measures with subjective lay assessments of the effect of VYC-17.5L treatment on perceived age and attractiveness.

Methods: A sample of 53 French women aged 40 to 65 years received VYC-17.5L treatment in both cheeks on Day 1 with optional touch-up treatment on Day 14. Effectiveness of treatment was evaluated on Day 45. Median total injection volumes of 4.0 mL and 2.0 mL were used for initial and touch-up treatment with VYC-17.5L, respectively. The primary endpoint was subject-assessed overall aesthetic improvement in dynamic radial cheek lines when smiling using the Global Aesthetic Improvement Scale (GAIS). Secondary endpoints included evaluating investigator assessments of improvement in dynamic radial cheek lines using the GAIS, subject Self-Perception of Age (SPA), subject assessments of treatment satisfaction and natural look of treated areas, and instrument-assessed changes in roughness, amplitude, and texture of radial cheek lines (DermaTOP®). Additional analyses evaluated changes in skin quality measures (skin hydration [MoistureMeterD®], skin elasticity/firmness [Cutometer®], and skin density/thickness [DermaScan® C]). Information on perceived age and attractiveness was collected from panels of German lay evaluators (mean age, 23.2 years) who viewed photographs and videos of subjects taken before treatment and on day 45. Separate panels of German lay evaluators evaluated videos of subjects recorded either before or after treatment to assess treatment noticeability. Safety assessments included injection site responses (ISRs).

Results: On Day 45, 98% of subjects reported their radial cheek lines were much improved or improved on GAIS, and independent investigators rated 95% of subjects as responders. Subjects who perceived themselves as the same age or older versus their current age before treatment (n=38) perceived themselves on average as 2.0 years and 5.5 years younger, respectively, after treatment. Mean satisfaction and natural look of treated areas on Day 45 were 7.9 and 7.2 out of 10, respectively. Static and dynamic radial cheek lines were significantly improved with respect to roughness, amplitude, and texture measures after treatment compared with baseline (P<0.001). VYC-17.5L treatment significantly improved skin water content (P<0.0001), elasticity/firmness (P<0.05), and dermis density (P<0.0001) versus baseline, with no significant change in overall thickness. In the photo review, lay assessors judged faces as significantly younger after treatment (P<0.001), with perceptions of attractiveness remaining unchanged. A smaller proportion of treated faces was identified correctly compared with untreated faces in the video review of treatment noticeability (P<0.001). The most commonly reported ISRs were hematoma (35.9%), bruising (30.2%), and mass (22.6%); most ISRs were mild and resolved within 15 days. No serious adverse events were reported.

Conclusions: VYC-17.5L is effective for correcting dynamic radial cheek lines, with 98% of subjects reporting improvement 45 days after treatment. Treatment resulted in sustained improvements in skin quality and perception of younger age as evaluated by subjects and independent assessors. In addition, lay assessments suggest that treatment with VYC-17.5L was not noticeable enough to allow independent observers to reliably identify treated versus untreated faces.

INTRODUCTION

- Facial appearance, including skin condition, affects perceptions of a person's age, health, and attractiveness, and facial aesthetic treatment can improve confidence and self-esteem[1,2]
- Injectable hyaluronic acid (HA) gels may be used to correct wrinkles and folds in the cheeks, known as "smile lines" or radial cheek lines, which can extend from the periorbital area to the masseter region[3]
- VYC-17.5L (Juvéderm® Volift™; Allergan plc, Dublin, Ireland), an HA-based filler indicated for the treatment of deep skin depressions due to conditions such as premature aging, was developed using Vycross® technology (Allergan plc, Dublin, Ireland), which combines low– and high–molecular-weight HA to improve the crosslinking efficiency of the HA chains; the tightly crosslinked HA network yields a higher viscosity gel with greater gel lift capacity and improved response durability[3]
- The purpose of this study was to evaluate the effectiveness of VYC-17.5L treatment of dynamic radial cheek line skin depressions

METHODS

Study Design

- A prospective, uncontrolled, open-label study conducted at a single site in France evaluated the effectiveness of VYC-17.5L for treating dynamic radial cheek lines (ANSM registration number 2016-A00909-42)
- VYC-17.5L was administered to subjects in both cheeks on Day 1 with optional touch-up treatment on Day 14; follow-up occurred through Day 45 after initial treatment

Subjects

- Women aged 40 to 65 years
- Inclusion criteria
  - Allergan Fine Lines Scale score ≤3 (5-point scale: 0=none, 1=minimal, 2=moderate, 3=severe, 4=diffuse)[4]
  - Agreement to refrain from facial skin-care regimen changes and antiwrinkle, filler, or skin resurfacing procedures or treatments during the study
- Exclusion criteria
  - Anticoagulant therapy during, before, or 3 days after study treatment
  - Anti-inflammatory drugs or substances that increase coagulation time 10 days before or 3 days after study treatment
  - Facial surgery, tissue grafting, or tissue augmentation with silicone, fat, or other permanent or semi-permanent dermal fillers during the study; temporary facial dermal filler injections within the year before the study

Analyses

Primary Endpoint

- Subject-assessed overall aesthetic improvement from baseline (Day 1) to Day 45 in dynamic radial cheek lines while smiling, using the Global Aesthetic Improvement Scale (GAIS; 2=much improved, 1=improved, 0=no change, −1=worse, −2=much worse)

Secondary Endpoints

- Investigator-assessed improvement in dynamic radial cheek lines from baseline to Day 45 using the GAIS
  - Subjects achieving a GAIS score of 1 or 2 (improved or much improved) for both cheeks were classified as responders by investigators; partial responders were those with a GAIS score of 1 or 2 for only 1 cheek; non-responders were those with a GAIS score ≤0 for both cheeks
- Subject assessments of treatment at Day 45:
  - Change from baseline in Self-Perception of Age (SPA; Q: How do you think your facial appearance looks compared to your age today? A: I look my current age; I look N years younger; I look N years older)
  - Natural look of treatment of dynamic radial cheek lines, satisfaction with treatment of dynamic radial cheek lines, and likelihood of recommending the treatment to another person, each rated using a 10-point scale (0=not at all, 10=very much)
- Instrument-assessed changes from baseline to Day 45 in mean roughness, amplitude, and texture for dynamic and static radial cheek lines at maximum smile (measured via DermaTOP® fringe projection [EOTECH SA, Marcoussis, France])

Additional Analyses

- Changes in skin quality
  - Changes in skin quality parameters from baseline to Day 45 in subjects' left or right cheek at rest: skin hydration measured by MoistureMeterD® (Delfin Technologies Ltd., Kuopio, Finland), skin elasticity/firmness measured by Cutometer® (Courage+Khazaka Electronic GmbH, Cologne, Germany), and skin density/thickness measured by DermaScan® C (Cortex Technology, Hadsund, Denmark)
- Independent lay panel review
  - Assessments of age, attractiveness, and health by lay evaluators during their review of photographs and videos of subjects smiling at baseline and Day 45
    - The order of each subject's before and after images was randomized, and evaluators were asked to indicate which face they considered to be younger looking, healthier, and more attractive
  - Lay evaluator assessments of treatment noticeability during a review of videos of subjects smiling either before or after treatment

Safety

- Injection site responses (ISRs) and adverse events (AEs) monitored by investigators

Statistics

- Quantitative variables summarized descriptively (i.e., mean, median)
- Paired t-test or Wilcoxon signed rank test for significance of changes from baseline

RESULTS

Subjects

- Subjects were French women, most with Fitzpatrick skin phenotypes II and III (Table 1)

Table 1. Baseline Demographics

Characteristic	Subjects (N=53[a])
Age, median (range), years	57 (40–65)
Weight, mean (SD), kg	60 (10.0)
Fitzpatrick skin phenotype, n (%)[b]	
II	20 (38)
III	24 (45)
IV	9 (17)

[a]One subject was lost to follow-up after Day 1, resulting in a total of 52 subjects who received treatment and were included in the effectiveness analyses. The safety population included all 53 subjects.
[b]There were no subjects with Fitzpatrick skin phenotypes I, V, and VI.

Treatment

- 53 subjects received VYC-17.5L in radial cheek lines on both cheeks (Day 1)
- 49 (92%) subjects received a touch-up injection on the right cheek and 48 (91%) received a touch-up injection on the left cheek on Day 14
- Median total injection volumes were 4.0 mL (range, 2.0–4.0) for initial treatment and 2.0 mL (range, 1.0–4.0) for touch-up treatment

Improvement in Dynamic Radial Cheek Lines

- On Day 45, 98.1% of subjects reported that their radial cheek lines were improved or much improved from baseline; only 1 subject (2%) reported no change (Figure 1)
- Similarly, investigators classified 95.2% of subjects as responders to treatment
- No subjects or investigators reported that radial cheek lines were worse or much worse

Figure 1. Subjects With Improved or Much Improved Dynamic Radial Cheek Lines on the GAIS After Treatment With VYC-17.5L

[a]For both cheeks in 52 subjects.
GAIS, Global Aesthetic Improvement Scale (2=much improved; 1=improved; 0=no change; −1=worse; −2=much worse).

Self-Perception of Age

- There was a 2-fold increase in the proportion of subjects who reported looking younger following VYC-17.5L treatment (Figure 2)
- Subjects who perceived themselves as the same age or older than their current age at baseline (n=38) perceived themselves on average as 2.0 years and 5.5 years younger, respectively, after treatment

Figure 2. Subjects' Self-Perception of Age After Treatment With VYC-17.5L
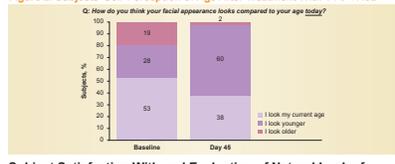
Q: How do you think your facial appearance looks compared to your age today?

Subject Satisfaction With and Evaluation of Natural Look of Treated Radial Cheek Lines

- Subjects were globally satisfied with treatment and natural results following VYC-17.5L treatment and stated that they would recommend treatment to a friend (Figure 3)

Figure 3. Subject Ratings for Satisfaction With Treatment, Natural Look of Treatment, and Likelihood to Recommend Treatment
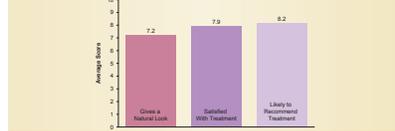
Ratings based on a 10-point scale (0=not at all, 10=very much).

Instrument-Assessed Changes in Wrinkle Parameters

- Static and dynamic radial cheek lines significantly improved with respect to roughness, amplitude, and texture measures at Day 45 after treatment vs baseline (P<0.001 for all comparisons)
  - Figure 4 shows improvements from baseline to Day 45 in roughness, amplitude, and texture through minimized skin depressions/creases, increased smooth areas, and less pronounced raised areas/bumps

Analysis of Skin Quality Measures

- Treatment with VYC-17.5L significantly improved skin hydration, elasticity/firmness, and density over baseline, with no significant change in overall thickness (Table 2)

Figure 4. Representative Images of Improvement in Instrument-Assessed Dynamic Radial Cheek Line Parameters With VYC-17.5L Treatment[a]
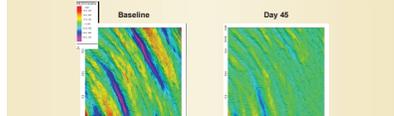
[a]Teal, blue, and purple indicate varying depth of skin depressions/creases; green indicates level surface (ie, smooth areas); yellow, orange, and red indicate increasing height of raised areas/bumps.

Table 2. Improvement From Baseline in Skin Hydration, Elasticity/Firmness, Density, and Thickness With VYC-17.5L Treatment

Skin Quality Parameter	Instrument	Day 45 vs Baseline
Hydration, measured at skin depth of 0.5 and 1.5 mm	MoistureMeter D	P<0.0001
Elasticity/firmness	Cutometer	P<0.05
Density	DermaScan C	P<0.0001
Thickness	DermaScan C	NS

NS, not significant.

Table 3. Results of Independent Lay Panel Photographic Review

	Perceptions of Facial Treatment on Age, Health, and Attractiveness Judgments, Mean (SD)			
	Before Treatment		After Treatment	
	Men	Women	Men	Women
Age *Which looks younger?[a,b]*	24.2 (5.2)	20.4 (5.6)	27.8 (5.2)	31.6 (5.6)
Health *Which looks healthier?[c]*	29.9 (7.3)	26.8 (5.2)	22.1 (7.3)	25.2 (5.2)
Attractiveness *Which looks more attractive?*	26.2 (4.7)	25.6 (6.3)	25.8 (4.7)	26.4 (6.3)

[a]Statistically significant difference between before- and after-treatment judgments (P<0.001).
[b]Statistically significant difference between judgments by men and women (P<0.05).
[c]Statistically significant difference between before- and after-treatment judgments (P<0.05).
SD, standard deviation.

Independent Lay Panel Reviews

- A total of 550 lay evaluators (mean age, 23.2 years) assessed the age, health, and attractiveness of subjects in photographs and videos
  - Those who viewed photographs of subjects at baseline and Day 45 judged faces as significantly younger after treatment (P<0.001), with perceptions of attractiveness remaining unchanged (Table 3)
  - Women evaluators were more likely than men to view images as younger than before treatment (P<0.05)
  - Women evaluators were more likely than men to judge subjects in post-treatment videos as more attractive (P<0.05)
- Lay evaluators who assessed the noticeability of subjects' treatment correctly identified a smaller proportion of treated vs untreated faces in the video review (P<0.001)
- These lay assessments suggest that treatment with VYC-17.5L results in natural-looking outcomes, as independent observers were unable to consciously discern treated vs untreated faces; Figure 5 shows representative examples of subjects before and after images viewed by independent lay evaluators

Safety Evaluation

- ISRs were reported by 33 of 53 subjects, with the most common being hematoma, bruising, and mass, and most being mild in severity (Table 4)
- Most ISRs resolved within 15 days
- No serious AEs were reported, and reported ISRs were expected for filler treatment

Table 4. Injection Site Responses

Category	Severity	N (%)
Bruising	Mild	16 (30.2)
Hematoma	Mild	18 (34.0)
	Moderate	1 (1.9)
Induration	Mild	2 (3.8)
Mass	Mild	12 (22.6)
Pain	Mild	2 (3.8)
Pruritus	Mild	1 (1.9)
Swelling	Mild	1 (1.9)

Figure 5. Representative Images Of Female Subjects (Subject A, 62 Years Of Age; Subject B, 64 Years Of Age) With Radial Cheek Lines At Baseline And At Day 45 Are Shown. Both Subjects Achieved A GAIS Score of 1 (Improved) by Day 45. Both Subjects had a SPA Score of 2; at Day 45, Subject A Reported Feeling 10 Years Younger And Subject B Reported Feeling 2 Years Younger vs Baseline.

Subject A — Baseline, Day 45; Subject B — Baseline, Day 45

CONCLUSIONS

- VYC-17.5L is effective for correcting dynamic radial cheek lines, with 98% of subjects reporting improvement on Day 45
- Treatment with VYC-17.5L led to significant improvements in instrument-assessed wrinkle parameters and skin quality
- Subjects who had been treated with VYC-17.5L in their radial cheek lines were independently assessed as younger looking and perceived themselves as younger looking
- Despite statistically significant effects of VYC-17.5L treatment on age ratings, independent observers were unable to consciously discern treated vs untreated faces; these findings suggest that treatment with VYC-17.5L can yield natural-looking outcomes
- VYC-17.5L demonstrated an acceptable safety profile for the treatment of radial cheek lines, with ISRs mostly mild and as expected

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