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Safe and Effective Chin Augmentation With the Hyaluronic Acid Injectable Filler, VYC-20L

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BACKGROUND VYC-20L is a hyaluronic acid soft tissue filler with lidocaine designed to restore facial volume.

OBJECTIVE Evaluate the safety and effectiveness of VYC-20L in patients with chin retrusion.

MATERIALS AND METHODS Adults with chin retrusion were randomized (3:1) to receive VYC-20L in the chin at study onset (treatment group) or 6 months later (control group). The primary effectiveness end point was ≥1-point improvement on the Allergan Chin Retrusion Scale (ACRS) from baseline at Month 6. Safety assessments included injection site responses (ISRs) and adverse events (AEs).

RESULTS VYC-20L was administered to 192 participants (treatment group, $n = 144$; control group, $n = 48$). At Month 6, significantly more participants had an ACRS response in the treatment versus control group (56.3% vs 27.5%; $p = .0019$). Effectiveness was also demonstrated by the proportion of participants with improved/much improved Global Aesthetic Improvement Scale scores and responses on the FACE-Q Satisfaction with Chin questionnaire and FACE-Q Psychological Wellbeing module. Treatment benefit remained evident at Month 12. Most common ISRs were tenderness (81.1%) and firmness (75.1%). One participant (0.5%) discontinued the study due to 2 treatment-related serious AEs of facial cellulitis and injection site inflammation, both resolved without sequelae.

CONCLUSION VYC-20L significantly improved an ACRS response and was generally safe and well tolerated.

Hyaluronic acid (HA) injectable gels are a proven treatment for facial rejuvenation with an established record of safety and effectiveness.[1] In 2018, more than 2.1 million HA injectable filler procedures were performed in the United States—a 48% increase over the past decade.[2,3] The FDA has approved a range of dermal and subcutaneous indications for HA injectable fillers, including facial wrinkles, folds, lip augmentation, and cheeks.[4] One such product, VYC-20L (Juvéderm Voluma XC; Allergan plc, Dublin, Ireland), which is a 20-mg/mL HA gel with lidocaine, was specifically designed for volumizing and has demonstrated effectiveness in restoring age-related volume deficit to the midface.[5] Compared with HA gels designed for correction of wrinkles and folds, VYC-20L improved qualities of lift and projection to the midface.

In addition to the midface, the chin area is another facial region where lift and projection are important aspects of volumizing. The chin is defined by the labiomental crease (superiorly), the oral commissures (laterally), and the submental cervical crease (inferiorly). The shape and projection of the chin contribute to a "well-balanced and harmonious" face.[6] For both men and women, good chin projection and a youthful jawline are considered the standards of beauty[7] and can influence an individual's psychosocial well-being.[8] Although congenital elements are the predominant factor in chin aesthetics, aging can result in bony resorption and produce sagging[9] as well as laxity and droop in the chin area.[10] In addition, aging can result in lumps, bulges, and depressions in the prejowl sulci.[11]

VYC-20L is a temporary HA soft tissue filler developed to provide a safe, minimally invasive method to restore facial volume, which is also reversible by hyaluronidase in case of adverse events (AEs) requiring treatment.[5,12] It is currently indicated in the United States for injection into the subcutaneous and/or supraperiosteal space of the midface to add volume in the cheek area and is approved in other countries for facial volumizing, including the chin and prejowl sulci.[5,12–16] As the chin and prejowl sulci are high-mobility areas, VYC-20L represents an ideal option for its volumizing and lifting capabilities. This study was designed to collect effectiveness

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and safety data for VYC-20L in participants seeking to correct volume deficit and retrusion in the chin and prejowl sulci.

Methods

Study Design

This multicenter, randomized, evaluator-blinded, delayed treatment-controlled study was designed to evaluate the safety and effectiveness of VYC-20L injectable gel for correction of chin volume deficit. A no-treatment control was used because there were no FDA-approved soft tissue fillers for chin augmentation at the time of the study. Participants were randomized in a 3:1 ratio either to have treatment with VYC-20L (treatment group) or a 6-month control period, followed by optional treatment (control group). At the Month 12 visit, participants in the treatment group had the option of receiving repeat treatment, with routine follow-up visits for safety and effectiveness through 1 month after repeat treatment. Treated control group participants were only followed for safety, and no effectiveness measures were performed. Participants underwent a touch-up treatment 30 days after initial treatment to achieve optimal correction if needed. The study was conducted at 14 sites in the United States, each of which had a treating investigator (TI) and at least one blinded evaluating investigator (EI).

The TIs performed the treatments and monitored participant safety throughout the study. Blinded EIs performed all effectiveness assessments. For treatment, the TI used 27 G 1/2 -inch needles for supraperiosteal and/or subcutaneous injections into the pogonion, menton, and prejowl sulci; 25 G 1½-inch cannulas were permitted for supraperiosteal and/or subcutaneous injections in the menton and prejowl sulci. An appropriate injection volume for the chin and chin area was determined by the TI but was not to exceed a maximum total volume of 4.0 mL for initial and touch-up treatments combined and 4.0 mL for repeat treatment. After each treatment, participants completed a daily safety diary for up to 30 days. Visits for both effectiveness and safety occurred at months 1, 3, 6, 9, and 12 after the last treatment.

Participants were required to be aged 22 or older and desire chin augmentation to correct moderate or severe chin retrusion (Grades 2 or 3 on the validated 5-point photonumeric Allergan Chin Retrusion Scale [ACRS]) as determined by a live assessment by both the EI and TI. Participants were ineligible if they had undergone cosmetic facial plastic surgery, tissue grafting, or tissue augmentation with silicone, fat, or permanent dermal fillers; had clinically significant malocclusion (severe overbite); had dentures; any device covering the palate; tattoos; piercings; facial hair; or scars that would interfere with visual assessment of the chin area. Mandatory facial treatment washout periods before study entry were 36 months for semipermanent dermal fillers, 24 months for dermal fillers in the chin or jaw area, 12 months for dermal fillers in the lips or perioral area, and 6 months for mesotherapy, botulinum toxin below the subnasale, or cosmetic treatment (laser, photomodulation, intense pulsed light, radiofrequency, dermabrasion, chemical peel, liposuction, lipolysis, or other ablative procedures). Applicable institutional review boards approved the study protocol, and all participants provided written informed consent before study enrolment (www.clinicaltrials.gov, identifier NCT02833077).

Response Measures and Statistics

The primary end point was based on the EI's blinded assessment of overall chin retrusion using ACRS grades defined as none (0), minimal (1), moderate (2), severe (3), and extreme (4) (See **Supplemental Digital Content**, Table S1, http://links.lww.com/DSS/A543). The primary effectiveness measure used a profile-view image cropped to include only the participant's lower face for ACRS assessment, which is based on the relationship between facial anatomical landmarks. Photograph assessments, rather than live assessments, facilitated consistent head positioning and were intended to help raters assess the relationship between landmarks. A participant showing $\geq$1-point improvement (decrease) in an ACRS score compared with baseline was considered a responder. The primary evaluation timepoint for efficacy was Month 6 after last treatment for participants in the treatment group and Month 6 after randomization for participants in the control group (untreated). The primary effectiveness end point was met if the treatment group responder rate was statistically greater (>50%) than the control group at Month 6 based on a 2-sided Fisher's exact test with a 5% significance level.

The Global Aesthetic Improvement Scale (GAIS), as well as the Satisfaction with Chin and Psychosocial Well-Being modules of the FACE-Q questionnaire, was used for assessment of secondary effectiveness end points. For the GAIS, responder rates for the treatment group (with 95% exact confidence intervals [CIs]) were based on EI and participant assessments. A "responder" was a participant who showed improvement (i.e., improved or much improved) on the overall aesthetic assessment in the chin area at the Month 6 visit. For the Satisfaction with Chin module of the FACE-Q questionnaire, the change from baseline to Month 6 visit in overall scores and a 2-sided paired *t*-test at the 5% level were used to demonstrate that the mean overall satisfaction score at the Month 6 visit was statistically greater than baseline for the treatment group. Volume change from baseline was measured by a blinded Canfield image analysis technician from three-dimensional (3D) imaging of the participant's facial profile pretreatment and post-treatment for both the treatment and control groups at the 6 Month visit.

Participants

A total of 221 participants were enrolled in the study, with an average of 14 (range 11–21) per investigational site. A total of 192 participants were randomized after 29 participants were screen failures, resulting in 144 in the treatment group and 48 in the control group. One hundred sixty-nine participants (88.0%) completed the Month 6 visit and 167 participants (87.0%) completed the study, with 25 participants (13.0%) discontinuing after

randomization. Eighty-eight participants received touch-up treatment and 74 received repeat treatment. For the treated control participants, 38 participants received initial treatment and 22 received touch-up treatment. All initial and touch-up treatments occurred between June 28, 2016, and January 25, 2018, and all repeat treatments occurred between July 11, 2017, and August 23, 2018. The treatment and control groups were similar in terms of all demographic and baseline characteristics (See **Supplemental Digital Content**, Table S2, http://links.lww.com/DSS/A544). Among the 192 enrolled participants, the majority were women (88.5%) and White (81.8%), with a median age at study entry of 52 years (range, 22–80) and mean body mass index of 25.0 kg/m^2. Fitzpatrick skin types were I/II (34.9%), III/IV (52.1%), and V/VI (13.0%).

Treatment

Anesthesia was administered to 75.0% (108/144) of participants in the treatment group, with the most common being topical (69.4%, 75/108; median duration 29.0 minutes) while ice was less common (34.3%, 37/108; median duration 15.0 minutes). The primary plane of injection used during the initial treatment was supraperiosteal (99.3%), followed by subcutaneous (63.0%). At touch-up and repeat treatments, the most common injection planes were also supraperiosteal (90.9% and 100.0%, respectively) and subcutaneous (53.4% and 59.5%, respectively). Planes and techniques were similar for the treated control participants. 99.3% of treatment group participants were treated in the pogonion, 77.8% in the menton, and 87.5% in the prejowl sulci. At the touch-up visit, 78.4% of treatment group participants were treated in the pogonion, 52.3% in the menton, and 65.9% in the prejowl sulci. At the repeat treatment visit, 93.2% were treated in the pogonion, 56.8% in the menton, and 66.2% in the prejowl sulci.

Needles were used for 100% of participants, and cannulas were used for 25.0% at initial treatment. There were no cannula/needle malfunctions. Treatment administration was similar for the treated control participants. Treating investigators rated ease of injection and product moldability on an 11-point scale, difficult (0) to easy (10), and stiff (0) to moldable (10), respectively. A total of 66.0% and 21.5% of participants were scored as 10 and 9, respectively, for ease of injection, whereas 62.5% and 20.8% of participants were scored as 10 and 9, respectively, for product moldability.

In the treatment group, 144 participants received initial treatment, 88 received touch-up treatment, and 74 received repeat treatment (Table 1). For the treated control participants, 38 participants received initial treatment and 22 received touch-up treatment, with injection volumes similar to the treatment group. The median total initial injection volume was 2.2 mL (range, 0.7–4.0 mL) for the treatment group (initial treatment and touch-up combined) and 2.8 mL (range, 1.3–4.0 mL) for the treated control group (initial treatment and touch-up combined). The median total injection volume for repeat treatment was 1.2 mL (range, 0.2–4.0 mL).

Results

Effectiveness

The primary efficacy end point was met with 56.3% ACRS responders (photograph assessment) at Month 6, which was greater than 50% and significantly greater than the responder rate for the untreated control group (27.5%, p = .0019) (Table 2). In addition, the ACRS responder rate in the treatment group was 70.1% at Month 1, 57.6% at Month 12, and 73.9% at Month 1 after repeat treatment (See **Supplemental Digital Content, Figure S1**, http://links.lww.com/DSS/A539). The median ACRS scores improved by a median of 1 point from a baseline score of 3 in the treatment group, whereas the control group remained at a score of 2.5. Notably, the Month 6 responder rate from the EI live assessment was markedly higher than results from

TABLE 1. Injection Volumes (Safety Population)

Total Volume Injected	Treatment (N = 144)	Control (N = 48)
Initial treatment volume (mL)		
Received treatment, *n* (%)	144 (100.0)	38 (100.0)
Mean (SD)	1.9 (0.6)	2.1 (0.6)
Median (range)	2 (0.7–4.0)	2 (1.0–3.8)
Initial/touch-up treatment volume combined (mL)		
Received treatment, *n* (%)	144 (100.0)	38 (100.0)
Mean (SD)	2.6 (1.0)	2.7 (0.8)
Median (range)	2.2 (0.7–4.0)	2.8 (1.3–4.0)
Repeat treatment volume (mL)		
Received treatment, *n* (%)	74 (51.4)	0 (0.0)
Mean (SD)	1.4 (0.8)	N/A
Median (range)	1.2 (0.2–4.0)	N/A

For the control group, data after receiving initial treatment at Month 6 are included.

TABLE 2. Allergan Chin Retrusion Scale Results at Month 6 (Modified Intent-to-Treat Population)

	Treatment (*N* = 144)	Control (*N* = 48)
Month 6		
Total participants, n*	126	40
Responder, *n* (%)	71 (56.3)	11 (27.5)
Nonresponder, *n* (%)	55 (43.7)	29 (72.5)
95% CI (%)†	(47.23–65.16)	(14.60–43.89)
Versus control		
Responder rate difference, %	28.85	
95% CI (%)‡	11.16–45.60	
p-value§	0.0019	

For the untreated control group, data before receiving initial treatment at Month 6 are included.
* Participants with analysis values at baseline and the specified visit.
† 95% CI is based on the exact binomial distribution.
‡ 95% exact CI for the responder rate difference is presented.
§ *p*-value is based on 2-sided Fisher's exact test comparing the responder rate between treated and untreated control.

the photograph assessment with 91.8% for the treatment group and 23.3% for the control group, a difference of 68.42% ($p < .0001$).

On the GAIS, EIs rated 91.2% (114/125) as "improved" or "much improved" in the treatment group and 19.5% (8/41) in the untreated control group at Month 6 (See **Supplemental Digital Content**, Figure S2, http://links.lww.com/DSS/A540). The treatment group responder rate remained high from Month 1 (94.0%) through Month 12 (91.2%) along with an increase at Month 1 after repeat treatment (98.6%; 70/71). The percentage of responders rated as "much improved" in the treatment group was notably high, with 61.6% at Month 6, 41.6% at Month 12, and 77.5% at Month 1 after repeat treatment. The participant self-evaluation on the GAIS was consistent with the EI assessments with most participants in the treatment group (87.3%; 110/126) rating as "improved" or "much improved" at Month 6. The treatment group responder rate remained high from Month 1 (95.5%) through Month 12 (82.4%) and was 97.1% at Month 1 after repeat treatment, similar to EI assessments. In addition, the mean change in chin volume assessed by 3D digital imaging showed a similar trend with (+)2.6 mL at Month 1, 2.4 mL Month 6, 2.2 cc at Month 12, and 3.9 cc at Month 1 after repeat treatment in the treatment group and 0.1 cc in the untreated control group.

The FACE-Q Satisfaction with Chin overall mean score for the treatment group was 34.9 at baseline and improved by a mean of 35.6 to a score of 71.3 at Month 6 ($p < .001$), whereas the mean score worsened by a mean of 3.3 from a baseline score of 35.1 for the untreated control group (See **Supplemental Digital Content**, Figure S3, http://links.lww.com/DSS/A541). The mean scores remained high from Month 1 (74.8) to Month 12 (66.4) and at Month 1 after repeat treatment (77.5).

The FACE-Q Psychological Well-Being overall mean score was 69.9 at baseline and improved by a mean of 15.4 at Month 6 for the treatment group, whereas the mean score worsened by a mean of −5.3 from 72.3 at Month 6 in the untreated control group (See **Supplemental Digital Content**, Figure S4, http://links.lww.com/DSS/A542). Most treatment group participants reported that they definitely/somewhat agree with each of the 10 individual FACE-Q Psychological Well-Being items at all timepoints, indicating positive well-being.

Safety

For initial/touch-up treatment, 14 treated participants (7.7%) had 20 treatment-related AEs (Table 3) while 3 (4.1%) had 7 treatment-related AEs after repeat treatment (See **Supplemental Digital Content**, Table S3, http://links.lww.com/DSS/A545). During the repeat treatment period, an injection site mass occurred in 2 participants (2.7%). The most common treatment-related AEs for the initial/touch-up treatment period were injection site erythema (1.6%, 3/182 participants) and injection site pain (1.6%, 3/182 participants). There were no deaths or unanticipated adverse effects. Facial sensation assessments found that treatment did not reduce chin area sensitivity at any timepoint throughout the study.

The type and frequency of injection site responses (ISRs) were similar in treatment group participants and treated control participants and are considered to be commonly reported events after treatment with HA soft tissue fillers (See **Supplemental Digital Content**, Table S4, http://links.lww.com/DSS/A546). Overall, 167 treated participants (92.3%) reported at least 1 ISR after initial treatment, 86 (82.7%) after touch-up treatment, and 55 (75.3%) after repeat treatment. The most frequently reported ISRs after initial treatment included tenderness to touch (81.8%), firmness (75.1%), and swelling (68.5%). Similar results were seen after repeat treatment, where the most common ISRs were also tenderness to touch (71.2%), firmness (69.9%), and swelling (58.9%). Most ISRs were mild or moderate in severity after initial, touch-up, and repeat treatment and resolved within 1 week based on total days from first to last occurrence according to the diaries. Participants assessed procedural pain (pain during injection) immediately after completion of each treatment on an 11-point scale ranging from 0 (no pain) to 10 (worst pain imaginable) and reported minimal pain, with a mean

TABLE 3. Common Treatment-Related Adverse Events (AEs) After Initial/Touch-Up Treatment				
Event, *n*	**Onset (d)**	**Duration (d)**	**Severity**	**Resolution**
Injection site abscess	6	9	Moderate	Resolved w/o sequelae
Gingival pain	1	2	Moderate	Resolved w/o sequelae
Acne cystic	6	134	Mild	Resolved w/o sequelae
Injection site cellulitis	7	36	Severe	Resolved w/o sequelae
Injection site inflammation	7	153	Severe	Resolved w/o sequelae

w/o, without.

score of 2.3 for the treatment group at each treatment (initial, touch-up, and repeat).

Most treatment-related AEs were mild or moderate in severity (See **Supplemental Digital Content**, Table S5, http://links.lww.com/DSS/A547). For initial/touch-up treatment, 2.7% (5/182) of participants had mild treatment-related AEs and 4.4% (8/182) had moderate AEs. For repeat treatment, 4.1% (3/74) of participants had mild and 1.4% (1/74) moderate AEs. Two participants (1.1%) had 3 severe treatment-related AEs, including injection site inflammation and cellulitis in one participant and injection site induration in another participant.

Most treatment-related AEs resolved within 1 week (See **Supplemental Digital Content**, Table S5, http://links.lww.com/DSS/A547). For initial/touch-up treatment, 3 participants (1.6%) had 4 treatment-related AEs that lasted longer than 30 days. The first participant had injection site inflammation that lasted 153 days and injection site cellulitis that lasted 36 days. Treatment consisted of antibiotics, anti-inflammatories, and hyaluronidase. These 2 events were considered to be serious AEs. A second participant had injection site erythema that lasted 264 days. A third participant had an acne cyst that lasted 134 days. For repeat treatment, 1 participant (1.4%) had an injection site mass that lasted 42 days. Most treatment-related AEs began within 7 days of treatment. There were no treatment-related AEs that began >30 days after repeat treatment. All treatment-related AEs resolved without sequelae during the study period.

A lower incidence of ISRs was observed for injections with a cannula than without a cannula after initial touch-up and repeat treatments (See **Supplemental Digital Content**, Table S6, http://links.lww.com/DSS/A548). For initial/touch-up treatment with a cannula, 2 treated participants (4.5%) had 2 treatment-related AEs; without a cannula, 12 treated participants (8.7%) had 18 treatment-related AEs. For repeat treatment with a cannula, there were no treatment-related AEs; without a cannula, 3 treated participants (5.6%) had 7 treatment-related AEs.

Discussion

Although the primary end point was met, the ACRS responder rate of 56.3% was lower than expected. Comparatively, the midface study met its primary end point at Month 6, with 85.6% of treated participants having a clinically meaningful improvement.[5] A possible reason for this discrepancy is the markedly higher injection volumes used in the midface study. This study used lower volumes, more closely representative of volumes used in real-world clinical practice. Another potential reason for this discrepancy is the different methods of evaluation. The midface study relied on live assessments, taking into account overall improvement. This study's assessment was limited to 2-dimensional cropped photographs, possibly obscuring a treatment effect because it relates to the whole face. This hypothesis is supported by the notably higher responder rate of 91.8% observed from the EI live assessments, which are more in line with the high responses observed with the GAIS and FACE-Q measures. Another supportive observation is the control responder rate at Month 6, which was observably lower in this study compared with the midface study, 27.5% versus 38.9%, respectively, indicating a lower false-positive rate.[5] Although photograph assessments, rather than live assessments, were intended to help raters more consistently assess the relationship between landmarks, the use of cropped photographs as a primary measure may represent a study limitation. Other study limitations may have included the single-blind design, which left participants and injectors unblinded, and that control data were only available through month 6, although data could still be compared with baseline beyond Month 6.

VYC-20L was well tolerated, with most treatment-related AEs being ISRs of mild to moderate severity. Notably, there was an overall decrease in the number of AEs with repeat treatment compared with initial/touch-up treatment. One possibility is the lower volume injected during repeat treatment. Lower AE rates are commonly observed after repeat treatment. In addition, a lower number of AEs were associated with the use of cannulas versus needle injection, which is likely due to the ability of cannulas to assist injectors in avoiding sharp trauma and bruising,[4,17,18] although there may be confounding factors as patients were not randomized to a needle or cannula. In a retrospective study of 50 patients treated with VYC 20L administered by a cannula, 8% of patients experienced procedure-related ecchymosis, which was self-limiting and nonserious.[19] In a study that compared needle versus cannula in the treatment of nasolabial folds found the use of a cannula had significantly fewer AEs (pain, edema, redness, and hematoma) while maintaining similar efficacy to needle injection.[17]

One patient experienced 2 serious AEs related to the treatment, injection site cellulitis and injection site

inflammation, which resolved without sequelae. The patient experienced severe inflammation beginning 7 days after touch-up treatment. She was admitted to the hospital for treatment with intravenous antibiotics and drainage of the abscess. Cultures of the abscess were negative for gram-positive and gram-negative bacteria. This type of event has been previously reported, although they are not typically observed in prospective clinical studies, in part due to their relatively low incidence.[20] The etiology of late-onset inflammation and nodules after soft tissue filler treatment is not well understood and has been attributed to hypersensitivity, foreign body reaction, injection placement, infection, and biofilm development.[21]

Several soft tissue fillers have been previously reported in the literature for use in chin augmentation[19,22–25]; VYC-25L (Juvéderm Volux; Allergan plc) being the first HA soft tissue filler designed for chin augmentation and systematically investigated in a randomized controlled clinical trial for safety and effectiveness.[25] Similar to VYC-20L, objective and subjective measures for VYC-25L showed sustained clinically meaningful benefits through Month 12, with comparable safety profiles where the incidence of ISRs and AEs were consistent for HA soft tissue fillers. The mean change from baseline to Month 12 in the glabella-subnasale-pogonion angle was 1.28°, and investigator and participant assessments on the GAIS at Month 12 were 83.5% and 77.2%, respectively. FACE-Q Satisfaction with Chin module and Psychological Well-Being module mean scores showed continued improvement over baseline (41.4 and 65.3, respectively) at Month 12 (61.6 and 74.4).

Conclusions

VYC-20L treatment is safe and effective when injected in the chin and prejowl sulci to treat chin retrusion, with results lasting through 1 year.

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