

A Prospective Open-Label Study for Treatment of Infraorbital Hollows Using a Volumizing Hyaluronic Acid Filler

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Abstract

This study aimed to prospectively evaluate the effectiveness, patient satisfaction, and early adverse events of using the hyaluronic acid filler VYC-20L for the treatment of infraorbital hollowing. A total of 21 participants underwent injection of VYC-20L. FACE-Q satisfaction surveys before and after treatment along with early adverse events surveys were conducted. Pre- and posttreatment photos were graded, and the Allergan Infraorbital Hollows Scale was used to assess the difference in infraorbital hollowing. The results showed infraorbital hollowing improvement with VYC-20L was significant ($p < 0.001$). FACE-Q Satisfaction with Eyes scores on average were 27 points higher after treatment ($p < 0.001$). The mean FACE-Q Satisfaction with Decision score was 74.1%. The most common short-term adverse symptoms were tenderness (67%), swelling (62%), and bruising (52%). This study concludes that VYC-20L is an effective nonsurgical treatment option for infraorbital hollowing with high patient satisfaction.

Keywords

- infraorbital hollows
- hyaluronic acid
- filler
- VYC-20L

Aging of the infraorbital region of the midface remains one of the most challenging areas of the face to reliably and most effectively rejuvenate. The thin lower eyelid skin, compromised lymphatic drainage, increased vascularity, and underlying orbital bony remodeling create a multifactorial dilemma for the facial plastic and reconstructive surgeon.^{1,2} A number of different nonsurgical and surgical interventions have been used to treat infraorbital hollowing, including filler injections, autologous fat transfer, topical agents, laser resurfacing, and lower blepharoplasty with or without fat repositioning.^{3–5} There continues to be a great trend in plastic surgery treatments toward interventions that optimize the balance of efficacious long-lasting treatments, while minimizing invasiveness and recovery time.^{6,7}

The aged appearance of the infraorbital region of the face most commonly starts with shadowing in the area of the orbitomalar ligament, leading to a tear trough deformity. The infraorbital hollowing can be more specifically

divided into the tear trough, nasojugal groove, and palpebromalar groove.^{1,3} Given the large volume of patients seeking correction of the infraorbital hollows, there is an increasing need to be more objective about the assessment of pretreatment severity and posttreatment correction. The Allergan Infraorbital Hollows Scale was designed to meet that need, providing a validated and reliable scale for physician rating of the infraorbital hollows.⁴

Much of the literature studying restoration of volume to infraorbital hollows with nonsurgical interventions has emphasized the use of lower hyaluronic acid (HA) concentration fillers.^{1,8–10} Our recent retrospective study of VYC-20L demonstrated safe and efficacious use of the higher HA concentration filler in the often-challenging infraorbital region.¹¹ We have continued to use VYC-20L (JUVÉDERM VOLUMA XC; Allergan Aesthetics, AbbVie Inc, Irvine, CA), hereto referred to as VYC-20L, for off-label use in the infraorbital hollows. The objective of this study was to evaluate the effectiveness

of VYC-20L for the treatment of infraorbital hollows, including objective measures and patient satisfaction at 1 month after treatment.

Methods

A prospective cohort study was designed for patients seeking nonsurgical correction of infraorbital hollowing at a single metropolitan private practice in the United States (Buckingham Center for Facial Plastic Surgery, Austin, TX) from April 1, 2017, to May 31, 2018. The study was designed and created to further explore and expound upon the retrospective findings published in *JAMA Facial Plastic Surgery* by Hall et al, “Novel use of a volumizing hyaluronic acid filler for treatment of infraorbital hollows.”¹¹ The difference of this study is the prospective nature, objective data collection, and adverse event reporting. The study design was reviewed and granted approval by IntegReview, an independent institutional review board, prior to commencement of patient enrollment. A total of 21 patients, or 42 infraorbital injections, successfully completed all required inclusion criteria for the prospective cohort study. All injections were elective in nature and performed under the supervision of the senior author (E. D. B.) by a certified facial plastic and reconstructive surgeon or a certified nurse injector. Each patient underwent an initial consultation and discussion of the risks and benefits of and alternatives to VYC-20L use for the correction of infraorbital hollows. Patients were then informed of the opportunity to be included in the study, for which participation was voluntary without any coercion. Each patient included in the study signed our research study consent form, which included the use of their medical records and patient photographs for the purposes of research. We did not receive any external funding or ancillary benefit from any other institution as a part of this study. Additionally, patients were not compensated for their participation.

Pretreatment photographs were obtained in the standardized fashion that all photographs are taken at our center. All photos were taken with a Canon EOS Rebel T2i Digital SLR camera in a professional studio with standard oblique frontal flashes, controlled settings, patient positioning, and standardized views. Each enrolled patient was then treated with

cosmetic injection of VYC-20L for correction of infraorbital hollowing bilaterally. The treatments begin with an infraorbital nerve block using lidocaine 1% via a gingivobuccal approach and 27-G 1.5-inch needle. The cheek and lower eyelid are then cleansed with chlorhexidine followed by creation of the puncture site on the anterior cheek with a 26-G 0.5-inch needle. The cannula, a 27-G 1.5-inch DermaSculpt microcannula (DermaSculpt, Dublin, Ireland), is then introduced through the puncture site and the filler is injected in a layered fashion in a supraperiosteal or submuscular plane. Patients then returned for their posttreatment visits anywhere between 3 weeks and 3 months for follow-up posttreatment photos. Photos were independently assessed by two authors (S. W. S. and E. D. B.) and graded using the Allergan Infraorbital Hollows Scale. In this study, only early adverse events were assessed at 3 days posttreatment using the FACE-Q Recovery Early Symptoms questionnaire via telephone. Longer safety data (mean follow-up, 12 months) were analyzed retrospectively in our previous study.¹¹ Patient-reported satisfaction outcomes were assessed using FACE-Q Satisfaction with Eyes (pre- and posttreatment) and Satisfaction with Decision (posttreatment) surveys. FACE-Q Satisfaction with Eyes and Satisfaction with Decision surveys were sent to all patients via email at 1 month posttreatment. FACE-Q surveys are highly validated and reliable patient-reported outcome questionnaires. The FACE-Q Satisfaction with Eyes and Decision surveys are scored with a raw scale that is converted to an equivalent Rasch transformed score (0–100), where higher scores reflect higher satisfaction and better outcomes.¹² In this study, we report the transformed scores with a scale of 0 to 100.

Patient before and after photographs were then evaluated separately by two facial plastics and reconstructive surgeons using the validated 5-point photonumeric Allergan Infraorbital Hollows Scale (Grade 0 = none; Grade 4 = extreme). Each physician performed graded scale assessments of the 21 patients (42 infraorbital regions). The two grading physicians were blinded to one another’s scores. ▶Table 1 and ▶Fig. 1 further describe and illustrate the Allergan Infraorbital Hollows Scale. Interrater reliability was analyzed using Cohen’s kappa coefficient. Paired sample *t*-tests (degrees of freedom = 20, two-tailed, significance level *p* = 0.05) were performed

Table 1 Allergan Infraorbital Hollows Scale descriptors

| Grade | Term | Descriptor |
|-------|----------|---|
| 0 | None | No visible hollowing or volume loss medially or laterally |
| 1 | Minimal | Presence of hollowing with some volume loss medial to the midpupillary line; smooth lateral lid–cheek transition |
| 2 | Moderate | Defined hollowing extending laterally beyond the midpupillary line with moderate volume loss; smooth lateral lid–cheek transition with mild volume loss |
| 3 | Severe | Defined hollowing extending laterally beyond the midpupillary line with moderate volume loss creating a defined groove along the lid–cheek junction |
| 4 | Extreme | Defined hollowing extends from medial to lateral canthus; severe volume loss creates a marked step along the lid–cheek junction |

Source: Copyright Allergan Aesthetics.

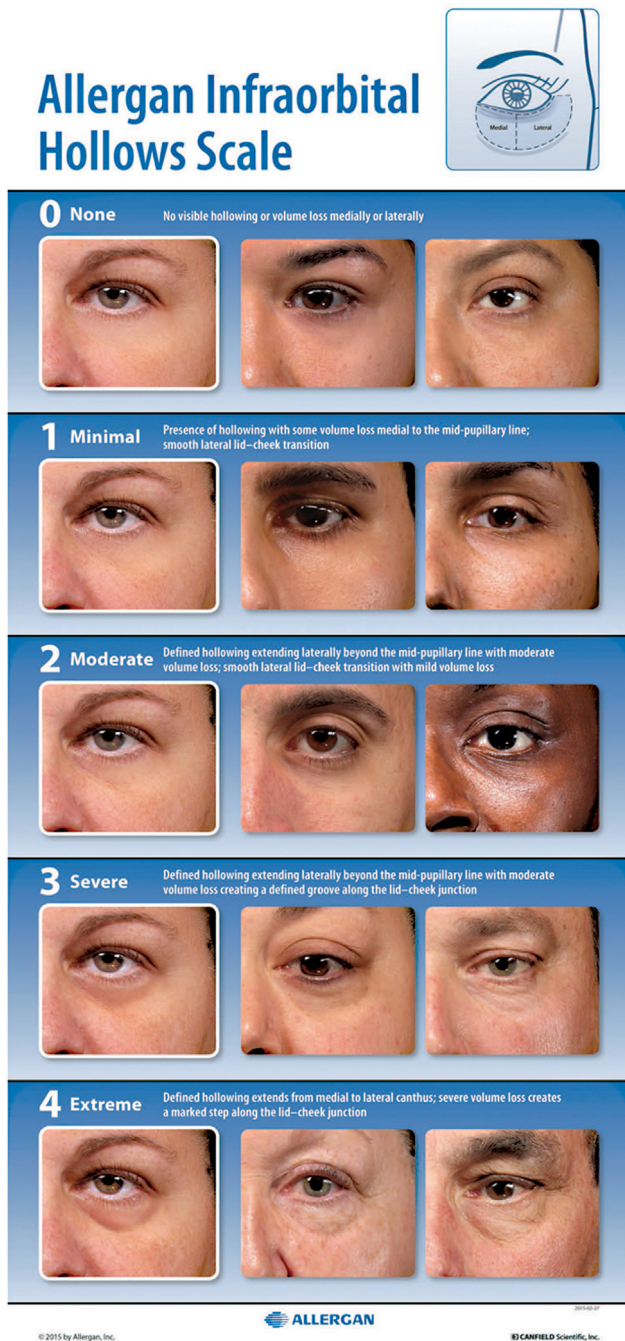


Fig. 1 Allergan Infraorbital Hollows Scale (copyright Allergan Aesthetics).

to test for statistical significance (FACE-Q Satisfaction with Eyes and infraorbital hollows data). Survey data were tested for normality using histograms and Shapiro-Wilk test, and were noted to be approximately normal. Surveys were administered via Survey Monkey (www.surveymonkey.com). Data were then analyzed using Microsoft Excel (Redmond, WA) and SPSS (IBM Corp., Armonk, NY).

Results

Initially, 38 patients were enrolled in this study. Twenty-one participants completed all study requirements and were

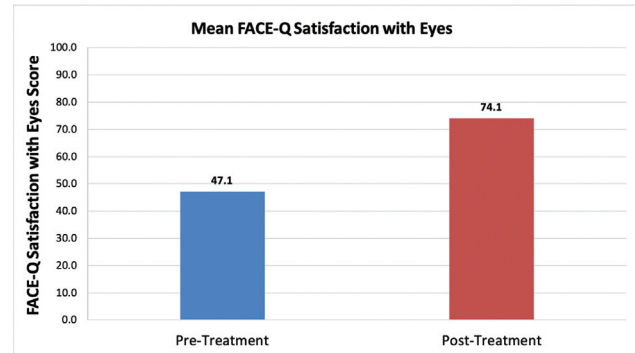


Fig. 2 FACE-Q Satisfaction with Eyes.

included in the data analysis. The remaining 17 patients either did not complete follow-up photos within the allotted 3 months or did not complete all surveys. Patient ages ranged from 27 to 77 years at the time of service, with a mean (standard deviation [SD]) age of 48 (12.7) years. The study was composed of 19 females and 2 males.

FACE-Q Satisfaction with Eyes surveys were administered pre- and posttreatment at 1 month. The pretreatment mean (SD) score was 47.1 (19.5), and posttreatment mean (SD) score was 74.1 (22.7). FACE-Q Satisfaction with Eyes scores were significantly higher after treatment, with a mean difference of 27.0 (95% confidence interval [CI], 14.1–39.8; $p < 0.001$). There were three patients whose posttreatment satisfaction scores were lower than pretreatment. ► **Fig. 2** further illustrates the mean FACE-Q Satisfaction with Eyes scores before and after treatment. The mean (SD) score of the FACE-Q Satisfaction with Decision survey was 74.1 (28.4) with a range of 21 to 100. Of these, 42.9% ($n = 9$) reported a satisfaction with decision score of 100.

Pre- and posttreatment photographs were evaluated independently by two authors using the Allergan Infraorbital Hollows Scale. This scale is composed of a 0 to 4 grading system, where higher grades indicate worse hollowing.⁴ Left and right eyes were rated separately by each physician rater, both before and after treatment. Analysis was conducted for each physician rater separately, as well as the combined average between the two raters to test for meaningful differences in infraorbital hollow grades. There were statistically significant improvements in infraorbital hollows scores within both separate and combined analyses ($p < 0.001$ for all comparisons). The combined right eye pre- and posttreatment mean (SD) scores were 2.38 (0.91) and 1.21 (0.75), respectively, with a mean difference of -1.17 (95% CI, -1.38 to -0.95 ; $p < 0.001$). The combined left eye pre- and posttreatment mean (SD) scores were 2.45 (0.86) and 1.1 (0.69), respectively, with a mean difference of -1.36 (95% CI, -1.57 to -1.14 ; $p < 0.001$). Mean infraorbital hollows scores before and after treatment for each physician rater are displayed in ► **Fig. 3**, and as a combined mean in ► **Fig. 4**. Representative patient photographs before and after treatment are shown in ► **Fig. 5**.

The Allergan Infraorbital Hollows Scale has been previously validated by Donofrio et al and shown to have

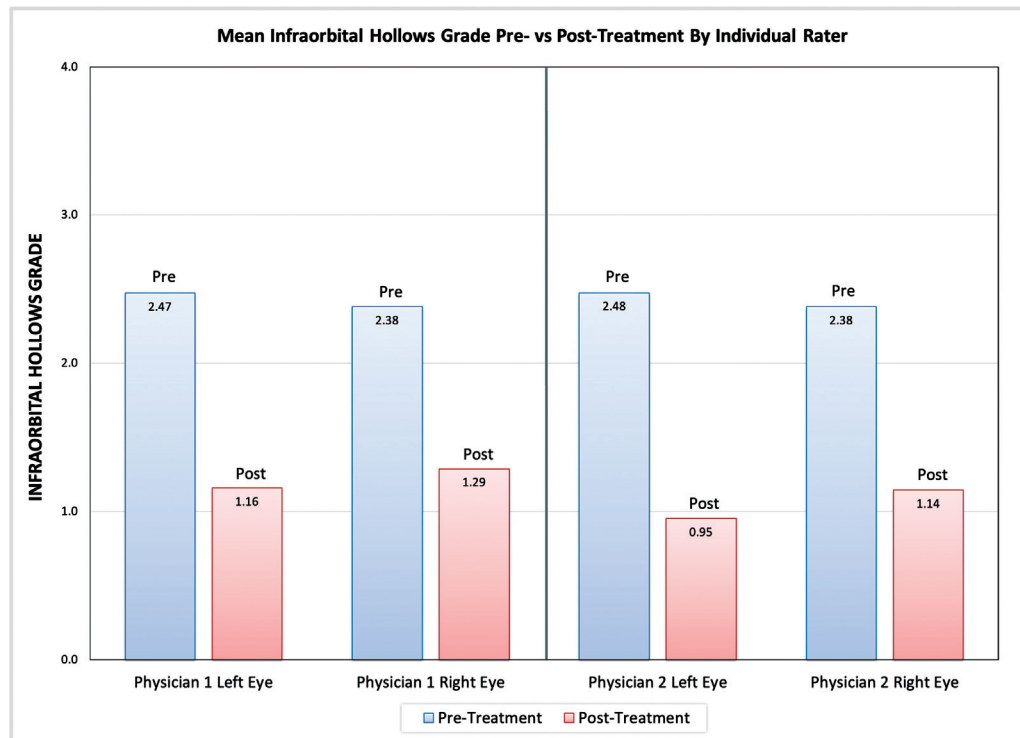


Fig. 3 Infraorbital hollows grading by individual rater.

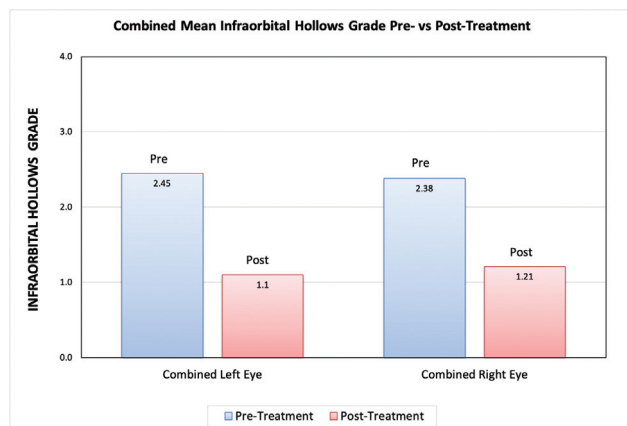


Fig. 4 Combined infraorbital hollows grading.

substantial interrater and intrarater reliability.⁴ We evaluated interrater reliability for all four data sets in our study, which was noted to be moderate to excellent (kappa values: 0.54, 0.78, 0.78, 1.0). There were five infraorbital regions scored as no improvement, which was 100% consistent in the scores of both physicians, as demonstrated with the high interrater reliability score. Of the five infraorbital hollow regions with no improvement, there were two patients with no improvement bilaterally (four regions) and one patient with no improvement on one side (one region). The two patients with no improvement on either side had the lowest FACE-Q Satisfaction with Eyes and Satisfaction with Decision scores within the entire cohort, and one received additional

touch-up filler. All other infraorbital region scores (88%) demonstrated improvement.

Early adverse events were assessed at 3 days posttreatment using the FACE-Q Recovery Early Symptoms questionnaire. The most common short-term adverse symptoms were tenderness (14 [67%]), swelling (13 [62%]), bruising (11 [52%]), and soreness (9 [43%]). Only three patients rated their adverse symptoms as “extreme,” those being swelling ($n = 2$) and tenderness ($n = 1$). Among the 11 patients who reported bruising, 6 patients rated the severity as “a little” and 5 as “moderate.” Of all adverse symptoms reported, 77.2% were rated as “a little” bothersome, 19% as “moderate,” and 3.8% as “extreme.” Adverse events are reported in further detail in **Table 2**. Most patients were treated with 1-mL syringe of VYC-20L (0.5 mL per side), while 4 of the 21 patients (19%) ultimately were treated with an additional 1-mL syringe for further correction or touch-up between 1 and 3 months following initial treatment.

Discussion

The infraorbital hollow is one of the most common cosmetic concerns that new patients present with today. As with any patient consultation, the most important component of the assessment is identifying the cause of the perceived concern and developing the appropriate solution.⁵ Aging of the lower eyelids can be multifactorial and therefore appropriate identification of a volume deficiency is paramount to achieving success with HA filler treatment of the infraorbital region.¹ Correct assessment of the lower eyelid region



Fig. 5 Patient photographs before and after treatment. (A) A 27-year-old woman before filler treatment of infraorbital hollows with 1 mL of VYC-20L (0.5 mL per side). This was the youngest patient in our study. (B) The patient is shown at 1 month posttreatment. (C) A 39-year-old man before filler treatment of infraorbital hollows with 1 mL of VYC-20L (0.5 mL per side). (D) The patient is shown at 2 months posttreatment. (E) A 64-year-old woman before filler treatment of infraorbital hollows with 2 mL of VYC-20L (0.5-mL bilateral tear troughs and 0.5-mL bilateral cheeks). (F) The patient is shown at 1 month posttreatment. (G) A 77-year-old woman before filler treatment of infraorbital hollows with 1 mL of VYC-20L (0.5 mL per side). This was the oldest patient in our study. (H) The patient is shown at 1 month posttreatment.

requires facial examination from multiple angles and dynamic assessment of the lower eyelid as it relates to the globe and infraorbital rim. The hollows refer to the volume deficiency or curvilinear depression under the eyes overlying the region of the inferior orbital rim, which can affect a wide range of different age groups.

Successful filler treatment of the infraorbital hollow requires a strong comfort with the use of different fillers as well as an understanding of the properties within each filler. The ideal filler should be nonimmunogenic, biocompatible, stable with long duration of benefit, and well-integrated into the surrounding tissue.⁵ While the number of different filler types and different manufacturers have continued to grow, VYC-20L continues to be the filler with the longest duration of action, which can be up to 2 years.^{13,14} Food and Drug Administration (FDA) approval for the use of VYC-20L continues to be limited to cheek augmentation and more recently the chin; however, as with this particular

investigation, its off-label uses have expanded.¹⁵ Many physicians avoid filler treatment of the infraorbital region due a higher rate of complications and undesirable results. Criticisms of VYC-20L product use in the infraorbital region include that it is too hydrophilic. In this author's experience, however, injecting the filler in layered fashion in the supra-periosteal or submuscular planes and not in bolus fashion has yielded excellent results and high patient satisfaction.

Our intent of this study was to provide an objective assessment for the use of VYC-20L in the infraorbital hollow. The validated Allergan Infraorbital Hollows Scale allowed for a more objective grading for the ultimate degree of improvement achieved from patient to patient.⁴ The use of objective validated metrics allows the data collected in this study to be compared with other similar studies in the future. The number and type of early adverse symptoms in this study were comparable to other studies using HA fillers in the infraorbital region.^{8,9,13,16}

In our initial retrospective study, bruising was documented in 10% of patients. In this study, mild-to-moderate bruising was reported in 52% of patients. It is important to note that adverse events were measured differently between these two studies. In our first study, adverse events were assessed using retrospective chart review, and recorded events were those noticed by physicians and included prolonged episodes, those requiring intervention, or those that were objectionable to the patient. In the present study, adverse events were measured at 3 days postinjection and were patient reported. Thus, it is expected that there would be a higher frequency of patient-reported minor or temporary adverse events in this prospective study. In summary, our previous study aimed to measure more long-term adverse events documented by the physician, while a secondary aim of this study was to assess short-term adverse events reported by the patient. This difference accounts for the discrepancy in adverse event frequency between our two studies.

Objectively assessing the degree of patient satisfaction is equally as important.¹⁷ FACE-Q surveys are among the most established and the most widely cited patient-reported outcomes scales in aesthetic medicine.¹² These validated surveys allow for researchers to provide strong and more complete assessments of patient perception of treatment success. The high rate of patient safety and satisfaction initially introduced in our retrospective study is further supported with the prospective and objective data generated from this prospective cohort. FACE-Q Satisfaction with Eyes and FACE-Q Satisfaction with Decision to Treat surveys allowed for validated quantification of patient's happiness with their treatment. Three of the patient's surveys did demonstrate a perceived worse appearance or happiness with their outcome. Among the three patients who had worse FACE-Q Satisfaction with Eyes scores after treatment, one patient had objective improvement in infraorbital hollows scores but after treatment had a MOHS (Micrographically Oriented Histogramic Surgery) defect along the right nasojugal groove present at the time of follow-up photos. Another patient had no objective improvement in infraorbital hollows scores and did not receive any additional touch-

Table 2 Early adverse events

| FACE-Q Recovery Early Symptoms survey | | | | | |
|--|------------|----------|------------|-----------|---------------------|
| | Not at all | A little | Moderately | Extremely | Total # with AE (%) |
| Tenderness | 7 | 11 | 2 | 1 | 14 (66.7) |
| Swelling | 8 | 7 | 4 | 2 | 13 (61.9) |
| Feeling bruised | 10 | 6 | 5 | | 11 (52.4) |
| Feeling sore | 12 | 9 | | | 9 (42.9) |
| Feeling that your face is too tight | 14 | 5 | 2 | | 7 (33.3) |
| Discomfort | 15 | 6 | | | 6 (28.6) |
| Numbness | 17 | 4 | | | 4 (19.0) |
| Headaches | 17 | 3 | 1 | | 4 (19.0) |
| Pain | 18 | 3 | | | 3 (14.3) |
| Feeling tired | 18 | 2 | 1 | | 3 (14.3) |
| Itching | 19 | 2 | | | 2 (9.5) |
| Feeling lightheaded | 19 | 2 | | | 2 (9.5) |
| Stinging | 20 | 1 | | | 1 (4.8) |
| Tingling | 21 | | | | 0 |
| Throbbing | 21 | | | | 0 |
| Burning | 21 | | | | 0 |
| Feeling feverish | 21 | | | | 0 |

Abbreviation: AE, adverse event.

Note: Five most common AEs in bold.

up filler. The third patient did not have any clear reason or confounding factors as to why the posttreatment FACE-Q Satisfaction with Eyes score was lower and did have objective improvement of infraorbital hollows scores. The main reasons stated for dissatisfaction were no appreciable change or underwhelming degree of improvement. The high degree of patient satisfaction (74.1%) in our current study is similar to other studies treating the infraorbital hollows and tear troughs with HA filler.^{7,11,13,18,19} In our retrospective study, satisfaction with decision was slightly lower at 65.6%, although there was only a 42% response rate.¹¹ Overall, this study demonstrated a high degree of objective improvement and patient satisfaction of the infraorbital hollows with VYC-20L.

Limitations

This study is limited by a smaller sample size of 21 patients with treatment at a single private ambulatory facial plastic surgery office, thus reducing statistical power and generalizability. Given the open-label design, there is potential for performance and detection bias. There were multiple injectors as well as injectors of variable degrees of experience, and interinjector differences are unable to be accounted for. However, all injectors followed the same protocol and injection technique as described earlier. As for the timing of photoanalysis, an effort was made to have all patients to follow up at the office 1 month postinjection for photos, but this was not feasible in some cases due to patient-related factors, and photos ranged from 3 weeks to 3 months post-

treatment. It should be noted that while efforts are made to ensure that photos taken before and after treatment are consistent and standardized, precise control of in-office photodocumentation is not possible, and there may be limitations to its accuracy. Thirty-eight patients were initially enrolled in the study; however, only 21 (55%) completed all study requirements within the allotted time period. Lack of timely follow-up for the study was higher than expected. This raises the possibility of attrition bias as the incomplete data may represent a population with different characteristics or outcomes from the study group. Long-term safety data were not evaluated in this study and thus do not account for possible late adverse events such as delayed-onset edema. Finally, there was no control group due to the within-subject design of the study.

Conclusion

Nonsurgical infraorbital rejuvenation remains a debated topic within aesthetic medicine. There remains a lack of consensus among providers regarding the unanimous HA filler of choice for infraorbital region. Our experience with the product VYC-20L as a soft-tissue filler for the treatment of infraorbital hollowing has yielded a high degree of objective improvement and patient satisfaction with a low rate of adverse effects. Future studies with consistent long-term follow-up are needed to better assess the safety profile and duration of patient satisfaction when using VYC-20L for the treatment of infraorbital hollows.

Conflict of Interest

None declared.

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