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 ORIGINAL ARTICLE

Effectiveness and Safety of a New Hyaluronic Acid Injectable for Augmentation and Correction of Chin Retrusion

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ABSTRACT

Background: A hyaluronic acid (HA) filler intended for non-surgical improvement of chin appearance should ideally be of high strength/firmness (high G') to allow for deep injections on the bone. HA_{SHA} (Restylane® Shaype™) is a new hyaluronic acid (HA) injectable with high G' and high HA concentration (25 mg/mL), engineered by the new NASHA-HD™ (High Definition) technology. HASHA is suitable to be placed periosteally, aiming to mimic the natural shape of the bony chin. This pivotal clinical investigation evaluated effectiveness and safety of HA_{SHA} for augmentation and correction of chin retrusion.

Methods: Subjects ≥18 years with mild or moderate chin retrusion by the Galderma Chin Retrusion Scale (GCRS), were randomized 3:1 to HA_{SHA} (n=103) or no treatment (n=37). Assessments included GCRS (blinded evaluator), aesthetic improvement (Global Aesthetic Improvement Scale [GAIS]), subject satisfaction, and safety.

Results: GCRS responder rate (≥ 1-grade improvement from baseline) was significantly higher for HA_{SHA} (83.3%) vs controls (10.8%) at month 3 (P<0.001), and maintained through month 12 (P<0.001). Aesthetic improvement was high throughout the study in the HA_{SHA} group, according to investigators (≥97%) and subjects (≥89%). Overall, subject satisfaction was high at month 3 and maintained at month 12. Product- or injection-related adverse events were mostly mild or moderate and transient. No product- or injection-related serious adverse events were reported.

Conclusions: HA_{SHA}, a new NASHA-HD™ injectable with extra strength/firmness, was safe and effective for chin augmentation and correction of chin retrusion, with high aesthetic improvement and subject satisfaction throughout 12 months.

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INTRODUCTION

The shape, projection, and profile of the chin are important components of facial attractiveness in both men and women. Chin retrusion may be perceived as less attractive and associated with a desire for chin correction or elongation.[1] Procedures for enhancing chin appearance include surgical procedures, such as permanent alloplast implants (eg, silicone) bony osteotomy, autologous fat transplant, and non-surgical alternatives, such as different types of dermal fillers (eg, silicone, calcium hydroxylapatite, and hyaluronic acid (HA) fillers).[2-4] For patients seeking a minimally invasive and reversible option, HA fillers have shown high patient satisfaction and low risk of severe complications.[5] In addition to a favorable safety profile, filler treatments offer fast recovery[3,6], and the flexibility to tailor treatments to meet individual needs, including changes in appearance due to aging. Even though the global market offers a wide variety of HA fillers with different physicochemical and rheological characteristics, there remains a need for a strong/firm HA injectable that mimics the natural shape of the bony chin.

NASHA® technology utilizes minimal modification and mild processing that preserves the long natural HA chains, resulting in strong/firm products with high G' (an indicator of strength/

firmness). The NASHA products are Restylane® (Galderma, Uppsala, Sweden) with a G' of 701 Pa (0.1 Hz) and Restylane® Lyft™ (Galderma) with a G' of 799 Pa (0.1 Hz). A new HA injectable, Restylane® Shaype™ (HA_{SHA}; Galderma), has been developed for lower face shaping and to be injected on bone. HA_{SHA} uses the new NASHA-HD™ (High Definition) technology, an evolution of the NASHA platform, using the same low modification and mild processing as NASHA but with increased efficiency of the crosslinking process.This results in HA_{SHA} being an even stronger/firmer product (G' of 916 Pa [0.1 Hz]) with high HA concentration (25 mg/mL). In addition, it is a stable product with high resistance to degradation by heat.

Here, we report the results from a pivotal clinical investigation evaluating the effectiveness and safety of HA_{SHA}, compared to a no-treatment control, for augmentation and correction of retrusion in the chin region.

MATERIALS AND METHODS

Study Design

This was a prospective, randomized, evaluator-blinded, no-treatment controlled, parallel-group, multicenter study, conducted at nine centers in Canada, between January 2021 and June 2022. Subjects were healthy men or non-pregnant women aged ≥18 years, with mild (Grade 1) or moderate (Grade 2) chin retrusion at baseline, as assessed by a treatment-blinded evaluator using the Galderma Chin Retrusion Scale (GCRS, where Grade 0 = none, Grade 1 = mild, Grade 2 = moderate, and Grade 3 = severe retrusion). Exclusion criteria included a history of multiple or severe allergies, known or previous allergy/hypersensitivity to local anesthetics; prior procedures in the lower facial region (eg, surgery, permanent/semi-permanent implants); HA or collagen filler treatments in the lower face within the last 12 months; energy-based aesthetic procedures (eg, lasers), mechanical or chemical procedures, botulinum toxin, or cryotherapy in the lower face within the last 6 months; deoxycholic acid treatment in the submental region within the last 6 months; the presence of disease or lesions near the area to be treated (eg, inflammation, infections, acne, psoriasis, scars, cancer or precancer); other underlying conditions (eg, HIV or bleeding disorders) or recent or concomitant medications (eg, anticoagulants, immunosuppressants, chemotherapy, topical facial or systemic corticosteroids) that could expose the subject to undue risk. The study was approved by the Institutional Review Boards at each site and was conducted in accordance with Good Clinical Practice and the Declaration of Helsinki. All subjects provided written, informed consent before starting the study.

Treatment and Follow-up

Subjects were randomized (3:1) to either HA_{SHA} (Restylane Shaype, Galderma, Uppsala, Sweden) injection with the initial treatment given on Day 1 or no-treatment control. HA_{SHA} gel (25 mg/mL HA plus 3 mg/mL lidocaine hydrochloride) was administered using a 1 mL syringe with a 27-gauge, ¾ -inch, ultra-thin wall needle into the chin and surrounding regions. The injection was made into the deep subcutaneous tissue or supraperiosteal plane, as chosen by the treating investigator, with additional local anesthetic if needed. On day 1, subjects received up to 4 mL HA_{SHA} for optimal retrusion correction, defined as ≥1-point improvement from baseline on the GCRS and the best correction that could be achieved (investigator and subject agreement). An optional touch-up treatment with up to 2 mL HA_{SHA} was allowed at month 1, if necessary to obtain optimal aesthetic improvement of the chin. Post-treatment procedures included gently massaging the treated area, applying an ice pack, and providing subjects with guidance on standard post-treatment care. Subjects were followed for up to 12 months from baseline. Subjects in the control group were offered HA_{SHA} treatment at the month 12 visit; where accepted, these subjects were followed for one month after injection.

Assessments

The primary objective was to demonstrate the superiority of HA_{SHA} vs no-treatment control for augmentation and correction of chin retrusion, using Blinded Evaluator live assessment of responder rate at month 3 post-baseline. Subjects were considered responders if they had ≥1-point improvement from baseline on the GCRS.

The secondary objectives were to assess effectiveness and subject satisfaction up to month 12 after treatment. These included Blinded Evaluator-assessed GCRS responder rates, investigator- and subject-assessed aesthetic improvement using the Global Aesthetic Improvement Scale (GAIS; a 7-point scale ranging from "very much worse" to "very much improved"), and a subject-completed Satisfaction Questionnaire. Subjects also completed a 4-week diary, starting on the day of the initial or touch-up treatment, which included documenting the time in hours from injection until they felt comfortable returning to social engagements, and the occurrence of the following predefined, expected post-treatment events (bruising, redness, pain, tenderness, itching, or swelling in the treated area; rated as tolerable, affecting daily activities, or disabling). Investigator-reported safety included documentation of adverse events (AEs) and physical examinations evaluating changes in hair growth in the chin region throughout the study.

Statistical Analysis

A sample size of 140 subjects (randomized 3:1 to HA_{SHA} or no treatment) based on a power calculation was needed to achieve approximately 90% power to demonstrate a difference between groups, assuming GCRS responder rates of 70% in the HA_{SHA} group and 35% in the no-treatment control group, using a two-sided significance level of 0.05.

All effectiveness analyses were performed in the intent-to-treat (ITT) population (all randomized subjects) and safety was assessed in the safety population (all treated subjects or those randomized to the control group). In the primary analysis, GCRS responder rates at month 3 from baseline were compared using Fisher's exact test and presented as estimated responder rates, with two-sided 95% confidence intervals (CI) and *P*-value. Missing data at month 3 were imputed using the Baseline Observation Carried Forward method for the primary analysis. The difference in responder rates was calculated using the Wald Approximation with a continuity correction. A value of $P<0.05$ for the treatment difference was considered significant. The same analysis method was used for the secondary endpoint of GCRS responder rates at months 6, 9, and 12, except that analyses were performed on observed cases (no imputation of missing data). For the GAIS, a responder was defined as a subject with a rating of at least "improved". The time until subjects felt comfortable returning to social engagement was analyzed using Kaplan-Meier methods. All other variables were analyzed descriptively. Post-hoc analyses of responder rates and safety profiles were conducted with stratification by total injection volume (> or ≤ median volume). Statistical analyses were performed using the SAS 9.4 software.

RESULTS

Subjects and Treatment

In total, 140 subjects were randomized to HA_{SHA} (n=103) or no-treatment (n=37) and comprised the ITT population. One subject randomized in error to HA_{SHA} was not treated; 89% completed the study. The most common reasons for withdrawal were subject loss to follow up (6.4%) and withdrawal of consent (2.9%). At Month 12, 25 subjects in the no-treatment group chose to receive HA_{SHA} and these were included in the safety analysis.

TABLE 1.

Demographics and Baseline Characteristics		
Demographic/Characteristic	**HA_{SHA} (n=103)**	**No Treatment (n=37)**
Age (years), mean (SD)	42.3 (12.86)	41.1 (12.54)
Female, n (%)	99 (96.1)	37 (100)
Race[a], n (%)		
White	85 (82.5)	32 (86.5)
Black or African American	2 (1.9)	0
Asian	11 (10.7)	5 (13.5)
Other	10 (9.7)	3 (8.1)
Ethnicity, n (%)		
Hispanic or Latino	3 (2.9)	1 (2.7)
Not Hispanic or Latino	100 (97.1)	36 (97.3)
Fitzpatrick skin type, n (%)		
I	4 (3.9)	0
II	26 (25.2)	8 (21.6)
III	45 (43.7)	20 (54.1)
IV	24 (23.3)	9 (24.3)
V	3 (2.9)	0
VI	1 (1.0)	0
Blinded Evaluator GCRS score, n (%)		
0	0	0
1	56 (54.4)	14 (37.8)
2	47 (45.6)	23 (62.2)
3	0	0

GCRS, Galderma Chin Retrusion Scale; SD, standard deviation
[a]Subjects who selected more than one race were counted once for each race. Totals may add up to over the total number of subjects in the study.

Demographic and baseline characteristics were generally similar between the two groups (Table 1). Most subjects were female (97%) and white (84%) and the mean age was 42.0 years (range: 21 to 67). The most common Fitzpatrick skin types were III (46%), II (24%) and IV (24%). All subjects had GCRS Grade 1 or 2 chin retrusion at baseline.

The volume (mean±standard deviation) of injected product for the HA_{SHA} group was 2.10±0.85 mL at initial treatment (N=102) and 0.99±0.55 mL at touch-up treatment (N=73), with a total injected volume of 2.81±1.20 mL. The median (range) total injected volume was 2.80 (0.70, 6.00) mL. The most common injection depth at initial treatment in the HA_{SHA} group was supraperiosteal (98%) and the most common injection method was bolus (76%).

Effectiveness

Improvement in Chin Retrusion (GCRS)

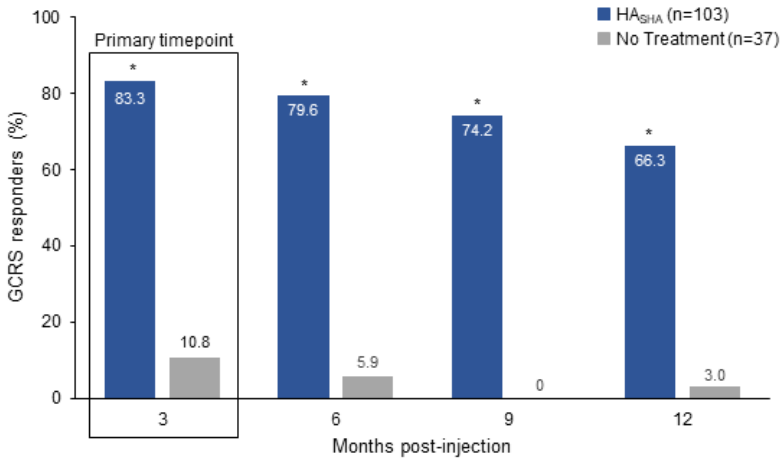
The primary objective to show HA_{SHA} superiority in improving chin retrusion was met. The Blinded Evaluator-assessed GCRS

TABLE 2.

Chin Retrusion Responder Rates[a] at Month 3 Based on the GCRS (ITT population)				
	HA_{SHA}	**No Treatment**	**Difference in responder rate[b] (95% CI)**	***P*-value[c]**
No.	102	37	--	--
Responders, n (%)	85 (83.3)	4 (10.8)	72.5	<0.001
95% CI, %	74.66–89.98	3.03–25.42	58.34–86.71	--

[a]Responders were defined as subjects with ≥1-point improvement from baseline on the GCRS according to the Blinded Evaluator

FIGURE 1. Blinded evaluator-assessed GCRS responder rates over time (ITT Population).



GCRS, Galderma Chin Retrusion Scale; ITT, intention-to-treat
[a]Responders were defined as subjects with ≥1-point improvement from baseline on the GCRS. At Month 3 (primary endpoint), missing values were imputed using the baseline observation carried forward method. Observed cases are shown for Months 6, 9 and 12. *p<0.001 HA$_{SHA}$ vs no-treatment control, Fisher's exact test

responder rate at month 3 was significantly greater in the HA$_{SHA}$ group compared with the no-treatment control group (83.3% vs 10.8%; *P*<0.001; Table 2). The GCRS responder rate remained significantly greater in the HA$_{SHA}$ group compared with the no-treatment group from month 6 (80% vs 6%; *P*<0.001) through month 12 (66% vs 3%; *P*<0.001) (Figure 1). Subgroup analyses based on injection volume (> or ≤2.8 mL [median volume]) showed similar treatment effects as observed for the full study population (Table 3).

Global Aesthetic Improvement

Aesthetic improvement on the GAIS was achieved in high proportions of subjects, ≥97% and ≥89% as assessed by the treating investigator and subjects, respectively, from month 1 through month 12 after treatment with HA$_{SHA}$ (Figure 2).

Subject Satisfaction

Overall, subject satisfaction was high through month 12, as per the subject satisfaction questionnaire (Figure 3). From month 3 to month 12 post-treatment, subjects in the HA$_{SHA}$ group were satisfied/very satisfied with the shape of their chin (range: 87% to 93%), the projection of their chin (range: 87% to 94%), and their chin profile (range: 82% to 93%). From month 3 to month 12 post-treatment, subjects in the HA$_{SHA}$group agreed/strongly agreed that their chin looked natural (range: 95% to 96%), made them feel more attractive (range: 71% to 73%), improved their overall satisfaction with their appearance (range: 81% to 92%), and made them feel better about themselves (range: 77% to 79%). A high proportion of subjects who received HA$_{SHA}$ said they would receive the treatment again (range: 80% to 84%) and would recommend the treatment to a friend (range: 92% to 97%).

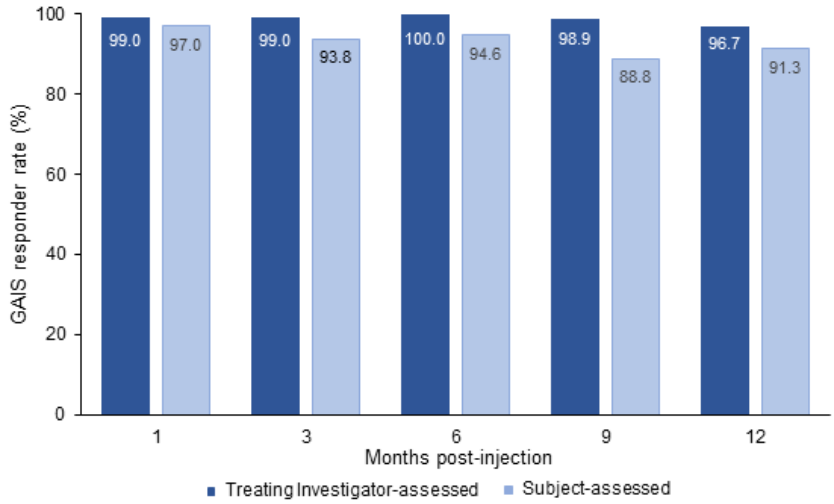
TABLE 3.

Post-Hoc Analysis of Blinded Evaluator-Assessed GCRS Responder Rates and Product- and Injection-Related Adverse Events by HA$_{SHA}$ Total Injection Volume (Including Initial and Touch-Up) ≤2.8 mL and >2.8 mL (Median Total Injection Volume)[a]

	Number of Subjects (m/n)	
	Total Injection Volume ≤2.8 mL (N=53)	Total Injection Volume >2.8 mL (N=49)
GCRS responders[b] at month 3	42/48 (87.5%)	43/48 (89.6%)
GCRS responders[b] at month 6	38/47 (80.9%)	36/46 (78.3%)
GCRS responders[b] at month 9	29/43 (67.4%)	37/46 (80.4%)
GCRS responders[b] at month 12	29/46 (63.0%)	32/46 (69.6%)
	Total Injection Volume ≤2.8 mL (N=53)	Total Injection Volume >2.8 mL (N=49)
Subjects reporting any product-related AEs	7/53 (13.2%)	11/49 (22.4%)
Subjects reporting any injection-related AEs	7/53 (13.2%)	6/49 (12.2%)
Subjects reporting implant site nodule/mass	3/53 (5.7%)	9/49 (18.4%)

AE, adverse event; GCRS, Galderma Chin Retrusion Scale; m=number of subjects with event; n=non-missing subjects
[a]Observed cases among subjects with any (mild or moderate) GCRS score at baseline in the HA$_{SHA}$ group; [b]Defined as a subject with ≥1-grade improvement from baseline on the GCRS

FIGURE 2. GAIS responder rates over time according to Treating Investigator assessment and Subject assessment (ITT population).



GAIS, Global Aesthetic Improvement Scale; ITT, intention-to-treat
[a]The responder rate was defined as the percentage of subjects with a rating of at least "improved" on the GAIS. Month 1 is counted from the last treatment (i.e. from touch-up for those who received a touch-up or from initial treatment for those who did not receive a touch-up). Months 3-12 are counted from baseline.

Return to Social Engagements

The self-reported median time until subjects felt comfortable returning to social engagements was 19.0 hours (95% CI, 5.0, 26.0) after initial treatment and 7.0 hours (95% CI, 2.0, 20.0) after touch-up treatment.

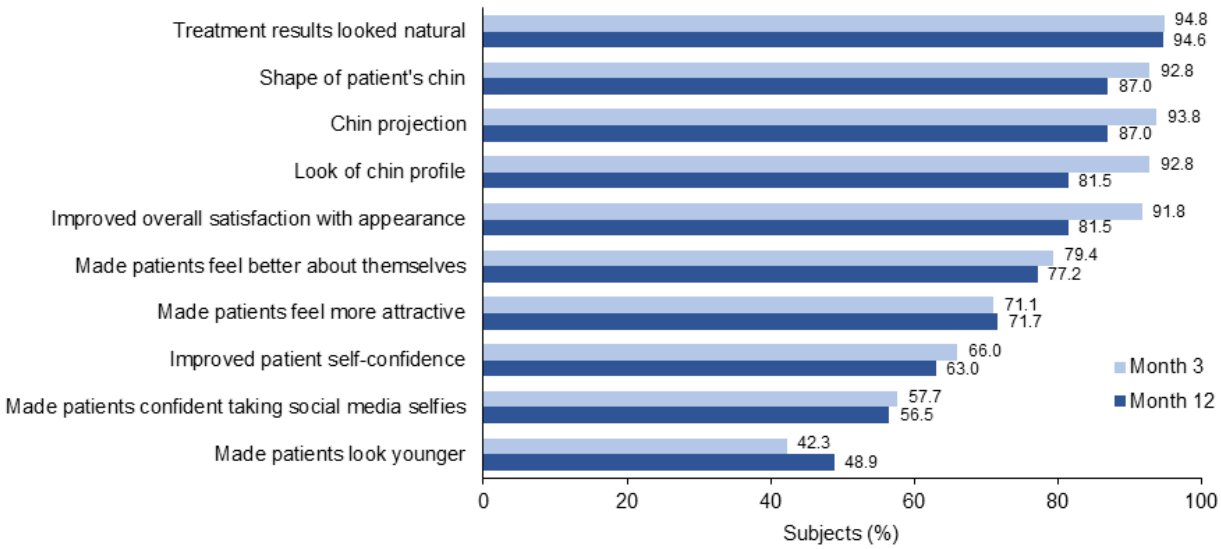
Subject Photographs

Example photographs of a subject before and after treatment with HA_{SHA} are provided in Figure 4.

Safety

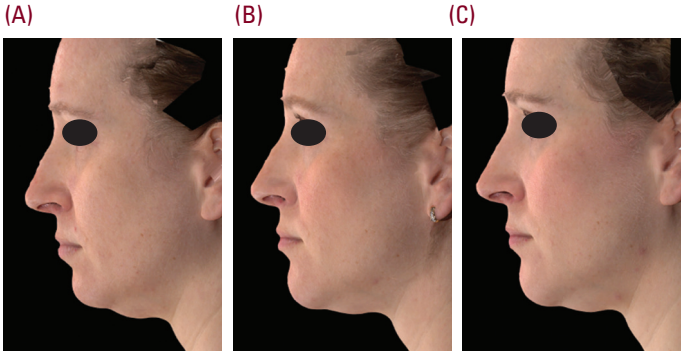
Safety results are reported for all subjects who were injected with HA_{SHA}(N=127), which included 25 subjects from the former control group who chose to receive treatment at month 12. Among the 123 HA_{SHA}-treated subjects who provided information in the 4-week subject diary, 100% reported at least one predefined, expected post-injection event (pain, tenderness, redness, bruising, swelling, or itching) after treatment. The most common diary-reported post-injection events after the initial

FIGURE 3. Subject satisfaction in the HA_{SHA} group at month 3 and month 12 (ITT population).



ITT, Intention-to-treat; The percentage of patients who responded "satisfied" or "very satisfied" or "strongly agree" or "agree" on the Subject Satisfaction Questionnaire.

FIGURE 4. Photographs of a 42-year-old female at baseline, GCRS=2 (A), month 3, GCRS=0 (B), and month 12, GCRS=0 (C). The subject was injected with 2.8 mL HA_{SHA} at initial treatment and with 1.7 mL HA_{SHA} at the 1-month touch-up.



injection were tenderness (99% of subjects), pain (97%), and swelling (95%; Figure 5). Most subjects reported these events as tolerable and as resolved within 1-2 weeks. A similar profile of post-injection events was reported after the touch-up injection (Figure 5).

In total, 24 subjects (19%) treated with HA_{SHA} experienced a product- or injection-related AE, 80% of which were mild or moderate in intensity. The most common product- or injection-related AEs (>2.0% of subjects) were implant site mass (5.5%), implant site pain (4.7%), implant site nodule (3.9%), and headache (3.1%). Implant site pain generally started on the day of injection and had a median duration of 2.0 days. There were 13 events of implant site mass (n=8) and nodules (n=5). Of these, no events of mass and 4 nodules were delayed (starting >21 days after treatment). Two events of nodule were inflammatory, and one of these had delayed onset. There were no product- or injection-related serious AEs reported. No subjects experienced a change in chin hair growth during the study.

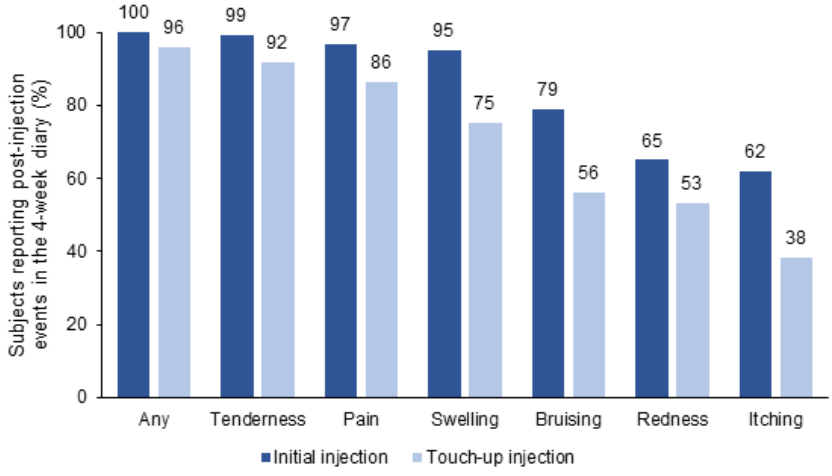
Post hoc analyses of product- or injection-related AEs based on injected volume (> or ≤2.8 mL, the median volume) showed that a larger proportion of subjects had AEs related to the product —including implant site nodules and mass—after injection with >2.8 mL (Table 3).

DISCUSSION

The results of this study demonstrate that HA_{SHA} significantly improves chin retrusion from baseline, compared with a no-treatment control. Notably, the GCRS response (Figure 1) was maintained in the majority of subjects, with a significant difference between the two groups for up to 12 months after the initial injection (with a touch-up at month 1). The long-term improvement in chin retrusion with HA_{SHA} treatment is supported by the GAIS results, which showed a high proportion of individuals (97% investigator assessment, and 91% subject assessment, Figure 2) with aesthetic improvement that was maintained at month 12. Even though not directly comparative, other pivotal studies evaluating chin augmentation with HA-based fillers, eg, using VYC-20L (Juvéderm VolumaXC[â], Allergan) have shown GAIS aesthetic improvement rates for chin augmentation at month 12 of 91%/82% according to investigators/subjects.[7] In a pivotal study of VYC-25L (Juvéderm Volux[â], Allergan) GAIS responder rates in the treatment of chin retrusion were 84%/77% at month 12 according to investigators/subjects, respectively.[8]

HA_{SHA} had an overall acceptable safety profile in relation to the positive results of treatment reported by the subjects, eg, high satisfaction and GAIS results (Figures 2 and 3). Subject-reported, predefined, expected injection-related events (pain, tenderness, redness, bruising, swelling, and itching, Figure 5) in the 4-week diaries were mostly tolerable and transient, usually resolving within 1–2 weeks. Most product- or injection-related AEs reported by the investigators were mild or moderate in intensity

FIGURE 5. Subject diary-reported predefined, expected post-injection events (safety population).



[a]Proportion of subjects reporting post-injection events in the 4-week diary completed after each injection.

and there were no product- or injection-related serious AEs. The most commonly reported product- or injection-related AEs were implant site reactions, mass, pain, and nodules, which were mostly mild or moderate in intensity and resolved during the study. Post-hoc analyses revealed a relationship between total injected volume (initial and touch-up) and product-related AEs, including mass and nodules, with a higher AE frequency with volumes above 2.8 mL (Table 3). The GCRS results tended to be similar for both subgroups (Table 3) indicating that both higher and lower volumes (≤ median and > median) achieved optimal aesthetic results. However, overall, these findings suggest that a smaller total injection volume may be preferable, to reduce the risk of developing nodules or mass. Smaller volumes of product per injection point have previously been reported to minimize the risk of serious AEs.[6] Overall, the safety profile for HA_{SHA} appears to be generally comparable with that reported for other HA fillers injected in the chin area.[7,8] Other pivotal studies have reported injection site mass/nodule rates of 21.8%/1.7% for VYC-25L[8] and 60.2% ('lumps/bumps') for VYC-20L,[7] while our study reported mass/nodule rates of 5.5%/3.9% for HA_{SHA}.

The patient perspective is important in aesthetic treatments, particularly as appearance can impact the perception of attractiveness and potentially psychological well-being.[1,2] Subject satisfaction rates in the HA_{SHA} group remained high throughout the present study (Figure 3). At month 12, most subjects (82 to 87%) remained satisfied/very satisfied with the shape, projection, and profile of their chin, as well as their overall appearance. Most subjects still felt after 12 months that the treatment results looked natural (95%), and made them feel more attractive (72%) and better about themselves (77%).

CONCLUSION

The results of this study showed that HA_{SHA} is safe and effective for chin augmentation and improvement of chin retrusion, with high aesthetic improvements and high subject satisfaction lasting through 12 months. The study findings support HA_{SHA} as a safe option for patients with mild to moderate chin retrusion (by GCRS) looking for a minimally invasive and reversible treatment option for chin augmentation.

DISCLOSURES

Andreas Nikolis is a paid consultant, speaker, and clinical trial investigator for Galderma, Allergan, Prollenium, and Merz. Vince Bertucci is a paid consultant, speaker, and/or clinical trial investigator for Galderma, Allergan Aesthetics, an AbbVie Company, Clarion, Cutera, Merz, Prollenium, Revance and Teoxane. Shannon Humphrey is a speaker, consultant, and/or investigator for Galderma, Merz, Revance, and Allergan Aesthetics, an AbbVie company. Jason K Rivers is an advisory board member, speakers' bureau member, and investigator for AbbVie/Allergan; advisory board member and paid consultant for Bausch Health; Investigator for Galderma; advisory board member, speakers' bureau member, paid consultant, and investigator for Leo Pharma; investigator for Medytox; consultant for MetaOptima Technology Inc; investigator for Pfizer; investigator for SaNOtize; founder, stockholder of Riversol Skin Care Solutions Inc. Nowell Solish is a clinical trial investigator for Galderma. Andrei Metelitsa is a paid consultant, speaker, and clinical trial investigator for Galderma and Allergan. Nathan Rosen is a clinical trial investigator for Galderma. Kristy Bailey is a clinical trial investigator for Galderma. William McGillivray is a clinical trial investigator for Galderma. Annika Rugheimer, Felipe Weinberg, Torun Bromée, and Inna Prygova are employees of Galderma.

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