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A Randomized Study on PLLA Using Higher Dilution Volume and Immediate Use Following Reconstitution

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ABSTRACT

Background: The reconstitution volume of a PLLA-containing injectable device has gradually increased in clinical practice, often in combination with adding lidocaine to the solution.

Objective: This study, SCRIPT (Sculptra Contemporary Reconstitution & Injection Procedure Trial) evaluated PLLA for correction of nasolabial folds after changes in reconstitution and injection procedures. Primary endpoint for effectiveness was change from baseline of nasolabial folds, assessed by blinded evaluation using a validated wrinkle assessment scale (WAS), at week 48.

Methods: Subjects were treated to optimal correction of nasolabial folds at a single treatment regimen consisting of ≤4 injection sessions, with PLLA reconstituted with 8 mL or 5 mL sterile water for injection (SWFI), randomized 2:1. The 8 mL product included an additional 1 mL 2%-lidocaine and was injected immediately following reconstitution. Assessments included wrinkle severity, aesthetic improvement and safety.

Results: A total of 80 subjects were included in the study. Most subjects were female (95%), mean age was 51.5 years. Primary endpoint was met and subjects from both study groups demonstrated high WAS responder rates (≥1-grade improvement from baseline) at week 24 (≥75%) and week 48 (≥67%). Aesthetic improvement was high (≥86%) throughout the study. Adverse events related to study product or injection procedure were mostly mild and transient.

Conclusion: PLLA reconstituted with 8 mL SWFI demonstrated a comparable treatment effect to that of the reference group in reducing wrinkle severity of nasolabial folds. Safety was not compromised using a higher reconstitution volume including lidocaine, injected immediately after reconstitution.

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INTRODUCTION

Sculptra Aesthetic is a poly-L-lactic acid (PLLA)-containing collagen biostimulator, indicated for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grid pattern (cross-hatch) injection technique is appropriate.[1] The product provides gradual, natural-looking improvement in skin thickness and appearance, as measured by wrinkle assessment score and aesthetic improvement.[2-4] Results are long-lasting with high levels (≥80%) of patient satisfaction[5] and investigator-assessed improvement,[6] reported 25 months post-treatment.

Sculptra Aesthetic is used in the form of a suspension, reconstituted from a dry powder by addition of sterile water for injection (SWFI). The original US approval for Sculptra from 2004, covered a reconstitution volume of 3–4 mL. A following pivotal study presenting a standardized protocol for reconstitution, resulted in approval of the increase in reconstitution volume to 5 mL,[4] which is per current US label. However, in clinical practice, the amount used to reconstitute the product has gradually increased, often in combination with addition of lidocaine,[7] and consensus recommendations for EU[8] and US[9] have been established, promoting final injection volumes of 9 mL including anesthetics for facial injections. In addition, physicochemical analyses of Sculptra Aesthetic have shown that proper shaking of the product after adding SWFI provides well-dispersed PLLA particles in a homogenous suspension, suitable for immediate injection with no standing time required.[10] These methods with a larger reconstitution volume and immediate use following reconstitution have been developed primarily to enhance the safety for patients, but also to provide a more flexible reconstitution protocol for health care practitioners, minimizing unnecessary standing time. This study, SCRIPT (Sculptra Contemporary Reconstitution & Injection Procedure Trial), was conducted to further evaluate alternative reconstitution methods and injection procedures for Sculptra Aesthetic as a single treatment regimen for correction of nasolabial fold contour deficiencies.

MATERIALS AND METHODS

This was a 48-week, randomized, evaluator-blinded, parallel-group, multi-center study (NCT03780244).

Subjects

Subjects were randomized 2:1 to treatment with Sculptra Aesthetic reconstituted with 8 mL (treatment group) or 5 mL (reference group) SWFI. In addition, 8 subjects with Fitzpatrick skin type (FST) IV and 8 subjects with FST V–VI were included in the treatment group but not randomized. Eligible subjects were ≥22 years of age and had nasolabial fold contour deficiencies with a Wrinkle Assessment Scale (WAS)[11] score between 2 (shallow wrinkle) and 4 (deep wrinkle) on left and right nasolabial fold (1-grade difference between sides was allowed). Subjects provided a written informed consent for participation in the study. Main exclusion criteria included contouring or revitalization treatment in or near the treatment area with collagen or hyaluronic acid within the previous 12 months, and calcium hydroxylapatite, poly-L-lactic acid or permanent filler(s) at any time prior to enrollment. Subjects had follow-up visits at weeks 16, 24, 32, 40, and 48.

Treatment

For the treatment group, Sculptra Aesthetic was reconstituted prior to use by addition of 8 mL SWFI and an additional 1 mL of 2%-lidocaine hydrochloride for a total volume of 9 mL. The vial was shaken vigorously for about 1 minute after adding SWFI, and no standing time was required before injection. For the reference group, Sculptra Aesthetic was reconstituted by adding 5 mL of SWFI. No lidocaine was added to the solution, but a local anesthetic could be used topically or injected separately. Two to 72 hours standing time was required. Characteristics for the study groups are presented in Table 1. All randomized subjects received a single treatment regimen consisting of up to 4 injection sessions with 4-week intervals. Subjects were treated on day 1 with up to 1 vial; a maximum of 4.5 mL per nasolabial fold per injection session was used in the treatment group and a maximum of 2.5 mL per side was used in the reference group. Dose amounts allowed were the same for all injection sessions. Subjects were treated to optimal correction, defined as grade 0 (no wrinkles) or grade 1 (just perceptible wrinkles) on the WAS. Injection technique was the same for both groups; Sculptra Aesthetic was injected in the subdermal regions (ie, subcutaneously or supraperiosteally), and injections were made using the bolus, fanning, linear-threading, or other techniques (at the discretion of the treating investigator), using a 25-gauge needle. Aseptic technique and standard practice to prevent cross-infections was to be observed at all times during the procedure.

Assessments

Primary endpoint for effectiveness was change from baseline on both sides of the face as assessed by blinded evaluation using WAS 48 weeks after the first injection. For the primary endpoint to be met, both right and left nasolabial folds had to be statistically significant less than 0 for the treatment group, and the 95% CIs for both groups should overlap to confirm comparable treatment effects. Secondary endpoints for effectiveness included:

- Change from baseline on both sides of the face as assessed by blinded evaluation using WAS. Right and left nasolabial folds were assessed separately and WAS scoring was based on visual live assessment. A responder was defined as having at least 1-grade improvement from baseline on both sides of the face.
- Aesthetic improvement (Improved/Much improved/Very much improved) of right and left nasolabial fold compared to baseline was assessed by subjects and the treating investigator using Global Aesthetic Improvement Scale (GAIS).
- FACE-Q™ appraisal of lines: Nasolabial fold questionnaire was filled out to assess treatment outcome from the subject's perspective. The sum of the scores was converted to a Rasch-transformed total score where a higher total score indicated greater subject satisfaction.
- Subject satisfaction with treatment results was assessed using a 5-point questionnaire.

Endpoints for safety included:

- Pre-defined, expected, post-treatment symptoms, ie, pain, tenderness, redness, bruising, swelling, itching, and lumps/bumps, were collected using subject diaries for 28 days following each injection session.
- Adverse events were collected throughout the study; seriousness and casual relationship with study product and/or injection procedure was assessed. In addition, the investigator was to determine if a suspected lesion

TABLE 1.

Study Groups	
Treatment Group	**Reference Group**
Reconstituted in **8 mL** SWFI	Reconstituted in **5 mL** SWFI
1 mL 2% lidocaine added	No lidocaine added
Maximum volume per treatment session **9 mL** (**4.5 mL** per nasolabial fold)	Maximum volume per treatment session **5 mL** (**2.5 mL** per nasolabial fold)
No standing time; immediate use	Standing time 2–72 hrs prior to injection

was visible, palpable, or inflammatory, and the size of the suspected lesion was measured (papules classified as <5 mm in diameter and nodules ≥5 mm in diameter). Other than that, it was up to the investigator to determine the categories of the lesions.

- An 11-point Numeric Pain Scale was used to assess pain at injection.

Statistical Analysis

All statistical analyses, including summary tables and data listings, were performed using the SAS® system (version 9.4). All effectiveness variables were analyzed based on the Intention-to-Treat (ITT) population (all subjects who were randomized). The Safety population included all subjects who were administered the study product and the Per Protocol (PP) population included all ITT subjects who had no protocol deviations considered to have a substantial impact on the primary effectiveness outcome. Primary endpoint for effectiveness was evaluated using a 1-sided Student's t-test. The null hypothesis of a change from baseline ≥0 was tested against the alternative hypothesis of a change from baseline <0 at the 2.5% significance level. For the treatment group, both the right and left side of the face needed to be statistically significantly <0 for the endpoint to be met. Confidence intervals (CIs) based on the binomial distribution were calculated for the proportion of responders on the WAS and GAIS for both groups. In general, effectiveness, safety, demography, and treatment-related variables were presented using descriptive statistics.

RESULTS

Subject Disposition and Demographics

A total of 80 subjects were enrolled in the study; the 8 mL treatment group included 59 subjects (43 randomized and 16 unrandomized), and the 5 mL reference group consisted of 21 subjects. All subjects completed the study, except one unrandomized subject from the treatment group that was lost to follow-up at week 48. The ITT and Safety populations included all 80 treated subjects and the PP population consisted of 78 subjects. Data from the unrandomized Fitzpatrick skin type IV–VI subjects were pooled with the treatment group in all analyses. Demographic and baseline characteristics were similar between the groups; overall, the majority were female (95%) and the mean age was 51.5 years (range, 23–75). The median nasolabial fold WAS score at baseline was 3.0 for both groups and for both sides of the face.

Treatment

The median number of injection sessions per subject was 4.0 for both groups and the total median injection volume for the whole treatment regimen was 18.9 mL in the treatment group and 10.3 mL in the reference group (Table 2), correlating to 2.10 and 2.06 vials, respectively. Median injection volumes per injection session for the treatment group were 5.50, 5.00, 5.00, and 5.50 mL for session 1, 2, 3, and 4, respectively (mean, 5.25 mL correlating to 87.5 mg PLLA). For the reference group, a decrease in injection volume by session was observed with median volumes of 3.60, 2.90, 2.70, and 2.00 mL for sessions 1, 2, 3 and 4, respectively (mean, 2.8 mL correlating to 84 mg PLLA). Note though that the total amount injected across the entire treatment regimen was similar between the groups.

TABLE 2.

Overall Injection Volume, Safety Population		
	Treatment Group (N=59)	Reference Group (N=21)
Mean number of sessions	3.6 (0.70)	3.7 (0.58)
Median number of sessions	4.0	4.0
Min, max number of sessions	1, 4	2, 4
Total injection volume (mL)*		
Mean (SD)	19.25 (9.32)	10.47 (3.78)
Median	18.90	10.30
Min, max	3.1, 33.6	4.2, 17.0

*Total injection volume for all injection sessions

TABLE 3.

Primary Objective: Week 48 WAS Change from Baseline, ITT Population			
		Treatment Group (N=59)	Reference Group (N=21)
Left nasolabial fold	Mean (SD)	-1.3* (0.97)	-1.3 (1.06)
	95% CI	(-1.6, -1.1)	(-1.8, -0.8)
Right nasolabial fold	Mean (SD)	-1.2* (0.81)	-1.3 (1.02)
	95% CI	(-1.4, -1.0)	(-1.8, -0.9)

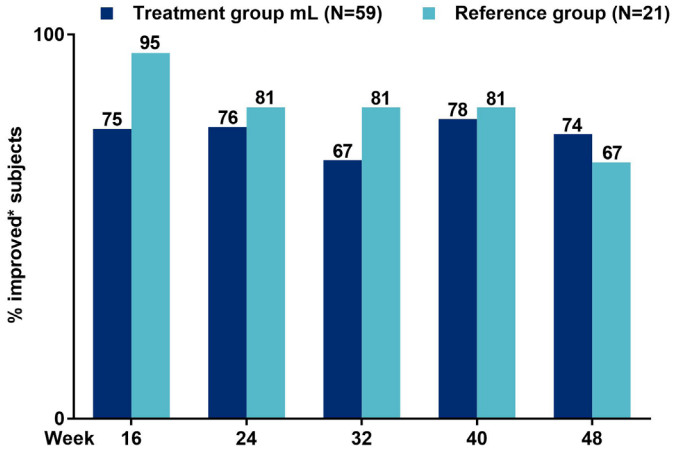
*P-value: <0.001, from 1-sided test of the null hypothesis that the mean change from baseline is ≥0

The most common injection method was linear threading for both groups (treatment group: 83.1%, reference group: 81.0%). Bolus injection was also used in a majority of subjects (treatment group: 59.3%, reference group: 61.9%). Subcutaneous injections were used for all subjects (100%) in both groups. Supraperiosteal injections were used in 59.3% for both nasolabial folds in the treatment group, and in 61.9% and 57.1% for the left and right sides, respectively in the reference group. Subjects may have experienced more than one injection depth and/or method.

Wrinkle Assessment Score

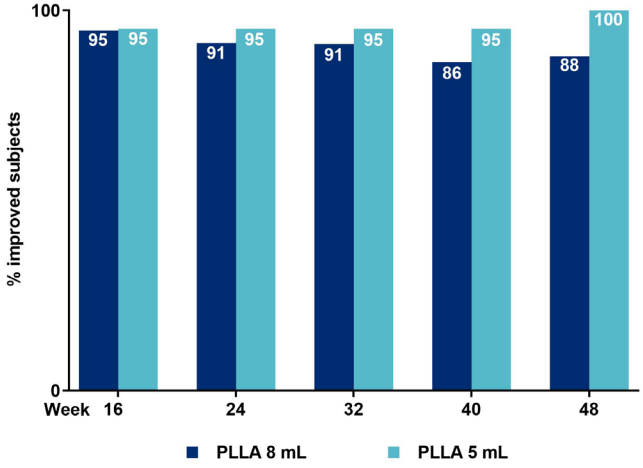
Treatment with Sculptra Aesthetic reconstituted with both 8 mL and 5 mL was effective as a single treatment regimen for correction of nasolabial fold contour deficiencies. The primary effectiveness endpoint was successfully met as mean change from baseline on both sides of the face was statistically significant (P<0.001) in the treatment group, as assessed by blinded evaluation using WAS 48 weeks after first injection (Table 3). The 95% CIs for the mean change from

FIGURE 1. WAS improvement rate, ITT population.



*At least 1-step improvement from baseline on both sides.

FIGURE 4. GAIS improvement (improved/much improved/very much improved) by visit, subject assessment, ITT population.



baseline for both groups overlapped for both sides of the face, confirming a comparable treatment effect. Responder rates based on WAS were slightly higher for the reference group than the treatment group at earlier time points in the study, however this difference decreased over time and values were similar between the groups at week 48 (Figure 1). The mean change from baseline in WAS score at week 48 for FST I–III, FST IV, and FST V–VI subjects within the treatment group was similar for both sides of the face. Representative subject photographs are presented in Figures 2–3.

FIGURE 2. Nasolabial fold appearance of a 41-year-old woman from the treatment group at (A) baseline, (B) week 24, and (C) week 48. Blinded evaluator-assigned WAS scores were 2 at baseline (both sides), 1 at week 24 (both sides), and for week 48: 1 (left side) and 0 (right side).

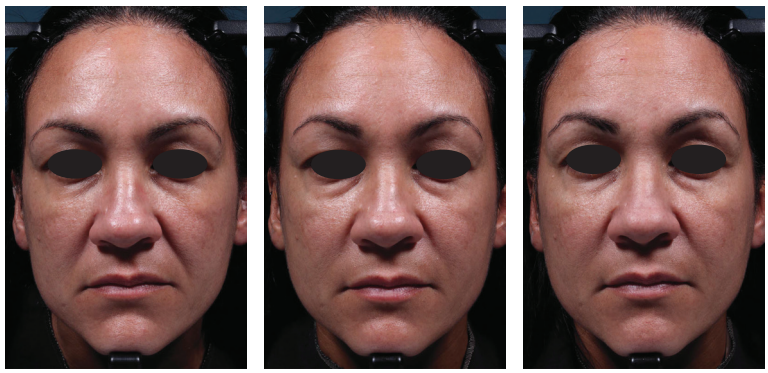


FIGURE 3. Nasolabial fold appearance of a 47-year-old woman from the treatment group at (A) baseline, (B) week 24, and (C) week 48. Blinded evaluator-assigned WAS scores were 3 at baseline (both sides), and 2 at weeks 24 and 48 (both sides).

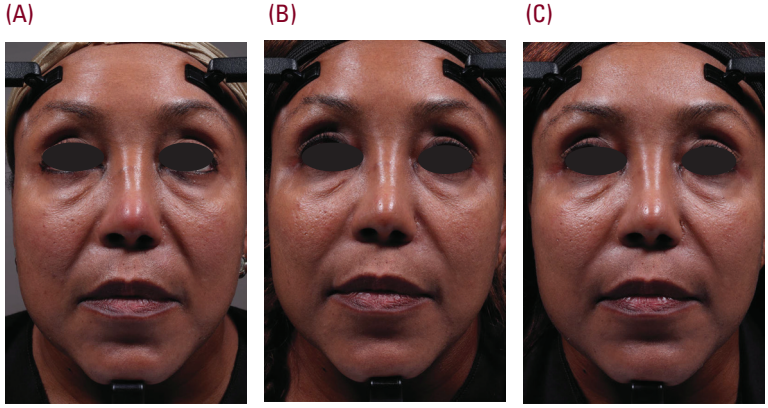
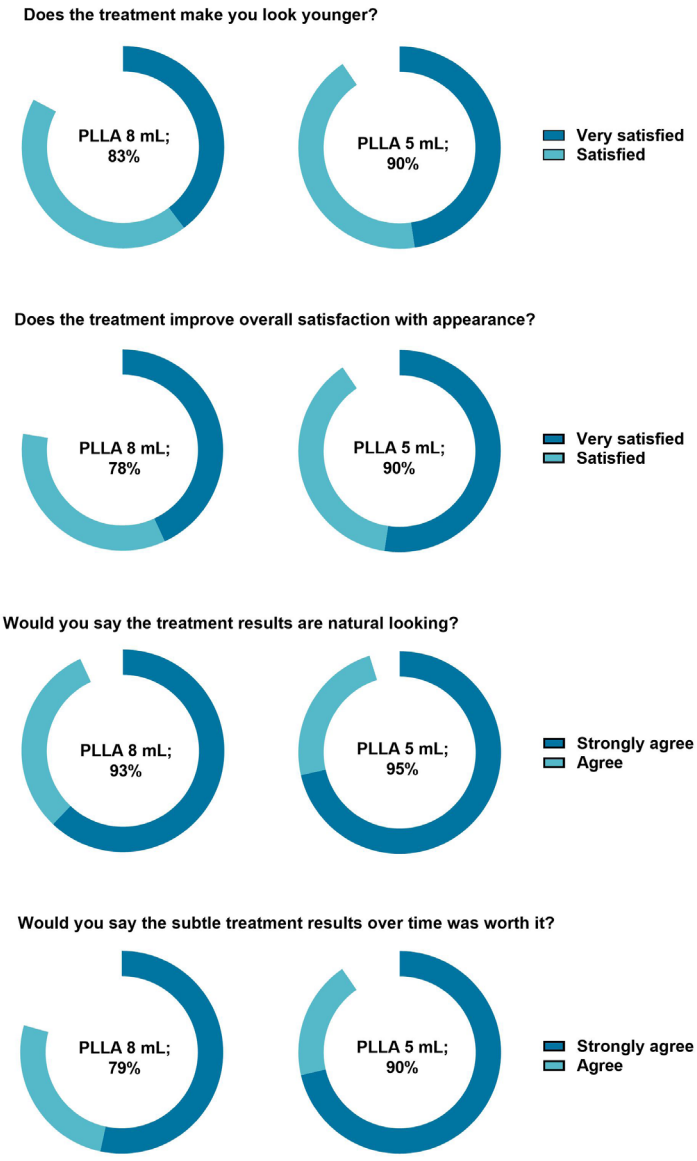


FIGURE 5. Subject satisfaction at week 48, ITT population.



Global Aesthetic Improvement Scale

Aesthetic improvement was high for both groups as assessed both by investigators and subjects. All subjects (100%) were improved at all visits for both sides of the face according to investigators, with ≥61% being very much improved. Also, the majority (≥86.4%) were improved during the study based on subjects' own evaluation (Figure 4).

FACE-Q Appraisal of Nasolabial Folds

Subjects from both groups were satisfied with how their nasolabial folds looked following treatment through week 48; mean total scores at baseline was 39.4 and 37.8 in the reference group and treatment group, respectively, increasing to 79.9 for the reference group and 74.3 for the treatment group at week 48, representing a change from baseline of 40.5 and 36.4, respectively.

Subject Satisfaction

Subject satisfaction was high and lasted across week 48 for both groups (Figure 5). A majority of subjects would recommend both the 5 mL (90.5%) and 8 mL (86.2%) treatment to a friend at week 48. Also, most subjects would choose to receive the treatment again (treatment group: 89.7%; reference group: 81.0%).

Safety

Sculptra Aesthetic, reconstituted with 8 mL SWFI + 1 mL of 2% lidocaine, was generally safe and well tolerated. Adverse events considered related to the study product or injection procedure were reported by 7 subjects (11.9%) in the treatment group and by 7 subjects (33.3%) in the reference group.

The most common related adverse events overall were headache (2 subjects in the reference group and 1 subject in the treatment group), rhinorrhea (2 subjects in the reference group), and perioral hypoaesthesia (1 subject each in the reference and treatment group). All related adverse events reported in the treatment group were mild in intensity. In the reference group, 2 subjects experienced related adverse events of moderate intensity (one event of rhinorrhea and 2 events of headache). No serious related adverse event was reported. The maximum duration for any resolved related adverse event was 166 days (papule) in the reference group and 11 days (herpes simplex) in the treatment group. In the reference group, 1 subject experienced a papule and 1 subject had a nodule. In the treatment group, a nodule (bump) was reported for 1 subject (ongoing at study end) and there was one event of short-lasting induration (hardening) for 1 subject. All these 4 events were palpable but not visible or inflammatory. They were considered mild in severity and no action was required.

As expected, almost all subjects reported symptoms through the subject diaries for either side of the face. The addition of 1 mL of 2% lidocaine in the treatment group was effective for reducing pain at injection; mean pain score difference (after treatment score minus before treatment score) was lower after all injections in the treatment group (range, 0.4 to 1.3) compared with the reference group (range, 2.1 to 3.0) based on the 11-point numeric pain scale.

DISCUSSION

This study evaluated alternative reconstitution and injection procedures for Sculptra Aesthetic, ie, 8 mL SWFI + 1 mL 2%-lidocaine injected subdermally immediately after reconstitution. The primary objective for effectiveness was to confirm comparable treatment results in reducing wrinkle severity of nasolabial folds in both study groups at week 48. The

analysis showed that nasolabial fold improvement from baseline by WAS score was statistically significant in the treatment group and with the CIs between the groups overlapping, resulting in the primary objective being successfully met.

Additional measurements of effectiveness further confirmed a comparable treatment effect between the groups; aesthetic improvement was high during the whole study for both groups from GAIS assessments by subjects and investigators. FACE-Q appraisal of nasolabial folds showed that subjects in both groups were more satisfied with how their nasolabial folds looked following treatment through week 48. Subject satisfaction with treatment was also high and lasted across week 48 for both groups. The decrease by session in median injection volume that was observed for the reference group did not affect the total amount injected across the entire treatment regimen, which was similar between the groups. However, the larger amount of PLLA that was injected for the reference group at the first and second session could explain the slightly higher WAS responder rates observed for the reference group early in the study.

Overall, both treatments were well tolerated; all related adverse events reported in the treatment group and most in the reference group were mild in intensity, and the majority resolved within 1 week after treatment for both groups. As expected, Sculptra Aesthetic reconstituted with the addition of 1 mL lidocaine was associated with less pain on injection, and safety was not complicated with the addition of lidocaine.

Nodules, papules, and induration are known non-immediate side effects of PLLA injections. Possible causes include using a too concentrated product (<5 mL dilution); injecting too much product in the same area; interval between sessions being too short; and injecting in hyperkinetic regions and/or too superficial.[9] The safety profile of Sculptra Aesthetic has improved over the years, resulting from increased knowledge in selection of treatment areas, and injection technique. Also, a decreased risk of adverse events and nodules in particular, has been noted with a larger reconstitution volume.[12,13] In the current study, two events of injection site nodule/papule that was experienced in the reference group, as well as the nodule and induration from the treatment group, were mild in severity and no intervention was required. In order to allow a sufficient depth of injection, both groups received subdermal (subcutaneous and supraperiosteal) injections, which is different from the current US label, where deep dermal injections are stated.

In a retrospective chart review,[7] information about the safety associated with reconstitution volumes of 7–10 mL including anesthetics was collected. Data from more than 4000 facial treatments performed in 1000 subjects was analyzed, and the results showed very few adverse events related to study product or injection procedure being reported (3.6% of subjects; nodules 0.4% of subjects). This could be reflective of well-functioning patient education of expected events by health care professionals, potentially leading to under-reporting in a retrospective chart review compared to a clinical trial. Still these results suggest that the rate of adverse events may be lower using a higher reconstitution volume than 5 mL.

Hydration of the product has historically been considered important with standing times of 2 to 168 hours implemented,[13] also in consensus manuscripts hydration with long reconstitution times has been recommended.[8,9] It is now known that the suspending agents included in the formulation will instantly start to swell (hydrate) when dispersed in water and shaken vigorously. PLLA particles themselves are insoluble in water but are uniformly distributed in the suspension from the viscosity achieved by the suspending agents. Indeed, physicochemical properties and PLLA particle shape and size distribution of Sculptra product suspension have been similar when comparing different standing times, including vigorous shaking after adding SWFI.[10] This unique immediate use protocol can be considered a paradigm shift in how injectors have been taught to reconstitute the product during a long period of time.

This study has shown that both procedures for reconstitution of Sculptra Aesthetic are effective and safe as a single treatment regimen for correction of nasolabial fold contour deficiencies. Evaluations were performed by blinded evaluators, as well as by treating investigators and subjects themselves, all assessments showing similar high effectiveness.

The effectiveness was not impacted when used in nasolabial folds of an ethnically diverse population. The results from this study support a change to the current US Sculptra Aesthetic label, which hopefully will benefit both patients and injectors.

CONCLUSION

Sculptra Aesthetic reconstituted with 8 mL SWFI + 1 mL 2% lidocaine injected in subdermal regions immediately after reconstitution, demonstrated a comparable treatment effect, high satisfaction and aesthetic improvement to that of the reference group in reducing nasolabial fold wrinkle severity at week 48. The new reconstitution and injection procedures were associated with a satisfactory safety profile.

DISCLOSURES

Dr Palm is an investigator, speaker, paid advisory board member, and consultant for Galderma. Dr Weinkle is an investigator for Galderma, Allergan, Revance, Teoxane, and Merz; a consultant for Galderma, Allergan, Merz, Teoxane, and Revance; a speaker for Galderma, Allergan, and Merz; and an advisory board member for Allergan and Merz. Dr Cho is an investigator for Galderma and FirstString Research; a consultant for Galderma, Allergan, and Merz; and a

speaker for Galderma and Allergan. Dr LaTowsky is an investigator for Galderma, AbbVie, Arcutis Biotherapeutics, Arena Pharmaceuticals, Brickell Biotech, ChemoCentryx, Eli Lilly, Pulse Biosciences, Soliton, Allergan, TARGET PharmaSolutions, Kiniksa Pharmaceuticals, Corrona, Teres Bio, Endo; a consultant for Pulse Biosciences and Soliton; and an advisory board member for Galderma, Endo, Allergan, the AAD, and Castle Biosciences. Dr Prather is an investigator for Galderma; and a trainer for Galderma, Allergan, and Merz.

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