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Effectiveness and Safety of Sculptra Poly-L-Lactic Acid Injectable Implant in the Correction of Cheek Wrinkles

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ABSTRACT

Background: The current study evaluated the effectiveness and safety of Sculptra® injectable poly-L-lactic acid (PLLA-SCA) treatment in correcting cheek wrinkles compared with a no-treatment control.

Methods: Male/female immune-competent adults (aged >21 years) with moderate/severe cheek wrinkles, graded using the Galderma Cheek Wrinkle Scale (GCWS) at rest, were randomized 2:1 to receive PLLA-SCA injections (150 mg; 8 mL reconstitution in sterile water for injection) + 1 mL lidocaine hydrochloride (2%), administered immediately after reconstitution, or no treatment (control). Up to 3 additional treatments were allowed at monthly intervals and follow up was at months 7, 9, and 12. The primary endpoint was ≥1-grade improvement in GCWS at rest for both cheeks at month 12.

Results: GCWS at rest responder rate was significantly higher with PLLA-SCA treatment versus the no-treatment control at months 7 (66.2% versus 38.6%; P=0.0043), 9 (70.6% versus 31.1%; P<0.0001), and 12 (71.6% versus 26.1%; P<0.0001). Treating investigators reported improvements in skin radiance (>95%), tighter appearance (>88%), and jawline contour (>85%). PLLA-SCA recipients reported high satisfaction levels regarding improvements in skin radiance (≥90%), sagging (≥84%), and firmness (≥91%) as well as natural looking results (≥85%) and a desire for repeat treatment (≥84%). Treatment-related adverse events were mostly mild in severity with no serious events related to PLLA-SCA injections.

Conclusion: Injectable PLLA-SCA treatments were well tolerated and significantly reduced the severity of moderate/severe cheek lines and wrinkles, while improving skin quality. Effectiveness was durable over the 12-month study period with high subject-reported satisfaction, natural looking appearance, and enthusiasm for repeat treatments.

Clinical trial registry number: NCT04124692

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INTRODUCTION

Sculptra® poly-L-lactic acid injectable implant (PLLA-SCA; Galderma, Sweden) is a plant-derived alpha-hydroxy-acid polymer.[1–4] When used for soft tissue augmentation, PLLA-SCA gradually stimulates collagen formation, over the course of several treatments, to provide semi-permanent correction of facial volume loss associated with aging.[1–4]

Injectable PLLA-SCA has demonstrated durable and natural looking results in randomized studies, with most recipients (80%) maintaining aesthetic correction of contour deficiencies until the 25-month data cut-off.[5,6] Growing experience has driven an improved understanding of optimal PLLA-SCA injection techniques to achieve high levels of treatment satisfaction and good safety outcomes.[2,7–9] PLLA-SCA studies

have demonstrated skin quality improvements and recipient-reported emotional and functional benefits, including elevated self-esteem and confidence.[10–12] Based upon current evidence, expert recommendations support the use of PLLA-SCA for facial rejuvenation, according to the approved indication.[13–15]

Since 2004, this product has been approved in the US for restoration and/or correction of signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus, and since 2009 also for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in immune-competent individuals.[5] Recently (2023), the US FDA approved an extension of the indication to include the correction of fine lines and wrinkles in the cheek region for use in immune-competent subjects, based on the study results presented here.

This study evaluated the effectiveness and safety of the PLLA-SCA injectable implant in the correction of cheek wrinkles compared with a no-treatment control, using the preparation and administration protocol published by Palm et al (2021), in which treatment was administered immediately after PLLA-SCA reconstitution in sterile water for injection (SWFI; 8 mL) + 1 mL lidocaine solution (2%), rather than waiting the standard 2 hours before injection.[5,16–18] The adapted protocol was intended to support safety and tolerability outcomes with PLLA-SCA, and to aid convenience for physicians.

MATERIALS AND METHODS

Study Design

A randomized, evaluator-blinded, no-treatment controlled study was conducted between November 2019 and August 2021 at 13 sites in the US to assess the effectiveness and safety of PLLA-SCA injections for the correction of cheek wrinkles (NCT04124692). The study was conducted in accordance with the Declaration of Helsinki and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice as applicable for medical devices. Subjects gave written informed consent and ethical approval was obtained from each relevant institutional review board.

Live study assessments were conducted by blinded evaluators and treating investigators, and subject self-assessment data were reported via questionnaires and subject diaries. During screening and throughout the study, the validated 5-point Galderma Cheek Wrinkles Scale (GCWS; none, mild, moderate, severe, or very severe) was used to grade the severity of wrinkles in repose (GCWS at rest) and when adopting a closed maximum smile (GCWS dynamic).

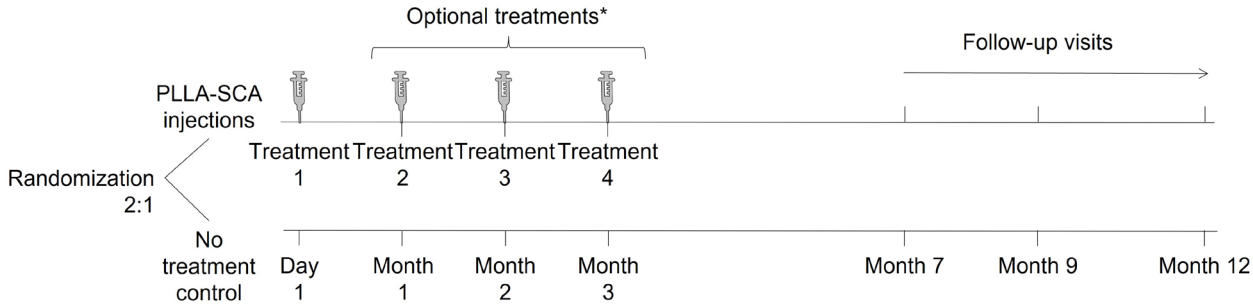
Study Population

The study included male/female immune-competent adults (aged >21 years) with cheek wrinkles graded as moderate or severe on each side of the face according to GCWS at rest assessments (blinded evaluator and treating investigator). The difference in wrinkle severity was no more than 1-grade between sides. Individuals who had known allergy to injectable PLLA-SCA or lidocaine had undergone previous tissue augmentation, contouring, resurfacing, or similar therapies, or had facial lesions in the treatment area were excluded. Subjects who were pregnant, planning a pregnancy, or breastfeeding were not allowed to enter the study.

Study Treatment

Figure 1 shows the study schedule. Eligible subjects were randomized 2:1 to receive either PLLA-SCA injections (PLLA-SCA group) or no treatment (control group). PLLA-SCA injections were administered on day 1/baseline (Treatment 1). Up to 3 additional treatments were allowed at monthly intervals (Treatments 2, 3, and 4). Follow up visits were conducted at months 7, 9, and 12 (taking place 3, 5, and 8 months after the fourth treatment session, respectively). Each vial containing sterile, freeze-dried,

FIGURE 1. Study schedule.



*Treatment in both cheeks until optimal results were achieved.

Subjects were randomized 2:1 to receive PLLA-SCA or no treatment (control). A maximum of 9 mL PLLA-SCA was administered by subdermal injection in each cheek on Day 1. Up to 3 additional treatments were allowed at monthly intervals until Month 3. Follow up visits were conducted at Months 7, 9 and 12.

injectable PLLA-SCA (150 mg) was reconstituted in SWFI (8 mL) and 1 mL lidocaine hydrochloride (2%) was added immediately prior to injection. PLLA-SCA solution (9 mL maximum) was administered sub-dermally into each cheek using a 25 G needle. The treated area was defined according to the superior, medial, inferior, and lateral anatomical cheek borders. The superior border comprised the area from the topmost part of the tragus to top of alar crease. The medial border encompassed the top of the alar crease, along the nasolabial fold to the inferior border of the mandibular ramus. The inferior border ran from the medial border at the mandibular ramus to the angle of mandibular ramus and the lateral border comprised the area from the angle of the mandibular ramus to the top of the tragus.

Effectiveness Endpoints

The primary effectiveness endpoint was the responder rate based on a blinded evaluator assessment of GCWS at rest at month 12 after baseline. A responder was defined as a subject with ≥1-grade GCWS improvement from baseline in both cheeks concurrently.

Secondary and exploratory endpoints included responder rate for GCWS at rest at months 7 and 9, and responder rate for GCWS dynamic at months 7, 9, and 12 (blinded evaluator assessments). Treating investigators assessed the combined improvement on both sides of the face using the 7-point Global Aesthetic Improvement Scale (GAIS: very much improved, much improved, improved, no change, worse, much worse, very much worse) at all visits for the PLLA-SCA group and at months 7, 9, and 12 for the control group. GAIS responders scored very much improved, much improved, or improved from baseline. Treating investigators also assessed the change from baseline regarding skin radiance, tightness, and jawline contour at months 7, 9, and 12.

PLLA-SCA recipients completed the subject satisfaction questionnaire at all visits, following treatment. Participants rated overall treatment results using a 5-grade scale: excellent, very good, good, satisfactory, or not satisfied. Subjects also indicated the extent to which they agreed with statements relating to the effectiveness of treatment using a 5-grade scale: strongly agree, agree, neither agree nor disagree, disagree, strongly disagree. The satisfaction with cheeks FACE-Q™ questionnaire examined subject-assessed outcomes regarding the change in symmetry, smoothness, attractiveness, contour, and youthful fullness. Subjects indicated their level of satisfaction with treatment outcomes using a 4-grade scale: very satisfied, somewhat satisfied, somewhat dissatisfied, very dissatisfied. The control group completed the satisfaction with cheeks FACE-Q questionnaire at months 7, 9, and 12. FACE-Q responses were converted to Rasch-transformed total scores. Subject diaries recorded the time to return to social engagement for 28 days after each treatment.

Safety Endpoints

Adverse events (AEs) were reported by the treating investigator throughout the study and included any abnormal findings from an evaluation of cheek firmness, symmetry, function, mass formation and palpability, cheek sensation, and visual function performed at all study visits. Subject diary cards were used to collect expected post-treatment symptoms (for 28 days after each treatment).

Statistical Analysis

All statistical analyses used the SAS® software. Confidence intervals (CIs) were 2-tailed and at a level of 95%. The intention-to-treat (ITT) and safety populations comprised all randomized subjects. Effectiveness analyses examined the ITT population. The per-protocol (PP) population comprised all ITT subjects completing baseline and month 12 visits without deviations considered likely to impact the primary effectiveness outcome. The primary endpoint analysis used Fisher's exact test with multiple imputations of missing data instead of baseline observation carried forward (defined in the study protocol) to manage the increased risk of premature study discontinuation or missed month 12 visits during the COVID-19 pandemic. Month 12 responder rate CIs used multiple imputations, but sensitivity analysis of the primary and secondary endpoints used the planned Clopper-Pearson intervals.

RESULTS

Study Population

Baseline demographics and characteristics are presented in Table 1. Overall, 149 subjects were included in the study, with 97 randomized to the PLLA-SCA group and 52 to the control group. Most subjects were female (96.6%), White (90.6%), and not of Hispanic/Latino origin (91.9%). Mean age was 60.7 (range: 41–89) years and subjects were typically aged ≥55 years (77.9%). All subjects had moderate or severe cheek wrinkles at baseline (blinded evaluator GCWS at rest assessments). Additional PLLA-SCA treatments were required at months 1, 2, and 3 for 95 (97.9%), 86 (88.7%), and 67 (69.1%) subjects, respectively. Injection volumes for each treatment are shown in Table 2.

Effectiveness Outcomes

Figure 2 shows the GCWS at rest responder rate at months 7, 9, and 12 (live blinded evaluator assessment). Concerning the primary endpoint, the GCWS at rest responder rate was significantly higher in the PLLA-SCA group (70.7% estimated; 71.6% observed cases), compared with the control group (25.9% estimated; 26.1% observed cases) at month 12 (P<0.0001 for both comparisons). GCWS responder rate was also significantly greater in the PLLA-SCA group, versus the control, at month 7 (66.2% versus 38.6%; P=0.0043) and at month 9 (70.6% versus 31.1%; P<0.0001).

TABLE 1.

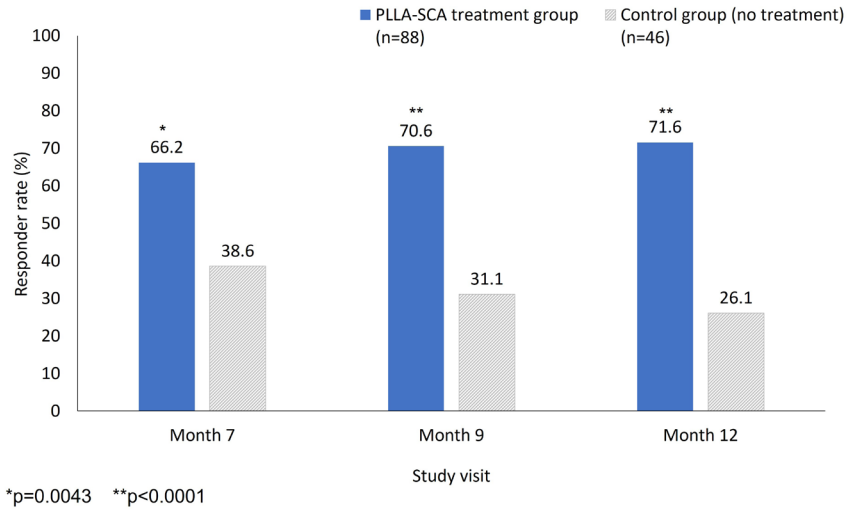
Baseline Demographics and Characteristics (ITT Population)					
	Control group (N=52)		PLLA-SCA group (N=97)		Total (N=149)
Age (years)					
Mean (range)	60.4 (45–88)		60.9 (41–89)		60.7 (41–89)
≥55 years	39 (75.0)		77 (79.4)		116 (77.9)
Gender, n (%)					
Female	50 (96.2)		94 (96.9)		144 (96.6)
Male	2 (3.8)		3 (3.1)		5 (3.4)
Race, n (%)					
American Indian/Alaska Native	0		1 (1.0)		1 (0.7)
Asian	1 (1.9)		1 (1.0)		2 (1.3)
Black/African American	4 (7.7)		7 (7.2)		11 (7.4)
White	47 (90.4)		88 (90.7)		135 (90.6)
Ethnicity, n (%)					
Not Hispanic or Latino	47 (90.4)		90 (92.8)		137 (91.9)
Hispanic or Latino	5 (9.6)		7 (7.2)		12 (8.1)
Fitzpatrick Skin Type, n (%)					
I	2 (3.8)		4 (4.1)		6 (4.0)
II	18 (34.6)		25 (25.8)		43 (28.9)
III	21 (40.4)		47 (48.5)		68 (45.6)
IV	6 (11.5)		12 (12.4)		18 (12.1)
V	4 (7.7)		5 (5.2)		9 (6.0)
VI	1 (1.9)		4 (4.1)		5 (3.4)
Baseline body mass index (kg/m2)					
Mean (SD)	23.93 (4.0)		24.74 (4.9)		24.46 (4.6)
GCWS – At Rest, Blinded Evaluator, n (%)	Left	Right	Left	Right	
None	0	0	0	0	
Mild	0	0	0	0	
Moderate	28 (53.8)	37 (71.2)	50 (51.5)	60 (61.9)	
Severe	24 (46.2)	15 (28.8)	47 (48.5)	37 (38.1)	
Very severe	0	0	0	0	
GCWS – At Rest, Treating Investigator, n (%)					
None	0	0	0	0	
Mild	0	0	0	0	
Moderate	28 (53.8)	33 (63.5)	49 (50.5)	62 (63.9)	
Severe	24 (46.2)	19 (36.5)	48 (49.5)	35 (36.1)	
Very severe	0	0	0	0	
GCWS – Dynamic, Blinded Evaluator, n (%)					
None	0	0	0	0	
Mild	0	0	1 (1.0)	0	
Moderate	18 (34.6)	23 (44.2)	24 (24.7)	39 (40.2)	
Severe	30 (57.7)	24 (46.2)	57 (58.8)	45 (46.4)	
Very severe	4 (7.7)	5 (9.6)	15 (15.5)	13 (13.4)	
GCWS – Dynamic, Treating Investigator, n (%)					
None	0	0	0	0	
Mild	1 (1.9)	0	0	0	
Moderate	15 (28.8)	17 (32.7)	21 (21.6)	30 (30.9)	
Severe	25 (48.1)	25 (48.1)	56 (57.7)	48 (49.5)	
Very severe	11 (21.2)	10 (19.2)	20 (20.6)	19 (19.6)	

Abbreviations: GCWS, Galderma Cheek Wrinkles Scale; ITT, intention-to-treat; N, number of subjects in ITT population; n, number of subjects in specific category; SD, standard deviation.

TABLE 2.

Injection Volume Administered Per Subject (Safety Population)					
	Injection volume per subject by treatment (left + right sides of the face)				Total injection volume (All treatments) (n=97)
	Treatment 1 (Day 1) (n=97)	Treatment 2 (Month 1) (n=95)	Treatment 3 (Month 2) (n=86)	Treatment 4 (Month 3) (n=67)	
Injection volume (mL)					
Mean (SD)	15.29 (3.04)	15.26 (3.03)	15.10 (3.57)	15.17 (3.34)	54.11 (15.30)
Median	16.00	16.00	16.00	16.00	58.50
Minimum, maximum	7.5, 18.0	8.0, 18.0	3.0, 18.0	6.1, 18.0	18.0, 72.0

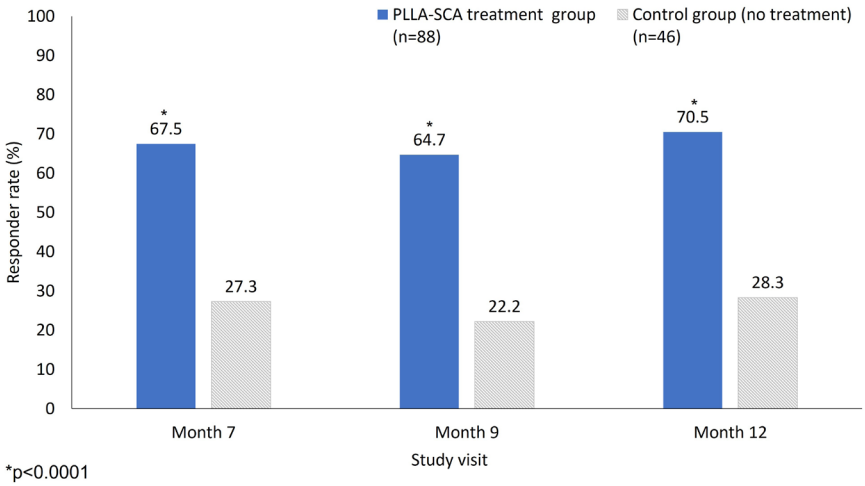
FIGURE 2. GCWS at rest responder rate, based on blinded evaluator assessment, by study visit (observed cases, ITT population).



*p=0.0043 **p<0.0001

Responders demonstrated ≥1-grade improvement from baseline on both sides of the face concurrently using the GCWS at rest. The difference in responder rate was statistically significant when comparing the PLLA-SCA and control groups at Month 7 (p=0.0043) and at Months 9 and 12 (p<0.0001). Two-sided p-value as calculated via Fisher's exact test. A p-value <0.05 was considered statistically significant

FIGURE 3. GCWS dynamic responder rate, based on blinded evaluator assessment, by study visit (observed cases, ITT population).



*p<0.0001

Responders demonstrated ≥1-grade improvement from baseline on both sides of the face concurrently using the GCWS dynamic. The difference in responder rate was statistically significant when comparing the PLLA-SCA and control groups at Months 7, 9 and 12 (p<0.0001). Two-sided p-value as calculated via Fisher's exact test. A p-value <0.05 was considered statistically significant.

TABLE 3.

Treating Investigator Assessment of Change From Baseline Concerning Skin Radiance, Tightness, Jawline Contour, and Dermal Thickness By Study Visit (ITT population)

	Control group		PLLA-SCA group	
	N	n (%)	N	n (%)
Improved skin radiance				
Month 7	44	2 (4.5)	77	75 (97.4)
Month 9	45	0	85	81 (95.3)
Month 12	46	0	88	85 (96.6)
Tighter skin appearance				
Month 7	44	2 (4.5)	77	73 (94.8)
Month 9	45	0	85	75 (88.2)
Month 12	46	0	88	84 (95.5)
Improved jawline contour				
Month 7	44	2 (4.5)	77	66 (85.7)
Month 9	45	1 (2.2)	85	73 (85.9)
Month 12	46	0	88	79 (89.9)

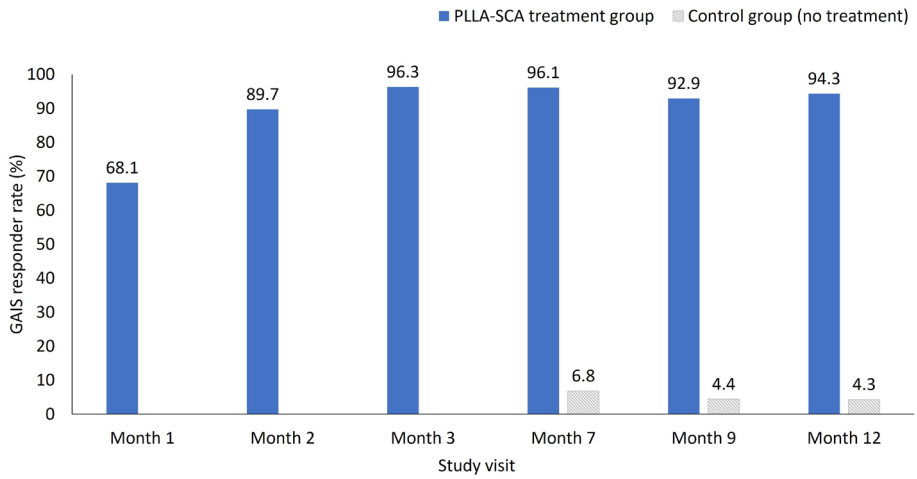
Abbreviations: ITT, intention-to-treat; N, number of subjects in ITT population; n, number of subjects in category

GCWS dynamic responder rate (live blinded evaluator assessment) was significantly higher in the PLLA-SCA group versus the control at months 7 (67.5% versus 27.3%; *P*<0.0001), 9 (64.7% versus 22.2%; *P*<0.0001), and 12 (70.5% versus 28.3%; *P*<0.0001; Figure 3).

Treating investigator-reported GAIS responder rate was 68.1% at month 1 and >92% from month 7 onwards in the PLLA-SCA group and <7% throughout the study period in the control group (Figure 4). After the PLLA-SCA injection, treating investigators agreed/strongly agreed that skin radiance was improved (>95%), skin appeared tighter (>88%) and the jawline contour was improved (>85%; Table 3).

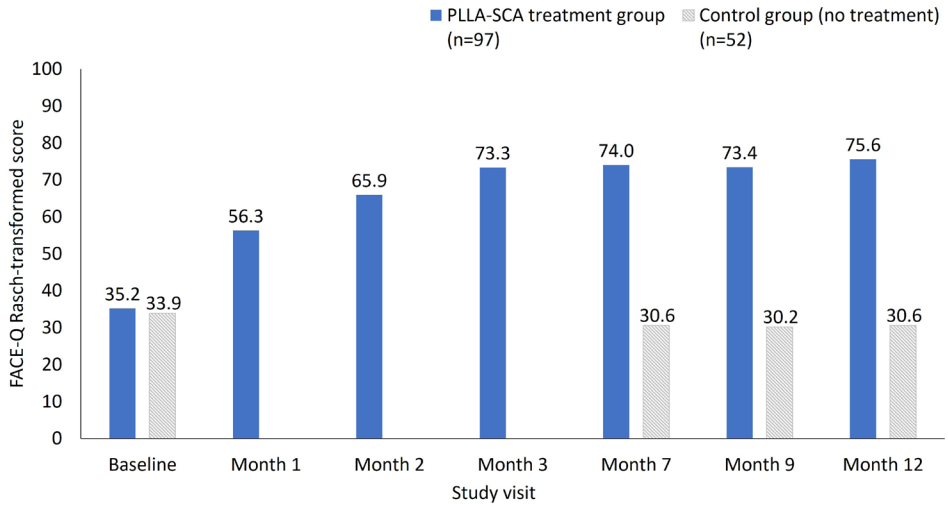
From month 7 through month 12, subject satisfaction questionnaires revealed that most PLLA-SCA recipients reported treatment results to be excellent, very good, good, or satisfactory regarding improvement in skin radiance (≥90%), sagging (≥84%) and firmness (≥91%). Most PLLA-SCA subjects saw improvements regarding looking younger (≥90%) and skin appearing more refreshed (≥91%). The majority reported improved overall satisfaction with their appearance (≥92%), natural looking results (≥86%), and a desire to have the same PLLA-SCA treatment again (≥84%). PLLA-SCA recipients indicated that they would recommend the treatment to a friend (≥88%). Other key satisfaction outcomes included feeling better about yourself (≥92%) and improved self-confidence (≥90%).

FIGURE 4. GAIS responder rate, based on treating investigator assessment, by study visit (ITT population).



GAIS responders were defined as subjects with cheek wrinkles that were very much improved, much improved or improved on both sides of the face (treating investigator assessment).
PLLA-SCA recipients were assessed at all study visits and control groups assessments were at Months 7, 9 and 12.

FIGURE 5. FACE-Q questionnaire Rasch-transformed scores regarding subject satisfaction, by study visit (ITT Population).



Rasch-transformed total scores were based on 5 FACE-Q questionnaire items assessing cheek symmetry, smoothness, attractiveness, contour and youthful fullness.

Speed of recovery, denoted by the median time to return to social engagement after PLLA-SCA treatment, ranged between 3.9 hours (after treatment 1) and 7.1 hours (after treatment 4).

Mean FACE-Q Rasch-transformed score was increased in the PLLA-SCA group from 35.2 at baseline to >73 (mean increase: 37.9–40.0) at months 7 through 12, indicating increased satisfaction, whereas mean scores decreased by 3.6–4.1 during the study period in the control group, indicating that satisfaction was not increased (Figure 5).

Subject photographs illustrating the improvements from baseline to month 12 are shown in Figure 6.

TABLE 4.

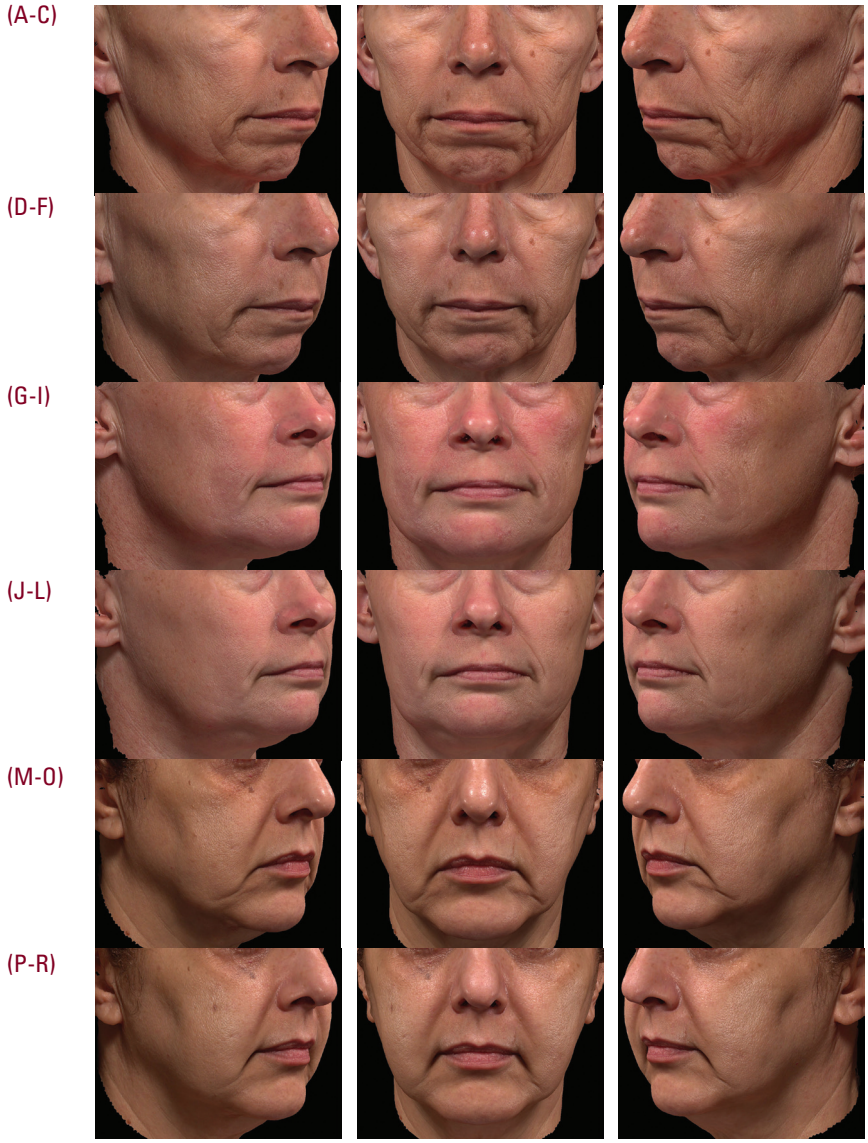
Treatment-Related Adverse Events (Safety Population)	
Preferred Term	**PLLA-SCA Group (N=97) n (%)**
Subjects with ≥1 related adverse event	20 (20.6)
Injection site bruising	11 (11.3)
Dizziness	2 (2.1)
Headache	2 (2.1)
Abnormal sensation in eye	1 (1.0)
Injection site erythema	1 (1.0)
Injection site irritation	1 (1.0)
Injection site nodule	1 (1.0)
Injection site pain	1 (1.0)
Injection site discolouration	1 (1.0)
Injection site swelling	1 (1.0)
Skin mass (small lump)[a]	1 (1.0)

[a]One subject experienced 2 events: small lump on lower left cheek, near corner of mouth; small lump below left corner of mouth. Subjects reporting more than 1 event in a category were counted only once in that category.
Abbreviations: N, number of subjects in safety population; n, number of subjects in specific category

Safety Endpoints

The most common self-reported (diary card) post-treatment symptoms were tenderness (93.5%), bruising (93.5%), swelling (87.1%), and pain (83.9%), most of which were mild/moderate in intensity (97.8%). Among the 97 subjects randomized to receive PLLA-SCA, 20 (20.6%) experienced treatment-related/injection procedure-related AEs (Table 4). Seventeen subjects (17.5%) in the PLLA-SCA group experienced mild treatment-related AEs and 3 (3.1%) had events that were moderate in severity. No serious treatment-related AEs were reported. The most common treatment-related AEs in the PLLA-SCA group were injection site bruising (11.3%), dizziness (2.1%), and headache (2.1%), all of which resolved within 1–13 days.

FIGURE 6. Subject photographs at baseline and month 12. All subjects were administered PLLA-SCA at 4 treatment sessions. The GCWS scores were assessed at rest by blinded evaluators. Subject 1) 54-year-old female with moderate (right)/severe (left) GCWS at baseline (A-C) had a 2-grade GCWS improvement to month 12 (D-F). Subject 2): 46-year-old female, with moderate (right)/severe (left) GCWS at baseline (G-I), had a 1-grade (right)/2-grade (left) GCWS improvement to month 12 (J-L). Subject 3): 59-year-old female, with moderate GCWS at baseline (M-O) had a 1-grade GCWS improvement to month 12 (P-R).



DISCUSSION

This study demonstrated that PLLA-SCA injections, given as up to 4 individual treatments (approximately 1 month apart), are effective and well tolerated in correcting the appearance of moderate and severe cheek wrinkles. Improvements in wrinkle severity were durable, with significant reductions in severity observed from month 7 (P=0.0043) that were sustained over the 12-month study period (P<0.0001) alongside enhancements in key indicators of skin quality. These outcomes are aligned with previous studies examining wrinkle correction with PLLA-SCA injections and reflect published data regarding the safety and effectiveness of the adapted protocol for immediate administration of reconstituted PLLA-SCA (approved by the US FDA) and support its use moving forward.[6,16,17]

Blinded evaluator-assessed GCWS responder rates (at rest and dynamic) were significantly greater in the PLLA-SCA group compared with controls throughout the study period. These data build upon the effectiveness outcomes previously reported concerning PLLA-SCA injections and provide an indication of the treatment outcomes that clinicians may expect to see in their clinics.[16,17] GAIS scores were high from month 1 (4 weeks after treatment 1) and endured for most PLLA-SCA recipients (>96%) through month 12. Again, this magnitude of treatment effectiveness as well as durability of treatment outcomes corresponds with the data reported for the adapted PLLA-SCA reconstitution protocol in nasolabial fold studies.[16,17] Treating investigators considered skin quality parameters, skin radiance, and firmness (tightness), to be increased following

PLLA-SCA treatment with improved jawline contour. These outcomes were corroborated by subject self-assessment data reporting improvements in skin quality (skin radiance, sagging, and firmness) following PLLA-SCA treatment (≥84%) and also mirrored published data demonstrating statistically significant increases in skin elasticity, radiance, and smoothness among individuals receiving repeated PLLA-SCA injections, compared with saline injections.[11]

Subjects recovered rapidly after each treatment, feeling confident enough to return to social engagement after approximately 4–7 hours. Treatment satisfaction was high throughout the study with PLLA-SCA recipients self-reporting natural looking results, younger looking and refreshed appearance, and improved self-confidence. Most (≥84%) said that they would choose to receive PLLA-SCA treatment again and would recommend it to others. Longer study periods may be of benefit for future investigations exploring cheek wrinkle improvement with PLLA-SCA treatments as nasolabial fold studies have demonstrated effectiveness, safety, and treatment satisfaction at 25 months, following the last treatment.[6]

PLLA-SCA injections were generally well tolerated with mainly mild treatment-related AEs, typically occurring at the injection site. The incidence of injection site nodule and papule formation was lower compared with previous trials examining PLLA-SCA and other dermatological fillers, potentially due to the increased reconstitution volume used in the current study.[6,16,17] Other investigations examining higher administration volumes showed comparable incidences of treatment-related AEs.[6,16,17] Improved safety outcomes may also be associated with enhanced administration techniques, informed by advances in the understanding of the anatomy of aging and the availability of expert recommendations and consensus.[3,8,13–15]

CONCLUSION

Injectable PLLA-SCA treatments, administered using an immediate injection protocol, were well tolerated and provided significant reductions in the severity of moderate or severe cheek wrinkles. Durable effectiveness and improvements in skin radiance, firmness (tightness), and jawline contouring were observed over the 12-month study period. PLLA-SCA recipients reported high satisfaction and natural looking appearance and most expressed a desire to have repeat PLLA-SCA treatments.

DISCLOSURES

Sabrina Fabi is an investigator and consultant for Galderma, Merz, Revance and Allergan. Tiffani Hamilton is an investigator for Galderma. Brenda LaTowsky is an investigator for Galderma. Rebecca Kazin is an investigator and trainer for Galderma. Keith Marcus is an investigator for Galderma, a speaker for Galderma, Allergan, and Evolus, a trainer for Galderma, and Merz, and an advisory board member for Galderma, Allergan, Merz, and Evolus. Flor Mayoral is an investigator for Galderma. John Joseph is an investigator and paid speaker for Galderma. Deirdre Hooper is an investigator, speaker, and trainer for Galderma, investigator consultant and trainer for Allergan, an advisory board member for Evolus, and a consultant for Revance. Sachin Shridharani is an investigator for Galderma, Merz, Revance, and Allergan. Jessica Hicks, Daniel Bråsäter, Felipe Weinberg, and Inna Prygova are employed at Galderma. **Funding:** This study was funded by Galderma R&D, LLC.

Selected data from the current study have been presented in the form of abstracts/posters at the following congresses: American Society for Dermatologic Surgery Annual Meeting, Denver CO, USA, 6-10 Oct 2022; Fall Clinical Dermatology Congress, Wynn Las Vegas, NV, USA, 20-23 Oct 2022; Maui Derm, Maui, Hawaii, USA, 23-27 Jan 2023; International Master Course on Aging Science, Paris, France 26-28 Jan 2023; AMWC North America, Miami, FL, USA, 23-25 Feb 2023, Annual Meeting of the American Academy of Dermatology, New Orleans, LA, USA, 17-21 Mar 2023; Aesthetic & Anti-aging Medicine World Congress, Monte Carlo, Monaco, 30 Mar-1 Apr 2023.

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