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Safety and Effectiveness of Poly-L-Lactic Acid (PLLA-SCA) for Improvement in the Appearance of Cellulite

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ABSTRACT

Background: Cellulite is related to collagen and elastic tissue degeneration in the dermis and hypodermis. Sculptra® poly-L-lactic acid (PLLA-SCA™) is a regenerative injectable, inducing collagen and elastin production to help restore the skin's inner structure.
Objective: This 12-month study was conducted to evaluate the effectiveness and safety of PLLA-SCA for the improvement of the appearance of cellulite in the posterior thighs.
Methods: Women with grade 2–4 cellulite severity on the Galderma Posterior Thigh Cellulite Scale (GTCS) were injected with PLLA-SCA in the posterior thighs (max 3 vials/thigh) at 1–3 treatment sessions, 4–6 weeks apart. Assessments included improvement in cellulite appearance on the Global Aesthetic Improvement Scale (GAIS), GTCS, skin laxity, subject satisfaction, and adverse events (AEs). The primary endpoint was investigator-assessed GAIS at month 9. Time to return to daily activities after each treatment, and pre-defined injection-site responses were collected in a subject diary.
Results: At month 9, 28/29 subjects (97%) had GAIS improvement on both thighs. Overall improvement rates were high on GAIS (≥93% months 2–12) and GTCS (79–100% months 6–12), with improved skin laxity in all subjects at months 6–12. Most subjects were satisfied with thigh appearance (97%) and reported improved skin sagginess (93%) and firmness (97%) at month 12. No treatment-related AEs occurred, and diary events were mainly tolerable and transient, resolving within 1 to 2 weeks.
Conclusion: Treatment with PLLA-SCA progressively improved cellulite appearance, reaching ≥93% at months 9 through 12. GTCS improvement rates and subject satisfaction were high. The treatment was well tolerated.

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INTRODUCTION

Cellulite is a topographic and localized skin condition, commonly found on the posterolateral thighs, buttocks, and abdomen, and related to collagen and elastic tissue degeneration in the dermis and hypodermis.[1] With age, collagen production in the body decreases, resulting in the visible signs of aging[2] such as an increase in skin laxity, which is a significant aggravating factor for cellulite.[3]

Numerous treatments have been proposed to treat cellulite,[1,4-6] all with varying efficacy[7] and most with modest and temporary results.[8] In addition, most treatments do not target the underlying structural causes of cellulite or require very advanced surgical training.[9]

Sculptra® (Galderma, PLLA-SCA™) is a soft tissue injectable containing microparticles of poly-L-lactic acid, a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy-acid family. It works as a regenerative biostimulator, inducing collagen and elastin synthesis over time to help restore the skin's inner structure.[10] In pivotal trials, PLLA-SCA has recently demonstrated effectiveness and safety for correction of cheek wrinkles,[11] and correction of midface (NCT04132518), enabling label extension for these facial indications. Further to facial aesthetic treatment, there is increased interest in using PLLA-SCA for non-facial indications,[12-15] with current certification in accordance with the Medical Device Regulation for PLLA-SCA use in décolletage, posterior thighs (cellulite), upper arms, and the gluteal area.

Based on the theory that a stronger skin structure, with a decrease in skin laxity and an increase in dermal thickness, could reduce the appearance of cellulite, this clinical study was performed to investigate the effectiveness and safety of PLLA-SCA for the improvement in appearance of cellulite in the posterior thighs.

MATERIALS AND METHODS

Study Design

This was a 12-month, prospective study (NCT05064761) conducted at one center in Canada between November 2021 and February 2023. The study complied with Good Clinical Practice and the ethical principles of the Declaration of Helsinki and its amendments. Ethical approval was obtained from the Institutional Review Board prior to study start, and all subjects provided signed written informed consent.

The primary and secondary objectives of the study were to evaluate the effectiveness of PLLA-SCA to improve the appearance of cellulite in the posterior thighs. The primary and secondary effectiveness endpoints are listed under assessments. Another study objective was to evaluate the safety of PLLA-SCA treatment of the posterior thighs to improve the appearance of cellulite.

Study Population

It was planned to include approximately 30 non-pregnant, immune-competent women, ≥18 years, with Grade 2–4 cellulite severity on the Galderma Posterior Thigh Cellulite Scale (GTCS) on both thighs (symmetrical grading not required), characterized by superficial to moderately deep depressions with undulations. Additional inclusion criteria included a BMI ≥18.5 and ≤25 kg/m^2 and that the subjects could benefit from treatment to improve the appearance of cellulite in the opinion of the Principal Investigator.

Study Treatment and Visits

All enrolled subjects were to receive a single regimen of PLLA-SCA, comprising three treatment sessions each spaced one month (+2 weeks) apart: at baseline, month 1, and month 2.

Each vial of 150 mg dry powder PLLA-SCA was reconstituted with 17 mL using sterile water for injection, with the addition of 1 mL 2% lidocaine hydrochloride, prior to use. A maximum of 3 vials, ie, up to 54 mL per thigh (in total 6 vials in both thighs), were administered per treatment session. Subjects were injected to achieve optimal correction, as agreed upon by the treating investigator and the subject. The study product was injected subcutaneously in the deep dermis or subdermal region using 25-Gauge 1.5-inch BD needles, evenly spread over the entire treatment area of both posterior thighs with a fanning, asterisk, or short linear threading technique with a distance of 1-2 cm using 0.05–0.1 mL per injection point. The treatment area was delimited by the infragluteal fold (superior border), the iliotibial band – posterior border (lateral border), the gracilis muscle – posterior border (medial border), and 2/3 from the infragluteal fold to the popliteal crease (inferior border).

Additional follow-up visits were conducted at months 6, 9, and 12.

Assessments

Global Aesthetic Improvement Scale (GAIS), primary and secondary endpoints

The 7-graded Global Aesthetic Improvement Scale (GAIS) was used to assess the aesthetic improvement of cellulite in the treatment area compared to a photograph taken at baseline before treatment, with response options: "Very much improved", "Much improved", "Improved", "No change", "Worse", "Much worse", and "Very much worse". The treating investigator assessed the aesthetic improvement live by comparison with the baseline photograph. Subjects assessed aesthetic improvement by comparing photographs taken at the current visit with photographs taken at baseline before treatment. The right and left posterior thighs were assessed separately. The primary endpoint was the treating investigator-assessed GAIS responder rate at month 9, with responder defined as at least "Improved" in both thighs. Secondary endpoints included GAIS responder rates assessed by the treating investigator at months 1, 2, 6, and 12, and by subjects at all visits, with responder defined as at least "Improved".

Galderma Posterior Thigh Cellulite Scale (GTCS), secondary endpoints

The GTCS at rest is a 5-graded, photographic-based scale assessing the severity of depressions and undulations associated with cellulite in the thigh. The five scores represent visibly distinct degrees of appearance, where 1=smooth skin with up to a few superficial undulations, 2=few superficial depressions with undulations, 3=shallow depressions with undulations, 4=moderately deep depressions with undulations covering the majority of the posterior thigh, and 5=deep depressions with undulations covering the majority of the posterior thigh with or without redundant skin bulges. Assessments were performed before and after treatment. Secondary endpoints included responder rates on the GTCS for each thigh at all post-baseline visits, as assessed live by the treating investigator. Responders were defined as subjects with ≥1 grade improvement from baseline.

Skin laxity assessment, secondary endpoints

Skin laxity change from baseline at months 6, 9, and 12 were secondary endpoints, assessed live by the treating investigator aided by photographs taken at baseline before treatment. The following aspects were reported for each thigh separately: "Has the skin laxity improved after treatment?" and "Does the skin appear tighter after treatment?".

Subject satisfaction questionnaire (SSQ), secondary endpoints

Subjects reported satisfaction with treatment results by responding to a Subject Satisfaction Questionnaire (SSQ) comprising 12 questions. The percentages of subjects in each response category were secondary endpoints.

Return to daily activities, secondary endpoint

Time to return to daily activities after treatment was collected as part of the 28-day subject diary and reported as a secondary endpoint.

Safety

Safety endpoints included standard collection of adverse events (AEs) throughout the study period, as well as a 28-day diary to collect pre-defined expected posttreatment events (pain/burning, tenderness, redness, bruising, swelling, itching). The injection-related events were graded as none, tolerable, affects daily activities, or disabling. Subjects also assessed pain on an 11-point Numeric Pain Scale (NPS) (from "0 - no pain" to "10 - worst pain imaginable") immediately posttreatment and 30 minutes posttreatment.

Statistical Analyses

Data were presented descriptively, using the Safety Analysis Set (SAF), defined as all subjects who were injected in at least one thigh, and the Full Analysis Set (FAS), defined as all subjects who were injected in both thighs.

RESULTS

Subjects

A total of 29 women were enrolled in the study with posterior thigh GTCS grades of '2' (a few superficial depressions with undulations) to '4' (moderately deep depressions with undulations covering the majority of the posterior thigh). All 29 subjects were treated in both thighs and thereby included in both SAF and FAS populations, and all subjects completed the study. Two (7%) subjects received two treatment sessions, and 27 (93%) subjects received all three treatment sessions. At each treatment session, the median volume injected per subject was 54 mL (ie, 3 vials) in each thigh.

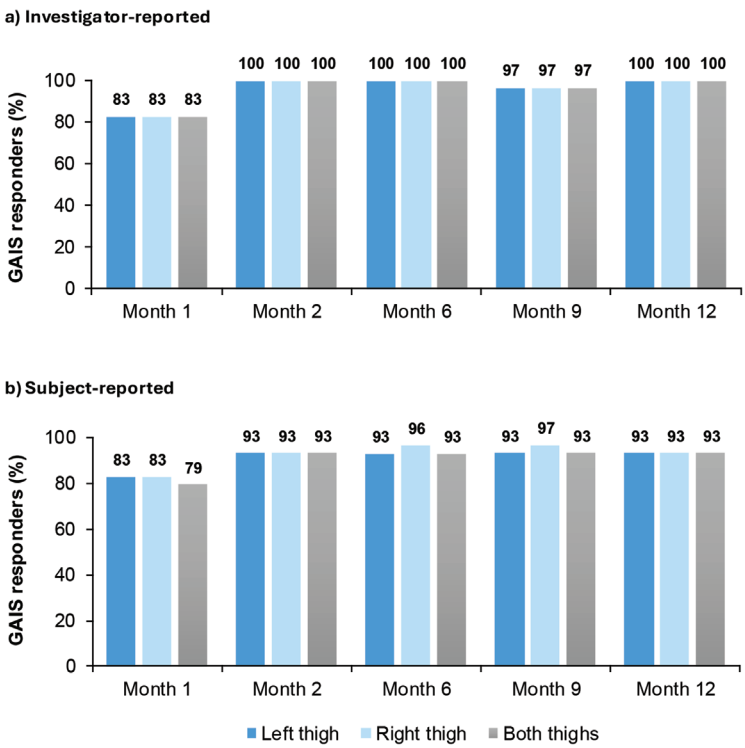
Demographics and Baseline Characteristics

The female subjects enrolled in the study had a mean age of 41.2 years (range: 25–63 years) and a mean BMI of 22.1 kg/m^2 (range: 18.8–24.2). The subjects were White (83%) and/or Asian (21%), and mostly 'Not Hispanic/Latino' (93%), with Fitzpatrick Skin Types I (10%), II (14%), III (55%), IV (14%), and V (7%) represented. Most subjects entered the study with GTCS Grade 2 (66% left thigh; 52% right thigh) or Grade 3 (17% left thigh; 34% right thigh), with fewer subjects reported as Grade 4 (17% left thigh; 14% right thigh).

Aesthetic Improvement (GAIS)

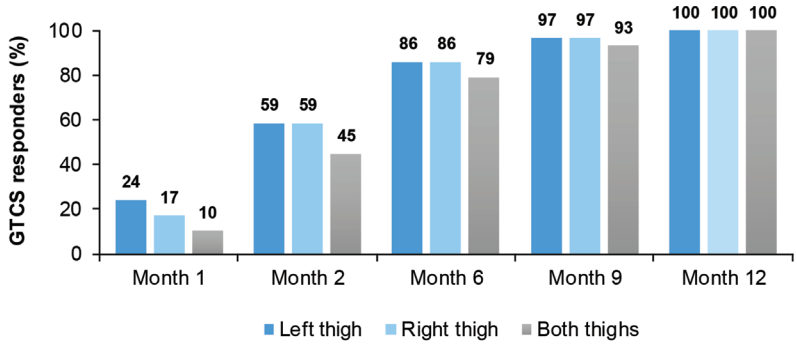
At month 9, treating investigators reported cellulite appearance as improved or better on both thighs on the GAIS in 28/29 subjects (97%) (primary endpoint), with no difference in responder rates between the two thighs (97% improved or better for left and right separately). All subjects (100%) showed aesthetic improvement in both thighs at months 2, 6, and 12, as reported by the treating investigator (Figure 1). A majority of left (79%) and right (83%)

FIGURE 1. GAIS responder rate over time (FAS population N=29).



FAS, Full Analysis Set; GAIS, Global Aesthetic Improvement Scale; A GAIS responder was defined as a subject who was assessed as Improved, Much improved, or Very much improved on the scale.

FIGURE 2. GTCS responder rates assessed by treating investigator (FAS population N=29).



FAS, Full Analysis Set; GTCS, Galderma Posterior Thigh Cellulite Scale
A response was defined as ≥1-grade improvement from baseline on the 5-graded GTCS.

thighs were reported to be "Very Much Improved" at month 9, with no thighs graded worse on the GAIS.

Subject-reported GAIS showed similar results as investigator-reported, with ≥93% of subjects reporting aesthetic improvement in their cellulite appearance in both thighs from month 2 through month 12. There was no major difference between subject-reported GAIS results in the left and right thighs at any timepoint (Figure 1).

Improvement on the Galderma Posterior Thigh Cellulite Scale (GTCS)

The investigator-assessed GTCS responder rate increased gradually over the course of the study, indicating a reduced severity of depressions and undulations in the thighs following PLLA-SCA treatment. At month 6, 86% of subjects (25/29) were responders in the left and right thighs separately, with 79% (23/29) being responders in both thighs. At month 9, 97% of subjects (28/29) were responders in the left and right thighs separately, with 93% (27/29) being responders in both thighs. At month 12, all 29 subjects (100%) were responders in both thighs. Responders had ≥1-grade improvement in GTCS from baseline (Figure 2).

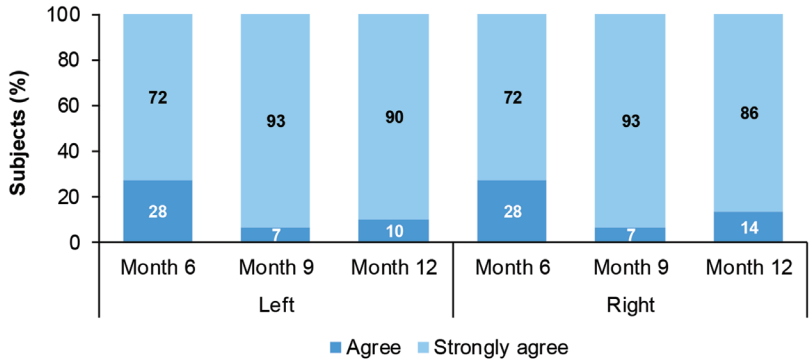
Improvement in Skin Laxity

For all 29 subjects (in both thighs), investigators agreed or strongly agreed that there was an improvement in skin laxity (Figure 3) and that the skin appeared tighter after treatment at months 6, 9, and 12.

Time to Return to Daily Activities

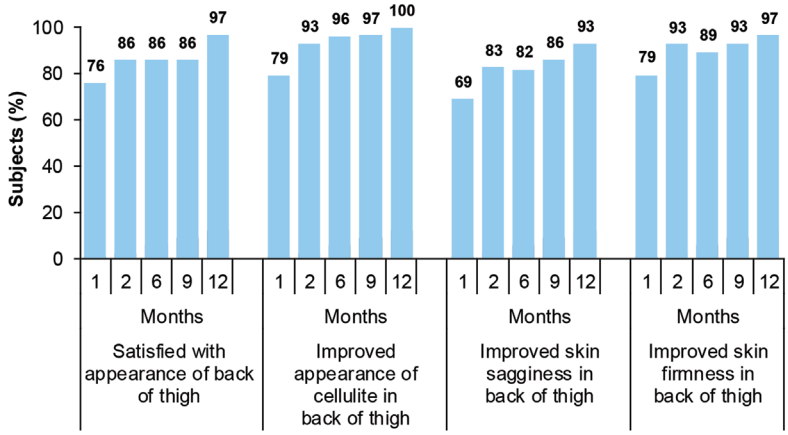
All subjects were able to return to their daily activities within a maximum of 4 days after treatment. Across all treatment sessions, the median time to return to daily activities was 4 to 5 hours.

FIGURE 3. Improvement in skin laxity after treatment (FAS population N=29).



FAS, Full Analysis Set
Skin laxity was assessed live by the treating investigator at each visit by comparing to baseline photographs.

FIGURE 4. Satisfaction with back of thigh appearance, and subject-reported improvement in cellulite appearance, skin sagginess and skin firmness in back of thigh (FAS population N=29).



FAS, Full Analysis Set
Responses are presented for subjects reporting improved/satisfied in both thighs at the same visit.
Satisfied – includes categories "Very satisfied", "Satisfied", "A little satisfied"
Improved – includes categories "Improved a lot", "Improved", "Improved a little"

Subject Satisfaction

High subject satisfaction was recorded from months 1 to 12, with 97% of subjects satisfied with the appearance of both thighs at month 12. At month 12, all subjects (100%) agreed that the appearance of their posterior thighs was improved, and the majority reported improvement in skin sagginess (93%) and firmness (97%) (Figure 4). In addition, the majority of subjects rated improvement in satisfaction with the appearance of the back of thigh in swimwear (93%) and satisfaction regarding the appearance of the back of thigh wearing a skirt or dress (90%) at 12 months. A vast majority, 83%, responded that they would do the treatment again, and 93% that they would recommend the treatment to a friend.

Numeric Pain Scale (NPS)

Pain assessed using the 11-point NPS (from 0 'no pain' to 10 'worst pain') showed ratings between 0 and 2 for most subjects across all treatment sessions, indicating no pain or only a low degree of pain. Immediately after each treatment session, the majority of subjects reported no pain or a low degree of pain (means ranging from 0.2 to 0.3), with pain levels increasing somewhat after 30 minutes (means ranging from 0.5 to 1.0), as expected, as the effect of the lidocaine diminished.

Adverse Events

Among the 29 subjects, 7 (24%) reported treatment-emergent AEs (TEAEs). All reported events were unrelated to the study treatment. No subject experienced a serious TEAE.

Pre-Defined Injection-Related Events From Subject Diary

A majority of subjects reported one or more pre-defined injection-related events, including pain/burning, tenderness, redness, bruising, swelling, or itching. For most subjects, the events were tolerable and resolved within a week. Bruising tended to last slightly longer, with a majority resolved within 2 weeks. Five subjects (17%) had pre-defined injection-related events with >2 weeks in duration (range: 15 to 28 days). The events were bruising (4 subjects) and tenderness (one subject). All events were considered tolerable.

DISCUSSION

PLLA-SCA is a new approach to addressing cellulite without using surgical subcision, and this prospective study investigated the effectiveness and safety of PLLA-SCA for improvement in the appearance of cellulite in the posterior thighs. The data showed a high proportion of GAIS responders, indicating aesthetic improvement in both thighs at month 9 (primary endpoint), with support from secondary effectiveness endpoints and consistent results from investigators and subjects. Further, subjects reported low treatment discomfort (pain), quick return to social engagements, and long-term sustained subject satisfaction up to month 12, which are key targets for aesthetic treatments.

In this study, treatment of the posterior thighs was well tolerated, with no treatment-related AEs, and mostly tolerable and transient pre-defined expected post-treatment events reported in the subject diary.

PLLA-SCA has demonstrated effectiveness and safety in pivotal trials correcting facial folds and wrinkles, such as nasolabial folds[16] and cheek wrinkles.[11] There is now an increased interest in using PLLA-SCA for treating non-facial indications, and patients

are looking for safe and effective minimally invasive aesthetic procedures.[12,13] Collagen stimulators such as PLLA-SCA have shown their ability to improve volume, skin laxity, and cellulite appearance.[12]

Limitations of the study included recruitment of subjects from a single center and the lack of a control group. However, the study provided positive treatment outcomes for an indication with limited treatment options, encouraging further research.

CONCLUSION

Overall, PLLA-SCA was shown to be effective for the improvement in the appearance of cellulite in the posterior thighs. The improvement remained consistent through month 12. There was a high level of subject satisfaction, and the treatment was well tolerated. The findings warrant further investigation in a larger study.

DISCLOSURES

KB is a speaker, investigator, and/or consultant for AbbVie/Allergan, Babor, Caliway, Galderma, Ipsen, L'Oreal, Merz, and Prollenium. SH is a speaker/consultant or investigator for AbbVie/Allergan, Babor, Caliway, Galderma, L'Oreal, Merz, and Revance. CW, FW, DB, and IP are employees of Galderma.

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