

Poly-L-Lactic Acid in Facial Rejuvenation: Volumetric Data Supporting Regenerative Outcomes

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Background: Poly-L-Lactic acid (Sculptra[®], PLLA-SCA[®]) is a biodegradable bio-stimulating agent composed of irregularly shaped PLLA particles capable of inducing extracellular matrix regeneration. Beyond traditional volumisation, emerging evidence suggests broader epigenetic and adipogenic effects, positioning PLLA as a key agent in regenerative aesthetics.

Objective: To retrospectively evaluate long-term outcomes of PLLA-SCA treatment in 28 female patients using 3D imaging analysis, focusing on two protocols; (1) full-face skin firming and (2) skin firming with additional targeted volumisation and/or asymmetry correction.

Methods: A retrospective review of clinical data and standardised 3D stereophotogrammetric imaging was performed two years post-treatment. Patients were divided into the two treatment strategy groups. Volume differences were quantified using validated reconstruction software, and clinical outcomes were assessed through physician evaluation and patient-reported satisfaction.

Results: All patients demonstrated measurable soft tissue volume formation at two years, ranging from 0.75cc to 6.4cc per vial of PLLA-SCA. Skin quality improvement and facial harmonisation were consistently observed. No untoward effects, such as vascular compromise, nodules, or granulomas, were reported.

Conclusion: PLLA-SCA produces sustained soft-tissue formation and skin firming effects, persisting for at least two years. The findings support PLLA-SCA as an effective regenerative agent with long-lasting volumising and tissue enhancing properties.

Keywords: poly-l-lactic acid, biostimulators, 3D imaging, facial rejuvenation, epigenetic pathways, regenerative aesthetics

Introduction

Poly-L-lactic acid (Sculptra[®], PLLA-SCA[®], Galderma Laboratories, Lausanne, Switzerland) is an alpha-hydroxy acid that has been in clinical use for many years, since its introduction in Europe in 1999. PLLA-SCA is a biocompatible synthetic polymer which has traditionally been used to restore and increase volume in specific areas of the face and body.¹⁻³ Although often described as “biodegradable”, PLLA-SCA undergoes slow hydrolytic degradation in aqueous environments, a physicochemical process rather than classical enzymatic biodegradation. Its microparticles are birefringent under polarised light and remain detectable histologically during breakdown.⁴

The polymer does not directly augment the skin but exerts an indirect effect.^{5,6} The microparticles trigger a controlled inflammatory cascade, recruitment of M2 macrophages and fibroblasts stimulation, resulting in neocollagenesis. When injected into the tissue, the PLLA particles degrade over time, only to be replaced by the patient’s own soft tissue, a process that persists for up to 25 months.^{6,7} Recent molecular studies have identified broader epigenetic effects of PLLA-SCA, including gene expression changes that promote elastin synthesis (ELN), antioxidant pathways (MT1A), and adipocyte-related metabolic activity (MARCO and VSIGA). These findings indicate that PLLA activates regenerative processes throughout the dermis, hypodermis, and adipose tissue compartments.^{8,9}

More recently, PLLA-SCA protocols have expanded beyond volumisation to include global skin firming and correction of mild to moderate laxity without creating overt augmentation.¹⁰ Currently, PLLA-SCA is also recommended

for treating skin laxity in various body areas, including the neck, chest, arms, abdomen, buttocks, thighs, knees, and hands.¹¹ Moreover, it is used to restore collagen in atrophic scars and striae distensae, as well as to diminish the appearance of cellulite.

The formulation of Sculptra includes microparticles of PLLA (150 mg), carboxymethyl cellulose (90 mg), and non-pyrogenic mannitol (127.5 mg).¹² The PLLA-SCA particles are irregular in shape and range from 40 to 63 microns in size. This size prevents phagocytosis by neutrophils, ensuring slow degradation and sustained stimulation. PLLA-SCA is maintained in lyophilised form to preserve particle integrity, sterility and stability. Before injection, the lyophilised powder must be suspended in sterile water for injection (SWFI).

Over the years, the reconstitution process has evolved, with the volume of SWFI added to the crystals gradually increasing from an initial 3cc to 5cc, and then to 7cc. Currently, the recommended dilution for facial applications is 10cc of sterile water containing lidocaine. For body treatments, dilutions of 16cc to 20cc are recommended. These higher dilutions enable a broader distribution of the particles across targeted facial and body areas, resulting in more uniform skin regeneration and, consequently, skin firming and tightening. Furthermore, due to these increased dilutions, the occurrence of nodule formation, an adverse effect linked with PLLA-SCA treatments, has been notably reduced to 0.04%.

Another relatively recent change in the treatment protocol is that PLLA-SCA is now injected into the subcutaneous layer immediately after reconstitution. Previously, however, the suspension was allowed to stand for at least 24 hours before use to allow the crystals to disperse.^{13,14}

This retrospective study analyses 3D stereophotogrammetric imaging data obtained two years after PLLA-SCA treatment using two distinct injection strategies: (1) full-face skin firming and (2) skin firming with additional targeted volumisation and/or asymmetry correction. The objective was to quantify soft-tissue changes and characterise long-term regenerative outcomes using validated 3D imaging technology.

Materials and Methods

The data from twenty-eight Caucasian female patients, aged 35 to 88, was analysed, two years after treatment with PLLA-SCA.

The patient population evaluated was divided into two groups:

1. Patients treated solely for skin firming (n=14).
2. Patients treated for skin firming and targeted volumization and/or asymmetry correction (n=14).

The weight and Basal Metabolic Index of each patient were recorded, and only those subjects who had maintained their weight (± 2 kg) at the end of the 2-year period were included in the retrospective analysis.

All subjects had not previously been injected in the face with other fillers and were free from any dermatological or systemic conditions.

The study subjects were models who had received treatment during the Aesthetics Anti-Aging Injectables courses conducted by the American Academy of Anti-Aging Medicine (A4M), Dubai.

Ethical Approval

Ethical approval for the injection of subjects during the hands-on training sessions was obtained from the Dubai Health Authority, a government body of the United Arab Emirates, prior to the course (reference number DHA/MERD/AC/24/0006).

Patient Consultation and Informed Consent

Comprehensive patient education and management of patient expectations are of utmost importance. This is especially crucial with PLLA-SCA treatment, as patients do not experience immediate satisfaction and must wait several months to see the desired results.

All patients received a comprehensive aesthetic assessment of the face, during which the degree of laxity, areas of volume deficit, and facial symmetry were evaluated. Furthermore, facial proportions were measured using a Golden Ratio Calliper, which provides a standardised method of facial assessment. Hence, it serves as a guide to identify the facial regions requiring treatment, to optimise the patient's facial shape and symmetry. Subsequently, the injection sites of the PLLA-SCA suspension were identified, and the volumes to be administered were estimated to achieve a natural and harmonious facial appearance. The precise volume of the suspension to be distributed to each side of the face was determined by the author. Written informed consent was obtained from the participants for the treatment and publication of their images. Data analysis was performed by the International Director of the A4M (author).

PLLA-SCA Reconstitution and Injection Protocol

PLLA-SCA is supplied as a freeze-dried solid in a clear glass vial. Each vial was initially reconstituted by adding 5 cc of SWFI and then shaken vigorously for a full minute. Subsequently, an additional three millilitres of SWFI was added, followed by 2 millilitres of plain 1% lidocaine, to reach a final volume of 10 millilitres. The suspension was injected immediately after reconstitution.

The PLLA-SCA suspension was administered using a 22G x 50mm blunt-tipped cannula into the superficial subcutaneous layer of the face, employing a linear retrograde fanning injection technique. This ensured the adequate deposition of particles across the entire treatment area. Small aliquots were deposited with each pass and accumulated to the pre-determined volume estimated for each area.

Following the injection of PLLA-SCA, the face was vigorously massaged with hypochlorous disinfectant solution to ensure the particles were evenly distributed. Patients were instructed to massage their faces five times daily, in five-minute sessions, over five consecutive days.

The initial treatment plan aimed for optimal correction and was based on the patient's age, with an average of one vial injected per decade of life. The sessions were spaced six weeks apart, and patients underwent clinical evaluations before each treatment session throughout the course. After the initial course, one vial was administered annually to maintain the results.

Two fundamental treatment strategies were implemented to optimise the placement of PLLA-SCA for personalised outcomes.

Protocol for Skin Firming and Rejuvenation

This method was selected for patients with overall skin laxity, good facial symmetry and without significant volume loss in any specific facial area. The PLLA-SCA suspension was injected evenly across the lateral face, lateral to the line of ligaments, to achieve a comprehensive firming and tightening effect. Typically, 5cc of the 10cc suspension was injected into each side of the face, with equal amounts deposited on both sides, in each anatomical area (Figure 1).

Protocol for Skin Firming with Targeted Volume Restoration in Specific Areas and/or Correction of Facial Asymmetry

In these cases, in addition to skin firming strategy, the suspension dosage was adjusted to deposit a larger volume proportionally in areas showing deflation to achieve optimal correction. (Figure 2).

In all cases, the exact volume of the suspension injected into each facial area was recorded as a reference and used as a guide for subsequent treatments. Follow-up treatment sessions were scheduled after a thorough assessment of the results from previous sessions.

After each injection session, patients were instructed to perform self-examinations to identify nodules. Additionally, before each subsequent treatment, the author checked the previous injection sites for any nodules, papules, or granulomas.

Imaging

Standardised photographs were taken prior to treatment and at regular intervals thereafter for up to two years.

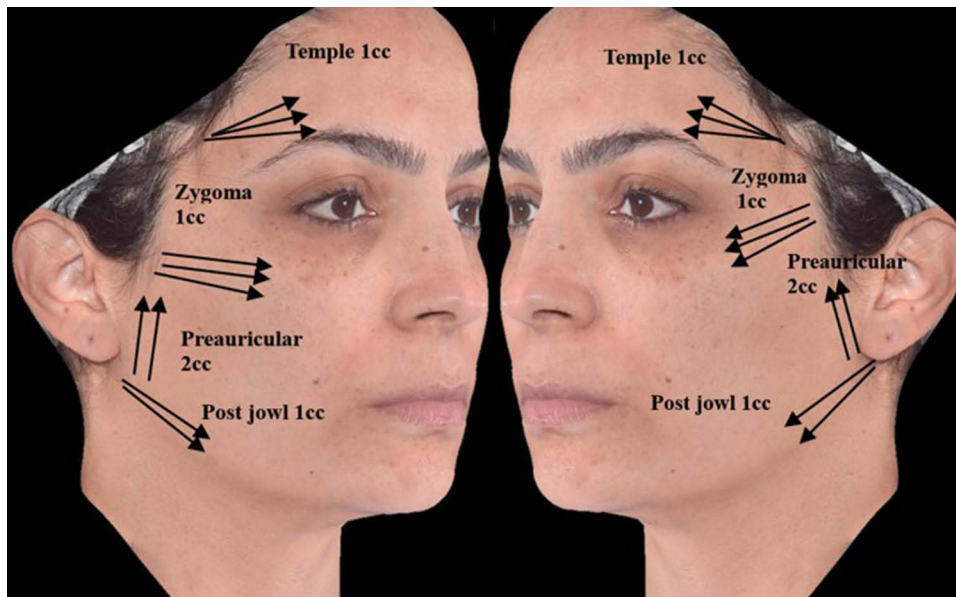


Figure 1 Injection pattern for skin firming in a 38 year-old patient.

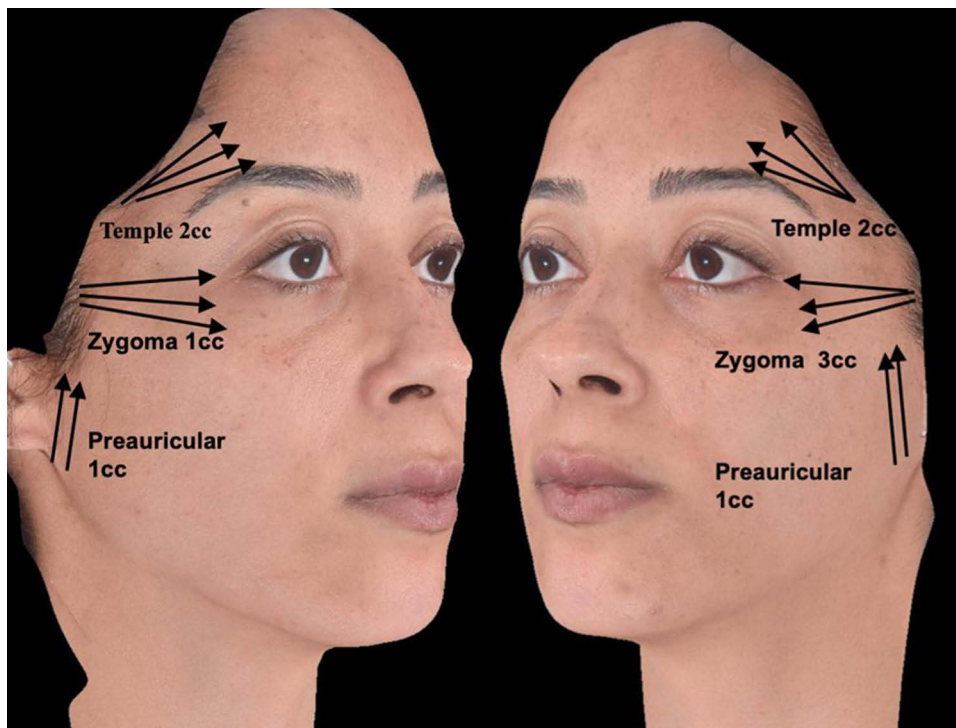


Figure 2 Injection protocol for skin firming and volumisation in a 42-year-old patient. Dissimilar volumes were injected bilaterally to address the area of deflation.

The Quantificaire Infinity Pro imaging system (Quantificaire SA, Sofia Antipolis, France) is used as part of the standard of care in our clinic. The system captures images at 180 degrees, and standardised full-face 2D and 3D images are generated. The high-resolution 3D images produced by the Quantificaire system can be used both for qualitative visualisation and quantitative volume measurements. All patients receiving PLLA-SCA underwent 3D imaging to quantify the effects of soft-tissue augmentation objectively. The quantificaire imaging system has been validated in several studies.^{15,16}

At each visit, accurately calibrated and stereoscopic images of the face were captured using the stereovision digital camera, and these images were then utilised to reconstruct the 3D surface. The anatomical volume variations (in cc) of the 3D images from baseline to the 2-year visit were assessed for each treated area outlined at baseline, on both sides of the face. The values obtained for each side were then summed to determine the total volume change of the entire face in each patient. Moreover, the total volume increase per vial of PLLA-SCA injected was computed.

The outcomes were also assessed based on subjective patient feedback and the clinician's evaluation and documented in the patient's electronic treatment notes (Capsule, Tendercare, Dubai, UAE). Any dissatisfaction with the results, expressed by either the patient or the physician, was recorded. Safety outcomes of interest included nodule formation, vascular compromise, and poor aesthetic results.

Results

None of the patients experienced any treatment-emergent adverse events; however, some expressed disappointment with the slow initial progress of the treatment.

All of the patients were pleased with the final outcome and the durability of the results. Written informed consent for publication of the images and details was obtained from the patient in each case.

Skin Firming and Rejuvenation

Figure 3 is a representative colour distance map of a patient who was treated with equal volumes of the PLLA-SCA suspension at the same anatomical sites on both the right and left sides of the face (as seen in Figure 1). The colour distance map indicates a qualitative change in volume over time. The colour scale is displayed, with any increase in volume shown in yellow and red. The colour distribution in this case is clearly very similar on both sides of the face. Precise volume measurements showed a similar increase on both sides, with a 12 cc increase on the right and a 13 cc increase on the left. A comparison of the pretreatment and 2-year follow-up images of the patient did not show any clinically apparent increase in volume in any specific area (Figure 4). However, the results of skin tightening became noticeable during animation (Figure 5), with a reduction in accordion lines while smiling.

Similarly, 3D analysis was conducted for all fourteen patients in this group, providing quantitative data for each side of their faces. In every instance, a bilateral increase in volume was observed, with both sides showing fairly similar volumes (see Table 1 and Figure 6).

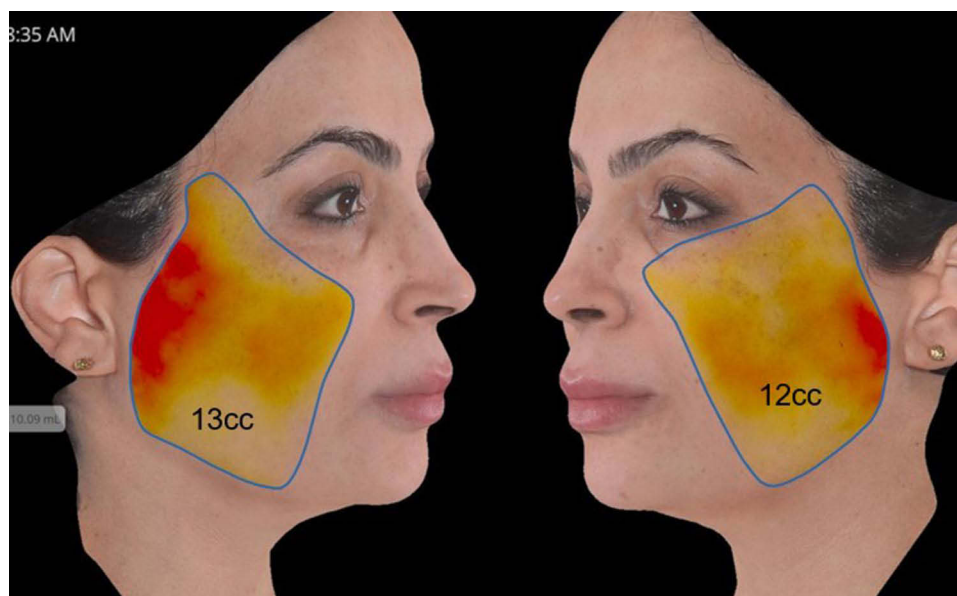


Figure 3 Colour distance map of 38-year-old patient treated with equal volumes of PLLA-SCA bilaterally.



Figure 4 Before and after photos of 38 year-old patient treated with equal volumes of PLLA-SCA bilaterally.



Figure 5 Before and after photos of 38 year-old patient with animation. Patient treated with equal volumes of PLLA-SCA bilaterally.

Skin Firming Through Targeted Volume Restoration and Correction of Asymmetry

Figure 7 shows a representative colour distance map of a 42-year-old patient who received additional treatment for facial asymmetry correction and deflation of the left zygomatic area. The disproportionate volumes of suspension injected on the right and left sides of the face (Figure 2) resulted in a distinct difference in the visual colour distance maps and volumes obtained on either side. The targeted left zygomatic arch showed increased volume compared to the right, as observed on both the colour distance map and the volume calculations. The increase in volume at 2 years was 3.82 cc on the right side and 10.71 cc on the left. The before-and-after images of the patient (Figure 8) clearly demonstrate a significant improvement in her facial shape. Previously, the patient lacked symmetry and had a more overall rounded

Table 1 Volumetric Data for the Right and Left Sides of the Face, at 2 years for Patients Treated Symmetrically with PLLA-SCA

Patient ID	Volume Calculation Left Side (mL)	Volume Calculation Right Side (mL)
1	12.07	13.19
2	4.66	4.58
3	4.27	5.19
4	8.8	6.66
5	12.87	12.78
6	2.78	3.6
7	2.55	1.84
8	2.13	1.8
9	2.3	2.86
10	3.55	5.49
11	7.49	10.57
12	6.04	7.33
13	1.83	1.94
14	4.86	6.18

appearance. After treatment, she adopted an oval shape with enhanced symmetry, both of which are linked to facial attractiveness.

All 14 patients in this group were analysed in a similar manner, and the volume was measured for each side of the face. In all cases, a notable bilateral volume discrepancy was evident. (Table 2 and Figure 9).

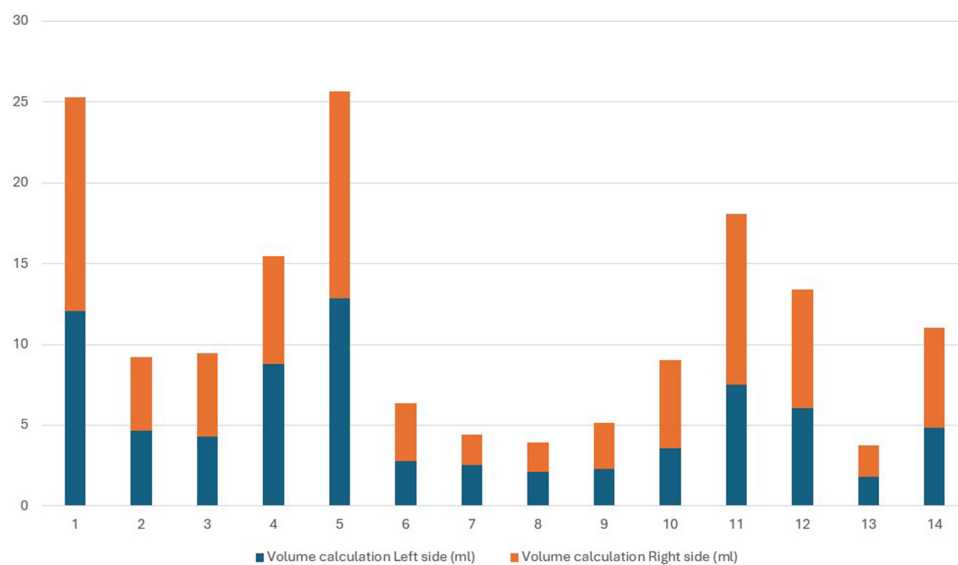


Figure 6 Volumetric bar diagram for the right and left sides of the face, at 2 years for patients treated symmetrically with PLLA-SCA.

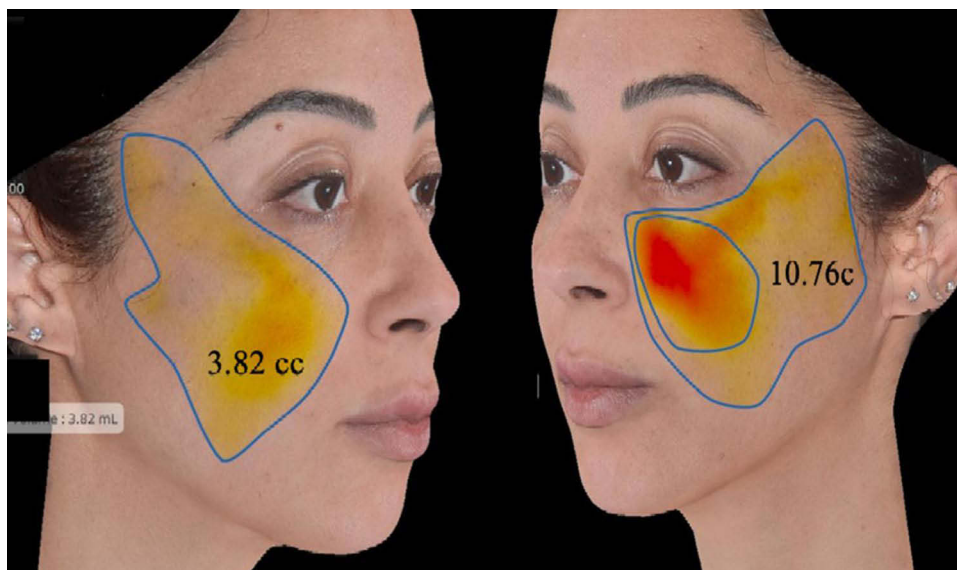


Figure 7 Colour distance map of 40 year-old patient treated with dissimilar volumes of PLLA-SCA bilaterally.

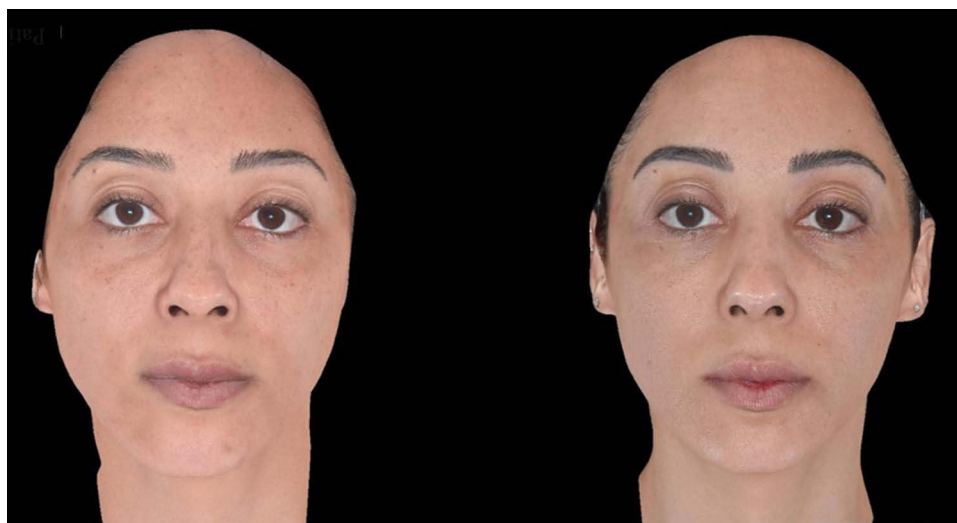


Figure 8 Before and after photos of 40 year-old patient treated with dissimilar volumes of PLLA-SCA bilaterally.

The data show that all twenty-eight patients exhibited an increase in the overall volume of their faces at two years, indicative of soft-tissue formation (Table 3 and Figure 10). Furthermore, on average, each 150mg vial of PLLA-SCA produced a volumetric tissue response ranging from 0.75 cc to a maximum of 6.4 cc.

In all cases, patients treated with a course of PLLA-SCA exhibited firmer, more toned skin and smoother facial contours.

Typical treatment results are seen in Figures 11 and 12. Both patients, in their fifties, each received four vials of PLLA, spaced six weeks apart.

Discussion

The ageing face is characterised by volume loss caused by changes across all anatomical layers, and soft tissue fillers such as Hyaluronans have traditionally been used to restore facial contours due to their direct volumizing effect.¹⁷ However, recently we have observed a paradigm shift towards procedures that yield more natural-looking, durable

Table 2 Volumetric Data for Right and Left Sides of the Face at 2 years in Patients Treated with Dissimilar Volumes of PLLA-SCA

Patient ID	Volume Calculation Left side (mL)	Volume Calculation Right Side (mL)
15	6.94	4.07
16	2.17	4.24
17	5.47	10.27
18	2.19	0.87
19	6.94	10.09
20	11.14	7.83
21	4.81	9.15
22	3.24	0.84
23	2.18	4.95
24	2.37	8.02
25	3.97	7.26
26	4.75	8.42
27	1.57	4.6
28	2.92	9.57

results, as bio-stimulating agents have become increasingly popular in this context. Ageing skin is associated with various cellular changes, such as fibroblast senescence and a decline in their numbers. Our improved understanding of the mechanisms responsible for skin degradation has resulted in increased research into treatments that can activate regenerative pathways to restore the skin's structure and function. Hence, the demand for regenerative aesthetics has surged with the use of cells and cell derivatives, bio-cues, and scaffolds. PLLA is a scaffold, increasingly recognised for

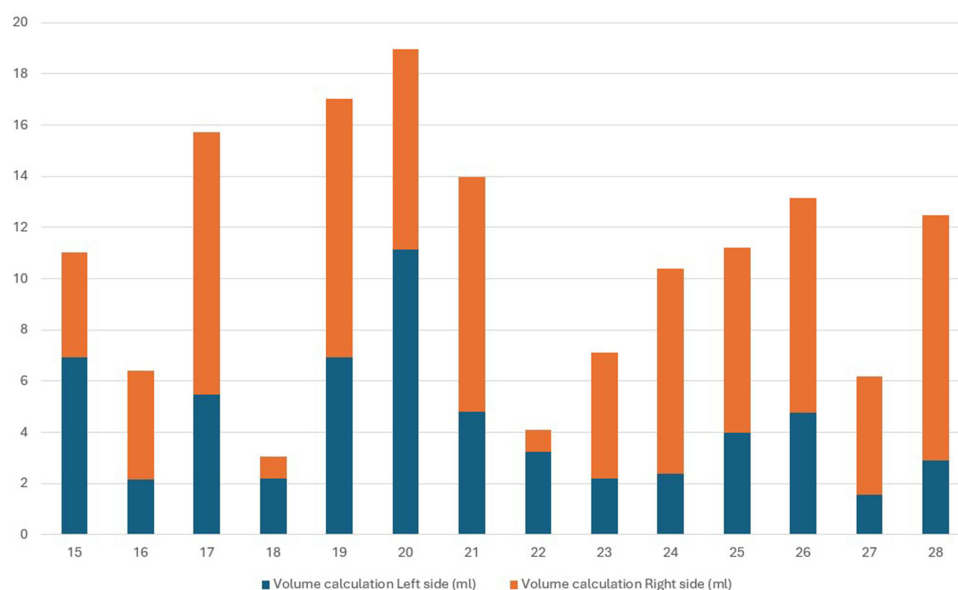
**Figure 9** Volumetric data for right and left sides of the face at 2 years in patients treated with dissimilar volumes of PLLA-SCA.

Table 3 Total Full Face Volume and Average Volume per Vial of PLLA-SCA in All Study Patients at 2 years Post-Initial Treatment

Patient ID	Total Volume (mL)	Average Volume per Vial of Sculptra (mL)
1	25.26	3.60
2	9.24	2.31
3	9.46	1.35
4	15.46	2.20
5	25.65	6.41
6	6.38	1.28
7	4.39	1.10
8	3.93	0.98
9	5.16	1.29
10	9.04	1.29
11	18.06	4.52
12	13.37	3.34
13	3.77	0.75
14	11.04	0.85
15	11.01	1.84
16	6.41	2.14
17	15.74	3.94
18	3.06	0.61
19	17.03	2.84
20	18.97	2.71
21	13.96	2.79
22	4.08	0.68
23	7.13	1.43
24	10.39	2.08
25	11.23	1.60
26	13.17	1.88
27	6.17	0.69
28	12.49	1.04

its potent regenerative and epigenetic properties that provide patients with a non-surgical option to address skin laxity and volume loss.¹⁸

PLLA-SCA is a safe and fully biodegradable polymer of lactic acid that has been widely used in various medical devices such as soft tissue implants and resorbable sutures. Its mechanism of action has been established through several

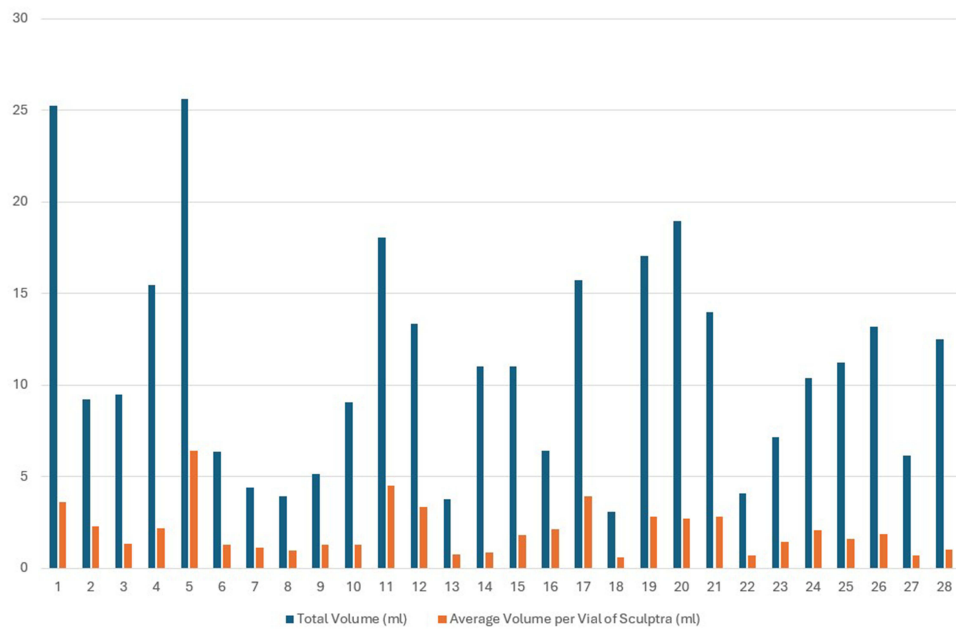


Figure 10 Total full face volume and average volume per vial of PLLA-SCA in all study Patient at 2 years post initial treatment.

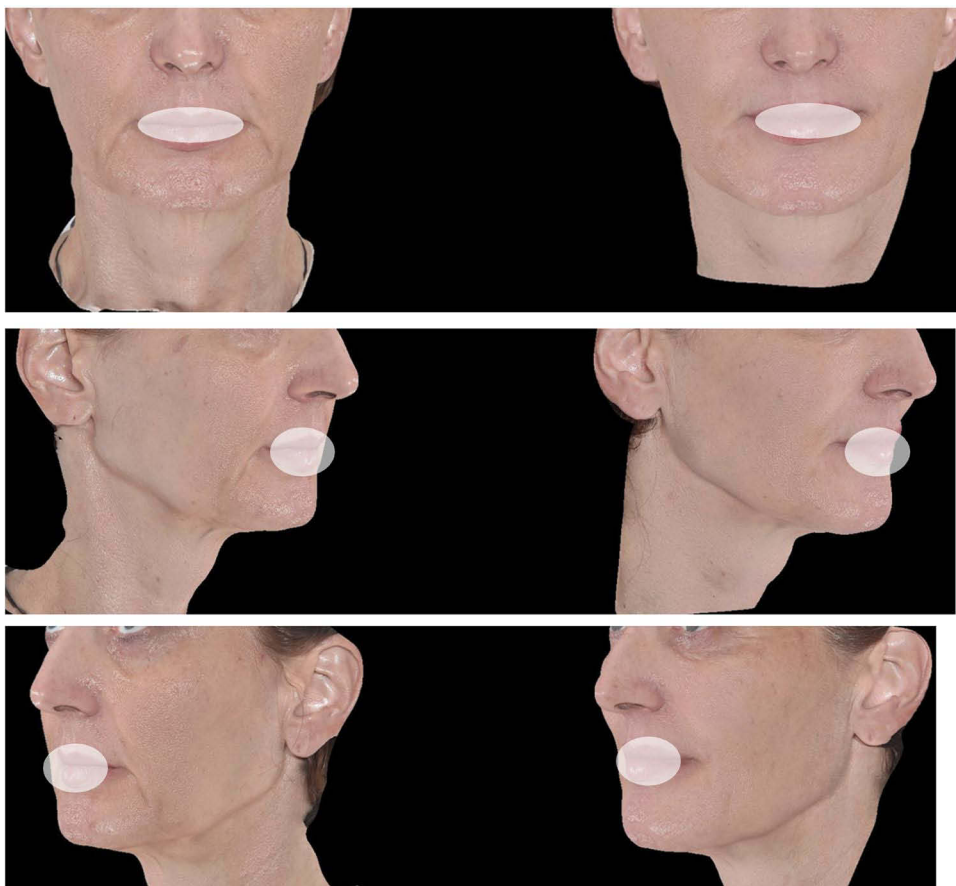


Figure 11 54 year old patient before and two years after 4 vials of PLLA-SCA.

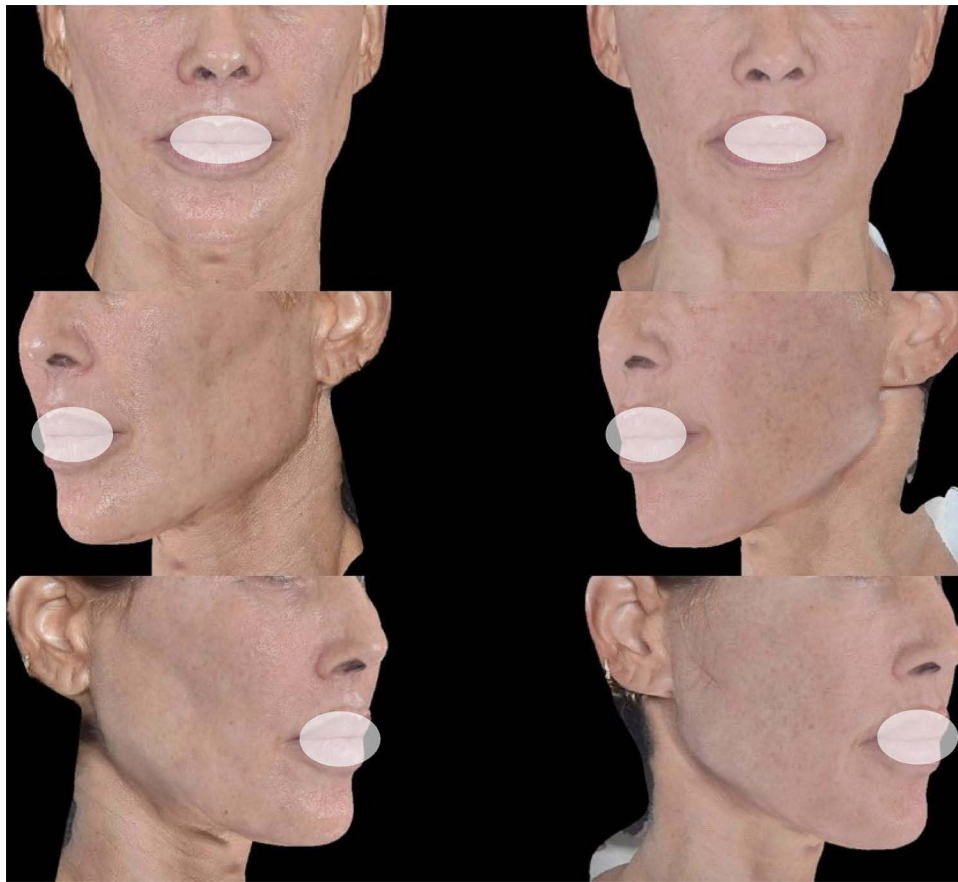


Figure 12 53 year old patient before and two years after 3 vials of PLLA-SCA.

studies, specifically in terms of its induction of neocollagenesis, leading to the formation of collagen type I. However, several studies over the past two years have revealed a far more complex mechanism of action for the regenerative effects of PLLA-SCA. Within a short period after injection, the PLLA-SCA microparticles induce a self-limiting inflammatory reaction whereby the recruitment of M2 macrophages and monocytes triggers a cascade of signalling molecules, including IL-1beta, TGF-Beta1, and VEGF, which upregulate gene expression for collagen types I and III. These molecular signals activate dermal fibroblasts, induce the production of type I collagen, and synthesise glycosaminoglycans and elastin.¹⁰ Recent detailed gene expression studies have revealed that PLLA-SCA exhibits significant epigenetic properties, regulating gene activity and altering the cellular environment and gene expression patterns to promote collagen synthesis and tissue regeneration. In a 13-week randomised study, volume change and gene expression were compared for PLLA-SCA and CaHA-R, another widely used bio-stimulating agent, injected into the nasolabial folds of 21 subjects.⁸ Gene analysis indicated distinct processes for each bio-stimulant. PLLA-SCA stimulated more components of the extracellular matrix with less inflammatory response, leading to a more regenerative pathway. In contrast, CaHA-R activated a more pro-inflammatory pathway that could hinder tissue regeneration. The study showed that PLLA-SCA upregulated ELN gene expression, which ultimately leads to elastin formation, MT1A expression, which encodes metallothionein-1A, an antioxidant that protects against free radicals, and the increased expression of DKK1, which regulates skin pigmentation and thickness. A follow-up study by the same authors revealed that PLLA-SCA has a potentially positive effect on adipocytes through various gene regulatory mechanisms.⁹ PLLA-SCA upregulates IL-6 and various gene-regulating mechanisms, including MARCO and VS1GA, thereby inducing positive changes in adipose tissue. The final outcome is an improvement in all three skin layers, which translates clinically into enhancement in facial fat, skin glow and a reduction in skin ageing.

There is substantial evidence that PLLA-SCA has long-lasting clinical effects, and various studies have shown it to have a volumising effect lasting between 2 and 3 years.¹⁹

Most studies on the longevity of PLLA-SCA have thus far relied on subjective assessments, including clinician observation, either directly or through the evaluation of 2D photographs, patient satisfaction surveys, and the Wrinkle Severity Rating Scale (WSRS). The use of 3D digital surface imaging is currently recognised as a more objective method of assessing volume changes after soft-tissue augmentation with fillers or fat transfer. Furthermore, 3D imaging is a valuable tool for showcasing results and effective patient communication.

A review of the literature identified only two other studies involving 3D photography used to assess the longevity of PLLA-SCA. The first, a single-centre, open-label study,²⁰ demonstrated an increase in volume at 24 weeks, while in the second prospective study, Chen et al²¹ observed an increase in volume at 48 weeks.¹⁸ To the best of our knowledge, this is the first study to include volumetric data at two years post-treatment. All twenty-eight patients exhibited an increase in total facial volume from baseline, with an average soft-tissue formation of between 0.75 cc and 6.4 cc per vial of PLLA-SCA. This emphasises the variability of soft tissue induction, which most likely varies in degree among different individuals. The volumetric changes observed across all patients, measured by 3D stereophotogrammetry, align with the regenerative pathways associated with PLLA-SCA and therefore correspond with the main findings of the study. The difference between symmetrical soft-tissue response and targeted asymmetry correction further supports the predictable behaviour of PLLA-SCA across different injection volumes. Although the results support the stated objectives, they should be considered in light of the study's methodological limitations. The limitations of the study include the lack of a control group, the absence of blinded assessments, and the fact that 3D volumetry was not correlated with subjective scales such as the Global Aesthetic Improvement Scale (GAIS) and/or the Wrinkle Severity Rating Scale (WSRS). Furthermore, the sample size was limited to cases available from the A4M training sessions. Nonetheless, the data offer valuable long-term, objective evidence for the literature, especially considering the lack of 2-year 3D volumetric follow-up studies.

Conclusion

PLLA-SCA exerts its regenerative effects through a complex interplay of macrophage polarisation, fibroblast activation, ECM remodelling, elastogenesis, and adipocyte-related epigenetic modulation. This is the first study to show 2-year 3D volumetric data for PLLA-SCA across two distinct treatment strategies. The significant and durable volumetric increases at 2 years affirm the role of PLLA-SCA as a regenerative biomaterial rather than merely a volumising agent.

This study provides the longest objective 3D imaging follow-up to date for PLLA-SCA, demonstrating reliable soft-tissue formation, improved facial harmony, and sustained clinical benefit across diverse patients. The findings support PLLA-SCA as a key technology for regenerative facial rejuvenation and highlight areas for future research into mechanisms and potential prospective clinical studies.

Disclosure

The author reports no conflicts of interest in this work.

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