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*Review*

# Injectable Poly-L-Lactic Acid (PLLA-SCA™) as a Versatile Treatment in Current Aesthetic Medicine: Expert Recommendations Based on Italian Clinical Experience

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## Abstract

Increasing experience in the use of PLLA-SCA™ suggests that a brief overview of recent studies and a standardization of treatment protocols based on new clinical data should be beneficial. The aim of this article is to provide guidance on the use of PLLA-SCA™ based on data from the literature and the experience of five plastic surgeons and one aesthetic physician, with a focus on Italian patients. To this effect, the authors convened online to discuss various aspects related to PLLA-SCA™ treatment of both the face and non-facial body areas. For each topic, the authors developed recommendations, addressing patient selection, product preparation and injection protocols. Suggestions regarding the combination of PLLA-SCA™ with other aesthetic treatments and the prevention of adverse events were also included. The authors suggest using dilution volumes of 8 mL of sterile water for injection (SWFI) plus 1 mL lidocaine for the face and 17 mL SWFI plus 1 mL lidocaine for body areas and immediate use after product reconstitution. By adhering to the latest instructions about product reconstitution, the occurrence of complications is minimized. In the Authors' experience, PLLA-SCA™ can be used safely and effectively for cosmetic enhancement of multiple body areas.

**Keywords:** poly-L-lactic acid; aesthetic medicine; aesthetic procedures; biostimulator; expert opinion



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## 1. Introduction

In the past few decades there has been an increasing demand for aesthetic procedures, mostly driven by the growing number of ageing subjects seeking to preserve or restore a youthful appearance, and the improvement of people's living standards. Although several intrinsic and extrinsic factors contribute to the skin aging process, the decreased synthesis and increased degradation of collagen (as well as other structural proteins) play a fundamental role [1,2]. Collagen is the most abundant protein in the extracellular matrix (ECM), where collagen fibrils form the key tension-resisting element of a complex fiber-composite system [2]. The age-related decrease in skin collagen content and dermal thickness leads to the typical features of the aging skin, mostly manifesting as thinning, laxity, loss of

elasticity, wrinkles and folds. Both surgical and nonsurgical procedures are available to correct the signs of aging, but minimally invasive and non-invasive interventions, such as use of energy-based devices and injectable fillers, are growing in popularity due to the limited patient discomfort, quick recovery times and relatively affordable costs [3–5].

In this article we focus on the use of poly-L-lactic acid under the Sculptra® tradename (PLLA-SCA™; Galderma), a synthetic, biocompatible and biodegradable polymer that acts by gradually stimulating the production of collagen, elastin and other key components of the ECM [6–8]. Polylactides have a long history of safe use in a vast array of medical applications [9]. The use of PLLA in aesthetic medicine for soft tissue augmentation dates back to 1999, when the first injectable PLLA product, New-Fill™ (Biotech Industry SA), was approved in Europe for the correction of scars and wrinkles [9]. The indications for PLLA use were subsequently extended to include large volume corrections of signs of facial lipoatrophy, as well as correction of skin depressions (e.g., creases, wrinkles, folds and scars) and skin aging [9,10]. Collagen neogenesis is the most widely documented effect induced by PLLA injection. Unlike other fillers that provide immediate volume replacement, PLLA-SCA™ stimulates new collagen production as a result of a subclinical foreign-body reaction. The inflammatory response subsides within approximately 6 months, while increased collagen deposition is observed for 8–24 months, with best results obtained after multiple treatments [4,5,11,12]. After injection, PLLA-SCA™ microparticles, which are unique in shape and size, induce a subclinical inflammatory response with recruitment of monocytes, macrophages and fibroblasts, eventually leading to encapsulation and neocollagenesis (consisting mostly of type I collagen) around the capsule [4,13,14]. PLLA-SCA™ microparticles are degraded slowly to carbon dioxide and water over a variable period of time up to 28 months, with no residual microparticles or scarring fibrosis being found thereafter [4,5,12,14]. Biopsies taken 30 months after the last treatment demonstrated increased type I collagen content and absence of PLLA-SCA™ microparticles [15]. Recently, gene expression profiling has been used to gain insight into the molecular pathways of PLLA-SCA™ biostimulatory and regenerative action on fibroblasts and the extracellular matrix. In a macrophage-containing 3D skin model, the significant increases in epidermal thickness and collagen I production observed after PLLA-SCA™ injection were found to be associated with the upregulation of integrins and laminins (e.g., LAMA3, ITGA6), which play an important role in controlling the volume and integrity of the basement membrane, as well as the upregulation of cytokines and chemokines that participate in collagen I synthesis (e.g., IL1B, CXCL6) [16]. Other recent studies suggest broader effects of PLLA-SCA™ on the ECM, such as increased production of elastin and modulation of matrix metalloproteinases (by activation of the TGF-β/Smad signaling), as well as stimulation of regenerative pathways mediated by modulation of adipocyte function [7,8].

Since the introduction of PLLA for aesthetic use, there has been an evolution over time in recommendations related to product preparation, reconstitution volumes and injection protocols. Higher dilution volumes than those previously suggested and immediate use after reconstitution have been included in current recommendations, based on robust scientific evidence from physicochemical analyses and clinical studies [10,17–19]. Over the years, the efficacy and safety of PLLA-SCA™ have been demonstrated in several clinical studies and confirmed in real-world practice, and recommendations on the use of PLLA have been published by various experts' groups [20–24]. However, there is a growing body of clinical data obtained after implementation of the latest product preparation methods that needs to be highlighted. Furthermore, the use of PLLA-SCA™ in the Italian population has not been adequately investigated.

The aim of this article is to provide guidance on the optimal use of PLLA-SCA™ for aesthetic improvement of the face and other body areas based on literature data and the

collective clinical experience of a panel of plastic surgery and aesthetic medicine experts, with a focus on Italian patients.

## 2. Methods

A group of experts in esthetic treatments, five plastic surgeons and one aesthetic physician, all experienced in the use of soft tissue augmentation techniques, convened online to discuss aspects related to PLLA-SCA™ treatment. A literature search (mostly based on PubMed, with Google Scholar as a secondary source) was conducted. In an initial experts' meeting all the aspects of the product were reviewed and key areas to be covered were defined (most suitable candidates, treatment protocols for the face and non-facial body areas, injection techniques, combination of PLLA-SCA™ with other aesthetic procedures and prevention of adverse events). Discussion was driven by literature and supplemented by personal experience where evidence was poor. A first draft of recommendation was then circulated, and contributions were integrated and cross reviewed until unanimous agreement on the statements was reached. Due to the limited number of participants, no formal consensus technique was used.

## 3. Treatment of the Face

In the pivotal registration study, a randomized, single-blind study that compared PLLA with human-derived collagen in 233 subjects, 1–4 injections of PLLA-SCA™ into the nasolabial folds (NLFs) at 3-week intervals resulted in a significant improvement from baseline in mean Wrinkle Assessment Scale (WAS) scores lasting up to 25 months, which was significantly greater than that achieved with collagen injections [25]. A time-dependent improvement in skin quality was documented in a randomized, double-blind, controlled study in 40 women, which found a statistically significant increase in stratum corneum hydration ($p < 0.0001$) and elasticity ($p = 0.0017$) in patients treated with PLLA-SCA™ vs. saline injections at the 12-month follow-up visit [26]. A retrospective study in 678 patients found PLLA-SCA™ to be most efficacious in contouring and enhancement of the lateral face; lifting, with impact on NLF lines; and improvement of skin texture and firmness [27]. Recent studies confirm the efficacy and tolerability of PLLA-SCA™ when prepared according to the latest recommendations (higher volume and immediate use) [19,28–30]. In the randomized Sculptra Contemporary Reconstitution & Injection Procedure Trial (SCRIPT), PLLA-SCA™, reconstituted to 8 mL of sterile water for injection (SWFI) + 1 mL lidocaine and injected immediately after reconstitution, demonstrated a comparable efficacy to the previous protocol (5 mL volume with SWFI, injected after a 2 to 72 h standing time) in the correction of NLF lines, with high WAS responder rates in both groups 24 weeks post-treatment (76–81%) and a good tolerability profile [19]. High volumes (8 mL SWFI + 1 mL lidocaine) were also used in a 24-month randomized controlled study from the US, conducted in 149 subjects [29]. PLLA-SCA™ treatment was found to be effective in the correction of cheek wrinkles (as assessed by the Galderma Cheek Wrinkle Scale, GCWS), with 71.6% of PLLA-SCA™-treated patients who were GCWS responders (≥1 grade improvement on the GCWS at rest for both cheeks) at 12 months vs. 26.1% of untreated patients ($p < 0.0001$), and PLLA-SCA™ recipients reported high levels of satisfaction regarding improved skin radiance (≥90%), sagging (≥84%) and firmness (≥91%), as well as natural looking results (≥85%). Efficacy and safety were maintained in the long term throughout the 24-month observation period [29,31]. PLLA-SCA™ also showed efficacy in the correction of midface volume loss (based on the Medicis Midface Volume Scale), with high levels of patients' satisfaction, in a recent randomized, controlled study from China [30].

### 3.1. Authors' Recommendations for Treatment of the Face

#### 3.1.1. Patient Selection

Age: PLLA-SCA™ has been used across a wide age range, and there are no absolute indications about age. Importantly, biological rather than chronological age should be considered. In the chart review by Palm and colleagues, PLLA-SCA™ was used in patients aged 20 to >80 years, with no age-related differences in the number of vials used per treatment [28]. In the authors' experience, the best results are obtained in patients aged 40–50 years, with a trend toward less consistent results as age increases. An attenuated response to collagen stimulation is to be expected in subjects aged $\geq$ 60 years. Information about age-related collagen synthesis in response to PLLA-SCA™ is lacking and it is unclear whether protocol modifications (i.e., increased amount of product/number of sessions) might be warranted in older patients. Age-focused post hoc analyses of current studies, as well as prospective trials, would help clarify this aspect.

Sex: Both sexes can be treated with PLLA-SCA™, with no evidence so far of gender-related differences in response, although the use in women is highly predominant.

Indications: The intended use of PLLA-SCA™, according to the European package insert, is for increasing the volume of depressed areas (particularly skin depressions such as creases, wrinkles, folds and scars), skin aging and large volume corrections of the signs of facial lipoatrophy [10]. In the authors' experience, skin laxity is the most rewarding indication for the use of PLLA-SCA™, while other aesthetic procedures are usually selected if well-defined volume augmentations or lifting are needed. PLLA-SCA™ should be considered as an option for improvement of sagging/laxity, correction of NLF contour deficiencies and cheek wrinkles, correction of mild volume losses and improvement of skin texture. The ideal candidate for PLLA-SCA™ treatment is the subject with the first signs of skin laxity but without the cephalometric structural defects that are better treated with aesthetic surgery or other procedures that provide immediate and more localized volume restoration.

Lifestyle/body composition: Subjects with a very low percentage (7–8%) of body fat (e.g., athletes of both sexes or persons engaged in high-intensity physical activities) are not always full responders to PLLA-SCA™ treatment. However, endogenous collagen biostimulation remains the best option for recontouring of the face in very lean subjects too, since it offers results that are more natural-looking compared with those obtained by using fillers. It is unclear which factor is responsible for the decreased response to collagen stimulation in these subjects (although hormonal supplements might play a role). Specific studies in this subgroup of patients would be helpful. Although heavy-faced subjects with excess of fat tissue are not generally considered as ideal candidates for PLLA-SCA™ treatment, satisfactory results can be obtained by adhering to specific injection protocols aimed at providing increased support and volume to the upper part of the face [23,32].

Patient attitudes/expectations: the advantages and limits of PLLA-SCA™ treatment should be clearly communicated to the patient, who should be aware of the gradual nature of the response to PLLA-SCA™, the need for multiple treatment sessions and the time required before the desired effects are visible. Patients should also be aware that each individual responds differently to PLLA-SCA™.

#### 3.1.2. Product Preparation and Treatment Protocol

Reconstitution: After adding 5 mL of SWFI to the PLLA-SCA™ preparation to be reconstituted (ensuring that both SWFI and PLLA-SCA™ are at the same room temperature), the vial should be vigorously shaken by hand or by means of a single vial swirling agitator for about 1 min to dissolve the excipients, until a translucent suspension with some foam on top is obtained. Up to 3 mL of additional SWFI should then be added and the vial should be shaken again to obtain a more diluted and homogenous suspension.

A subsequent optional step is the addition of 1 mL of 2% lidocaine solution to ensure an adequate level of comfort for the patient during the injection procedure [10]. No standing time before use is necessary. Based on their experience, the authors recommend the higher volume reconstitution method, with a two-step approach 5 + 3 mL in the preparation, and the routine addition of lidocaine (8 mL SWFI volume + 1 mL lidocaine). A more diluted suspension may be considered in selected cases.

Injection technique: The authors' recommended technique consists of subdermal injections using 22 G or 25 G cannulas, avoiding injections into the dermis. The areas of the face that can be treated with PLLA-SCA™ and the injection techniques recommended for each site have been reviewed elsewhere [20,21,32]. Briefly, sites suitable for PLLA-SCA™ use are the malar area, cheeks, jawline and temples, whereas hyperdynamic and central facial areas (including forehead, eyelids, nose, lips, periorbital and perioral areas) should be avoided. Recommended injection techniques for correction of NLF contour deficiencies and cheek wrinkles include retrograde linear threading and fanning [17]. One or two vials per session (according to the clinical indication) are generally used for facial treatment.

Aftercare: At the end of each session, the treated area should be massaged for a few minutes to ensure even distribution of the product. Patients should also be advised to massage the treated area at home for the first few days after each session, following the '5/5/5' rule (massage for 5 min, 5 times per day for 5 days). The massage should be carried out with the help of a moisturizing cream or lotion suitable for sensitive skin. In the authors' experience, Cetaphil® Moisturizing Lotion (Galderma) has an optimal texture for this purpose.

Treatment plan: the standard protocol consists of 2 or 3 sessions 30–40 days apart. Because of PLLA-SCA™'s mode of action, it is important to re-evaluate the patient $\geq$ 4 weeks after each session to assess whether further treatment is needed to achieve the desired degree of correction. Yearly injections for maintenance treatment are advisable.

Two examples of facial treatment with PLLA-SC™ are illustrated in Figures 1 and 2.

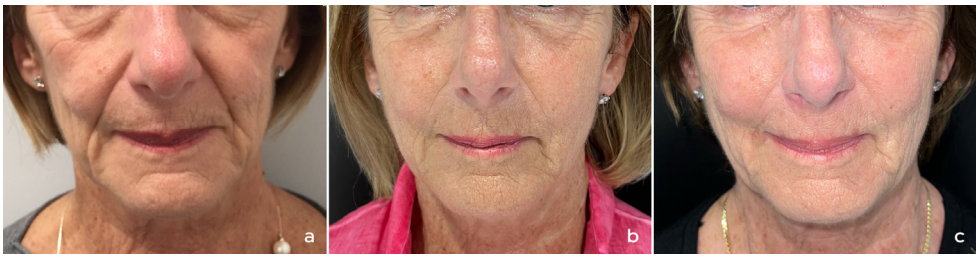


**Figure 1.** Patient with advanced signs of facial volume loss and sagging who underwent 5 treatment sessions with PLLA-SCA™ over a 4-year period: (**a**) at baseline; (**b**) at 2.5 years after starting treatment (4 sessions, 4 vials in total); (**c**) at 4 years after starting treatment (5 sessions, 5 vials in total). Notice the volume restoration, correction of marionette lines and improvement of skin texture. (Courtesy of Dr. Massimiliano Leporati, MD).


**Figure 2.** Volumetric improvement in the mid-lower face and enhanced skin quality in a patient after 3 sessions of PLLA-SCA™ treatment (3 vials in total): (**a**) at baseline; (**b**) at 22 months after starting treatment (Courtesy of Dr. Massimiliano Leporati, MD).

## 4. Treatment of Non-Facial Body Areas

The positive results obtained with PLLA-SCA™ in facial rejuvenation have triggered an increasing interest in its use in other body areas such as neck and décolletage, upper arms, hands, abdomen, buttocks, thighs and knees. In parallel, new validated aesthetic assessment scales for non-facial areas have been developed [33]. However, most published studies are case series involving limited numbers of patients; treatment protocols vary and the results are often presented for multiple areas. It is only recently that larger and/or controlled clinical studies have been published, mostly on treatment of the gluteal and thigh areas [34–36].

Buttocks/thighs: With aging, the declining skin elasticity and the loss of subcutaneous fat, together with a less firm gluteal suspension system, lead to a decreased volume of the buttocks and gluteal ptosis. Skin quality is also impacted by this process, with the development or worsening of striae distensae and cellulite [33]. PLLA-SCA™ is being increasingly used in the gluteal and thigh area for improvement of contour and texture, reduction in cellulite, volume augmentation and lift [24,37]. In a recent randomized, double-blind, split-body trial that evaluated the effects of PLLA-SCA™ vs. placebo in the buttocks and/or thighs in 20 women, improvements in skin appearance, laxity and cellulite (as evaluated by the Hexsel Cellulite Severity Scale) were observed in the treated buttocks at 330 days of follow-up. Treatment of the thighs resulted in more modest improvements [34]. Some authors have reported satisfactory results in the improvement of cellulite by combining subcision (a minimally invasive technique that involves sectioning the fibrous septa in selected cellulite depressions) and PLLA-SCA™. In a randomized, double-blind, placebo-controlled, split-body study conducted in a small number of patients, subcision followed by PLLA-SCA™ injections (3 sessions 1 month apart) in the buttocks and posterolateral aspect of the thighs resulted in a significant improvement vs. placebo injections in the Global Aesthetic Improvement Scale (GAIS) at the 3- and 6-month follow-up visits [38]. In a double-blind, split-body study of PLLA-SCA™ vs. saline injections in 15 women, PLLA-SCA™ was effective in improving the aspect of the hip dell, and the improved volume of the biostimulator-treated area was found to be associated with an increased thickness of the dermis and adipose tissue layers, suggesting a stimulation of adipogenesis and elastogenesis [39].

Other body sites: The skin quality of the neck and décolletage is affected by aging but also by exposure to ultraviolet light and pollution. The use of biostimulators addresses the need to correct skin laxity, dermal thinning and fine lines and wrinkles. PLLA-SCA™ was found to be effective and safe in neck/chest rejuvenation in several prospective studies and retrospective case series that used different reconstitution volumes and injection techniques, as reviewed by Haddad et al. [24]. In a recent prospective study that evaluated the safety and effectiveness of two reconstitution volumes of PLLA-SCA™ (8 mL or 17 mL plus 1 mL lidocaine for both) in approximately 30 women, both reconstitution volumes were found to be well tolerated and effective in improving wrinkle severity, as measured by the Galderma Décolletage Scale at 9 months post-treatment, with high rates of subjects satisfaction regarding skin texture, smoothness and radiance [40]. PLLA-SCA™ has been recommended for the treatment of mild abdominal skin laxity resulting from weight loss or pregnancy, although data are still limited [24,41]. PLLA-SCA™ treatment was also found to be effective in the correction of skin sagging and cellulite in the medial upper arms and appears to be potentially beneficial in treating skin laxity of the knee and thinning of the intermetacarpal spaces of the hand [24,33].

Recommendations and specific treatment strategies on PLLA-SCA™ use in off-face body areas have been proposed by several groups of experts [22–24,37,42]. In particular, Sarubi et al. have developed the so-called ‘Firm and Up’ technique, an individualized

approach for PLLA-SCA™ injection in the gluteal region that specifically targets the three main factors that need to be improved: skin quality, contour and lifting or projection and volume [42]. In the authors' experience, PLLA-SCA™ has proved to be most beneficial in the aesthetic enhancement of buttocks and thighs, neck, inner arms and abdomen. Recommendations will be provided for these sites only.

### *4.1. Authors' Recommendations for Treatment of Non-Facial Body Areas*

#### 4.1.1. Patient Selection

Age and sex: There are no absolute indications about age or sex and the same considerations made above for facial treatment apply here. Age influences the type of intervention and the body areas selected for treatment. In general, older people typically ask for rejuvenation procedures for the neck, décolletage and upper arms, while correction of supraumbilical skin laxity is most frequently requested by younger women after pregnancy.

Indications for buttocks/thighs treatment: According to the authors' experience, PLLA-SCA™ treatment is best used for toning and firming of the buttocks and posterior aspect of the thighs, correction of cellulite and skin laxity, and volumetric augmentation of dip hip deformity of moderate entity. Generally, cellulite and skin laxity are the main aesthetic concerns of Italian women, who most often seek a lifting effect and optimization of the skin texture in the gluteal/thigh region. Requests for volumetric expansion and major reshaping of the gluteal region, although rapidly increasing, are still fewer in Italy compared with what is reported for Hispanic or South American patients. In the authors' experience, PLLA-SCA™ performs better in the gluteal area when it is used as a lifting treatment, or to improve skin quality, than for volumetric augmentation purposes.

Indications for treatment of other body areas: PLLA-SCA™ is used by the authors for improvement of wrinkles and skin laxity of the neck and the medial aspect of the upper arms, and improvement of supraumbilical skin laxity in the abdomen (i.e., post-partum or after liposuction).

Body composition: Patients who are significantly underweight or overweight tend to have unsatisfactory responses to PLLA-SCA™. Ideally, patients should have a BMI < 30 kg/m$^2$.

Patient attitudes/expectations: Responses to PLLA-SCA™ seem to be slower in body areas compared with the face. Patients need to be aware that the peak effects of treatment are generally observed 8–9 months after the first session.

#### 4.1.2. Product Preparation and Treatment Protocol

Reconstitution: The reconstitution method is similar to that described for treatment of the face but the dilution with SWFI should achieve a volume of 17 + 1 mL of lidocaine 2% per vial.

Treatment: PLLA-SCA™ should be administered subcutaneously, and the injection techniques vary according to the sites and the desired effects. Cannulas (18–23 G) are used for most procedures, while needles (25 G or 26 G) can be used for cellulite treatment. Retrograde fanning and linear threading are the most frequently adopted techniques, with volumes of approximately 0.05–0.1 mL/cm$^2$ (or 0.1–0.2 mL/cm$^2$ for the gluteal area). Approximately 1 vial per area equivalent to a A4 page is generally needed for body areas. Treatment of the buttocks requires 2–4 vials/side, while half to 1 vial is usually sufficient for the neck. After treatment, patients should be advised to massage the treated area following the '5/5/5' rule (as explained for facial injections). The recommended treatment plan consists of 2–4 sessions 30–60 days apart, followed by maintenance treatment at 12–18 months' intervals.

Two examples of PLLA-SCA™ treatment in the gluteal region are illustrated in Figures 3 and 4.

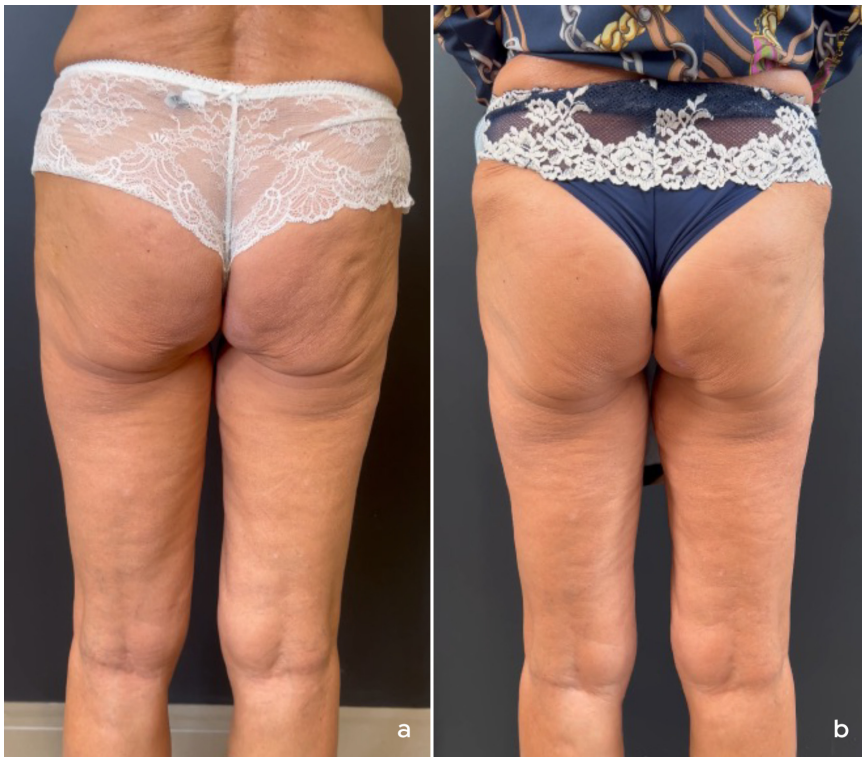


**Figure 3.** Improvement of skin laxity and texture of the gluteal area in a patient after 3 sessions of PLLA-SCA™ treatment (2 vials for each side per session): (**a**) at baseline; (**b**) at 6 months after starting treatment (Courtesy of Dr. Massimiliano Leporati, MD).

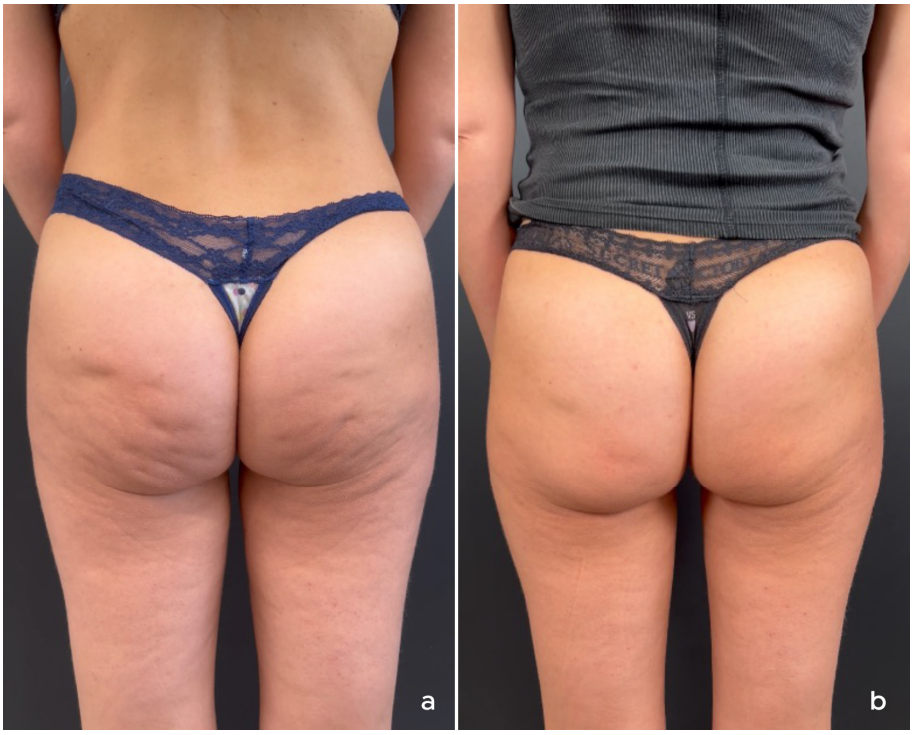


**Figure 4.** Correction of cellulite in the gluteal region of a patient after 2 sessions of PLLA-SCA™ treatment (2 vials for each side per session): (**a**) at baseline; (**b**) at 6 months after starting treatment (Courtesy of Dr. Massimiliano Leporati, MD).

## 5. Combination of PLLA-SCA™ with Other Aesthetic Treatments

In current practice, PLLA-SCA™ is often used in combination with other rejuvenation procedures such as hyaluronic acid (HA) fillers or skinboosters, neurotoxins, chemical peels and energy-based devices [21,23,43,44]. The different characteristics of PLLA-SCA™ and HA complement each other when the two treatments are used in combination. While the effects of PLLA-SCA™ are long lasting but not immediately visible, HA will achieve results that are noticeable immediately after treatment. Furthermore, HA fillers enable soft tissue augmentations that are site specific and localized, whereas PLLA-SCA™ biostimulatory activity involve broader areas. Importantly, HA can be used in the hyperdynamic and central areas of the face that are not suitable for PLLA-SCA™ [23]. Protocols for optimal use of combined treatment with PLLA-SCA™ and HA have been described by various experts' groups [44,45].

Overall, there is a lack of evidence-based information about optimal timing of combined procedures. When distinct facial areas are treated, PLLA-SCA™ and HA can be used in the same session. If two collagen-stimulating methods are used in the same areas of the face, European experts recommend a 4- to 6-week interval between treatments, while the interval can be shorter (1 week) if the other treatment has no biostimulatory activity on collagen [21]. Ablative laser treatments and PLLA-SCA™ should be spaced 3–4 months apart [21]. Neurotoxins are usually injected in the same session as PLLA-SCA™ [23]. Radiofrequency (RF) and high-intensity focused ultrasound (HIFU), both collagen stimulators, are often used in combination with PLLA-SCA™ to obtain amplified effects. Generally, PLLA-SCA™ injections are carried out 1 week to 1 month before RF, and 1 week before HIFU [23,43].

Although the results of combined treatments are promising, more evidence from larger-sized and controlled studies is needed about synergistic effects, optimal timing, overall efficacy and safety of specific treatment combinations.

*Authors' Recommendations for Treatment Combinations*

PLLA-SCA™ can be used in combination with HA fillers or boosters to obtain individualized treatment results in the face. PLLA-SCA™ and HA can be used in the same session when distinct facial areas are treated. If two collagen-stimulating methods are used in the same areas of the face, they should be spaced 4–6 weeks apart, while the interval can be shorter (1 week) if the other treatment has no biostimulatory activity on collagen.

In some authors' experience, PLLA-SCA™ plays an important role in tissue conditioning prior to thread lifting procedures in patients with poor skin quality. PLLA-SCA™-induced collagen formation could also enhance the anchoring strength of the barbs of thread, thus enabling improved results in facial soft tissues' support.

Neurotoxins can be injected in the same session as PLLA-SCA™, provided that different areas are treated. Ablative laser treatments and PLLA-SCA™ should be spaced 3–4 months apart.

If used in combination with RF or HIFU, PLLA-SCA™ treatment should be carried out 1 to 4 weeks before RF, while HIFU can be performed 1 week after PLLA-SCA™ injections.

## 6. Safety of PLLA-SCA™

The safety of PLLA-SCA™ is well established. Injection-site reactions, including transient bleeding, pain and bruising, generally resolve within 2–6 days. These reactions can occur with all injectables and are not specifically related to PLLA-SCA™ but to the administration technique. The adverse events more frequently associated with PLLA-SCA™ treatment are papules and nodules in the injection areas, which can develop early (3–6 weeks post-treatment) or have a delayed appearance (1–14 months post-treatment) and

may persist up to 2 years. However, their occurrence can be minimized by proper dilution and injection techniques [9,10]. In a US chart review of medical records of 1002 patients who had been treated with PLLA-SCA™ diluted to 7–10 mL (4483 treatments in total), nodules were reported by 0.4% of patients, and all resolved during follow-up [28]. In comparison, two previous studies in which dilution volumes of 3–5 mL were used reported an incidence of nodules of 5.7% and 6.9% [25,46].

The safety and efficacy of PLLA-SCA™ have not been investigated in patients with autoimmune diseases and it is controversial whether autoimmune diseases should or should not be considered a contraindication to the use of fillers and/or biostimulatory treatments [47–49]. When considering PLLA-SCA™ treatment in these patients, therefore, a very careful assessment on a case-by-case basis is absolutely essential.

*Authors' Recommendations for Safety*

To minimize the risk of formation of nodules, PLLA-SCA™ should be properly diluted with SWFI (suggested total volumes, including lidocaine, are 9 mL for the face and 18 mL for the body) and injected subcutaneously, massaging the area for a few minutes ('5/5/5' rule) after injection.

A full medical history of the patient (including skin conditions, systemic diseases, allergies, current medications, previous experiences with cosmetic procedures) should always be taken to minimize the risk of hypersensitivity reactions or other adverse outcomes. As specified in the package insert, PLLA-SCA™ should not be used in patients at increased risk of adverse outcomes, including those with a history of hypersensitivity to any of the products' constituents (including lidocaine), anaphylaxis or multiple severe allergies, patients with active disease (i.e., inflammation, infection or tumors) in or near the intended site of injection and patients with a history of keloid formation or hypertrophic scarring [10]. PLLA-SCA™ should not be used in pregnant or breastfeeding women, or in subjects aged < 18 years, since its safety in these populations has not been established. Active autoimmune diseases are a contraindication to the use of PLLA-SCA™. In patients with stable autoimmune diseases, the use of PLLA-SCA™ can be considered but a careful case-by-case assessment is needed.

The main recommendations for the use of PLLA-SCA™ are summarized in Table 1.

**Table 1.** Summary of recommendations for the use of PLLA-SCA™.

| Topic | Recommendations |
| --- | --- |
| **TREATMENT OF THE FACE** | PATIENT SELECTION<br>• Expect an attenuated collagen response in patients aged ≥ 60 years.<br>• Preferential use of PLLA-SCA™: improvement of skin laxity or sagging, correction of NLFs or cheek wrinkles, correction of mild losses of volume and improvement of skin texture.<br>• Clearly communicate advantages and limits of PLLA-SCA™ to patient, especially regarding delayed treatment effects.<br>PRODUCT PREPARATION/TREATMENT PROTOCOL<br>• Reconstitution of PLLA-SCA™ (with SWFI): final volume of 9 mL (including 1 mL of 2% lidocaine). Use immediately after preparation.<br>• Inject subdermally (22 G or 25 G cannulas). Massage area for a few minutes after injection (instructing patient to massage the area at home for the next few days).<br>• 2 or 3 treatment sessions 30–40 days apart usually sufficient for facial treatment.<br>• Yearly injections for maintenance recommended. |

**Table 1.** *Cont.*

| Topic | Recommendations |
| --- | --- |
| **TREATMENT OF NON-FACIAL BODY AREAS** | PATIENT SELECTION<br>• Preferential use of, PLLA-SCA™ for gluteal/thigh area: toning and firming, correction of cellulite and skin laxity, and volumetric augmentation of dip hip deformity of moderate entity.<br>• Other body areas that respond well to PLLA-SCA™: neck (correction of wrinkles and skin laxity), medial upper arms (correction of skin laxity) and abdomen (treatment of supraumbilical skin laxity).<br>• Underweight or overweight patients tend to have unsatisfactory responses.<br>• Inform patient of delayed treatment response to treatment (generally 8–9 months for peak effects). |
| | PRODUCT PREPARATION/TREATMENT PROTOCOL<br>• Reconstitution of PLLA-SCA™ (with SWFI): final volume of 18 mL (including 1 mL of 2% lidocaine). Use immediately after preparation.<br>• Both needles (25 G or 26 G) and cannulas (18–23 G) can be used. Mostly retrograde fanning and linear threading, with volumes of approximately 0.05–0.2 mL/$cm^2$.<br>• 2–4 treatment sessions 30–60 days apart usually required for body areas.<br>• Maintenance treatment at 12–18 months' intervals recommended. |
| **TREATMENT COMBINATIONS** | • PLLA-SCA™ and hyaluronic acid or neurotoxins can be used in the same session when distinct facial areas are treated.<br>• When using two collagen-stimulating methods in the same areas of the face, space 4–6 weeks apart.<br>• Traditional ablative laser treatments and PLLA-SCA™: space 3–4 months apart.<br>• PLLA-SCA™ treatment should be carried out 1 to 4 weeks before radiofrequency, 1 week before high-intensity focused ultrasound. |
| **SAFETY** | • A detailed medical history should always be taken.<br>• Contraindications to PLLA-SCA™: history of hypersensitivity to any of the products' constituents, anaphylaxis or multiple severe allergies, active disease (i.e., inflammation, infection or tumors) in or near the intended site of injection and a history of keloid formation or hypertrophic scarring.<br>• PLLA-SCA™ should not be used in pregnant or breastfeeding women, in patients aged < 18 years or in patients with active autoimmune diseases.<br>• Proper dilutions minimize the occurrence of nodules or papules.<br>• Always keep injections in the subdermal layer and aspirate before injecting to rule out intravascular placement. |

## 7. Limitations

This work has some limitations that should be acknowledged. First, the recommendations presented here are based on the collective analysis and discussion of a relatively small panel of six experts, and therefore cannot be considered fully representative of the broader community of clinicians using poly-L-lactic acid (PLLA). Second, the absence of a formal consensus methodology, such as a Delphi process, reflects the limited size of the panel and the exploratory nature of this effort. Despite these limitations, we believe that our paper could be a starting point that could stimulate further discussion and serve as the basis for a larger, methodologically rigorous, international consensus initiative.

## 8. Conclusions

Literature data and real-life experience have documented the safety and efficacy of PLLA-SCA™ treatment as a versatile tool to improve skin laxity and firmness in the

face and in multiple body areas. Since PLLA-SCA™ acts by stimulating the production of collagen, elastin, adipose tissue and other key components of the ECM through regenerative pathways, the cosmetic effects are gradual, natural looking and long lasting. Product handling, treatment protocols and indications for use of PLLA-SCA™ are continuously evolving and we have highlighted the treatment approach that, in our current experience, achieves the most satisfactory outcomes for the patient. However, we acknowledge that our recommendations are based on the experience of a small team of experts.

Further clinical trials are needed to gain insight into areas that are still unclear, such as combination of PLLA-SCA™ with other aesthetic procedures and changes in response to collagen stimulation related to age or other conditions, where modified treatment protocols may be required.

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