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Recommendations on the Use of Injectable Poly-L-Lactic Acid for Skin Laxity in Off-Face Areas

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ABSTRACT

Injectable poly-L-lactic acid (PLLA) is a biodegradable synthetic polymer that stimulates collagen production, leading to gradual volume restoration. The treatment of sagging skin in body areas is still a big challenge, as there are few aesthetic procedures aiming to improve it. This article provides recommendations on the use of PLLA in the treatment of skin laxity in off-face areas, as the neck, décolletage, arms, abdomen, buttocks, and thighs, including the patient selection, product preparation, and injection techniques. The use of PLLA is a promising method for the treatment of skin laxity in corporal areas, improving body contour and appearance. Further investigation is needed to better understand the efficacy and durability of PLLA in non-facial indications and to provide the best evidence for optimal patient outcomes.

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INTRODUCTION

Aesthetic treatments are becoming increasingly popular among patients, especially nonsurgical procedures.[1] According to statistics from the American Society of Facial Plastic Surgery (ASAPS), there was a 37.6% increase in the number of nonsurgical treatments from 2012 to 2017.[2] Rejuvenation of non- facial areas is becoming a frequent complaint in patients who recognize the disparity and stigma that arise between their treated face and their non-treated body areas.

The biochemical properties of the skin are determined by the epidermis, dermal collagen and elastin network and subdermal composition.[3,4] The capacity to synthesize collagen is lower in sun exposed and aged skin than in healthy, young skin. Fibroblasts in severely damaged skin (either photoaged, naturally aged, or both) experience a loss of mechanical tension as a result of decreased interaction with intact collagen, which in turn leads to a diminished production of skin macromolecules.[5,6]

The body mass index (BMI) of the patient, which may be used as an indicator for tissue composition, has a negative correlation with skin firmness and thickness, and a positive correlation with energy absorption.[4] When patients present with body sculpting concerns, most often there is both a component of fat excess and skin laxity, with a decrease in neocollagenesis at fibrous septae and fascial planes level that accounts for changes that bother them.[1] It is important to perform a correct diagnosis of the involved components in order to select the best candidates for PLLA treatments.

As we age, the cellular turnover rate declines, and skin structure begins to deteriorate. Age-related skin changes include:

1) Increase in the disorderly arrangement of the collagen fiber network[7]
2) Decrease in the quantity of fibroblasts[8]
3) Decline in collagen production by fibroblasts[8]
4) Increase in matrix metalloproteinases levels, the primary enzymes responsible for degradation of collagen fibers[8]
5) Decreased metabolic activity of the skin[9]
6) Massive elastosis or deposition of abnormal elastin fibers, exaggerated microvasculature, and collagen degeneration[9]

These damaging events promote atrophy of the dermal layer. The biochemical properties of the skin degenerate, leading to loss in flexibility and more pronounced skin laxity. Skin viscoelasticity is further diminished by a decrease in glycosaminoglycan concentration in the dermal layer.10

Evaluating skin laxity is still a challenge. Objective and subjective measures are often combined in most studies. Objective assessments may include digital photographs and 3-dimensional imaging, allowing surface shape to be precisely captured, giving quantitative volume measurements. Subjectively, the degree of satisfaction is often asked.[11] The Pittsburgh Rating Scale[11] is a validated tool for assessment of contour deformities after bariatric weight loss and can be applied in preoperative planning or to evaluate surgical outcomes. However, there is still a lack of standardization for accurate body laxity classification in each specific area.

This article provides recommendations for the best use of PLLA in neck, décolletage, arms, abdomen, buttocks and thighs, including handling and reconstitution, treatment recommendations and injection techniques according to the experience of eleven specialists in the clinical use of PLLA for body skin laxity.

PLLA Mechanism of Action

Injectable soft-tissue augmentation agents have become popular alternatives to face and body rejuvenation. In contrast to temporary, space-occupying replacement fillers such as collagen-based and hyaluronic acid products, PLLA has been demonstrated to gradually promote deposition of collagen via a biostimulatory response, with therapeutic effects lasting approximately two years.[12]

Originally developed and marketed in Europe as New-fill®, PLLA has been successfully recruited for aesthetic indications since 1999, in over 150,000 clinical cases in more than 30 countries.[13] In 2004, the FDA approved its use for rejuvenation of facial contours secondary to lipoatrophy associated with antiretroviral therapy for HIV infection, marketed as Sculptra®.13 By 2009, PLLA was FDA-approved for the correction of nasolabial fold deficiencies and other lines and wrinkles.[12] However, there are promising results for the use of PLLA for non-facial volumization as well, including the neck, décolletage, arms, abdomen, buttocks, and thighs.[12,13] Although the published experience is limited, preliminary data and expanding clinical knowledge suggest that PLLA is a versatile option for treating skin laxity and contour deficiencies of many non-facial areas.[14]

PLLA is a synthetic polymer of lactic acid derived from the alpha-hydroxy-acid family, biocompatible and biodegradable that has been used in medicine for more than three decades. The diameter of the microparticles is tightly controlled, measuring 40 µm to 63 µm on average.[15,16] The product is considered a deep tissue regenerator, providing soft-tissue augmentation through fibroblast stimulation. In contrast to temporary, space occupying replacement fillers such as hyaluronic acid, PLLA has been shown to exert biologic activity by stimulating neocollagenesis.[12] Once injected, PLLA induces local and subclinical inflammatory response shortly after application, recruiting monocytes, macrophages, and fibroblasts. It is then hydrolysed into lactic acid monomers and eliminated; nonetheless, an increased deposition of collagen produced by fibroblasts remains, with the resulting increase in dermal thickness.[17] The results persist for 18-24 months, with some reports stating that effects can last up to 3 years.[12] Over a period of several months, the particles are degraded into lactate, and exhaled as carbon dioxide. Given that the PLLA mechanism of action induces a local and gradual reaction that can lead to recovery of the hypodermis and collagen network that were lost during the aging process, the hypothesis of its use for the treatment of skin sagging in off-face areas was raised.[17,18]

General Recommendations for Treatment with PLLA

Pre-treatment preparation is important to minimize risks and unwanted side effects. Patients must be properly informed to ensure that their expectations are realistic. Written informed consent must always be obtained, as well as pre-treatment photographs. A complete medical history is always necessary, including information about any past experience with cosmetic treatments, use of anticoagulants, history of recurrent herpes simplex, and presence of inflammatory processes (eg, upper airways, sinus, dental or any structure related to the area to be treated) or autoimmune diseases. It should also cover allergic or hypersensitivity reactions to any substance, including anaesthetics.[19]

Patients should be instructed not to take any medication that might increase the risk of bleeding from 10 to 14 days prior to treatment. Pictures, diameter measures, BMI (body mass index) and weight are important parameters to be assessed.[19]

In general, two to three sessions of PLLA injections are required to reach the desired outcome, depending on the particularities of each patient: area treated, degree of volume loss, and aging.

The strategy is to carry out the subsequent session 4 to 6 weeks after the initial injection, as in our experience the onset of the results in off-face areas occurs later than in facial treatments.19

It is important to note that injectable PLLA is a polymeric device containing microparticles of PLLA with carboxymethylcellulose and mannitol, which must be reconstituted with 7 to 8 mL of sterile water for injection.[20] The vial should be left hydrating for 24 to 72 hours before use.[21] Topical anaesthetics can be used depending on the pain threshold of the patient. For off-face areas, the product should be injected in the superficial

subcutaneous plane, avoiding superficial injection.[21,22] It should be noticed that the instructions for use may vary in different countries.

In order to reduce pain and distress, topical anaesthetics and/or incorporation of 1 to 2 mL of lidocaine into the product have been used. Studies and authors' experience have shown that incorporation of lidocaine into the product significantly reduces pain and discomfort.[23,24]

One of the dilemmas about the addition of lidocaine solution is the possibility of patients presenting an allergic reaction to lidocaine. However, reactions to amide anaesthetics, including lidocaine, are rare. The incidence of true immunoglobulin E-mediated lidocaine allergy remains uncertain and is presumed to be very low.[23,24]

After treatment with injectable PLLA, massage is an integral component of the injection procedure and post-treatment care.[13] Physicians should massage the treated area immediately after injection to evenly distribute the product, during approximately five minutes to assure proper dispersion, optimize results and avoid nodule formation.[13,24] According to Ballin et al,[24] treatment sessions should be scheduled four to six weeks apart so that adequate time elapses to observe volume enhancement and three treatment sessions are often required to reach full correction. Patients may apply topical products a few hours after treatment.[25]

Regarding the longevity of PLLA, a review of the literature focused on patient satisfaction and effect duration by Palm and Goldman[26] concluded a longevity of at least two years following injection and high patient satisfaction, especially with continued treatment.

Recommendations for Nonfacial Use of PLLA

In 2017, eleven dermatologists with wide experience using PLLA discussed the best practices for injectable use of PLLA in body skin laxity. This paper presents treatment recommendations for PLLA in non-facial areas, including patient selection, product preparation and injection techniques in regions such as neck, décolletage, arms, abdomen, buttocks, and thighs.

According to the clinical practice of the authors, fewer patients search for aesthetic body treatments in comparison to facial rejuvenation. The most frequent complaints for non-facial areas are: skin sagging, cellulite, localized fat, stretch marks, scars and décolletage/neck wrinkles.

The experts consider that the volume of PLLA to be applied and the number of sessions needed vary according to age and degree of sagging. The best outcomes are seen in patients younger than 60 years old, as treatment response tends to be lower with age advance.

The product can be used alone or combined with another techniques (eg, radiofrequency) to achieve optimal outcomes in the treatment of sagging skin.

The authors also consider that clinicians should ensure that their patients understand the benefits of the treatment with PLLA, and that they should be attentive to other factors involved in the aesthetic appearance of body areas such as body mass index, localized fat, muscular tone, and gradual response to treatment.

PLLA in Sagging Body Skin: General Recommendations

According to the authors, PLLA (Sculptra®) can be indicated for treatment of skin laxity, localized atrophy after liposuction, as well as old stretch marks and cellulite associated with sagging. The use of PLLA in breasts, calves and genitals is not recommended, as safety and efficacy data and experience in the treatment of these areas are unavailable.

Before the treatment, it is important to consider the following aspects that could interfere with the outcome: skin quality; lifestyle, as sun exposure and diet restrictions could lead to lower responses, more sessions or need of higher total volume and nutritional supplementation; and menopause, which could potentially decrease collagen production and require a higher number of treatment sessions.

The authors experience is reconstituting the Sculptra® vial with 8 mL of sterile water for injection (SWFI) with hydration time between 24 and 72 hours. Just before injection, 2 mL of lidocaine 2% and 6 mL of SWFI are added to the suspension, giving a final dilution of 16 mL. An easy way to carry this out is using a 20 mL syringe to aspirate the 8 mL of the suspension from the vial, 2 mL of lidocaine and 6 mL of SWFI. With the help of a sterile connector, transfer the content to smaller syringes (1 or 3 mL) to perform the injections. Usually, the authors use 1 vial of PLLA per area equivalent to a A4 page for all non-facial areas per session.

Massaging the injected area for a few minutes immediately after injection is recommended. The patients are instructed to massage the region 2 times a day for 7 days as post-treatment care. Another post-treatment recommendation includes avoiding physical activity in the first 24 hours and sun exposure in case of bruising.

For skin tightening, 2 to 4 sessions of PLLA injection are usually recommended, with intervals between 30 to 60 days. In most cases the first results appear after 30 days.

For treatment maintenance, an additional session every 12 to

18 months is recommended, depending on the degree of laxity. Table 1 presents the general recommendations and treatment plan for use of PLLA (Sculptra®) in nonfacial areas.

PLLA in the Treatment of Skin Laxity in Off-Face Areas: Practical Recommendations for Injections

Photographic documentation throughout the process is very important, given its gradual results over several months. The patient should be photographed in different positions and the areas to be treated should be marked in the standing position. Skin antisepsis with 2% alcoholic chlorhexidine is recommended. Topical anaesthetics should be applied 30 minutes before injection.

According to our experience, injection of 0.05 to 0.1 mL of this final volume of Sculptra® per cm^2 in the subcutaneous plane is recommended. Superficial injection must be avoided. The areas can be treated with linear threading using a 26½ G needle (fanning or cross-hatching techniques) or fanning technique with a 22–23G 50 mm cannula, which has the advantage of fewer needle sticks. Caution is required to avoid multiple deposits at the apex of the fan entry point.

Detailed recommendations for PLLA injection techniques to treat skin sagging in different body areas are discussed below. TABLE 2 summarizes these recommendations.

In the neck, the treatment area should be extended close to the clavicle for better results, as shown in Figure 1. Regarding injection technique, 0.05–0.1 mL/cm^2 can be applied with cannula or needle in fanning or linear threading.

Décolletage injections can be applied with 0.05–0.1 mL/cm^2 with cannula or needle, in fanning or linear threading, as show in Figure 2.

For arm treatment, selecting patients whose skin laxity is more prominent than the fat component is important, and the best outcomes are achieved when the whole circumference is treated, as observed in Figure 3. Regarding injection technique, 0.05–0.1 mL/cm^2 can be applied with cannula or needle in fanning or linear threading, as show in Figure 4.

In the abdominal area, injections should be placed radially around the umbilicus, using 0.05–0.1 mL/cm^2 in fanning or short linear threading technique with cannula or needle (Figure 5). Figure 6 and 7 present results of PLLA application in patients with sagging skin in the abdominal region.

In the gluteal region, the product should be applied preferentially in the superior and lateral quadrants of the buttocks, to

TABLE 1.

General Recommendations for Use of PLLA (Sculptra®) in Nonfacial Areas	
PLLA in off-face indications	
Skin laxity, localized atrophy after liposuction, old stretch marks or cellulite associated with flaccidity	
PLLA not recommended in the following areas	
Breasts, calves and genitals	
Predictive positive factors for treatment	
Younger than 60 years old	
Balanced diet	
Body Mass Index up to 25	
Non-smoker	
Moderate and regular physical activity	
Absence of localized fat in the area to be treated	
Reconstitution/Dilution	
Diluent Volume	8 mL of sterile water for injection (SWFI)
Hydration Time	24-72 hours
Final Injection Volume	16 mL
Treatment plan	
PLLA quantity	Approximately 1 vial per area equivalent to a A4 page
Number of sessions	2-4 sessions
Interval	30-60 days
Maintenance	Every 12-18 months
Post-injection recommendations	
Massage	If bruising occurs, avoid physical activity and sun exposure in the first 24h

TABLE 2.

Recommendations on the Use of PLLA (Sculptra®) in Off-face Areas				
Neck	0.05-0.1 mL*/cm^2	Cannula or needle	Fanning or linear threading	Treat also the supraclavicular area
Décolletage	0.05-0.1 mL*/cm^2	Cannula or needle	Fanning or linear threading	--
Arms	0.05-0.1mL*/cm^2	Cannula or needle	Fanning or linear threading	Treat the whole circumference
Abdomen	0.05-0.1mL*/cm^2	Cannula or needle	Fanning or short linear threading	--
Buttocks	0.05-0.1mL*/cm^2	Cannula or needle	Fanning or linear threading	--
Thighs	0.05-0.1mL*/cm^2	Cannula or needle	Fanning or linear threading	Treat completely

*Final Sculptra® volume: 16 mL

FIGURE 1. Linear threading technique for application of PLLA in the neck with needle (A) or fanning with cannula (B).

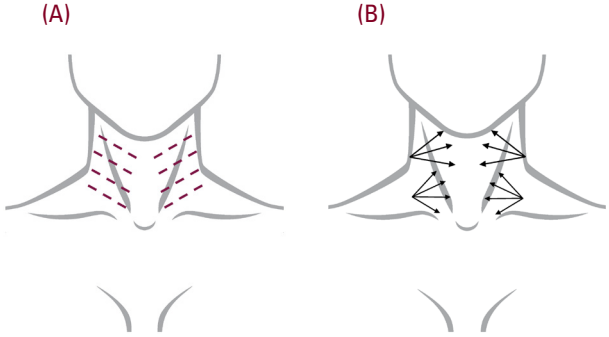


FIGURE 2. Techniques for application of PLLA on the décolletage in linear (A) or fanning (B) threading.

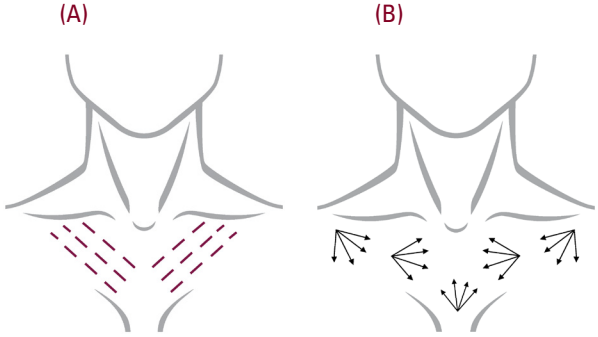


FIGURE 3. Arms of a 72-year-old woman before (A) and 3 months after (B) 2 monthly sessions (1 vial per session) of PLLA (Sculptra®). Note the improved appearance of the skin. *Courtesy of Juliana Sarubi, MD.*

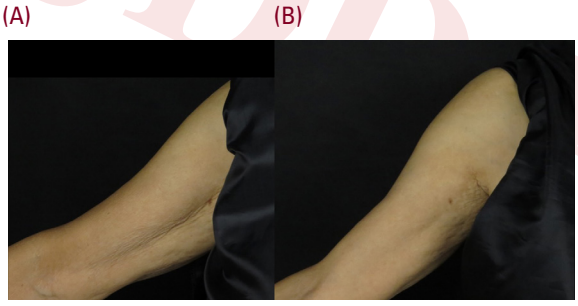


FIGURE 4. Techniques for application of PLLA on the arms in linear (A) or fanning (B) threading.

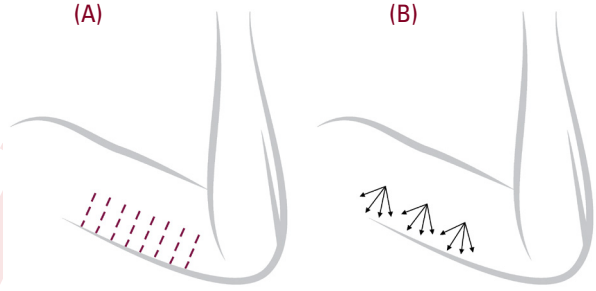


FIGURE 5. Techniques for application of PLLA in the abdominal area in short linear (A) or fanning (B) threading.

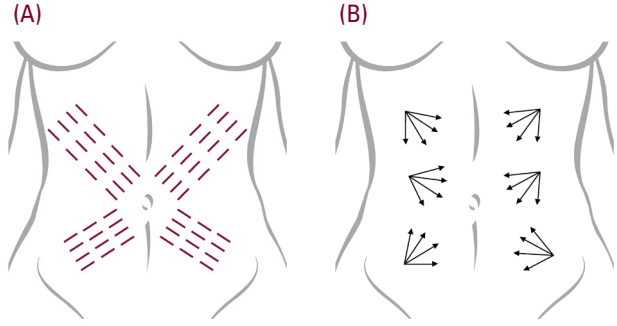


FIGURE 6. Abdomen of a 43-year-old woman, with localized lipoatrophy post liposuction and skin laxity, before (A) and 45 days after (B) the injection of 1 vial of PLLA (Sculptra®). *Courtesy of Rosemarie Mazzuco, MD.*

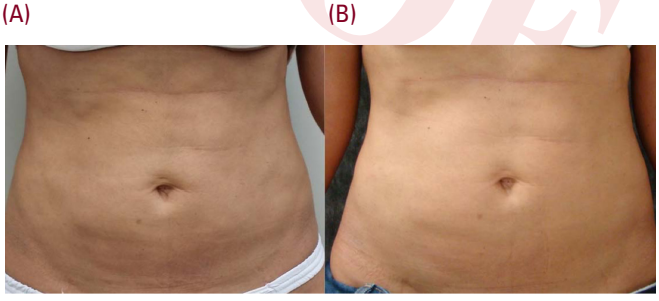


FIGURE 7. Abdomen of a 59-year-old woman before (A) and 4 months after (B) 3 monthly sessions (1 vial per session) of PLLA (Sculptra®). Improvement of the skin laxity. *Courtesy of Juliana Sarubi, MD.*

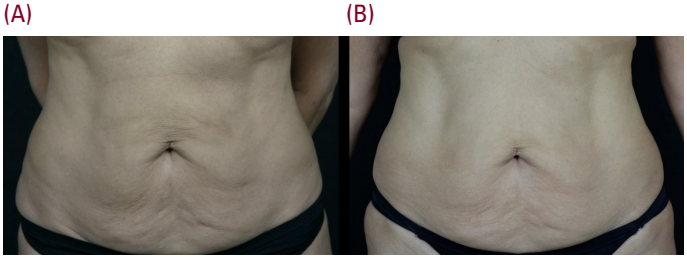


FIGURE 8. Techniques for application of PLLA on the buttocks in linear threading (A) or fanning (B).

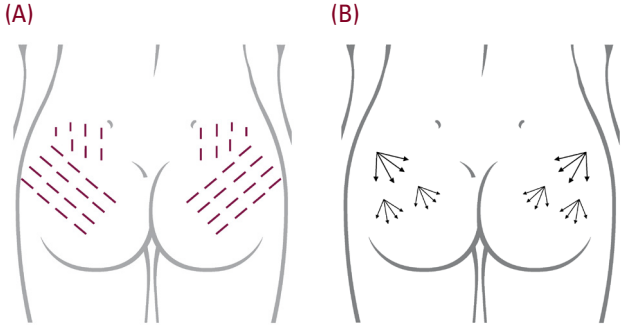


FIGURE 9. Buttocks of woman before (A and C) and 3 months after (B and D) the first treatment. Two treatment sessions with PLLA (Sculptra®) were carried out, with 1 vial per session. Notice the improved appearance of skin laxity, stretch marks and cellulite. *Courtesy of Marisa Gonzaga, MD.*

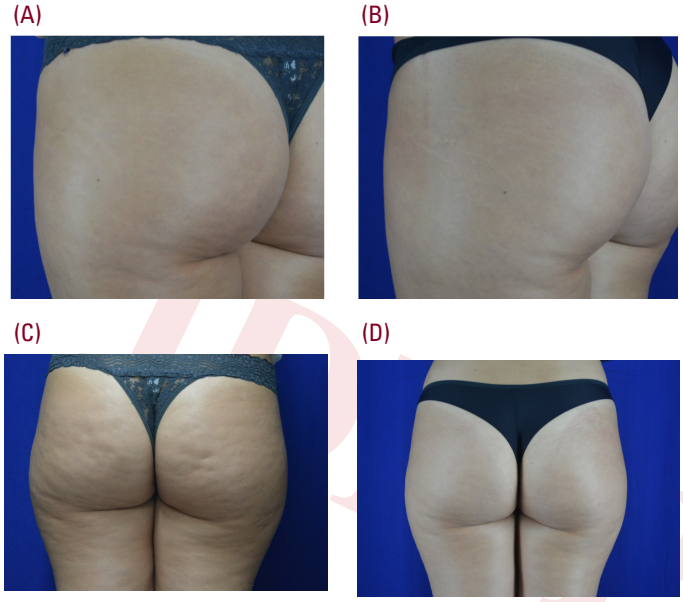
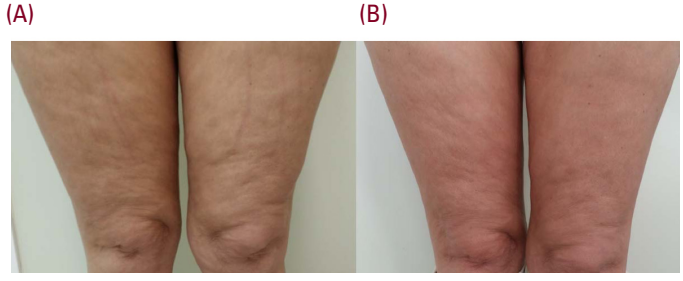


FIGURE 11. Thighs of a 49-year-old woman with skin laxity and cellulitis before (A) and 2 months after (B) 1 session with 1.5 vial of PLLA (Sculptra®). *Courtesy of Rosemarie Mazzuco, MD.*



favour lifting effect and contour improvement. Regarding techniques, 0.05–0.1 mL/cm² can be applied with needle or cannula in fanning or linear threading (Figure 8). Stretch marks and cellulite associated with sagging can be reduced with application of PLLA as show in Figures 9 and 10.

Figure 8: Techniques for application of PLLA on the buttocks in linear threading (A) or fanning (B).

Anterior and medial regions of the thighs should be treated to achieve the best results (Figure 11). Regarding injection technique, 0.05–0.1 mL/cm² of PLLA can be applied with cannula or needle, in fanning or linear threading, as show in Figure 12.

FIGURE 10. 34-year-old woman before (A) and after (B) treatment at rest and with gluteal contraction, before (C) and 4 months after (D) 3 monthly sessions (1 vial per session) with PLLA (Sculptra®). *Courtesy of Juliana Sarubi, MD.*

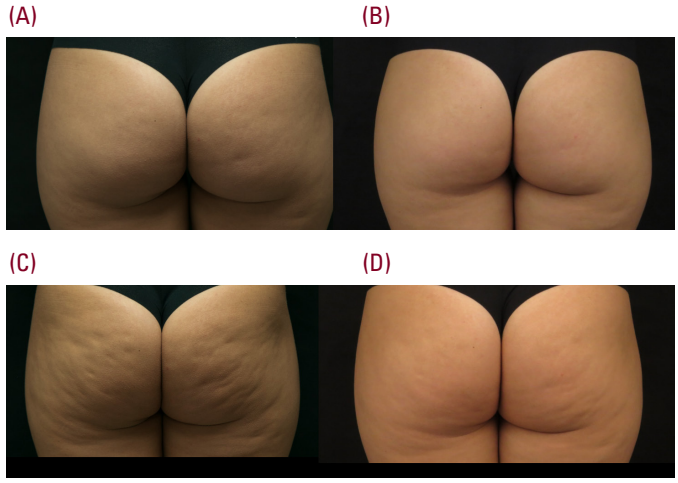
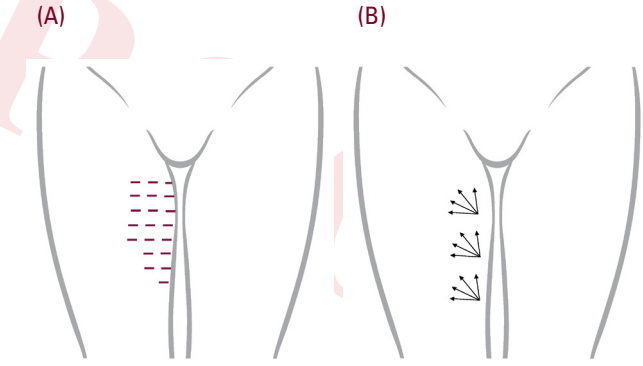


FIGURE 12. Techniques for application of PLLA in the thighs in linear threading (A) or fanning (B).



CONCLUSION

Preliminary data and evolving clinical experience have demonstrated that Sculptra® (PLLA) is a versatile option for treating skin laxity in different areas of the body due to its unique mechanism of action, gradually promoting collagen deposition via a biostimulatory response. In our experience, Sculptra® provides efficient and safe results, improving skin firmness and appearance. Further prospective clinical studies are needed to provide data on its duration when used in body areas and deepen our understanding of this promising and exciting treatment.

DISCLOSURES

Dr Cazerta is a former employee of Galderma Brasil and is a advisor for Galderma Brasil. Dr Kamamoto is a medical consultant of Galderma. Drs Haddad, Guarnieri, Sarubi, Avelar, Del Nero, Cunha, Mazzuco, Menezes, Coimbra, and Ribeiro have been speakers and advisors for Galderma Brazil.

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