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Consensus Recommendations on the Use of Injectable Poly-L-Lactic Acid for Facial and Nonfacial Volumization

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ABSTRACT

Poly-L-lactic acid (PLLA) was approved for use in Europe in 1999. In the United States, it was approved by the Food and Drug Administration in 2004 for the treatment of facial lipoatrophy associated with human immunodeficiency virus, and in 2009 for cosmetic indications in immune-competent patients. The need for consistent, effective PLLA usage recommendations is heightened by an increased consumer demand for soft tissue augmentation and a shift toward a younger demographic. Over the past 14 years, considerable experience has been gained with this agent, and we have come to better understand the clinical, technical, and mechanistic aspects of PLLA use that need to be considered to optimize patient outcomes. These consensus recommendations regarding patient selection, proper preparation and storage, optimal injection techniques, and other practical considerations reflect the body of evidence in the medical literature, as well as the collective experience of this author group.

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INTRODUCTION

Poly-L-lactic acid (PLLA) was approved for use in Europe in 1999. In the United States, it was approved by the Food and Drug Administration in 2004 for the treatment of facial lipoatrophy associated with human immunodeficiency virus (HIV),[1] and in 2009 for cosmetic indications in immune-competent patients.[2] Over the past 14 years, considerable experience has been gained with PLLA; and its safe and effective use has been well documented.[3-24]

The need for consistent, effective usage recommendations is heightened by an increased consumer demand for soft tissue augmentation, and a shift toward a younger demographic that may have a lower tolerability for adverse events.[25,26] The demonstrated preference of patients for gradual, long-lasting effects[27,28] is well matched to the mechanism of action of PLLA,[7,29-31] which provides distinct clinical advantages over other available options, including cosmetic benefits lasting 2 years or more.[1,29]

Our detailed review of the literature reveals that most of the early problems encountered with PLLA resulted from suboptimal methodology, including inadequate reconstitution volumes, short hydration times, injection of large volumes of highly concentrated product with short intervals between treatments, and injection into the dermis and in locations that were not optimally chosen vis-à-vis its mechanism of action.[5,6,9,12,18,32] As clinical experience has grown, we have come to better understand the technical and mechanistic aspects of PLLA use that need to be considered to optimize patient outcomes (Table 1). With this enhanced understanding, PLLA utilization can now achieve predictable cosmetic benefits that are completely controlled by the treating clinician.

The consensus recommendations that follow reflect the body of evidence in the medical literature, as well as the collective experience of this author group, each of whom have more than a decade of experience in the clinical utilization of PLLA.

Patient Selection

As with all cosmetic procedures, it is important that there be clear communication between physician and patient (Table 1). In addition, patients should be well matched to the mechanism of action and clinical effects of the treatment.

- Patients should have realistic treatment goals, be educated on aging-associated volume loss and the gradual nature of PLLA cosmetic benefits, and understand the need for multiple treatment sessions and periodic maintenance for an enduring effect.
- Experience with facial augmentation has taught us that patients with very empty faces or those with a very elastotic outer skin envelope may be challenging to volumize, requiring a substantial amount of product, any product, to achieve a desirable result. This should be expected in this patient population and discussed prior to any filler treatment to prevent unnecessary frustration on the part of both the patient and the physician.
- Patients are starting cosmetic treatments earlier than they have traditionally done. The 2012 American Society of Plastic Surgeons statistics revealed that 66% of cosmetic patients are now between the ages of 30 and 54, while only 26% are age 55 or older. This younger group often needs less product and fewer treatment sessions than the older group, and is gratifying to treat.[33]
- Patients with permanent fillers, or active auto-immune or connective tissue disease (eg, multiple sclerosis, lupus) may be less predictable hosts.
- Active granulomatous disease should be considered a contraindication to PLLA use.

Poly-L-Lactic Acid Preparation and Storage

Recommendations on the preparation and storage of PLLA focus on ensuring complete and homogenous dispersion and hydration of PLLA in sterile water for injection (SWFI) or bacteriostatic water, in a volume that facilitates injection (Table 2).

- Reconstitution/Dilution
  - Prior to reconstitution, tap the vial to ensure there is no powder sticking to the top of the vial or rubber stopper.
  - Use an antiseptic to clean the rubber stopper.
  - Add 7–8 mL SWFI or bacteriostatic water slowly to the powder.
    - Dilution in this volume range leads to:
      - Even PLLA distribution.
      - Easier injection, with reduced risk of needle blockage.
      - Decreased incidence of papules and nodules.
- Hydration
  - Hydrate at room temperature for ≥24 hours.
    - Adequate powder hydration allows the avoidance of injecting dry PLLA microclumps, which will hydrate in vivo and potentially lead to nodule formation.
  - Do NOT shake the vial during hydration.
    - Shaking can result in the deposition of dry PLLA clumps on the vial wall.
- Storage of reconstituted PLLA
  - Prior to use, reconstituted PLLA can be stored for up to:
    - 48 hours at room temperature.
    - 3–4 weeks in a refrigerator (4°C) [with bacteriostatic water]

Final Poly-L-Lactic Acid Preparation

Final steps prior to injection should ensure a hygienic approach and a smooth injection process.

- Patient/Clinician (Table 1)
  - Patients should wash their face with soap and water.
  - The clinician should wipe the areas for injection with chlorhexidine/alcohol immediately prior to injection to reduce risk of infection or biofilm formation.
- PLLA preparation
  - Warm the PLLA solution to room temperature (if stored at 4°C).
  - Dilute to final injection volume.
    - For facial injections, a final dilution of 9 mL is recommended, and may be achieved by the addition of 1–2 mL lidocaine (with or without epinephrine).
    - For décolletage injections, a final dilution of 11–16 mL is recommended, and may be achieved by further dilution with addition al SWFI or bacteriostatic water and 1–2 mL lidocaine (with or without epinephrine).
  - Ensure product is evenly suspended by slowly rolling the vial; do not shake. Shaking can create foam, which may clog the needle.

Poly-L-Lactic Acid Injection and Aftercare

Key factors in the utilization of PLLA include site selection (Table 1); injection depth, quantity, and frequency; and aftercare, as well as other practical considerations (Table 3).

Injection Site Selection

Injection sites associated with the most favorable outcomes are dynamically stable, with sufficient dermal thickness to allow a proper depth of injection.

TABLE 1.

Optimizing Results With Poly-L-Lactic Acid

Category	Tip
Patient Interactions	• Reinforce the goals of PLLA use (eg, deep, global volumization), as compared with other treatments. • Use diagrams to demonstrate expected cosmetic changes. • Calibrate expectations regarding the gradual nature of the cosmetic enhancement. • Document cosmetic changes with photographs (at baseline and each subsequent visit).
Product Handling	• Warm PLLA to body temperature before injection to facilitate injection. • Avoid agitation immediately prior to injection to decrease risk of clogging. • If foaming is an issue, remove the rubber stopper and slowly draw product out of the vial.
Injection Techniques	• Understand facial anatomy to avoid injection in or too close to blood vessels. • Apply a thin, uniform coating to entire surface of the treatment region. • Treat, wait, and assess; avoid over-application within a single session to decrease risk of overcorrection.

PLLA, poly-L-lactic acid

TABLE 2.

Poly-L-Lactic Acid Preparation and Storage

Step	Recommendations
Reconstitution/Dilution	• Ensure there is no powder sticking to the top of the vial or rubber stopper. • Use an antiseptic to clean the rubber stopper. • Slowly add 7–8 mL sterile water for injection or bacteriostatic water.
Hydration	• Hydrate at room temperature for ≥24 hours. • Do NOT shake the vial during hydration.
Storage of Reconstituted Poly-L-Lactic Acid	• 48 hours at room temperature. • 3–4 weeks in a refrigerator (4°C).
Final Injection Volume for Facial Treatment	• 9 mL, achieved by the addition of 1–2 mL lidocaine (with or without epinephrine) immediately prior to injection.
Final Injection Volume for Décolletage Treatment	• 11–16 mL, achieved by further dilution with additional SWFI or bacteriostatic water and 1–2 mL lidocaine (with or without epinephrine) immediately prior to injection.

SWFI, sterile water for injection.

TABLE 3.

Practical Considerations for Poly-L-Lactic Acid Injection

- The viscosity of PLLA is very low compared with hyaluronic acid gel; therefore, caution should be exercised to avoid inadvertent overcorrection.
- A 25-gauge, 1.5-inch needle is recommended for PLLA injection; the syringe needle should be primed prior to injection.
  - o A 22-gauge, 50-mm cannula may also be considered.
- Excessive foam in the syringe may lead to needle clogging; this may be addressed by removing the needle from the syringe and pushing the plunger until the foam is expelled through the syringe hub. A new needle can then be attached.
- Any product remaining after a patient's session should be discarded.

PLLA, poly-L-lactic acid.

- The authors have achieved optimal results in the following areas:
  - Temporal fossa
  - Malar/submalar areas
  - Chin and mandible
  - Décolletage
- Potentially problematic areas include:
  - Areas of hyperdynamic muscle movement (eg, perioral and periocular regions)
    - This may lead to microparticle clumping, localized overcorrection, and nodules/papules.
  - Neck and hands
    - The thin skin in these areas requires superficial injections, increasing the possibility of nodule and papule formation.

Injection Techniques

Favorable injection techniques allow slow, safe, uniform dispersion of PLLA at the proper depth for optimal cosmetic benefit.

General considerations include:

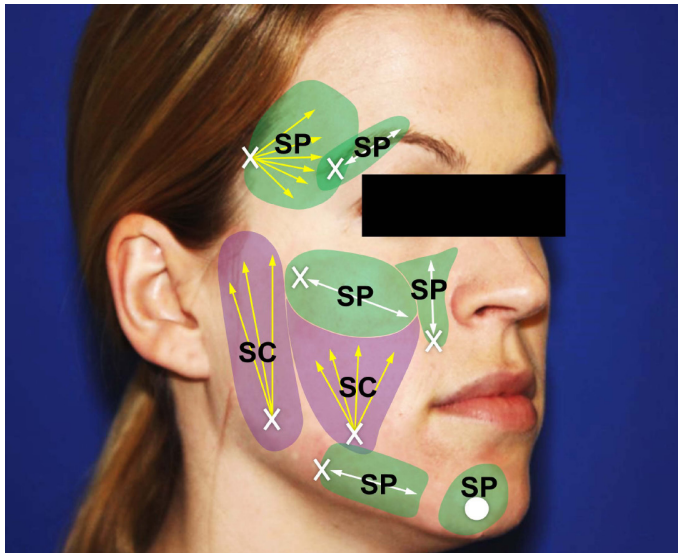
- Injection should be into the subcutaneous or supraperiosteal plane.
  - Superficial injection (ie, into the dermis) should be avoided, as this may lead to visible neocollagenesis.
- A reflux maneuver should be performed routinely to eliminate any risk of inadvertent intravascular injection.
- Injection should be performed slowly.
- If the needle clogs, it should be removed and the foam pushed out of the syringe hub. A new needle should then be affixed and primed prior to injection.
- Injection technique can generally be selected based on the experience and comfort level of the clinician, with consideration given to the anatomic area being treated (see below).
  - A cross-hatch pattern should be considered, especially while becoming familiar with PLLA.
  - With more experience, fanning, cross-fanning, and depot approaches are also commonly utilized.
    - Fanning has the advantage of fewer needle sticks; however, vigilance is required to avoid multiple deposits at the apex of the fan.

Site-specific recommendations on the injection of PLLA for facial soft tissue augmentation include (Figure 1)[34]:

- Medial cheek/Mid-face
  - Inject supraperiosteally over the zygoma, maxilla, and canine fossa/pyriform aperture.
  - Inject into the deep subcutaneous plane in the submalar/mid-cheek, where bony background is absent.
- Lateral face
  - Inject in the superficial subcutaneous fat above the parotid gland and masseter muscle.

FIGURE 1. Site-specific recommendations for the injection of poly-L-lactic acid (PLLA).[34]

- Potential areas amenable to correction with PLLA are indicated on this model. Recommended points of entry for each anatomic site are marked with a white X.
- Injectable PLLA should be placed supraperiosteally in the temples, lateral brow, zygomatic area, maxillary area, mandibular area, and mental area (green areas marked with "SP").
- Injectable PLLA should be placed in the subcutaneous fat in the mid-cheek regions and preauricular area (purple areas marked with "SC").
- Depending on the anatomic area, recommended techniques include fanning (yellow arrows), retrograde linear threading (white arrows), or depot (white circle) injection.



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- Mandible/Chin
  - Inject supraperiosteally over the menton, pre-jowl sulcus, and antegonial notch
- Temporal fossa/Lateral brow
  - Inject supraperiosteally at the origin of the temporal muscle.
  - Inject supraperiosteally at the tail of the brow.
- Periorbital supraperiosteal injections approached through the orbicularis oculi muscle should be avoided.
  - This approach may lead to papule formation, perhaps resulting from extrusion of PLLA along the needle tract during muscular contraction.

Injection Quantity and Frequency

- The amount of surface area to be treated is the sole determinant of the amount of PLLA used during a session.
  - The vast majority (~98%) of patients should receive 1-2 vials per session if treating the whole face (0.5–1 vial per side).
    - Up to 3 vials may be required for a patient requiring treatment over a very large surface area.

- A uniform distribution of product should be ensured for each treated region (ie, coat the region); injection should not vary by particular focal areas or based on specific cosmetic deficits.
- The final volumetric correction is determined by the number of treatment sessions.
- Treatment can continue until the patient is satisfied with the results.
    - Most experts find 3–5 sessions to be optimal.
    - Younger or fuller faces need less product and fewer sessions.
- An interval of at least 4 weeks between sessions is recommended.
- Subsequent courses of treatment (ie, "top-up" courses) typically occur 2 years after the initial course.
    - During these courses, less PLLA per session, and a fewer number of sessions, are generally required.
    - Some patients prefer once-a-year, single-session maintenance treatments to keep pace with the aging process.

Post-treatment Massage

- Although data to support post-treatment massage are limited, massaging the injected area for a few minutes after treatment is recommended.
- Continued self-massage by patients may be left to the discretion of the treating physician.

"As clinical experience has grown, we have come to better understand the technical and mechanistic aspects of poly-L-lactic acid use that need to be considered to optimize patient outcomes."

SUMMARY

These recommendations are consistent with the authors' perspectives on "best practices" with the use of PLLA for soft tissue augmentation. It is our hope that these recommendations will both increase clinicians' confidence in the use of this agent and lead to predictable, consistent, and favorable outcomes across the range of patients seeking cosmetic enhancement.

Facial Volumization With Poly-L-Lactic Acid: Representative Results

Due to an increasing societal emphasis on the importance of a youthful appearance, as well as the development of new treatment options, there is a rising consumer demand for procedures that can reverse the signs of aging. For many patients with facial volume loss, poly-L-lactic acid (PLLA) is an excellent treatment choice. Its mechanism of action results in cosmetic effects that have a gradual onset and last 2 years or more, which is well-matched with reported patient preference for durable benefits. Refined PLLA methodology, along with a better understanding of the structures in the aging face and how they interrelate, now allows for favorable and predictable results across a range of patient types.[31]

In the above consensus recommendations, we detail procedures for the proper administration and aftercare of PLLA including: careful patient selection and education, proper preparation and storage, optimal injection techniques, and after-injection massage. Here, we provide some representative before-and-after photographs of several of our patients, which illustrate how the implementation of these recommendations during PLLA soft tissue augmentation can replace lost facial volume and sustain this restoration.

Figure 2 shows a 34-year-old patient before and after her PLLA therapy, with injected areas indicated. Figure 3 demonstrates the progression of PLLA enhancement in a 38-year-old female patient at 6 months and 1 year after beginning therapy. In Figure 4, a 30-year-old female patient is shown at baseline, 2 months, and 2 years after PLLA therapy was initiated. In this patient, PLLA was injected in the supraperiosteal space to enhance the jaw line.

FIGURE 2. Thirty-four-year-old female patient with early signs of facial volume loss. The image on the left **a)** shows the patient prior to beginning poly-L-lactic acid (PLLA) therapy. The image on the right **b)** was taken 5 months after the initial PLLA injection session. One vial of PLLA was injected monthly at 3 sessions (3 vials total). Injection areas included the temple, cheek, preauricular area, pyriform fossa, and marionette line/chin area. Photographs courtesy of Melanie D. Palm MD MBA.

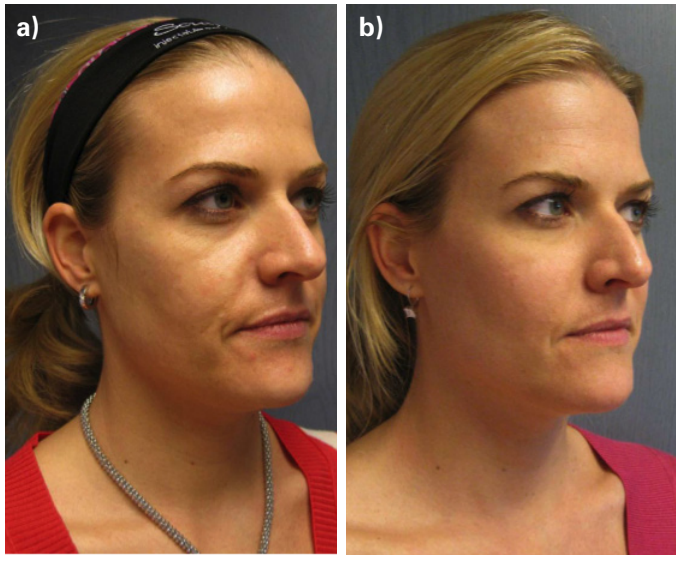
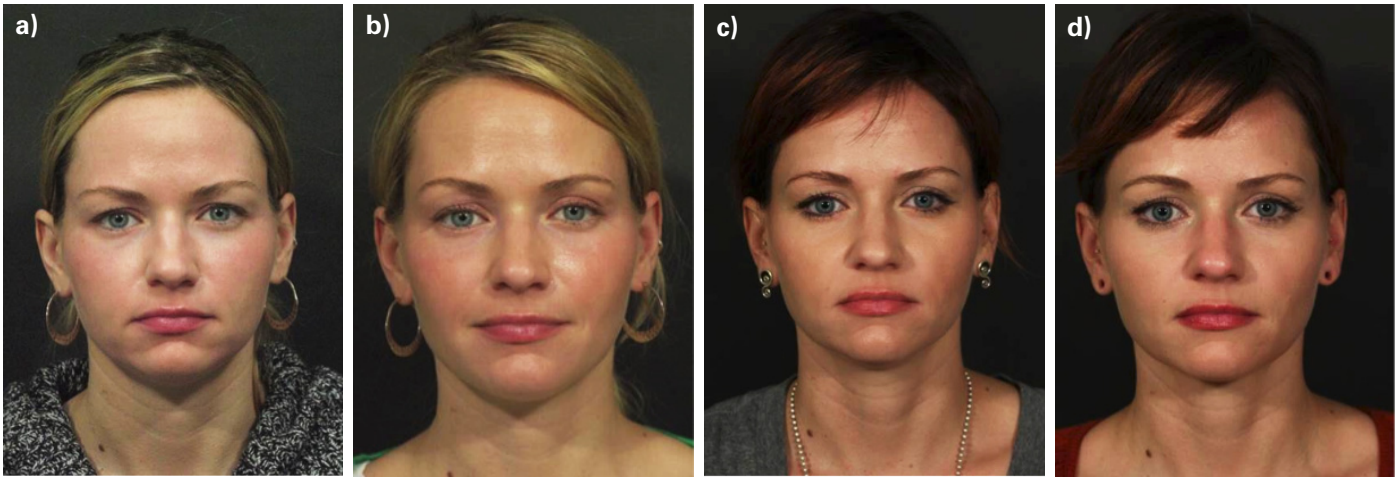


FIGURE 3. The progression of the restoration of facial volume loss and correction of facial asymmetry with poly-L-lactic acid (PLLA) injections in a 38-year-old female patient. This patient had 3 sessions of PLLA injections, 2 vials per session, spaced 1 month apart. The first photograph **a)** shows the patient before the administration of PLLA, and the "after" photographs show the results at **b)** 6 months and **c)** 1 year after beginning therapy. Photographs courtesy of Rebecca Fitzgerald MD.

FIGURE 4. These are photographs of a 30-year-old female patient treated with poly-L-lactic acid (PLLA), 2 vials/session, 2 sessions spaced 1 month apart over a period of 29 months. **a)** Baseline; **b)** 3 months after treatment was initiated; **c)** 27 months after initial treatment; and **d)** 1 month following touch-up with 1 vial of PLLA. The patient received no other treatment. Note the brow elevation and change in the perioral area with supraperiosteal injections along the supraorbital rim, zygoma, maxilla, and mandible. Photographs courtesy of Rebecca Fitzgerald MD.



DISCLOSURES

Danny Vleggaar MD has been a medical consultant for Sinclair IS Pharma, France; PharmaSwiss SA, Switzerland; Valeant Eastern Europe; and Cutanea Life Sciences, Inc. He also has been a trainer for Valeant Pharmaceuticals International, Inc./Medicis Corporation.

Rebecca Fitzgerald MD has been a consultant and speaker for Valeant Pharmaceuticals North America LLC/Medicis Corporation; Merz Aesthetic, Inc; and Allergan USA, Inc.

Z. Paul Lorenc MD FACS has been a consultant for Johnson & Johnson; La Lumiere, LLC; Medicis Corporation; Merz Corporation; and Mentor Corporation. In addition, he holds the following patents: US Patent 5/611,814–Resorbable Surgical Appliance for Use in Supporting Soft Tissue in a Superior Position; US Patent 60/950,423–Composition and Method of Use for SoftTissue Augmentation/Drug Delivery; US Patent 12/797,710–Method for Measuring Change in Lip Size After Augmentation; and US Patent 13/604,012–Light Therapy Platform System.

J. Todd Andrews MD has been a medical consultant for Sinclair IS Pharma, France. He has also been a consultant and trainer for Valeant Pharmaceuticals North America LLC/ Medicis Corporation, and Allergan USA, Inc.

Kimberly J. Butterwick MD has served as an Advisory Board member for Allergan, Inc. and has received honoraria as a consultant for Allergan, Inc., Merz Corporation, and Valeant Pharmaceuticals International, Inc.

Jody A. Comstock, MD has been a physician trainer, speaker, and consultant for Allergan, Inc., Lumenis, and Valeant Pharmaceuticals International, Inc. He has also been a speaker and consultant for Obagi Medical Products, Inc., a division of Valeant Pharmaceuticals North America LLC and SkinCeuticals International.

C. William Hanke MD has served as a consultant for and has received clinical research grants from Valeant Pharmaceuticals International, Inc. to conduct studies on poly-L-lactic acid.

T. Gerald O'Daniel MD FACS serves as a physician trainer for Sculptra for Valeant Pharmaceuticals International, Inc.; he receives no support or financial assistance. He has no other relationships to disclose.

Melanie D. Palm MD MBA has served as a physician trainer, speaker, and consultant for Valeant Pharmaceuticals.

Wendy E. Roberts MD has served as a consultant, speaker, and Advisory Board member for and has received honoraria from: Allergan Medical, Allergan Cosmetic, Kythera Biopharmaceuticals, La Roche-Posay, L'Oréal, MELA Sciences, NeoStrata Company, SkinMedica, Top MD, Theraplex, and Valeant Pharmaceuticals International, Inc.

Neil Sadick MD has received research grants from Allergan, Inc. and Valeant Pharmaceuticals North America LLC, and is a member of the Advisory Board for Merz Pharmaceuticals and Valeant Pharmaceuticals North America LLC.

Craig F. Teller MD has conducted research for Allergan, Inc. and Amgen Inc., and has received consultant honoraria from and served as a member of the Advisory Board and/or Speakers' Bureau for AbbVie Inc., Allergan, Inc., Amgen Inc., Celgene Corporation, Merz Corporation, Taro Pharmaceuticals U.S.A., Inc., and Valeant Pharmaceuticals International, Inc./Medicis Corporation.

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