

# Poly-L-lactic Acid for Chest Rejuvenation: A Retrospective Study of 28 Cases Using a 5-Point Chest Wrinkle Scale

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Photoaging occurs as a result of excessive actinic damage. In the chest area, or décolletage, photodamage is characterized by skin laxity, rhytides, hyperpigmentation, erythema, tactile roughness, atrophy, and telangiectases. Rejuvenation of the décolletage is a common inquiry of patients presenting to cosmetic dermatology and plastic surgery offices. Injectable poly-L-lactic acid (PLLA) received its US Food and Drug Administration indication for correction of shallow to deep nasolabial fold (smile line) contour deficiencies and other facial wrinkles in 2009. Off-label use of PLLA has been shown to improve rhytides and texture in the chest area. Using a 5-point chest wrinkle scale to assist in patient assessment, this article provides a retrospective review of 28 cases in which PLLA was used in the décolletage.

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Poly-L-lactic acid (PLLA) has been used in various medical applications for more than 3 decades.<sup>1</sup> Poly-L-lactic acid is a biocompatible, biodegradable, immunologically inert, semipermanent synthetic soft tissue filler derived from the  $\alpha$ -hydroxy family. Induction of neocollagenesis by fibroblasts follows the placement into the reticular dermis and subcutaneous tissue planes, and correction lasts up to 2 years or beyond.<sup>1,2</sup> Originally, the US Food and Drug Administration approved PLLA in 2004 for human immunodeficiency virus-associated lipoatrophy. In 2009, PLLA (Sculptra Aesthetic, sanofi-aventis US LLC) gained an additional approval for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles. Poly-L-lactic acid also has been used in other locations including the hands,<sup>3-5</sup> neck,<sup>6,7</sup> chest,<sup>3,5,7,8</sup> atrophic scars,<sup>6</sup> and other atrophic regions.<sup>3-8</sup> Herein we

describe 28 patients treated with PLLA for chest rejuvenation of moderate to severe rhytides. Improvement of the rhytides was determined by using a novel validated 5-point chest wrinkle scale. Additionally, 3 of 28 patients underwent adjuvant intense pulsed light (IPL) treatment (Lumenis One, Lumenis Aesthetic) immediately between their PLLA injection sessions.

## METHODS

Using electronic medical record entries and coding information, we collected data retrospectively and obtained written consent for photography release prior to images being taken. Telephone calls were placed to patients requesting additional information or photography when appropriate. Study protocol conformed to current ethical guidelines according to the 1975 Declaration of Helsinki.

### Patients

All nonimmunocompromised patients who were treated with chest PLLA by physicians at our clinic between March 2008 and February 2011 were included in Table 1. Eligibility was determined based on depth and characteristics of chest rhytides at baseline. A 5-point wrinkle scale was designed to assess the extent of each patient's rhytides at baseline compared to those after treatment. Although multiple wrinkle scales have been described in the literature, all are based on facial wrinkles and photodamage; therefore, we created a scale specifically to address photodamage and rhytides of the chest (Fabi-Bolton 5-point chest wrinkle scale [Figure 1]). Patients with baseline scores of 3 or higher were considered candidates for PLLA injection into the chest. Validation of the scale was accomplished with an independent verification process performed by 5 dermatologist colleagues in our clinic. The patients did not have any treatments to the chest other than PLLA, except for 3 patients who additionally had IPL treatments between injections (Table 1).

### Material

Poly-L-lactic acid is produced through corn dextrose fermentation and prepared as micronized lipophilic polylactic acid with an average particle size of 4 to 63  $\mu\text{m}$ . Each glass vial contains 150 mg of PLLA in a suspension of sodium carboxymethylcellulose and nonpyrogenic mannitol.<sup>3</sup> Reconstitution with bacteriostatic water and lidocaine 1% with epinephrine 1:100,000 always occurred at least 2 hours prior to injection and usually overnight. Technically, the manufacturer recommends sterile water for the reconstitution. However, the vast majority of physicians use preservative (bacteriostatic water) because the preservative makes it hurt less upon injection. A 16-cc dilution (14 cc bacteriostatic water;

2 cc lidocaine) was used primarily in our patients (86% of treatments [55/64]). Based on provider preference, dilutions of 10 to 13 cc were used in 6 of 28 patients early in the evaluation period. Of note, 3 of those 6 also had at least 1 treatment using the 16-cc dilution. No topical anesthetic, regional nerve block, or ice application was used before PLLA injections.

### Treatment Administration

The PLLA was agitated in a laboratory vortex (Vortex-Genie 2, Scientific Industries, Inc) and transferred to 3-mL syringes attached to 26-gauge, 1.5-in needles in preparation for injection. All patients were treated using similar injection technique into the décolletage; we began with rhytides centrally between the breasts and then proceeded laterally and superiorly. All visible rhytides and areas of shallowing were treated. Four physicians at our facility performed all of the PLLA injections. Prior to injection, the area to be treated was cleansed with alcohol, and following administration, the treated chest area was vigorously massaged for 5 minutes using a liquid soap. Total product administered varied per patient based on the severity of rhytides and volume loss, with most patients receiving 16 cc (1 vial) per treatment session. Patients were then instructed to follow the 5-5-5 rule: massage the treated area for 5 minutes, 5 times daily, for 5 days. Successive treatments were at least 4 weeks apart.

## RESULTS

All 28 patients who received PLLA injections were female. The mean age of patients was 52.9 years (range, 39–70 years; Table 1). Patients received a mean of 2.3 treatments (range, 1–7 treatments). On average, patients had a total of 28.5 cc of PLLA solution injected over the entire treatment course (range, 3.75–104 cc), with the large majority receiving a 16-cc dilution at each treatment session (range, 10–16 cc). The best improvement was noted in patients who received at least 3 PLLA injections at a 16-cc dilution with 16 cc injected per treatment. No adverse events were reported during the study period, and no nodule formation was observed.

Follow-up photography was available for 11 of 28 patients. Using the Fabi-Bolton 5-point chest wrinkle scale, on average a 1- to 2-point improvement was observed (Figures 2–4).

Three patients additionally received chest IPL treatments following their injections of PLLA, with no adverse effects. Patient 6 received IPL treatments after her first and second PLLA injections but not after her third injection. Patients 10 and 18 only had 1 chest PLLA treatment, which was then followed by 1 IPL treatment. None of the 3 patients who received adjuvant IPL treatments

TABLE 1

## Patient Data

Patient No.	Sex	Age, y	No. of Treatments	Dilution, cc	Total Volume Injected, cc	No. of Adjuvant IPL (560 nm) Treatments
1	F	48	4	16	64	0
2	F	40	3	16	48	0
3	F	59	1	10	6	0
4	F	58	2	12, 16	9	0
5	F	63	3	12, 12, 16	40	0
6	F	53	3	16	40	2
7	F	59	4	13, 13, 13, 16	20	0
8	F	50	1	16	16	0
9	F	51	1	12	6	0
10	F	45	1	16	16	1
11	F	40	1	16	8	0
12	F	42	3	16	24	0
13	F	69	3	16	48	0
14	F	50	1	10	3.75	0
15	F	51	5	16	32	0
16	F	42	1	16	16	0
17	F	60	7	16	104	0
18	F	62	1	16	16	1
19	F	62	2	16	32	0
20	F	70	2	16	32	0
21	F	39	1	16	8	0
22	F	59	1	16	8	0
23	F	66	1	16	16	0
24	F	59	2	16	32	0
25	F	55	1	16	8	0
26	F	47	3	16	48	0
27	F	40	4	16	64	0
28	F	42	2	16	32	0

Abbreviations: F, female; IPL, intense pulsed light.



**Figure 1.** Fabi-Bolton 5-point chest wrinkle scale. Grade 1 represents absence of wrinkles (A); grade 2, shallow but visible lines (B); grade 3, moderately deep lines (C); grade 4, deep with well-defined lines (D); grade 5, very deep with redundant folds (E).

demonstrated improvement of the photoaging of the chest beyond that seen in patients who received PLLA injections alone, except for a decrease in the appearance of solar lentigines and telangiectases.

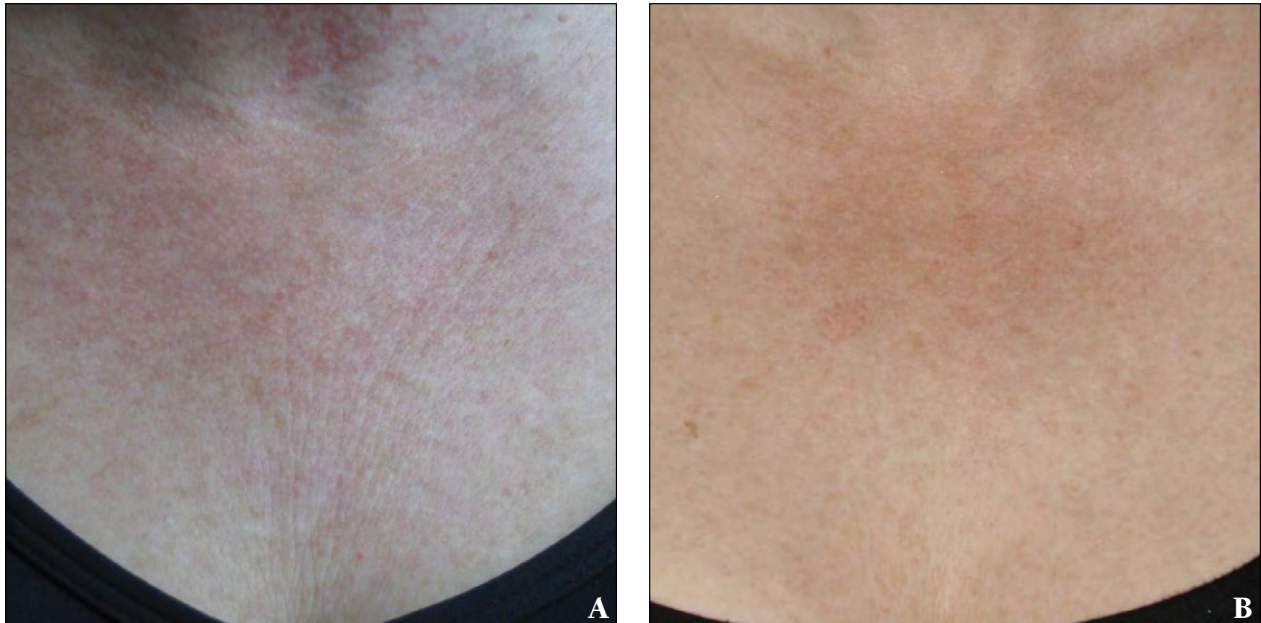
#### COMMENT

The first case series of PLLA for rejuvenation of the aging neck and chest was described in 2009 by Mazzuco and Hexsel.<sup>5</sup> Thirty-three patients received PLLA injections

using a 10-cc dilution to the neck area, and another 3 patients had injections to the chest and neck areas. Injections were performed using the depot technique, with 0.05 cc of reconstituted product being placed at the intersection of the dermis and subcutaneous tissues. Injection sites were distributed every 1 cc, and patients were instructed to massage the treatment areas at home.<sup>5</sup>

Overall, the average number of treatment sessions was 1.8; however, patients with mild signs of





**Figure 2.** Patient 2, a 40-year-old woman (Fabi-Bolton scale grade 3), before treatment (A) and 4 months after second treatment (B) with 16-cc dilution and total poly-L-lactic acid volume of 32 cc. Noted 1-point improvement to Fabi-Bolton scale grade 2 in after photograph.



**Figure 3.** Patient 1, a 48-year-old woman (Fabi-Bolton scale grade 3), before treatment (A) and 6 months after fourth treatment (B) with 16-cc dilution and total poly-L-lactic acid volume of 64 cc. Noted 2-point improvement to Fabi-Bolton scale grade 1 in after photograph.

photoaging and moderate to severe signs of photoaging received an average of 1.0 and 2.38 treatments, respectively.<sup>5</sup> Volumes of reconstituted product per treatment session varied between 4 and 7 cc in the neck and 1 cc in the chest. Improvement in the signs of photoaging,

including flaccidity, atrophy, and rhytides, was noted in the vast majority of patients. Results were sustained for the 18 months of follow-up. All patients in this case series developed either hematomas or bruising posttreatment. One patient developed multiple nodules in the neck area



**Figure 4.** Patient 27, a 40-year-old woman (Fabi-Bolton scale grade 4), before treatment (A) and 4 months after third treatment (B) with 16-cc dilution and total poly-L-lactic acid volume of 48 cc. Noted 2-point improvement to Fabi-Bolton scale grade 2 in after photograph.

that were visible only on neck extension. Of interest, this patient denied using massage as a part of her postprocedure home regimen.<sup>5</sup>

Redaelli and Forte<sup>8</sup> described 568 patients treated with Sculptra Aesthetic injections; 72 of these patients received treatment to the décolletage with a 7- to 8-cc dilution. The overall incidences of adverse events for all locations were 35% for bruising, 15.3% for edema, and 1% for nodules. Other adverse events included itching and pain.<sup>8</sup> Unfortunately, the authors did not separate the incidence of adverse events by site.

Adverse events for PLLA include ecchymosis, edema, pain, pruritus, inflammation, palpable nonvisible and visible nodules, and hematomas.<sup>3-5,7-9</sup> Our practice recently reported an 8.5% incidence of nodules in 130 nonimmunocompromised patients treated with PLLA to the face, hands, chest, or thigh. During this retrospective analysis, dilutions of 8 cc were used for the face and 12 cc for the hands, chest, and thigh areas. Only 2 of 130 patients received PLLA injections to the chest area, and no nodules were reported in either of these patients.<sup>3</sup>

Various techniques to decrease nodule formation have been suggested and can be found in Table 2.<sup>3,5,7-9</sup> Reconstitution of PLLA with 5 cc of sterile water at least 2 hours prior to injection is currently recommended by the manufacturer<sup>10</sup>; dilutions less than 5 cc are associated with an increased incidence of nodules.<sup>9</sup> As a result, many experts recommend dilutions greater than 5 cc and

TABLE 2

### Techniques to Decrease the Incidence of Nodule Formation With Injectable Poly-L-lactic Acid

- Do not overcorrect.
- Avoid intradermal injection.
- Use dilutions greater than 5 cc.
- Avoid excessive quantities of product injected per treatment session.
- Space treatment sessions no sooner than 4 weeks apart.
- Reconstitute overnight.
- Massage area posttreatment.

reconstitution overnight or longer.<sup>3,5,8,9</sup> In the current study, we found that dilutions of 16 cc showed the best improvement in rhytides, with no adverse effects. Post-treatment massage is thought to aid in the dispersement of PLLA microparticles with a resulting decrease in the incidence of nodule formation.<sup>3,5</sup>

There have been 79 cases of PLLA injection to the chest area reported in the literature.<sup>4-9</sup> This study examines the results of PLLA injections for chest rejuvenation in 28 additional patients demonstrating a 1- to 2-point observable improvement of photodamage without significant complications or formation of nodules.

Our primary limitations to this study were a small patient population and lack of long-term follow-up beyond 6 months posttreatment; therefore, although PLLA appeared to improve rhytides, texture, contour, and laxity of chest skin in the patients examined, larger studies are needed. Although patient satisfaction was not formally included as a measure in this retrospective study, many patients volunteered their satisfaction with the treatments and intent to continue treatment with PLLA chest injections in the future if needed. In the future, larger prospective trials are needed to further evaluate the potential benefit of using PLLA alone or in combination with IPL treatments for chest rejuvenation and to better assess patient satisfaction with these treatment modalities and duration of effects.

## REFERENCES

1. Vleggaar D. Soft-tissue augmentation and the role of poly-L-lactic acid. *Plast Reconstr Surg*. 2006;118(suppl 3):S46-S54.
2. Butterwick K, Lowe NJ. Injectable poly-L-lactic acid for cosmetic enhancement: learning from the European experience. *J Am Acad Dermatol*. 2009;61:281-293.
3. Palm MD, Woodhall KE, Butterwick KJ, et al. Cosmetic use of poly-L-lactic acid: a retrospective study of 130 patients. *Dermatol Surg*. 2010;36:161-170.
4. Lam SM, Azizzadeh B, Graivier M. Injectable poly-L-lactic acid (Sculptra): technical considerations in soft-tissue contouring. *Plast Reconstr Surg*. 2006;118(suppl 3):S55-S63.
5. Mazzucco R, Hexsel D. Poly-L-lactic acid for neck and chest rejuvenation. *Dermatol Surg*. 2009;35:1228-1237.
6. Schulman MR, Lipper J, Skolnik RA. Correction of chest wall deformity after implant-based breast reconstruction using poly-L-lactic acid (Sculptra). *Breast J*. 2008;14:92-96.
7. Narins RS. Minimizing adverse events associated with poly-L-lactic acid injection. *Dermatol Surg*. 2008;34(suppl 1):S100-S104.
8. Redaelli A, Forte R. Cosmetic use of poly(lactic acid): report of 568 patients. *J Cosmet Dermatol*. 2009;8:239-248.
9. Fitzgerald R, Vleggaar D. Using poly-L-lactic acid (PLLA) to mimic volume in multiple tissue layers. *J Drugs Dermatol*. 2009;8:S5-S14.
10. Sculptra Aesthetic (package insert). Bridgewater, NJ: sanofi-aventis US LLC; 2009. ■