

Painful Red, Hot Bumps After Injectable Poly-L-lactic Acid Treatment: A Case Report

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Poly-L-lactic acid (PLLA) is a synthetic filler that is approved by the US Food and Drug Administration. PLLA is widely used for treating facial lipodystrophy secondary to human immunodeficiency virus disease and is also used off-label for the cosmetic treatment of facial wrinkles and lipoatrophy secondary to the aging process. We present a case of a complication secondary to PLLA treatment.

A 50-year-old man with a 10-year history of human immunodeficiency virus (HIV) and hypercholesterolemia presented with type VI facial lipodystrophy and substantial submental lipoptosis. He felt that his facial lipoatrophy was an overt sign of his disease and was motivated to treat his condition following the reduced pricing promotion offered to the HIV population by the manufacturers of poly-L-lactic acid (PLLA). His concomitant medications included lopinavir/ritonavir, nevirapine, tenofovir, fenofibrate, escitalopram, and ezetimibe. His medications and immune status were stable, his medical history was noncontributory, and no drug or environmental allergies were reported.

MATERIAL AND METHODS

Following consultation and informed consent, the patient agreed to undergo a series of treatments with PLLA. According to manufacturer recommendations, a vial of PLLA was prepared with 5 cc of sterile water 48 hours prior to each treatment using aseptic technique. The product then remained in a locked clinic room until the time of administration.

Immediately prior to each treatment, the patient was

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prepped with an alcohol pad followed by povidone iodine antiseptic paint. Anesthetic was not used. The PLLA dilution was swirled and then aspirated into a 5-cc syringe through a 22-gauge needle. A 25-gauge needle was transferred onto the syringe, and the product was injected in a fanning motion into the defect in the subcutaneous and subdermal spaces of each cheek. Multiple passes were performed to ensure a minimal conservative deposit with each pass. A total of 5 cc of product was placed into each cheek. After the treatment, the patient was given a 4×4-in gauze pad and an ice pack to hold over the area for 20 minutes. No further manipulation or massaging of the cheeks was performed or recommended. The patient was discharged in stable condition.

The patient returned at 4 weeks, 7 weeks, and 11 weeks posttreatment for 3 additional treatments. At each visit, the preparation and injection procedures were repeated. The only difference was that at the final treatment visit, 1 cc of product was injected into each temple region using a serial depot method. The patient was very satisfied with the results. His satisfaction was confirmed by his agreement to be displayed on the senior author's Web site.

In December 2006, approximately 1 year following the final treatment, the patient, who lived out of state, called complaining of progressive hot, hard, painful, and distorting bumps that had developed at the injection sites, which were causing him extreme discomfort and preventing him from moving his face normally. The distressed patient was advised to send in a photograph of himself for visual confirmation (Figure 1). It was also recommended that he come in to be examined.

Figure Not Available Online

A

Figure Not Available Online

B

Figure 1. Patient with warm, erythematous, and fibrotic skin bilaterally extending into the temple region 1 year posttreatment with poly-L-lactic acid (A) and distinguishable bilateral nodules recognized in the temple region and flat nonfluctuant plateaus (B). Reprinted from *Aesthetic Surg J*, vol. 28, Dayan SH, Bassichis BA, Facial Dermal Fillers: Selection of Appropriate Products and Techniques, page 13, Copyright 2008, with permission from Elsevier.

The patient presented approximately 3 weeks later with warm, erythematous, and fibrotic skin located on both cheeks and extending into the temple region. There were also distinguishable bilateral nodules in the temple region as well as flat, nonfluctuant plateaus in both cheeks. There had been no change in the patient's medications, and he denied trauma, recent infection, or a change in immune status. It was surmised that a delayed allergic reaction had occurred. The patient refused a biopsy of the lesions. He was therefore treated empirically with 1.75 cc of intralesional triamcinolone, with 20 mg/cc injected to each side of his face, and 4 weeks of 500 mg clarithromycin twice daily.

Six weeks after the triamcinolone injections, the patient returned with approximately 50% improvement in his condition. He was able to open his mouth with full range of motion and the heat-emanating nodular lesions had decreased significantly. The patient had regained his confidence and agreed to a biopsy. Under sterile conditions, a 3-mm punch biopsy was performed on the largest lesion just inferior to the left orbital rim (Figure 2). Unfortunately, the pathologic diagnosis was inconclusive and showed no inflammatory lesions, necrobiosis, or malignancy. Immediately following the biopsy, an additional 1.75 cc of intralesional triamcinolone, with 20 mg/cc was injected into each side of the face. Six weeks later he was treated again with intralesional steroids at the same concentration by a local physician. The patient reported that the bumps, although still palpable, were no longer visible or painful and that he had regained normal function of his mouth. Subsequently, per his request he was treated cosmetically with the dermal filler calcium hydroxylapatite by his cosmetic physician in July 2007 and February 2008, approximately 7 and 14 months,

respectively, after his presentation with complications. All signs and symptoms of the inflammatory lesions have ultimately resolved.

Poly-L-lactic acid is a biodegradable polymer used as an injectable intradermal implant.^{1,2} In August 2004, PLLA was approved by the US Food and Drug Administration (FDA) for the treatment of lipoatrophy related to HIV treatment.³ It is the first injectable facial volumizer approved by the FDA for treating lipoatrophy.³ When injected into soft tissue, PLLA induces a foreign body reaction that results in fibroplasia and collagen growth. This process gradually leads to the thickening of skin and enhances facial contours for up to 2 years posttreatment.^{2,4} Prior to FDA approval, PLLA was used in Europe.⁵

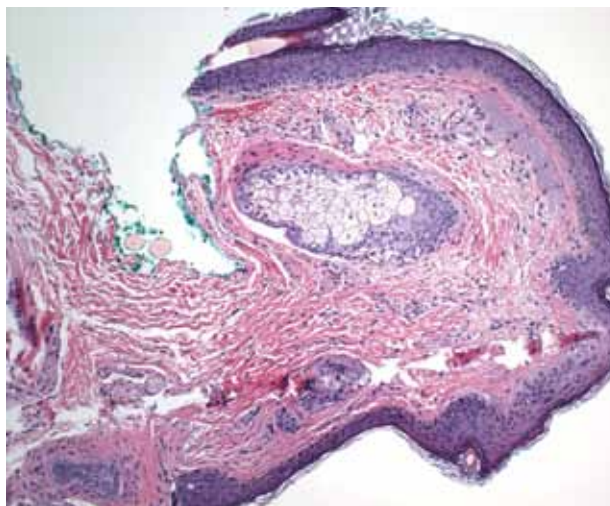


Figure 2. A 3-mm punch biopsy just inferior to the left orbital rim, approximately 2 months following the initial adverse reaction of poly-L-lactic acid (H&E, original magnification $\times 100$).

PAINFUL BUMPS AFTER PLLA INJECTIONS

Initial studies recommended dilution of PLLA with 2 cc of sterile water.⁶ Currently, 5 to 10 cc of sterile water per vial is recommended to reduce the risk of complications.⁵ Additional measures, such as massaging the injection site, may also be beneficial.⁷ Adverse events, such as nodules and granuloma formation, have been reported to be related to injection technique and the amount of product injected.⁵

SUMMARY

The reaction to PLLA that we witnessed in our patient occurred 1 year after administration of the product, a delay that is consistent with a delayed hypersensitivity reaction. Our choice of intralesional steroids and clarithromycin to treat the reaction was based on previous experiences in treating hypersensitivity reactions secondary to filler complications.⁸ Although unlikely, an underlying infectious process could not be ruled out as an etiology since there have been reports of atypical skin and soft tissue organisms associated with delayed reactions in facial augmentation procedures.⁹ Fortunately, this patient has done well, with complete resolution and no residual

defects. However, even with the minimized risk related to proper technique and dilution, PLLA injections are rarely offered in our practice.

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