Letter to the Editor

The case presented by Dayan et al (Dayan SH, Antonucci CM, Stephany M. *Cosmet Dermatol.* 2008;21:388-390) concerns a 50-year-old man with a 10-year history of human immunodeficiency virus (HIV) who experienced hot, hard, painful, and distorting bumps approximately one year after treatment for HIV-associated facial lipoatrophy.[1] While adverse events (AEs), including nodules, papules, and granulomas, can occur following the use of injectable poly-L-lactic acid (PLLA), such events have been reported for all currently available injectable dermal agents, including collagens, hyaluronic acids, and calcium hydroxylapatite.[2-4] In most cases, as the authors pointed out, these AEs following treatment with injectable PLLA are related to improper injection technique and dilution.[5-7]

The authors hypothesize that the AEs observed in this patient resulted from a delayed hypersensitivity reaction to injectable PLLA. However, in the photomicrograph provided in the original article, there is no evidence of PLLA particles or inflammatory lesions within the area of suspected inflammation. In fact, the authors state that the "pathologic diagnosis was inconclusive."[1] This is unusual, as histologic examination can usually confirm the type of implant causing the granulomas.[6] No such foreign material was observed in the histologic sample provided in the case.

As with all injectable devices, adherence to the manufacturer's recommended injection and posttreatment procedures with injectable PLLA is advised. Injectable PLLA is unique among dermal fillers in that it is supplied as a lyophilized powder and requires the injecting physician to carefully follow the reconstitution procedures as they are described in the prescribing information (PI).[8] While the reconstitution of injectable PLLA (with 5 mL sterile water 48 hours prior to use) and injection into the subcutaneous and subdermal spaces of each cheek described in this case were consistent with the PI, a number of technique-related issues may have contributed to the poor outcome and should be emphasized. First, massage was not provided by the physician during or after the injection. Further, the patient was not advised to massage the area in the days following treatment. Massage is an important component of the injection process and posttreatment procedure as described in the PI and is essential for even distribution of the product.[8,9] Further, patients should be counseled to massage the treatment area for 5 minutes at least twice a day for 1 to 2 weeks after an injection session to promote a natural-looking correction.[7-9]

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Additionally, the authors injected 1 cc of injectable PLLA into the temple, which may have been too high a volume for a single treatment session. The PI specifies that the volume of product to be injected into the temporal fascia should be reduced to 0.05 mL using the depot injection technique.[8] Massaging this specific area following each injection is also included in the PI. In the case study, injection into the temporal fascia was not stated; the nodular presentation in the temple in Figure 1B is indicative of a superficial injection, as the observable injection track appears to emulate an injection technique that differs from the depot technique that is recommended in the PI. Other technique-related differences in this case include the use of a 25-gauge needle in place of the recommended 26-gauge needle and the use of the fanning injection technique rather than the threading or tunneling technique specified by the PI.[8]

Injectable PLLA was approved by the US Food and Drug Administration in 2004 for the restoration/correction of the signs of facial fat loss (lipoatrophy) in people with HIV.[8] Therefore, at the time of this patient's treatment (approximately mid-2005), injectable PLLA was still a relatively new product for the treatment of HIV-related facial lipoatrophy in the United States. It is imperative that physicians understand how to use injectable PLLA correctly. Sanofi-aventis has responded to the need for appropriate training by providing a well-established and continually updated, award-winning, hands-on training program for physicians to learn injection methods and to gain experience with the use of injectable PLLA. The program was implemented concurrently with the approval of injectable PLLA in 2004 and was designed to provide physicians with individualized training

by qualified trainers who remain accessible throughout the learning phase of the device's use. Obtaining the appropriate training from a physician who is an experienced injector enables novice physician injectors to learn the theory and practice of optimal injectable PLLA reconstitution, injection, and application of posttreatment procedures. Thus, physicians recognize the need for and the availability of training by experienced physician injectors in order to help optimize patient outcomes for the treatment of HIV-associated facial lipoatrophy.

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REFERENCES

1. Dayan SH, Antonucci CM, Stephany H. Painful red, hot bumps after injectable poly-L-lactic acid treatment: a case report. *Cosmet Dermatol*. 2008;21:388-390.
2. Gladstone HB, Cohen JL. Adverse effects when injecting facial fillers. *Semin Cutan Med Surg*. 2007;26:34-39.
3. Andre P, Lowe NJ, Parc A, et al. Adverse reactions to dermal fillers: a review of European experiences. *J Cosmet Laser Ther*. 2005;7(3-4):171-176.
4. Broder KW, Cohen SR. An overview of permanent and semipermanent fillers. *Plast Reconstr Surg*. 2006;118(suppl 3):7S-14S.
5. 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):55S-63S.
6. Lowe NJ, Maxwell CA, Patnaik R. Adverse reactions to dermal fillers: review. *Dermatol Surg*. 2005;31(11 Pt 2):1616-1625.
7. Narins RS. Minimizing adverse events associated with poly-L-lactic acid injection. *Dermatol Surg*. 2008;34(suppl 1):S100-S104.
8. Sculptra [prescribing information]. Berwyn, PA: Dermik Laboratories; 2004.
9. Vleggaar D. Facial volumetric correction with injectable poly-L-lactic acid. *Dermatol Surg*. 2005;31(11 Pt 2):1511-1517.

AUTHOR RESPONSE

Dr. Ghorayeb presents very valid points. Poly-L-lactic acid is a product that is preferred by many of my most respected colleagues. However, in my early experiences with PLLA I felt our case report warranted mention. It is up to the individual aesthetic physician to prudently review the medical literature and then decide which product(s) best fits into their practice.

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