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CASE REPORT

Duration of Correction for Human Immunodeficiency Virus-Associated Lipoatrophy After Retreatment with Injectable Poly-L-Lactic Acid

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Abstract The Blue Pacific study assessed the effect of injectable poly-L-lactic acid (PLLA) (Sculptra; Dermik Laboratories, a business of Sanofi-Aventis U.S. LLC, Bridgewater, NJ, USA) for the treatment of human immunodeficiency virus (HIV)-associated facial lipoatrophy. This case report describes a patient treated originally with injectable PLLA in the Blue Pacific study, then retreated with injectable PLLA 12 months after completion of his initial treatment sessions. Retreatment was well tolerated and resulted in a correction of facial lipoatrophy for a duration of 2 years 7 months.

Keywords Blue Pacific · Duration · Facial lipoatrophy · Poly-L-lactic acid · Retreatment

Introduction

Injectable poly-L-lactic acid (PLLA) currently is approved in the United States and Europe for restoring or correcting the signs of facial lipoatrophy in patients with human immunodeficiency virus (HIV) [7]. Clinical trials with this population have shown that treatment with injectable PLLA results in sustained (up to 24 months) increases in skin thickness and high patient satisfaction [1, 3–6].

In the open-label Blue Pacific study, patients with HIV-associated facial lipoatrophy had up to six treatments with injectable PLLA [2]. At 12 months posttreatment, the patients were eligible for a retreatment study. This report describes a sustained facial correction after retreatment with injectable PLLA experienced by a man originally treated in the Blue Pacific study.

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Case Report

A 45-year-old white man presented initially to our office 14 September 2002 as a participant in the Blue Pacific study. Study treatment began 24 October 2002. At the baseline assessment (Fig. 1a), the severity of the man's facial lipoatrophy was grade 2 on the James scale from a range of 1 (mild) to 4 (severe). Skin caliper measurements obtained at the intersection of the vertical axis through the lateral canthus of the eye and the horizontal axis of the nares were 11 mm (right) and 10 mm (left) [2].

The patient had five injectable PLLA sessions (2 vials per session) at 3-week intervals per protocol. Each vial was diluted with 3 ml of sterile water for injection. Injectable PLLA was administered to the midface in four treatment sessions and to the midface and temples in the fifth treatment session. Although the manufacturer recommends using a 26-gauge needle [7], treatment was administered into the deep dermal/subcutaneous layers via a 25-gauge 1.5-in. needle using the cross-fanning technique. No additional treatment was administered from the end of the treatment phase to the 12-month follow-up visit.

At the 12-month follow-up visit (22 January 2004; Fig. 1b), the patient's James scale grade was 0 (no lipoatrophy), and his skin thickness was 15 mm (right) and 16 mm (left). The patient reported being very satisfied (due to the longevity of the correction). However, because he resided at a distance from the study site and feared loss of correction, he elected to receive a one-time retreatment. Injectable PLLA was administered to the previously treated

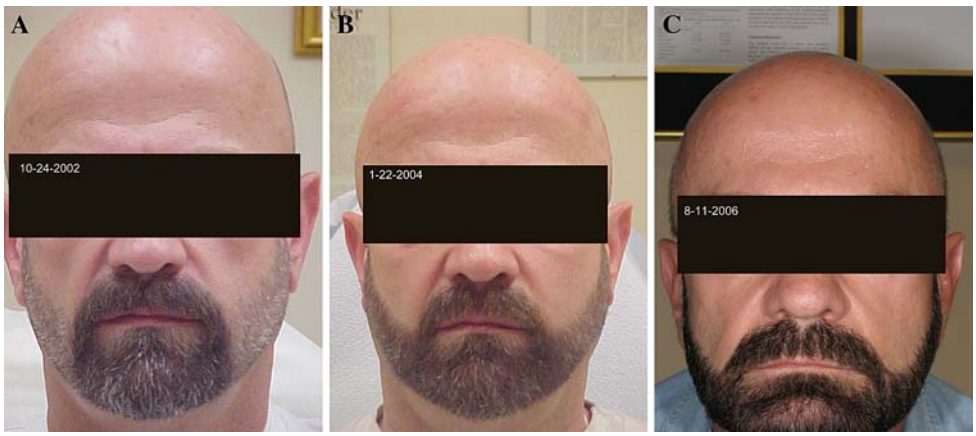

Fig. 1 (**a**) Before any treatment with injectable poly-L-lactic acid. The patient subsequently underwent five treatment sessions, each 3 weeks apart). (**b**) View 12 months after last treatment with injectable PLLA (before the first retreatment session). (**c**) View 2 years 7 months after retreatment with injectable PLLA

areas (midface) and along the zygomatic arch to lift and thereby treat the nasolabial fold.

The patient's facial correction was sustained for a total of 2 years 7 months from the retreatment session to the next follow-up visit (11 August 2006; Fig. 1c). At this time, beyond the time frame of the retreatment study, lipoatrophy was James scale grade 1 (mild), and skin thickness was 14 mm (right) and 15 mm (left). Although the manufacturer recommends reconstitution of the PLLA with up to 5 ml of sterile water for injection [7], the midface and temples were retreated using a 6-ml dilution (5 ml of sterile water per vial added the day before and 1 ml of lidocaine 2% per vial added immediately before injection). Notably, the skin thickness before the second retreatment session had remained 3 to 5 mm greater than the measurements at the initial presentation (right side: 14 mm vs 11 mm at baseline; left side: 15 mm vs 10 mm at baseline).

At a follow-up visit 6 months later, clinical improvement in facial contours was noted. However, additional treatment was deemed appropriate and administered to the midface and temples.

The patient experienced no product-related adverse events. Localized bruising with injection resolved within 1 week afterward. Based on self-report, there were no changes in the patient's highly active antiretroviral therapy, and his body weight was stable throughout the follow-up period.

Discussion

The technique for administering injectable PLLA in our practice evolved during the period of this case based on our clinical experience and reports suggesting that administration procedures/techniques can have an impact on the occurrence of papules [8, 10]. To minimize the risk of these adverse events, the frequency of treatment/follow-up visits was extended from 3 weeks to 5 weeks, and the total dilution volume was increased from 3 to 6 ml per vial. Because the onset of correction is gradual, it is important to assess the results of treatment no less than 5 weeks after injection to evaluate the full cosmetic effect (hence potentially avoiding overtreatment) [9]. Other measures, such as massaging of the area after injection, may further minimize adverse events.

The reported patient's facial lipoatrophy corresponded with the changes observed during advanced aging, with significant creases noted in the nasolabial folds. During the Blue Pacific study, the patient required treatment in the temple area only once. However, during retreatment, the temple area required repeated sessions. It may be that facial wasting continued in this area because the PLLA does not prevent further facial lipoatrophy.

The patient needed more than one retreatment session after 31 months. This was expected because he had initially required five treatment sessions to obtain complete correction during the Blue Pacific study. In our clinical experience, most patients presenting with his degree of lipoatrophy require two to three retreatments for full correction [4].

In conclusion, this report shows the long duration of correction for HIV-associated lipoatrophy that can be obtained after retreatment with injectable PLLA. Retreatment was well tolerated and produced facial correction that was sustained for 2 years 7 months. More studies should be conducted to evaluate the long-term outcomes of treatment with injectable PLLA.

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