

Poly-L-Lactic Acid Reconstitution Technique to Reduce Needle Obstruction

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Facial lipoatrophy in patients with HIV is a well-established adverse effect of highly active antiretroviral therapy (HAART), further augmenting stigma and decreasing treatment adherence. Poly-L-lactic acid (PLLA) is approved by the US Food and Drug Administration for the correction of facial fat loss in this population. Unfortunately, needle obstruction from microparticles is a common obstacle that clinicians may encounter during this procedure. We describe a simple and effective way to mitigate this problem by utilizing a water bath to warm the filler prior to injection.

Practice Gap

Lipoatrophy associated with HIV is characterized by loss of adipose tissue in distinctive anatomic areas, most prominently in the nasolabial folds, temples, and medial cheeks.¹ This adverse effect further stigmatizes patients with HIV, and its association with highly active antiretroviral therapy (HAART)—specifically protease inhibitors—may contribute to suboptimal adherence to treatment.^{1,2} Moreover, this finding is not uncommon: The prevalence of facial lipoatrophy after receiving HAART can range from 28% in patients treated for less than 5 years to 54% in those treated for a median of 10 years.² The associated stigma, notable decrease in quality of life, and known affiliation as an adverse effect of HAART make correction of facial lipoatrophy in patients with HIV an important management option.

Poly-L-lactic acid is approved by the US Food and Drug Administration for addressing fat loss due to HAART in patients with HIV.^{2,3} When used as a dermal filler for correction of facial lipoatrophy, PLLA is well tolerated

and has been shown to improve quality of life.^{2,3} Poly-L-lactic acid is available for clinical use as microparticles of lyophilized alpha hydroxy acid polymers. Once injected (after the carrier substance is absorbed), PLLA induces an inflammatory response that ultimately leads to the production of new collagen.³ Unfortunately, PLLA microparticles often obstruct needles and make the product difficult to use, potentially hindering effective injection; thus, it is in the best interest of the patient to mitigate needle obstruction during this procedure. In this article, we describe a simple and effective way to mitigate this problem by utilizing a water bath to warm the filler prior to injection.

Technique

The required supplies include a thermostatic water bath, reconstituted PLLA, a syringe, and a 26-gauge injection needle. Because laboratory-grade heated water baths typically cost between \$300 and \$3000,⁴ we recommend using a more affordable, commercially available thermostatic water bath (eg, baby bottle warmer)(Figure 1) to warm the filler prior to injection, as the optimal temperature for this technique can still be achieved while remaining cost effective. Vials of PLLA reconstituted with 7 mL of sterile water and 2 mL lidocaine hydrochloride 1% should be labeled with the date of reconstitution and manually agitated for 30 seconds. The reconstituted product should be stored for 24 hours to ensure even suspension and powder saturation.⁵ On the day of the procedure, the vial should be placed into the water bath (heated to 100 °C) for 10 minutes prior to injection and

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FIGURE 1. Commercially available baby bottle warmer used to heat vials of poly-L-lactic prior to injection.



FIGURE 2. Placement of the poly-L-lactic acid vial in the bottle warmer prior to injection.

agitated again immediately before withdrawal into the syringe. The clinician then should sterilize the rubber top and draw the product from the warmed vial using the same size needle that will be used for injection. Although a larger gauge needle may make drawing up the product easier in typical practice, drawing and injecting with the same gauge needle helps prevent larger particles from clogging a smaller injection needle. Using a 26-gauge injection needle for withdrawal further reduces clogging by serving as a filter to prevent larger product particles from entering the injection syringe. The vials of PLLA can be kept in the water bath throughout the procedure between uses to keep the filler at a consistent temperature.

Practice Implications

Although many clinicians reduce needle obstructions by warming PLLA before injection, a published protocol currently is not available. One consideration when utilizing this technique is the limited data on the clinical stability and efficacy of PLLA at varying temperatures. Two studies recommend bringing the reconstituted vial to room temperature prior to injection, while others have documented an endothermic melting point in the range of 120 °C to 180 °C for PLLA, which lies well above the physiologic temperature readily achievable by baby bottle warmers.^{6,7} Easily accessible bottle warmers can maintain the suspension at approximately 100 °C, keeping it in its crystalline polymer form and preventing melting. With this technique, the authors observed an improvement in efficacy due to fewer clogged needles, resulting in the

delivery of more filler to the patient. In addition to comparable clinical results to not warming the product, our experience has shown that warming the PLLA prior to injection is not associated with increased patient discomfort and is well tolerated. Furthermore, patients experience less bruising and bleeding, as fewer needle sticks are necessary. This combination of a consistently heated filler with the added benefit of needle filtration yields dramatically fewer needle obstructions, fewer needle sticks, and increased patient satisfaction, improving the experience of patients with HIV-associated lipoatrophy seeking correction.

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