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## Journal of the American Academy of Dermatology

Volume 52, Issue 2, February 2005, Pages 233-239

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Report

### Assessment of the safety and efficacy of poly-L-lactic acid for the treatment of HIV-associated facial lipoatrophy

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<https://doi.org/10.1016/j.jaad.2004.08.056>

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#### Background

Lipodystrophy syndrome is uniquely associated with the use of highly active antiretroviral therapy (HAART) containing protease inhibitors or nucleoside reverse transcriptase inhibitors. Between 15% and 80% of patients on HAART develop facial lipoatrophy within 10 months of initiating therapy. At present, no ideal treatment strategies have emerged in spite of the psychosocial stress, resulting in depression and isolation in many HIV-infected patients. Most soft tissue fillers seem to be well tolerated; however, various reactions such as allergic reactions, infection, and inflammatory and allergic granulomatous nodules are possible. Poly-L-lactic acid (PLA; New-Fill, Biotech Industry SA, Luxembourg) is currently being used in Europe and is approved by the Food and Drug Administration (FDA) in the United States for soft tissue augmentation in HIV-associated facial lipoatrophy.

## Objective

To determine the safety and efficacy of PLA for dermal enhancement of facial lipoatrophy in immunocompromised HIV-infected patients with prior use of HAART.

## Methods

Sixty-one immunocompromised, HIV-infected male patients (52 whites, 7 African Americans, 1 Latino, and 1 Asian) underwent multiple treatment sessions with PLA over a 5-month period for facial lipoatrophy. The severity of facial lipoatrophy was assessed and photographs were taken at baseline and before each treatment session. Periodic monitoring for adverse reactions and degree of improvement were assessed by the patient, the treating physician, and a non-treating physician.

## Results

At the 6-month follow-up, all 61 immunocompromised HIV patients had a successful outcome, defined as smoothing of the skin with less concavities or depressions, and improved overall appearance in an average of 3 treatment sessions. Although all patients were very pleased with their results, two patients developed persistent asymptomatic palpable intradermal papules in the infraorbital region as a result of the site of placement and concentration of PLA. On long-term follow-up (18 months), 48 of 61 (79%) required an average of 3 visits to achieve the desired enhancement and 13 of 61 (21%) patients requested additional treatment sessions beyond the initial 3 sessions. Although the patient and the physicians rated the level of improvement as "Excellent," the desire for further dermal enhancement was purely subjective. In general, the procedures were well tolerated without the clinical development of adverse reactions.

## Conclusion

The use of PLA to treat facial lipoatrophy resulted in significant and prolonged improvement in HIV-infected patients. The effect was long lasting, for up to 2 years in some patients, depending on when treatment was initiated. There were no reported cases of infection, allergies, or serious adverse reactions, and the treatment was well tolerated.



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## Abbreviations used

FDA, Food and Drug Administration; HAART, highly active antiretroviral therapy; NNRTIs, non-nucleoside reverse transcriptase inhibitors; NRTIs, nucleoside reverse transcriptase inhibitors; OSHA, Occupational Health and Safety Administration; PUI, personal use importation; PLA, poly-L-lactic acid; PI, protease inhibitor

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Funding sources: None.

Conflicts of interest: None identified.

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