



The Clinical Utility, Safety, and Tolerability of Poly L-lactic Acid Injections for HIV-Related Facial Lipoatrophy at the San Francisco VA Medical Center

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Abstract

The development of facial lipoatrophy (LA) in the setting of antiretroviral therapy has been associated with decreased quality of life (QOL) and adherence to life-prolonging antiretroviral therapy. Poly L-lactic acid (PLLA) injections were recently FDA approved for HIV-associated LA, but the cost of therapy (on average \$4000 per patient for 4 monthly sessions) may be prohibitive in publicly funded HIV clinics. At the SFVAMC, facial LA was identified as a common complaint of HIV-infected patients seen in the Infectious Diseases (ID) Clinic. We obtained funding to provide PLLA injections to HIV-infected patients with moderate and severe lipoatrophy. Eligibility for PLLA was established using a standardized clinical assessment of lipoatrophy (0=no lipoatrophy, 1=mild lipoatrophy, 2= moderate lipoatrophy, 3=severe lipoatrophy) by an independent panel of at least 1 infectious disease physician and 1 registered dietitian experienced in the management of lipoatrophy. Of 16 number of patients who self-referred from the ID Clinic, 8 patients were identified as having an average LA score >2 and referred to a dermatologist with expertise in PLLA injections for at least 3 monthly injections. We will describe the outcomes of HIV-infected patients who received PLLA injections using objective measures including changes in facial anthropometry, QOL and actual facial photos from baseline. The cost of PLLA coverage for our clinic has been surprisingly low because of the identification of relatively few patients with moderate to severe facial lipoatrophy, possibly because delayed access to this intervention led to patients seeking treatment in non-VA health care settings.

Aims

- To describe screening criteria for the use of PLLA in HIV-infected patients with facial lipoatrophy in a public HIV clinic setting.
- To measure baseline severity of LA by anthropometric measurements, photography, and quality of life (QOL) in a cohort of patients with HIV-associated LA.
- To measure the changes in LA by anthropometric measurement, photography, and QOL in patients having received 3 PLLA injections over 16 weeks.
- To evaluate safety and tolerability of PLLA in HIV-infected patients with LA in a clinic setting.

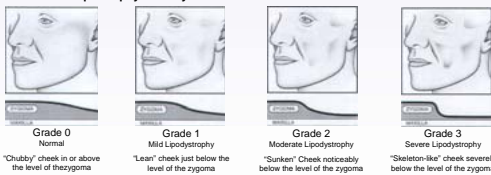
Background

- Facial LA is one of the most obvious and stigmatizing manifestations of HIV and antiretroviral therapy which occurs in up to 50% of patients with chronic HIV disease.
- The association of LA with antiretroviral therapy has been shown to decrease quality of life and adherence life-prolonging antiretroviral therapy (1).
- Many interventions have been proposed as treatments for HIV-associated facial LA including withdrawal of nucleoside analogues (2,3), use of medications such as thiazolidinediones and other insulin sensitizers, plastic surgery with silicone or autologous fat injections.
- The recent FDA approval of PLLA injections for HIV-associated LA is based upon studies (4) demonstrating short-term benefit in terms of patient self-assessment, photographic assessment, and anxiety and depression scores, although the long term durability of such benefit is not known.

Methods

- Population:** 16 HIV+ patients with facial lipoatrophy, referred from the ID clinic at SFVAMC.
- Eligibility established using the Global LA severity score (GLSS) (5)**
 - A standardized clinical assessment of lipoatrophy by at least 1 infectious disease physician and 1 registered dietitian

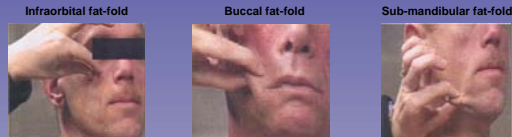
Figure 1: Global Lipoatrophy Severity Score



- A standardized quality of life questionnaire was performed at baseline and prior to each PLLA treatment
- BIQLI (Body Image Quality of Life Instrument) is a self-administered questionnaire based on 19 questions on perceived body image, with a dynamic scale of score between -57 and +57 (a negative score correlates with poorer body image, a positive score correlating with better body image). (6)

Methods (con't)

- Detailed facial anthropometric measurements** were performed at screening visit, and repeated at the week 16.
 - Measurements adapted from AIDS Clinical Trials Group Anthropometric training video (7)
 - 3 skinfold measurements performed using Lange skinfold calipers on right and left sides of face:



- The Procedure:**
 - One vial (2cc) of poly L-lactic acid (Sculptra™, Sanofi-Aventis) was diluted with 4 cc of sterile water and 2 cc of 2% sterile lidocaine, and injected into each cheek at each session.
 - A cross-hatch technique was used for injection, and there were approximately 20 injections into each cheek in order to deliver 6 cc of solution over a large surface area of the subzygomatic concavity.
 - The majority of the volume was injected into the central cheek area, which was typically the area which was most severely affected.
 - After the procedure, the patient was instructed to massage the area for approximately 10 minutes, 5 times per day, for 14 days.
 - Patients received a total of 3 to 6 treatments into each cheek approximately one month apart.
- Standardized facial photography** was obtained prior to each PLLA treatment, and scanned into the medical record
- Follow-up:**
 - GLSS score, the same facial anthropometric measurements, QOL questionnaire, and photography were performed at week 16, 1 month after completion of 3rd PLLA treatment.

Results

- Of the 16 screened, between October and November, 2006, 8 were excluded due to GLSS score <2. Of these 8, 3 had undergone treatment with PLLA previously.
- Side effects related to treatment included mild to moderate pain with injection, bruising, and the development of palpable but not visible subcutaneous nodules.
- The mean GLSS improved from 2.2 at baseline to 1.1 at week 16.
- Anthropometric measurements reflected increased facial fat folds (Table 1), the majority of increase in the R and L middle cheek areas, where the maximum amount of PLLA was injected.

Table 1:

Patient	Baseline GLSS score	Change from Baseline Measurements			Total Treatments Planned	
		GLSS score	Infraorbital fat-fold (mm)	Buccal fat-fold (mm)		Sub-mandibular fat-fold (mm)
1	1.8	-0.3	0.0	4.0	1.5	5
2	2.0	-1.25	2.0	2.0	0.0	5
3	2.2	-1.2	2.0	4.0	2.0	3
4	2.0	-1.5	2.0	5.0	2.0	4
5	2.5	-1.5	3.0	9.0	4.0	3
6	3.0	-0.5	0.0	1.0	1.0	6
7	2.0	-1.5	1.0	7.0	1.0	6
8	2.0	-1.25	4.0	6.0	5.5	4
Average:	2.2	-1.1	1.8	4.8	2.1	4.5

- BIQLI QOL scores improved by week 16, baseline scores ranged -10 to +50, mean +17; week 16 scores +11 to +51, mean +37
- The average number of treatments anticipated for these 8 patients was 4.5.
- The average total cost of treatment per patient (given acquisition cost of \$960 per treatment) was \$4320, leading to a total cost of treatment for these 8 patients of \$34,560.

Results (con't)

Baseline 1 month after treatment completion



Conclusions

- PLLA is an effective short-term treatment for patients with HIV related lipoatrophy in the VA system
- Facial anthropometry appears to be a useful objective measure of facial skinfold change in response to PLLA treatment
- QOL measures significantly improved in the treated population
- GLSS and digital photography appear to be useful adjunctive clinical measures for severity of LA and response to treatment
- It is anticipated in the future that approximately 8 – 10 patients will be treated per year in our clinic which follows approximately 550 HIV-infected veterans.

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