

## Cost consequences of HIV-associated lipoatrophy

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HIV-associated lipoatrophy may affect up to 35% of patients who have received antiretroviral (ARV) regimens for more than one year, and may result in depression, social isolation, and career barriers. Interventions including the injection of dermal fillers for restoration of facial fat loss are being used for treating HIV-associated lipoatrophy. Since reimbursement is often lacking, patients must consider the pros and cons of such interventions, weighed against the other costs of daily life.

The primary goal of the study is to provide reliable estimates of the costs of treating HIV-associated lipoatrophy, specifically facial lipoatrophy. Costs are provided for a single site and are estimated from published studies reporting administration patterns of dermal fillers, publicly available list prices, and physician service fees for similar subcutaneous injections of the face.

Fourteen studies were identified that reported experience with five dermal fillers used to treat HIV-associated facial lipoatrophy: poly-L-lactic acid, calcium hydroxylapatite, polyalkylimide gel, hyaluronic acid, and silicone oil. Typical courses involve four physician visits, but could vary from 1 to 13. The cost of a course of dermal filler treatment at a single site ranges across four products (all other than hyaluronic acid) from \$3690 to \$16,544, and is typically not covered by the payers. Physician fees for an entire course of similar outpatient procedures reimbursed by insurers are approximately \$500, and may vary according to location, specialty, and market conditions. These procedures need to be repeated per site injected with intervals of 1–3 years.

Treatment of HIV-associated lipoatrophy may represent a considerable out-of-pocket expense for many patients with HIV. This could have implications for deciding whether to undergo a restorative procedure, which procedure to undergo, and whether to pursue other options that may include switching ARV regimens.

**Keywords:** HIV; lipoatrophy; economics; costs

### Introduction

Lipoatrophy is characterized by the loss of subcutaneous fat primarily from the cheeks, arms, buttocks, thighs, and legs (Engelhard, 2006). The severity of facial lipoatrophy has been graded, and varies between loss of subcutaneous fat restricted to the cheeks (malar depression; Grade I) to generalized fat loss involving periorcular and temporal regions (malar depression, buccal extension, defined melolabial ridge, and generalized facial wasting; Grade IV) (Funk, Bressler, & Brissett, 2006). Interest in the past decade has centered on the growing number of patients with lipoatrophy who are also infected with the human immunodeficiency virus (HIV) receiving antiretroviral (ARV) therapy. Prevalence estimates of HIV-associated lipoatrophy vary widely, between 3 and 35% due to study differences in patient characteristics, such as age, gender, geography, lifestyle, and types and duration of ARV regimens (Hansen

et al., 2006; Jacobson et al., 2005; Pujari et al., 2005; Saghayam et al., 2004; van Griensven et al., 2007).

Various studies have indicated the negative impact of lipoatrophy on patients living with HIV disease. The negative impact can range from psychological symptoms of distress, depression, anxiety, stigma, social isolation, career barriers to impairment of functioning ability and ultimately, to a reduction in one's quality of life (Collins, Wagner, & Walmsley, 2000; Echavez & Horstman, 2005; Martinez, Garcia-Viejo, Blanch, & Gatell, 2001; Power, Tate, McGill, & Taylor, 2003; Rajgopalan, Laitinen, & Birgitta, 2008). Some patients report reducing their adherence to ARV therapy to limit the occurrence of lipoatrophy (Ammassari et al., 2002).

Since 2004, the US Food and Drug Administration (FDA) have licensed two dermal fillers for correction or restoration of facial fat loss in persons infected with HIV. Other restorative surgery options include

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transplantation of fascia and fat from other body sites, reinjection of autologous fat, and free flaps from thigh and abdominal muscles. However, these procedures are more invasive than the use of injectable fillers, require general anesthesia and hospitalization and a prolonged recovery period (Sutinen, 2005). Furthermore, HIV-associated lipoatrophy patients frequently have minimal donor fat reserves (Jones, 2005).

The positive effects of restorative treatments for lipoatrophy extend beyond correction of undesirable facial appearance. Studies assessing quality of life improvements report positive changes in the patients' satisfaction in health perception, mental health, social function, and emotional status (Cattelan et al., 2006; Lafaurie et al., 2005; Loutfy et al., 2007; Silvers, Eviatar, Echavez, & Pappas, 2006; Valantin et al., 2003). Challenges that patients face with restorative treatments using dermal fillers are that few, if any, health plans reimburse the cost of the procedure. Physicians and patients, therefore, consider whether the benefits are sufficient to warrant the direct costs that patients will bear. Furthermore, payers lack credible evidence upon which to consider reimbursement decisions. Our study goal, therefore, was to estimate the direct costs of treating a single site of HIV-associated facial lipoatrophy with proven effectiveness.

## Methods

The target population consists of HIV-infected patients eligible for restoration or correction of facial lipoatrophy.

### *Literature search and analysis*

We conducted a systematic review of the published literature using PubMed (US National Library of Medicine) to determine which dermal fillers have been studied in countries similar to the USA and the patterns of filler administration for HIV-associated facial lipoatrophy. All fillers that have been studied for HIV-associated lipoatrophy, regardless of approval by the FDA, are included in this analysis. The inclusion criterion for the search was use of the terms: HIV-associated lipoatrophy, dermal fillers, collagen, calcium hydroxylapatite, hyaluronic acid, liquid silicone oil, polyacrylamide, polyalkylimide gel, poly-L-lactic acid, and polymethylmethacrylate. Eighty studies on the use of dermal fillers for HIV-associated facial lipoatrophy were identified. The abstracts of these studies were reviewed and studies reporting on the use of dermal fillers to correct HIV-associated facial lipoatrophy were included in the analysis. Studies that were: (1) on lipodystrophy

alone; (2) non-English; (3) non-HIV; (4) case reports and case series (less than 10 patients); (5) overview of managing adverse events; (6) with no primary data; and (7) other miscellaneous, such as papers that referred only to the pathophysiology of the condition were excluded. Fourteen studies met all inclusion and exclusion criteria, providing evidence on five dermal fillers, poly-L-lactic acid, calcium hydroxylapatite, polyalkylimide gel, hyaluronic acid, and silicone oil (Borelli et al., 2005; Burgess & Quiroga, 2005; Cattelan et al., 2006; Denton & Tsaparas, 2007; Hanke & Redbord, 2007; Jones et al., 2004; Lafaurie et al., 2005; Loutfy et al., 2007; Mest & Humble, 2006; Moyle et al., 2004; Ramon, Fodor, & Ullmann, 2007; Silvers et al., 2006; Treacy & Goldberg, 2006; Valantin et al., 2003).

### *Data analysis*

Data were abstracted from the 14 studies on the dosage, treatment schedule, and amount administered for each product. The findings were summarized using descriptive statistics (mean, median, range) to determine the typical treatment patterns. Cumulative cost of dermal filler for a single site (i.e. single malar site) was estimated as the product of (1) the number of visits per course; (2) units of product used per visit; and (3) the price per unit of filler. We also included the physician fee associated with the subcutaneous procedures. Because of lack of specific data from published studies, we did not include other potential costs related to the management of HIV-associated facial lipoatrophy, such as the indirect costs to patients due to travel and missed work for clinic visits or the potential costs of switching ARV regimens, or non-adherence to the ARV regimen as a means to limit risk of worsening severity of lipoatrophy. The costs of adverse events emerging from dermal filler restorative surgery were omitted from the primary analyses, as these were relatively uncommon and were reported as readily managed in the outpatient setting.

### *Prices*

Unit list prices were obtained from a search of publicly available retail pharmacy lists (Global Drugs Direct, 2007; PharmacyChecker.com., 2007; WestCoastSkin, 2007) and information obtained from manufacturers. Actual costs to clinics and patients may involve discounts that are not disclosed publicly; hence, the list prices may over-estimate the actual cost. Pricing of one product, polyalkylimide gel could not be identified in US dollars. We identified a UK price (Boston Clinic (UK) Ltd, 2007) and adjusted the price to US dollars based on

prevailing currency exchange rates (one US dollar = 0.492 Great Britain Pounds, October 2007).

### **Physician reimbursement**

Dermal filler restorative surgery is generally performed as an outpatient procedure. However, because of the low number of insurance plans that reimburse for dermal filler restorative surgery for HIV-associated facial lipoatrophy, publicly available information on the physician fee for the procedure is limited. Web sites summarizing information for the public on the service – e.g. The Body: The Lipoatrophy Resource Center (The Lipoatrophy Resource center, 2007) – suggest that physician fees for such services are subject to a variety of market forces, such as specialty, location, and level of competition in the area. To estimate fees for physician services if reimbursed by insurers, we examined reimbursement established by the Centers of Medicare and Medicaid Services (Physician Fee Schedule, 2007). Current procedural terminology (CPT®; copyright 2006 American Medical Association) codes for these procedures were determined to be 11950, 11951, 11952, and 11954 for “subcutaneous injection of filling material (e.g. collagen).”

### **Results**

The literature search identified 14 studies reporting primary research findings of five dermal fillers for restoration or correction of the effects of HIV-associated facial lipoatrophy (Table 1). Two products, poly-L-lactic acid and calcium hydroxylapatite, are semi-permanent injectable fillers and are approved by the FDA. The three other products, polyalkylimide gel, hyaluronic acid, and silicone oil, are not approved in the USA. Hyaluronic acid is a temporary filler and polyalkylimide gel and silicone oil are permanent fillers which are in various stages of development for use in the USA (Werschler, Rendon, Sengelmann, & Weinkle, 2006). Most of the studies ( $n=8$ ) have been published on poly-L-lactic acid, along with three studies for polyalkylimide gel, and one each for the other three dermal fillers. Study sample sizes varied from 11 to 100 patients (Table 2). Studies showed wide variation in reporting descriptive statistics of the administration of dermal fillers. Herein, we report the published measure of central tendency (mean or median), and the range for the number of visits and units of product used per visit (Table 2).

The unit list prices for these dermal fillers were: \$123 for 1 mL of poly-L-lactic acid, \$280 for 1 mL of calcium hydroxylapatite, \$752 for 1 mL of

polyalkylimide gel, \$229 for 1 mL syringe of hyaluronic acid and \$1250 for 1 mL of silicone oil. The dermal filler with the lowest cumulative cost was hyaluronic acid at \$687, primarily because the study reported only the dose administered at baseline and for this reason was excluded from further analyses. Cumulative costs for other dermal fillers varied between \$3690 and \$16,544 (Table 2). These costs are for a single site in each case; if multiple sites were to be injected, the costs would be multiplied by the number of sites injected in each case.

Various fillers have different degrees of permanency. The treatment benefits of temporary fillers, such as hyaluronic acid, usually last for less than one year (Denton & Tsaparas, 2007; Werschler et al., 2006). The effect of semi-permanent fillers like poly-L-lactic acid and calcium hydroxylapatite likely last between 18 and 24 months (Burgess & Quiroga, 2005; Moyle et al., 2004; Valantin et al., 2003; Werschler et al., 2006). The remaining two fillers are permanent. The temporary and semi-permanent fillers may require repeat injections in one or more years and may further affect cost in the future.

CPT codes for physician services vary from 1 ml or less to >10 mL, depending on the amount of filler administered (Table 3). The physician fee based on Centers of Medicare and Medicaid Services (CMS) rates for similar services of four 5–10 mL subcutaneous injections to a malar site in a non-facility setting is \$526.48.

### **Discussion**

The consequence to patients with HIV experiencing lipoatrophy goes well beyond the desire to enhance body appearance and image. Studies compellingly reveal that lipoatrophy can have profound effects not only on patients' psychological well-being and social interactions, but also on physical comfort (Collins et al., 2000; Echavez & Horstman, 2005; Martinez et al., 2001; Power et al., 2003; Reynolds, Neidig, Wu, Gifford, & Holmes, 2006).

Many web sites from patient and professional organizations provide information to patients about HIV-associated lipoatrophy and its management (The Lipoatrophy Resource center, 2007). Several of these sites include specific information about the costs of dermal-filler surgery, yet provide minimal substantiation for the cost estimates. Hence, our study is the first one to systematically analyze and record the range of costs across several products associated with this procedure.

A number of technology assessments have modeled the long-term clinical and economic implications of later stage and salvage ARV regimens (Hornberger et al., 2007). However, not one of the existing models

Table 1. Summary of published reports on dermal fillers for HIV-associated facial lipoatrophy.

Product	FDA approved for HIV-associated lipoatrophy	Indication	Number of published studies	Description	Formulation
Poly-L-Lactic acid (Sculptra™, Dermick Laboratories, Berwyn, PA, USA)	Yes (08/04)	Restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus	8	Biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy-acid family	Single-use vial, reconstituted with sterile saline
Calcium Hydroxylapatite (Radiesse®, Bioform Medical Inc., Franksville, WI, USA)	Yes (12/06)	Restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus	1	Sterile, non-pyrogenic, semi-solid cohesive implant, whose principle component is calcium hydroxylapatite	1.3 mL single-use syringe and 0.3 cc syringe small-volume applications
Polyalkylimide (Bio-Alcamid™, Polymekon Research, Milan Italy)	No	NA	3	Injectable product consisting of 96% pyrogen-free water and 4% synthetic polymeric polyalkylimide	1 mL single-use syringe
Hyaluronic acid (Perlane®, Medicis Aesthetics Inc., Scotssdale, AZ, USA)	No	NA	1	Sterile gel of hyaluronic acid generated by Streptococcus species of bacteria, chemically cross-linked with BDDE	1 mL single-use syringe
Silicone oil (purified polydimethylsiloxane) (Silikon®, 1000, Alcon Laboratories, Fort Worth, TX, USA)	No	NA	1	Highly purified long chain polydimethylsiloxane trimethylsiloxy terminated silicone oil	10 mL glass vials filled with 8.5 mL of silicone oil

Note: BDDE, butanediol diglycidyl ether.

has included the potential effects of lipoatrophy on patient outcomes and costs. Our study suggests that future development of economic appraisals should include lipoatrophy as a potential factor that may influence the comparative cost-effectiveness of various ARV regimens.

Prevention and management of HIV-associated lipoatrophy also has implications for the choice of ARV regimen. In clinical trials, lipoatrophy was found to be partially ameliorated by switching to regimens containing tenofovir (TDF) or abacavir (ABC) from regimens that contained other thymidine analogues, especially stavudine (d4T) (Martin et al., 2004; McComsey et al., 2004; Milinkovic et al., 2005; Moyle et al., 2006). In the AIDS Clinical Trial Group (ACTG) 5142 study, 9% of patients who were randomized to the combination of lopinovir/

ritonavir (LPV/r) and efavirenz had a significant body fat loss measured by dual energy X-ray absorptiometry (DEXA) scan. This contrasted with the rates of 17% and 32% of significant body fat loss associated with LPV/r and EFV, respectively, when used in combination with lamivudine (3TC)+d4T XR or TDF or zidovudine (ZDV) (Haubrich et al., 2007). In another study, M03-613, a nucleoside-sparing maintenance regimen of LPV/r monotherapy following induction with LPV/r+ZDV/3TC resulted in 5% of patients experiencing lipoatrophy compared with 35% of patients who continued on EFV+ZDV/3TC (Cameron et al., 2007).

Our study has several limitations that warrant caution in interpreting its findings. Dermal filler restorative surgery remains a non-reimbursed procedure for most public insurers. Hence, it is infeasible to

Table 2. Summary of number of injections and units per injection, by product and study.

Product	Study	Sample Size	Number of visits			Number of units per visit	Cumulative units, mean/median	Cost per unit	Cumulative cost per site	
			Mean/Median	Low	High					
Poly-L-lactic acid	Mest et al.	97	5	2	6	6 mL	30 mL	\$123	\$3690	
	Lafaurie et al.	94	5	1	7					
	Burgess et al.	61		3	4					
	Valantin et al.	50	4	3	5					
	Cattelan et al.	50		4	6					2 vials
	Moyle et al.	30	3							
	Hanke et al.	27	5							
Calcium hydroxyapatite	Borelli et al.	12		5	9	9 mL	27 mL	\$280	\$7560	
	Silvers et al.	100	3	1	3					
Polyalkylimide	Loutfy et al.	31	3	1	5		17 <sup>a</sup> mL	\$752	\$12,784	
	Ramon et al.	13	1	1	2		9 mL <sup>b</sup>			
	Treacy et al.	11	1				22 mL <sup>b</sup>			\$16,544
Hyaluronic acid	Denton et al.	18	1			3 syringes	3 syringes <sup>c</sup>	\$229	\$687	
Silicone oil	Jones et al.	77	4	1	13	1.7 mL	7 mL	\$1250	\$8750	

Note: Blank cells represent data not reported in study. All values are rounded to nearest digit.

<sup>a</sup>It is reported by Loutfy et al. that a median amount of 16.6 mL were injected during the course of the treatment.

<sup>b</sup>Investigators reported ranges of cumulative dose (Ramon et al. 5–13mL<sup>37</sup>; Treacy et al. 15–30 mL<sup>38</sup>). We selected the mid-range for cumulative dose computation.

<sup>c</sup>Package insert states that several studies have been conducted. Study MA-1400-02 ( $n=283$ ) corrected most fissures with 1.9–4.6 mL administered (max 9 mL).

analyze publicly available claims databases for patterns of administration and reimbursement. We therefore relied on information contained in published studies. With an exception of poly-L-lactic acid, there is a lack of high quality evidence data such as clinical trials for other dermal fillers. Majority of the studies are case series from private practices of the investigators. There is no consistent reporting of the data. There was a wide spectrum of descriptive statistics used to report data on dosage and frequency of visits. Due to lack of complete data on hyaluronic acid use, we had to exclude this treatment from our

cost comparison. It was difficult to estimate the amount of product being used for the complete correction of lipoatrophy as the data on number of sites injected per person were unclear in most of the studies. A wide variety of scales was used to define grades of lipoatrophy from mild to severe. Therefore, it was impossible to present the cost estimates based on the severity of facial lipoatrophy.

List prices for dermal fillers may not reflect transaction prices; for example, manufacturers may offer discounts or rebates to physicians. List prices, thus, may represent an upper bound on the actual

Table 3. Non-facility and facility physician fees for subcutaneous injection of filling material.

CPT-4 code	Amount	Non-facility fee			Facility fee		
		Median	Low	High	Median	Low	High
11950	1 mL or less	\$70.69	\$57.73	\$95.11	\$45.18	\$39.45	\$54.77
11951	1.1–5.0 mL	\$97.21	\$79.24	\$129.43	\$64.17	\$55.40	\$76.80
11952	5.1–10.0 mL	\$131.62	\$107.64	\$173.00	\$90.66	\$78.24	\$108.10
11954	> 10 mL	\$156.73	\$125.48	\$206.51	\$104.93	\$88.39	\$125.64

Note: Facility fees pertain to services performed in: inpatient or outpatient hospital settings, emergency rooms, skilled nursing facilities, or ambulatory surgical centers (ASCs), inpatient psych facilities, comp inpatient rehabilitation facilities, community mental health centers, military treatment facilities, ambulance (land), ambulance (air or water), psychiatric facility partial hospital, and psychiatric resort treatment centers. Non-facility fees pertain to services performed in all other settings.

Source: CMS Annual Physician Fee Schedule Payment (2007).

costs of fillers. By contrast, physician fees for services reimbursed by the public sector, i.e. Medicare, probably reflect a lower bound for these costs when offered in the private sector. Because of the uncertainty on exact list prices and physician fees, it is difficult to know the actual out-of-pocket costs that would be borne by the patients.

There is no reliable data on the indirect costs related with HIV-associated facial lipoatrophy, such as lost work productivity, changes in ARV regimens to prevent or limit the effects of facial and other lipoatrophy (limbs, or buttocks), and costs of adverse events that in general tend to be minor and manageable in an outpatient setting. Further research is needed to assess how the risk and occurrence of lipoatrophy affects ARV treatment decisions. In addition, we estimated the costs associated with restorative surgery in a single, usually malar, site, whereas facial lipoatrophy is frequently a bilateral disorder.

In summary, HIV-associated lipoatrophy, a condition potentially leading to depression, anxiety, stigma, social isolation, physical discomfort (when limbs and buttocks are involved) and lost work opportunities is treatable in some cases, but primarily a non-curable condition. The FDA has licensed two dermal fillers for correction and restoration of facial lipoatrophy in patients with HIV and there are three others available internationally. For many patients, undergoing such surgery may represent a difficult decision due to the considerable out-of-pocket expense ranging from \$3690 to \$16,544 per injected site, which then could have implications for deciding whether to undergo a restorative procedure, which procedure to undergo, and whether to pursue other options, such as switching ARV regimens. Furthermore, for purposes of guidelines, payers' decisions, and optimal ARV regimens, future health technology appraisals should include the incidence and costs of treating HIV-associated lipoatrophy.

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