Aesth Plast Surg (2008) 32:552–554
DOI 10.1007/s00266-008-9112-3

CASE REPORT

Treatment of Facial Asymmetry with Poly-L-Lactic Acid: A Case Study

C. M. Burgess

Published online: 30 January 2008

Abstract Poly-L-lactic acid (PLLA) (Sculptra®, Dermik Laboratories, Bridgewater, NJ, a business of sanofi-aventis US, LLC) is a novel biocompatible and biodegradable injectable device currently under review by the Food and Drug Administration for a cosmetic indication. When implanted into soft tissues, PLLA is thought to elicit a foreign body reaction, resulting in fibroplasia and subsequent collagen formation. This process leads to a gradual thickening of the dermis and long-lasting augmentation of facial contours. In the reported case, PLLA was used to treat a 69-year-old African-American woman who had undergone numerous unsuccessful procedures for correction of prominent facial asymmetry. One vial of PLLA (5-ml dilution) was injected into the dermal-subcutaneous plane using a lattice distribution in the right upper cheek and malar regions, followed by massage. The procedure was repeated 6 weeks later. Several months after the two separate PLLA treatment sessions, the contours of the right upper cheek and malar regions were visibly and cumulatively enhanced, and facial symmetry was gradually restored, to the patient's full satisfaction. The treatment was well tolerated on both occasions, and the benefits of treatment have been sustained 18 months after the last procedure. The author concludes that injectable PLLA is a safe and effective minimally invasive treatment for facial contour defects.

Keywords Case study · Facial augmentation · Poly-L-lactic acid · Sculptra

C. M. Burgess (✉)
Center for Dermatology and Dermatologic Surgery,
2311 M Street, Suite 504, Washington, DC 20037, USA
e-mail: cheryl.burgess@ctr4dermatology.com

Numerous techniques and devices have been used in attempts to augment the facial volume deficits that result from age or disease. Traditional fillers such as collagen- and hyaluronic acid-based products are generally effective in correcting lines and wrinkles for 3 to 12 months. The degree and longevity of correction is dependent on the composition of the specific material used [4]. Sculptra® (Dermik Laboratories, Bridgewater, NJ, a business of sanofi-aventis US, LLC), an alternative to traditional fillers, is currently approved by the U.S. Food and Drug Administration for the restoration and/or correction of volume associated with facial lipoatrophy in patients with human immunodeficiency virus (HIV) [16]. The approval for a cosmetic indication is currently pending.

In the European Union, Sculptra received its CE Mark in 1999. It is licensed to increase the volume of depressed areas, particularly to correct skin depressions such as skin creases, wrinkles, folds, and scars, and skin aging. It was licensed more recently (2004) for large-volume corrections of the signs associated with facial lipoatrophy. Since 1999, more than 150,000 patients have been treated with Sculptra for age-related changes and for larger areas of facial lipoatrophy [20].

Sculptra is composed of poly-L-lactic acid (PLLA) microparticles, nonpyrogenic mannitol, and sodium carboxymethylcellulose. Supplied as a lyophilate, it is recommended that Sculptra be reconstituted with 3 to 5 ml of sterile water for injection [16]. As a synthetic, absorbable, and biodegradable polymer, PLLA is biocompatible. It has been proved effective and well tolerated in a variety of medical applications for more than 40 years [10, 11, 14, 15, 17]. When implanted into soft tissues, PLLA is thought to elicit a foreign body reaction, resulting in fibroplasia and subsequent collagen production [7, 8]. The final result is a

gradual thickening of the dermis, with several months required for full realization of the effect.

In vivo, PLLA particles are degraded via nonenzymatic and possibly enzymatic pathways [8]. The results of PLLA treatment may last up to 2 years [3, 5, 13, 18, 19], which is in contrast to most other nonpermanent injectable products that provide immediate improvements but less durable results. The gradual transformation with PLLA allows the physician to monitor the degree of augmentation accurately and tailor treatment sessions to obtain the most natural look [20].

Facial volume deficits are commonly associated with age, but they also can arise as a result of disease [2]. Patients with HIV who are treated with highly active antiretroviral therapy (HAART) often present with lipoatrophy, a facet of lipodystrophy characterized by fat loss from the face, most noticeably from the cheeks, temples, orbits, and preauricular areas [6, 9, 12]. The loss of fat can be so severe that a complete lack of facial fat has been observed in some cases [1, 9]. The successful treatment of patients with severe lipoatrophy with PLLA is a testament to the product's ability to correct large areas of substantial volume loss [3]. This article details the case study of a patient treated successfully with PLLA for recontouring and correction of naturally occurring facial asymmetry.

Case Study Background

A 69-year-old African-American woman had noted a prominent right nasolabial fold crease (not HIV treatment-related) at the age of 50 years (Fig. 1). Her dentist documented the initial states of right maxillary bone and fat loss. She underwent several oral surgeries and received bovine collagen to the right nasolabial fold on two separate occasions in 1990.

In 1994, because of only partial improvement with the temporary filler and persistent facial asymmetry, the patient underwent S-lift facial reconstruction, rhinoplasty, and surgery of the upper lip. Since 2003, she had received repeated botulinum toxin A injections to her frown lines, forehead creases, and crow's feet for cosmetic relaxation of the muscles of facial expression as well as hyaluronic acid into the nasolabial folds. In 2004, PLLA was suggested for contouring and correction of her facial asymmetry.

Materials and Methods

One vial of PLLA was reconstituted with 5 ml of sterile water for injection. Topical anesthesia using Betacaine LA (prilocaine, lidocaine, and dibucaine) (Custom Scripts Pharmacy, Tampa, FL, USA) was applied 1 h before injection. Additionally, before PLLA injections, 2 ml of 1% xylocaine was injected to block the infraorbital nerves. Altogether, 5 ml of PLLA was injected (3.5 ml to the right side and 1.5 ml to the left side of the face) with a 3-ml syringe (25-gauge 1½-in. needle) using a lattice distribution (fanning technique) into the dermal-subcutaneous plane of the upper and lower cheeks as well as the preauricular and malar regions. Massage was performed using finger thimbles to roll and smooth the contours. The procedure was repeated 6 weeks later. Both treatment sessions were well tolerated and did not require cold compresses or postoperative analgesics.

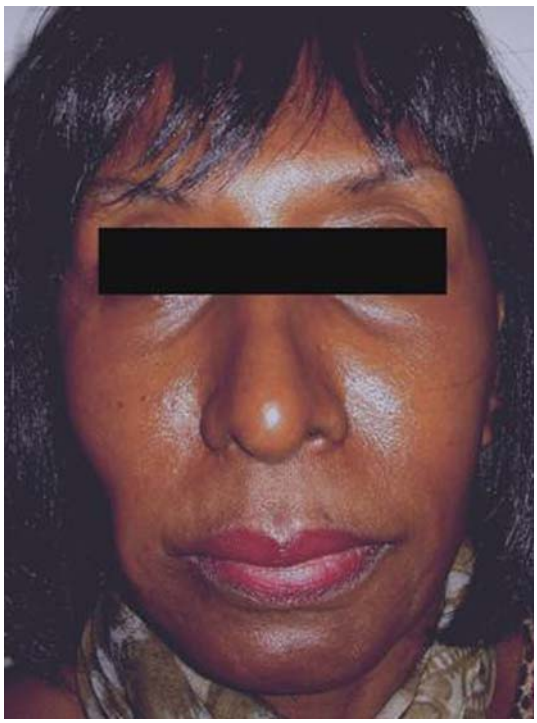

Fig. 1 Patient before treatment with poly-L-lactic acid

Results

The patient responded well to facial augmentation with an injectable reconstructor (PLLA). Enhancement of the right upper cheek and malar regions suspended the cheek, thus lifting and smoothing the right nasolabial fold (Fig. 2). Two treatment sessions, with one vial (5 ml) of PLLA administered at each session, were required to obtain the desired results. At this writing, the patient is pleased with the outcome, and results have been sustained 18 months since the procedure.

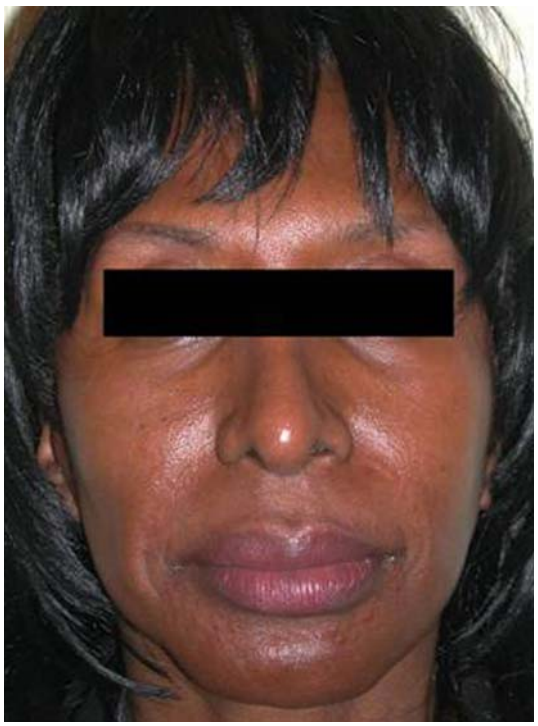

Fig. 2 Patient 18 months after the final treatment with poly-L-lactic acid

Discussion

The use of PLLA represents a well-tolerated and effective minimally invasive treatment for facial contour defects caused by lipoatrophy. As seen in the reported case study, the recontouring effects of PLLA treatment can be especially pleasing in the midface, where volume loss associated with aging or disease-related lipoatrophy may be most visible. Unlike traditional dermal fillers that offer only temporary correction of individual lines and wrinkles, PLLA provides long-lasting, often dramatic, enhancement of facial contours, allowing restoration of facial symmetry or a more youthful appearance.

Acknowledgments Dermik Laboratories, a business of sanofi-aventis US, LLC, provided editorial support for this article. The opinions expressed are those of the author.

References

1. Amard P, Saint-Marc T, Katz P (2000) The effects of polylactic acid (PLA) as therapy for lipoatrophy of the face. Presented at the 2nd International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV. Medscape HIV/AIDS 6(5)
2. Ascher B, Coleman S, Alster T, Bauer U, Burgess C, Butterwick K, Donofrio L, Engelhard P, Goldman MP, Katz P, Vleggaar D (2006) Full scope of effect of facial lipoatrophy: A framework of disease understanding. Dermatol Surg 32:1058–1069
3. Barton SE, Engelhard P, Conant M (2006) Poly-L-lactic acid for treating HIV-associated facial lipoatrophy: A review of the clinical studies. Int J STD AIDS 17:429–435
4. Bergeret-Galley C (2004) Comparison of resorbable soft tissue fillers. Aesth Surg J 24:33–43
5. Burgess CM, Quiroga RM (2005) Assessment of the safety and efficacy of poly-L-lactic acid for the treatment of HIV-associated facial lipoatrophy. J Am Acad Dermatol 52:233–239
6. Carr A, Miller J, Law M, Cooper DA (2000) A syndrome of lipoatrophy, lactic acidaemia, and liver dysfunction associated with HIV nucleoside analogue therapy: Contribution to protease inhibitor-related lipodystrophy syndrome. AIDS 14:F25–F32
7. Gogolewski S (1992) Resorbable polymers for internal fixation. Clin Mater 10:13–20
8. Gogolewski S, Jovanovic M, Perren SM, Dillon JG, Hughes MK (1993) Tissue response and *in vivo* degradation of selected polyhydroxyacids: Polylactides (PLA), poly(3-hydroxybutyrate) (PHB), and poly(3-hydroxybutyrate-co-3-hydroxyvalerate) (PHB/VA). J Biomed Mater Res 27:1135–1148
9. James J, Carruthers A, Carruthers J (2002) HIV-associated facial lipoatrophy. Dermatol Surg 28:979–986
10. Kronenthal RL (1975) Biodegradable polymers in medicine. In: Kronenthal RL, Oser Z, Martin E (eds) Polymer Science and Technology. Plenum Press, New York, p 119–137
11. Kulkarni RK, Pani KC, Neuman C, Leonard F (1966) Polylactic acid for surgical implants. Arch Surg 93:839–843
12. Moyle G, Sutinen J (2004) Managing HIV lipoatrophy. Lancet 363:412–414
13. Moyle GJ, Brown S, Lysakova L, Barton SE (2006) Long-term safety and efficacy of poly-L-lactic acid in the treatment of HIV-related facial lipoatrophy. HIV Med 7:181–185
14. Nakamura S, Ninomiya S, Takatori Y, Morimoto S, Kusaba I, Kurokawa T (1993) Polylactide screws in acetabular osteotomy: 28 dysplastic hips followed for 1 year. Acta Orthop Scand 64:301–302
15. Pettit DK, Lawter JR, Huang WJ, Pankey SC, Nightlinger NS, Lynch DH, Schuh JA, Morrissey PJ, Gombotz WR (1997) Characterization of poly(glycolide-co-D,L-lactide)/poly(D,L-lactide) microspheres for controlled release of GM-CSF. Pharm Res 14:1422–1430
16. Sculptra® Product Information, sanofi-aventis, 2006. Retrieved August 2007 at http://www.products.sanofi-aventis.us/sculptra/sculptra.html
17. Spenlehauer G, Veillard M, Benoit JP (1986) Formation and characterization of cisplatin loaded poly(d,l-lactide) microspheres for chemoembolization. J Pharm Sci 75:750–755
18. Valantin MA, Aubron-Olivier C, Ghosn J, Laglenne E, Pauchard M, Schoen H, Bousquet R, Katz P, Costagliola D, Katlama C (2003) Polylactic acid implants (New-Fill) to correct facial lipoatrophy in HIV-infected patients: Results of the open-label study VEGA. AIDS 17:2471–2477
19. Vleggaar D (2006) Soft tissue augmentation and the role of poly-L-lactic acid. Plast Reconstr Surg 118:46S–54S
20. Vleggaar D, Bauer U (2004) Facial enhancement and the European experience with poly-L-lactic acid. J Drugs Dermatol 3:526–530