

# Sculptra: A Stimulatory Filler

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## ABSTRACT

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Sculptra is a biocompatible, resorbable injectable filler composed of poly-L-lactic acid (PLLA). It falls in the class of a stimulatory filler that creates its effect through encouraging neocollagenesis when injected. As it differs from traditional, static fillers such as hyaluronic acid and collagen, it requires a special understanding of how it works, where it can be used, and how it should be injected. The goal of this article is to review the nature of stimulatory volume replacement with a focus on PLLA and its unique considerations. Both the natural method of volume restoration and the persistence of results of up to 2 to 3 years make this product one worthy of inclusion in the first line of tools for cosmetic rejuvenation as well as for reconstructive soft tissue deficits and lipoatrophy.

**KEYWORDS:** Sculptra, PLLA, poly-L-lactic acid, filler, lipoatrophy

Sculptra (Dermik Laboratories, Paris, France, a business of Sanofi-Aventis LLC) is the brand name for injectable poly-L-lactic acid (PLLA). In the arena of facial fillers and volumizers, PLLA is one of a few stimulatory fillers as opposed to the traditional immediate fillers like collagen or hyaluronic acids. A stimulatory filler does not take up space and create immediate results but rather causes the growth of fibrous tissue or collagen by the body, which then results in volume restoration gradually. Poly-L-lactic acid is a synthetic polymer from the  $\alpha$ -hydroxy-acid family that is similar to absorbable suture material.<sup>1</sup> PLLA can be used for deep tissue filling or in the dermal subcutaneous junction to firm under the skin and soften lines and wrinkles. It is not meant to be injected intradermally. Results occur over a series of injections as the collagen builds and improvement progresses. In general, a series of at least three sessions per treatment area is necessary for optimal results. Once results occur, the PLLA is gradually resorbed<sup>2</sup> and benefits last for 2 to 3 years or longer.<sup>3-5</sup> A review of current state-of-the-art injection techniques and methods will aid in achieving reproducible results and avoiding potential adverse events.

Sculptra should not be used as a line filler. For example, vertical lip rhytides and crow's-feet are not meant to be treated with PLLA. Global hollowing, deep folds and creases, or even scars are good candidates as well as general cheek wrinkling caused by fat loss. Examining the face as a whole and looking for concavities and hollows brought on by heredity, aging, weight loss, or disease-associated lipoatrophy can direct the treatment plan for a natural-looking rejuvenation of the whole face or just problem areas. Often, education of the patient as well as newer physician-injectors is important to set expectations and ensure satisfaction with stimulatory types of fillers. This is not the type of treatment for those wanting instant gratification. It is a good option for those desiring longer term results and or results over a larger surface area.

## HISTORY

Injectable PLLA has been used as a cosmetic volume enhancer since 1999. In Europe, it was first marketed as New-Fill by Biotech Industry SA, Luxembourg. By 2004, Sculptra was introduced to the American market by Dermik Laboratories for use in HIV-associated

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Injectable Fillers; Guest Editor, Theda C. Kontis, M.D., F.A.C.S.

Facial Plast Surg 2009;25:95-99. Copyright © 2009 by Thieme Medical Publishers, Inc., 333 Seventh Avenue, New York, NY 10001, USA. Tel: +1(212) 584-4662.

DOI 10.1055/s-0029-1220648. ISSN 0736-6825.

lipoatrophy. Estimates of worldwide use since 1999 are that upwards of 150,000 patients have been treated.<sup>1,6</sup> One of the pioneers of this product, Danny Vleggaar, M.D., reported in 2004 on personal experience with more than 2500 patients. Since then, numerous studies have been published attesting to the safety, effectiveness, and longevity of injectable PLLA.<sup>1,3,11,13</sup>

The early use of PLLA differed from current recommendations in several important ways that contribute to the safety of the product. The particle size of the product is now more uniform under the auspices of Dermik Laboratories. The product is prepared in a more diluted suspension and is reconstituted further in advance than originally reported. With experience, injection techniques have been refined to eliminate intradermal placement of the product, and intervals between injections have lengthened to 4 to 6 weeks. Each of these factors is believed to be helpful in the drastic diminution of adverse events being reported. A review of the literature by Kates and Fitzgerald recently showed that earlier rates of 31 to 52% incidence of papules have been reduced to 0 to 7% in numerous more recent studies.<sup>1</sup>

### WHERE IT IS USED

Sculptra is used in most parts of the face, and even off-the-face use is reported in the literature. As with most fillers, studies comparing the product to collagen in the nasolabial fold have been performed, both outside and in the United States. In a recent study out of Brazil, 40% of patients showed permanence of the effect in the nasolabial fold at 36 months.<sup>5</sup> A multicenter Sculptra Cosmetic Trial Group study has been completed but not yet published. A poster of partial results was presented in 2007. Those results showed continued progression of significant improvements in the nasolabial fold out to 13 months.<sup>7</sup> Common areas of use include cheeks, temples, inframalar region, chin, prejowl sulcus, and marionette lines. More advanced areas include infraorbital regions and lateral brow. Creative uses have been reported in treatment of acne and varicella scars, chest wall deformity after breast reconstruction, prominent facial asymmetry/Romberg syndrome, the dorsum of the hands, and postoperative soft tissue lost after melanoma excision.<sup>6,8-10</sup> Of note, use in the lips and in the plane of the orbicularis oris or oculi is highly discouraged.

### HOW IT WORKS: WHAT IS PLLA?

The science behind PLLA involves more than 40 years of use in human medical applications.<sup>6</sup> From absorbable suture to resorbable screws, it has proved biocompatible, well tolerated, and effective. The mechanism of action is thought to be stimulation of a foreign-body reaction

characterized by increased macrophages, mast cells, and lymphocytes. This influx leads to slow degradation of the product-increased fibroblastic activity and gradual neocollagenesis.<sup>2</sup> Werschler et al identified increased levels of type I collagen in histologic studies of treated skin.<sup>11</sup> New collagen appears to form by 1 month and continues to increase for 9 months to a year. The PLLA particles show signs of breaking down around 6 months and are gone by 9 months.<sup>2</sup>

Duration of effect has been repeatedly demonstrated in prospective clinical studies of at least 2 years. These include the VEGA, Westminster, Blue Pacific, and Apex studies.<sup>1</sup> Follow-up reports on 2-year data, now out 3 years, are showing good continued persistence of results.<sup>3,5,11,12</sup>

### HOW IS IT RECONSTITUTED?

The product comes from the company in a glass bottle as a sterile freeze-dried powder composed of PLLA, sodium carboxymethylcellulose, and nonpyrogenic mannitol. Two vials are provided in each box as well as two vials of sterile water for injection. The package insert states that from 3 to 5 mL of water should be added to the product at least 2 hours prior to use. The author and many high-volume users are adding the 5 mL of water and letting stand undisturbed from 24 to 72 hours minimum prior to use to facilitate reconstitution. Package guidelines also recommend discarding any product more than 72 hours old. In practice, as with many other types of injectables including botulinum toxin type A, it is common and still as effective even when kept for a month or longer. Should there be concerns about maintaining sterility, bacteriostatic water can be used and the vials kept in the refrigerator until the day of use. It is desirable for the PLLA suspension to be at room temperature or warmer at the time of injection to minimize clogging of the needle.<sup>4</sup>

Just prior to injection, 2 mL plain lidocaine 2% is added to the bottle, for a total of 7 mL. The suspension is then agitated in a vortex for 5 to 10 minutes before it is ready for use.

### HOW IS IT INJECTED?

Patient preparation involves complete five-view photographs (front, two sides, and two obliques), cleaning the face of makeup and creams, and optional anesthetic. For most patients, the most uncomfortable portion of a treatment is the needle entering the dermis or a depot that lands the needle on the bone. Once an area is partially treated, the lidocaine helps to anesthetize the remaining injections. The author is a proponent of maximal pain control and tends to perform infraorbital and mental blocks on all filler patients and then intradermal skin wheals in selected areas before beginning

treatment. This is especially important when training a new injector as the process is not as smooth as it can eventually become. Some injectors prefer topical numbing creams, though they are often not very effective and make the skin slippery and slightly edematous. This can efface the textural and contour changes important to look for during the injection. Many patients do very well from a pain management standpoint with skin wheals only or nothing at all.

At least a 26-gauge needle is recommended for PLLA injections though many prefer using a 25-gauge needle to minimize clogging of the suspension particles. Many advanced injectors use a 25-gauge, 1½-inch needle with a 1 mL Luer Lock syringe to minimize the number of needle entry points and thereby both pain and subsequent bruising.

There are several techniques for proper injection, but most important is getting it to the proper depth in the correct part of the face or skin. In the upper half of the face, the goal is to place the product on the periosteum or as deeply into the temporal region as possible. The plane remains the same regardless of whether the tear trough, lateral orbital rim, tail of the brow, or temple are treated. Especially under the eye, it is important not to inject into or through the orbicularis oculi muscle as this area is the one with the highest rate of nodularity if performed incorrectly and should be considered an advanced injection area regardless of what type of fillers are used. Care should be used to place the injections at the highest point of the infraorbital rim to prevent augmentation of the cheek bulge if a concave tear trough is being targeted. The technique best used in this upper half of the face is serial depot injections of from 0.1 to 2 mL. The reason for using a longer needle is to allow the point of entry to be in the thicker skin of the midcheek region passing under the orbicularis muscle without creating a tract through it. Not only does this minimize bruising in the thin skin under the eye, but also it eliminates the possibility of product being pulled back through the muscle.

In the lower half of the face, the plane of injection as well as the technique is very different than that for the upper face. The ideal place for the product is at the dermal/subcutaneous junction. This level is relatively superficial yet clearly not in the dermis where any resistance or blanching of the skin would occur during injection. When using a ¾-inch or 1-inch needle, the optimal technique is retrograde injection in serial threads with cross-hatching. Use of the longer 1½-inch needle, for experienced injectors comfortable with this length, facilitates fanning of threads through a limited number of puncture sites. Decreased discomfort from fewer needle entries through the dermis and less bleeding are advantages. Care must be taken not to inject when withdrawing the needle too close to the apex of the fan

to avoid overdeposition of product in one area. The goal, regardless of technique, is to spread the product as uniformly over the targeted area as possible without any focal accumulations. New injectors of Sculptra currently undergo one-on-one hands-on training prior to beginning use of the product.

After the injection, it is important for the injector to deeply palpate and massage the treated areas to ensure even distribution of product. Once at home, the patient should be instructed to do the same massage several times a day for a week to 10 days (for example: twice a day for 5 minutes for 10 days). The addition of massage after treatments and higher dilutions used during reconstitution are believed to be largely responsible for the much lower incidence of postinjection nodularity found in earlier studies.<sup>2,13</sup>

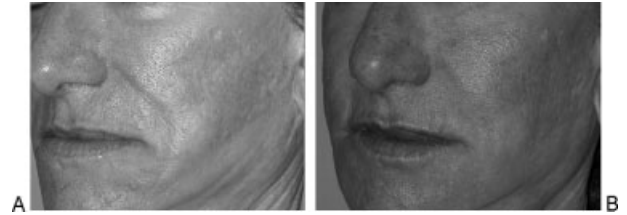
### **MANAGING PATIENT EXPECTATIONS IN THE PERI-INJECTION PERIOD**

With a stimulatory filler of any kind, it is important to carefully and clearly explain the process and goals of the treatment before beginning treatment. Sculptra in particular requires this education because it is administered in usually three or more sessions covering a 3-month period or more with ultimate results achieved over a 4- to 6-month time frame. Patients not willing or able to wait for improvement may need additional augmentation with a hyaluronic acid to tide them over in the mean time. Because of the volume of the water in the suspension, patients will leave the office looking filled; however, they should be aware that the improvement they see immediately will be gone in 2 to 4 days and they will then await the collagen growth that can be seen starting at 6 to 8 weeks. Patients should also be cautioned to prepare for the possibility of bruising and avoid non-steroidal anti-inflammatory medications prior to an injection.

Experience and clinical trials bear out that multiple sessions of 1 to 2 vials per session and up to six to eight sessions in those with severe wasting or lipoatrophy are necessary for complete correction.<sup>1,4,11</sup> Typical cosmetic patients receive 3 to 6 vials over three sessions. When treating the lower half of the face only, 1 vial is used per session. Two vials per session are used if both the upper and lower halves of the face are addressed. Undertreatment is a common error of new injectors who are rightfully interested in being cautious. However, the nature of injectable PLLA is that unless the patient has had three vials over time, they have not even had one conservative treatment. Using less than this amount results in overly subtle results that disappoint both the patient and the injector. Equally important is the use of preoperative photography, which reminds everyone of the amount of improvement as it comes on gradually. Just as the signs of aging occur gradually and are not



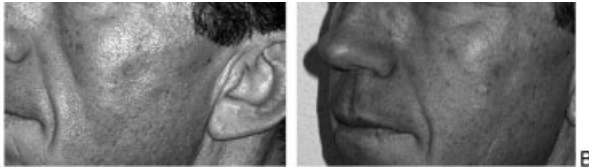
**Figure 1** A 59-year-old woman: (A) no previous treatments; (B) PLLA 2 vials per treatment (6 weeks after treatment).



**Figure 5** A 65-year-old woman: (A) no previous treatments; (B) PLLA 2 vials per treatment, 3 treatments, 6-week intervals (shown at 2 years).

realized by the patient until advanced, improvement over time with a stimulatory filler can be overlooked at first.

Once volumization has been achieved, results can be expected to last for 3 to 3 years or longer (Figs. 1–7).



**Figure 2** A 43-year-old man: (A) no previous treatments; (B) PLLA 2 vials per treatment, 6-week intervals.



**Figure 6** A 41-year-old woman: (A) no previous treatments; (B) PLLA 2 vials per treatment, 3 treatments, 6-week intervals.



**Figure 3** A 53-year-old woman: (A) no previous treatments; (B) PLLA 2 vials per treatment, 2 treatments, 6-week intervals.



**Figure 7** A 61-year-old woman: (A) no previous treatments; (B) PLLA 1 vial per treatment, 3 treatments, 6-week intervals.



**Figure 4** A 59-year-old woman: (A) no previous treatments; (B) PLLA 2 vials per treatment, 3 treatments, 6-week intervals.

## CONCLUSION

Sculptra has shown to be a safe and effective stimulatory filler for both cosmetic and lipoatrophy patients. Appropriate use of this product as described above and through hands-on injection training will result in good correction of soft tissue volume loss. Once the ease of use and long-lasting natural results are realized, the value to both injector and patient become relatively clear. Skillful and careful use of the product-specific guidelines can avoid potential adverse events and high levels of treatment satisfaction.

## DISCLOSURE

Dr. Lacombe is a speaker and trainer for Sculptra/Sanofi-Aventis, as well as Allergan and Medicis. He did not receive any financial aid in the production of this article.

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