



# Sculptra: the New Three-Dimensional Filler

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Sculptra (Dermik Laboratories, A Division of Aventis Pharmaceuticals, Inc., Berwyn, PA) was approved by the US Food and Drug Administration (FDA) on August 3, 2004 as the first synthetic injectable medical device for the treatment of HIV-related facial lipoatrophy [1]. HIV lipodystrophy syndrome is a complication of highly active antiretroviral therapy (HAART) with protease inhibitors (PIs) or nucleoside reverse transcriptase inhibitors (NRTIs) [2–7]. HIV lipodystrophy syndrome is characterized by metabolic abnormalities, central fat hypertrophy, and peripheral fat atrophy. Metabolic aberrations (insulin resistance/diabetes, hypercholesterolemia, and hypertriglyceridemia) and central fat hypertrophy are more commonly seen with PIs, whereas NRTIs are more likely to contribute to fat wasting or lipoatrophy [6]. Metabolic changes may eventually require medication with oral hypoglycemic, antilipid agents, or both.

The phenomenon of abnormal fat distribution, affecting 30% to 80% of patients on HAART, may be a consequence of PIs and NRTIs or may be interpreted as a long-term complication of HIV disease [2,6]. The search for optimal treatment of these abnormal fatty changes continues. Hypertrophic fat deposition occurs most commonly in the truncal area with a predilection for the dorsocervical region (buffalo hump/hoarse collar), lower abdomen (crix belly/protease paunch), and breasts. Although human growth hormone has been demonstrated to improve central obesity of the abdomen, breasts, and buffalo hump, recurrence with cessation of therapy is likely [8]. Localized liposuction of hypertrophic fatty deposits using tumescent anesthesia is safe, effective, and provides cosmetic improvement [9].

Atrophic fatty changes may present as peripheral wasting of the face, extremities, and buttocks.

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Prolonged duration of antiviral therapy, specific antiviral agents (especially stavudine [Zerit]), combination therapy using PIs and NRTIs, advancing age, low body weight, and incomplete viral suppression contribute to the progression of lipoatrophy [10]. The treatment of the atrophic component of HIV lipodystrophy syndrome represents a therapeutic and cosmetic challenge. Androgens, such as testosterone and nandrolone, may increase muscle mass, enhancing body form and camouflaging lipoatrophy of the extremities [6,11,12]. Chronic steroid use may, however, increase the risk of hepatotoxicity and lead to diabetes, making such treatment regimens controversial for HIV lipodystrophy syndrome [6].

Facial wasting may be severe and distressing for patients who are otherwise stable. The HIV lipoatrophy patient has a characteristic cachectic and emaciated appearance [13]. The face shows progressive loss of orbital, buccal, parotid, and preauricular fat. Eyes appear prominent and hollow. Progressive orbital lipoatrophy causes a flattening and lengthening of the lower eyelids, leading to increased scleral show. Cheeks appear sunken with loss of the preauricular and buccal fat pads. As severity progresses, skeletal and muscle visibility become prominent features. Often, the nasolabial folds flatten and, along with atrophy of the cheeks, gives a prominence to the perioral region. The face develops a simian appearance. For many, this appearance becomes the overt sign of HIV and the source of social, emotional, and physical debilitation [14]. FDA approval of Sculptra, a volumetric and global filler lasting 18 to 24 months, provides a therapeutic alternative for HIV lipoatrophy patients [15].

### The Vega study

The Vega study, an open-label, single-arm pilot study of poly-L-lactic acid (PLLA) for the treatment of HIV lipoatrophy, assessed efficacy, safety, and durability over 96 weeks [16]. Fifty patients who had severe lipoatrophy (determined by ultrasonography to be <2 mm facial fat thickness) were enrolled. The median facial fat thickness was equal to 0 (0.0–2.1 mm) and a median total cutaneous thickness (TCT) was 2.9 mm (range, 2.0–5.5 mm). Injections were performed at day 0 and at weeks 2, 4, and 6. Reconstitution of product included 3 to 4 mL of sterile H<sub>2</sub>O injection USP. One milliliter of lidocaine was injected locally for pain control. Patient assessment was performed by clinical examination, ultrasound, and photography at baseline and at weeks 6, 24, 48, 72, and 96.

Four patients received only three sets of injections due to adequate response, 26 received four sets, and 20 received an additional fifth set because facial TCT

was less than 8 mm. The primary end point was the proportion of responders, defined as patients who had a TCT greater than 10 mm measured at the nasogenian fold (located below the malar bone, ahead of the masseter), at 24 weeks. Secondary end points were changes in TCT and quality of life.

The proportion of patients who had a TCT of at least 10 mm was 19% at week 6, 41% at week 24 (primary end point), 61% at week 48, 52% at week 72, and 43% at week 96.

The median increases in TCT from baseline were significant at all weeks. Median TCT increases of +5.1 mm at week 6, +6.4 mm at week 24, +7.2 mm at week 48, +7.2 mm at week 72, and +6.8 mm at week 96 were documented.

As cosmetic improvement occurred, a significant increase in quality-of-life scores from baseline was noted.

Further benefits of PLLA injections in HIV lipoatrophy are presented in the Chelsea and Westminster Hospital study [17].

### Lipoatrophy

Lipoatrophy is not unique to HIV disease. Other disorders such as diabetes, dermatomyositis, panniculitis, and chronic disease states associated with malnutrition and anorexia nervosa may lead to loss of subcutaneous fat. Focal trauma, superficial surgical dissection planes, aggressive liposuction, steroid injections, and cystic acne with scarring may lead to loss of deep dermal tissue or subcutaneous fat. Other contributing factors include genetics, diet, exercise, and tobacco and alcohol use. Fat loss or redistribution is the primary reason for volume loss in the chronologic aging face [18]. As the face ages, the skin develops an undulating/wavy quality. Areas that were once convex now appear concave, such as the temples, preauricular areas, cheeks, and lateral aspects of the chin. The tear trough/nasojugal folds, nasolabial folds, and marionette lines appear deeper and shadowed. Experience and results with Sculptra for global volumetric restoration in HIV lipoatrophy has opened the door for "off-label" use in cosmetic patients who have volume loss. Sculptra is marketed in Europe as New-Fill and used internationally in over 30 countries, with over 150,000 patients treated for skin wrinkles and folds since 1999. In February 2004, the indication for New-Fill was broadened to include lipoatrophy [19].

### The Sculptra concept

Sculptra is a volumizer lasting 18 to 24 months. Sculptra's longevity is based on the slow degradation kinetics of the PLLA microparticles, a result

of irregularly shaped microparticles measuring approximately 40 to 63 micrometers and having a high molecular weight of 140,000 d. The implanted PLLA microparticles remain and act as a stimulant for fibroblast production and collagen synthesis [20]. Gogolewski and colleagues demonstrated fibroblast activation and collagen production in the mouse model [20]. Further histologic studies are planned for documentation of the PLLA effect in human skin.

Sculptra is not a line filler. For most patients, Sculptra is best used for global volumetric augmentation of the mid and lower thirds of the face. The injector should approach the lower two thirds of the face as a whole. As a three-dimensional (3-D) filler, Sculptra moves soft tissue in a medial to lateral, superior, and anterior direction. The injector should volumize areas that are concave, blending these depressed atrophic areas into those that are convex. This technique allows the injector to establish a uniform 3-D enhancement with smooth transition between cosmetic units while maintaining facial contour. This re-establishes the so-called “bloom of youth”—a full yet contoured face.

A criterion for a volumetric filler is that it must be placed deeply to exert its effect. Whether implanted at the dermal–subcutaneous junction, within the superficial subcutaneous fat, or just above the periosteum (at the orbital rim, zygomatic arch, or temporal bone), the PLLA microparticles are able to ultimately stimulate production of fibroblasts and collagen. The optimal depth of implantation, however, is the dermal–subcutaneous junction.

The mantra “Treat, Wait, and Assess” guides an injector through a Sculptra series, whereas the triad of depth, volume, and distribution of PLLA remains key for optimal clinical and cosmetic success.

As PLLA microparticles slowly degrade, the stimulus for fibroblast and collagen production dissipates. A patient’s appearance (in terms of the filling effect) offered by PLLA would be expected to gradually change over 18 to 24 months. As clinical change occurs, touch-up injections may be required. One would expect less total volume or fewer injection sessions required to regain optimal enhancement.

### Injection supplies

Sterile bacteriostatic H<sub>2</sub>O injection USP (increases shelf life to 1 month); nonbacteriostatic (shelf life 72 hours)

Lidocaine 1% or 2% with or without epinephrine  
3-mL or 1-mL B-D (Becton-Dickinson and Co., Franklin Lakes, NJ) or Terumo Luer-Lok (Terumo Corp., Tokyo, Japan) syringes  
25-gauge 1-in or 26-gauge 0.5-in B-D needles

18-gauge B-D needles  
Marking pencils (eyebrow or lip liner) and sharpener  
Ice packs  
Alcohol/chlorhexidine prep  
Gauze  
Gloves  
Topical anesthetic

### Reconstitution

For reconstitution of a uniform homogeneous hydrogel suspension, add 5 mL sterile water injection (USP) 24 hours before injection. For uniform hydration do not agitate but allow the powder-cake to absorb the sterile H<sub>2</sub>O slowly over night. Add 1 mL lidocaine 1% immediately before injection, slowly, dripping through an 18-gauge needle. When added too quickly, lidocaine can precipitate the hydrogel suspension, leading to difficulty with injection (ie, clogging) (Fig. 1). To facilitate withdrawal of PLLA, allow the 18-gauge needle to remain in the vial, allowing equilibration with the atmospheric pressure and easy filling of syringes. Do not introduce air into the vial with extraction of PLLA because this may also cause precipitation.

It is fine to swirl, agitate, or shake hard after hydration overnight. Occasionally, there may be a situation in which overnight mixing did not occur. In such cases, the PLLA may be hydrated and held close to the body (eg, in a pant pocket) to “melt” the particles into suspension.

Variations on reconstitution volumes exist. Injectors who use regional blocks or local anesthesia may prefer hydration with 6 mL sterile bacteriostatic H<sub>2</sub>O alone without the addition of lidocaine. Others may prefer 4 mL sterile bacteriostatic water and 2 mL lidocaine 1% or 2% with or without epinephrine. Regardless of the ratio of sterile water to lidocaine, in the author’s experience, a total reconstitution volume of 6 mL per vial provides an optimal suspension for ease of injection and efficacious results. A 6-mL dilution may further minimize the



Fig. 1. Add lidocaine slowly to avoid precipitation of PLLA.

possibility of papules or nodules that may occur with more concentrated or less dilute suspensions of the PLLA hydrogel. A 6-mL dilution per vial also provides adequate volume for complete distribution over the lower two thirds of half the face in cases of severe lipoatrophy (ie, one vial [6 mL] per side of the face). Smaller volume dilution, in the author's experience, makes uniform distribution and complete coverage more difficult when dealing with severe cases or larger faces. Those who inject dorsal hands for volumetric rejuvenation have used even greater dilution volumes (10–12 mL total). This higher dilution may decrease the risk for papule or nodule formation in extremely thin skin of the dorsal hands.

### Shelf life

Reconstitution with 5 mL sterile bacteriostatic water injection USP and 1 mL preserved lidocaine 1% creates a multidose vial, extending shelf life. One month, stored at room temperature or refrigerated, remains the general consensus on shelf life after reconstitution with sterile bacteriostatic water and preserved lidocaine 1%. If refrigerated, allow to stand at room temperature or to warm to body temperature before injection. This practice aids in suspension of PLLA microparticles. Less precipitation with fewer clogs equates with ease of injection. Date and list reconstitution ingredients and dilution volumes on stored Sculptra vials.

### Prep and anesthesia

The patient's face is cleansed with soap and H<sub>2</sub>O and the skin is prepped with chlorhexidine (Hibiclens) or alcohol.

Topical anesthetic cream or ointment applied 30 minutes before treatment may help blunt the pain of needle sticks. Ice packs applied before and after injection may mitigate pain, stimulate vasoconstriction, and decrease bruising/hematoma formation.

Given the addition of lidocaine to the suspension, a tumescent anesthetic effect is achieved, minimizing discomfort. Regional infraorbital or mental nerve blocks add volume and may cause swelling, which can lead to confusion with injection volumes of Sculptra and the desired end-point correction. Pain is minimal, given the depth of injection (optimally, the dermal–subcutaneous junction). Intradermal injections of other fillers are more painful secondary to the dermal location of sensory nerve endings for pain.

### Pretreatment baseline photos

Documentation of improvement is important for physician and patient satisfaction, especially in

a serial procedure that has gradual benefit over several months (Figs. 2–4).

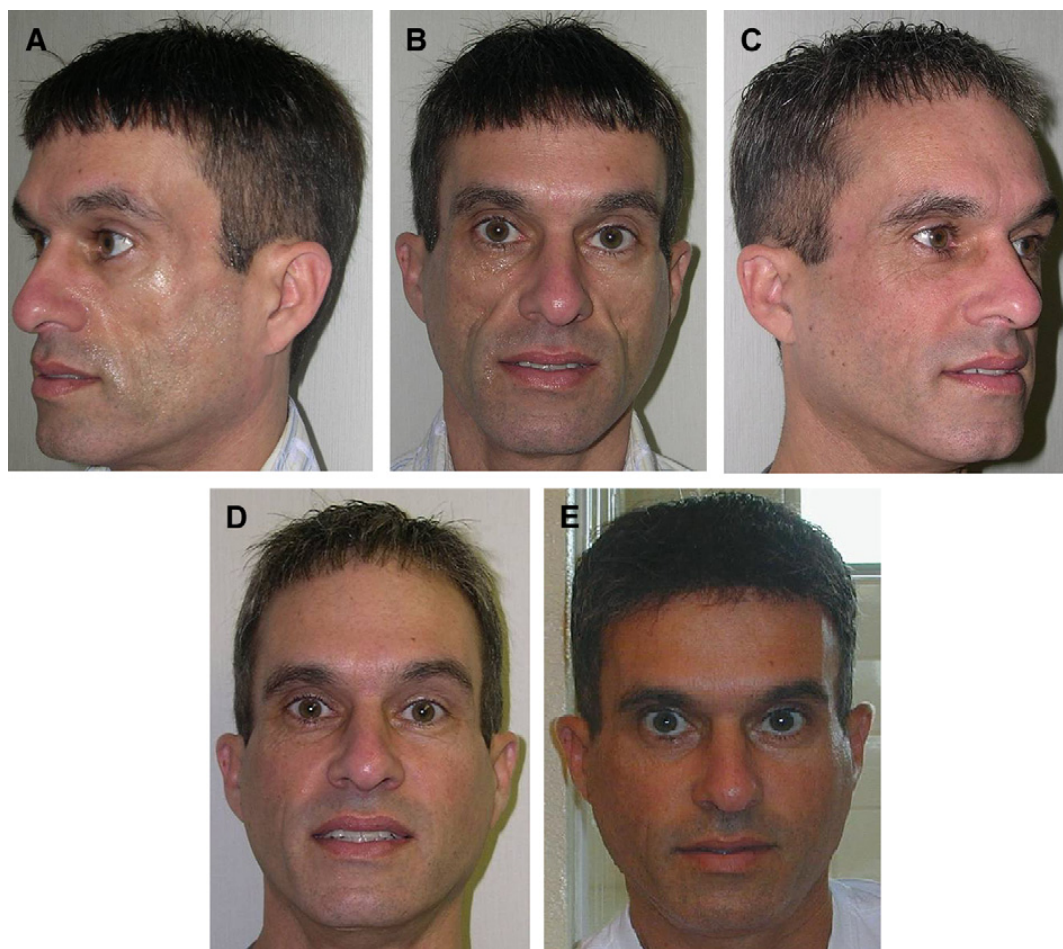
### Marking the patient

Marking with an eyebrow or eyeliner pencil, which is easily removed with alcohol, may help the injector plan the case (Fig. 5). The malar fat pad is blended and elevated, thus beginning the restoration of facial volume: elevating concavity and blending to meet convexity. This uniform plane is established while maintaining facial contour. Titration of volume is important as one moves from the superior to the inferior aspect of the face and allows the injector to maintain contour and avoids a heavy or squared off appearance to the lower face. In female patients, this titration restores the more feminine heart-shaped face. Convex areas of skin may be marked with X's to indicate a no filling zone. Facial bone structure also helps guide volume restoration. Planning and individualization of each case is key to cosmetic success.

In the author's experience, it is most comfortable for the physician to inject while he or she is standing and the patient is reclined at approximately 45°. The author usually completes one side of the face and then moves to the opposite side. When treating the full lower two thirds of the face, the author prefers to begin at the most superior medial aspect, the nasojugal fold/tear trough, and to move in a superior-lateral direction to augment the medial, mid, and lateral cheek, followed by the temple and preauricular areas. The author then moves inferior and medial to treat the nasolabial fold and the cutaneous upper lip, followed by the inframalar/buccal fat pad region. Finally, the author moves to the cutaneous lower lip, chin, prejowl, and jawline. The basic principle is to begin superiorly, injecting from medial to lateral, and progress inferiorly, again injecting from medial to lateral. After completion of both halves, one should assess from coronal and frontal views, check for symmetry, and balance the face with a small amount (0.25–0.50 mL) of PLLA that is reserved for touch-ups at the end of the injection session.

### Method of injection: retrograde tunneling versus depot

By far, retrograde tunneling is the workhorse type of injection. Enter the skin at a 30° to 45° angle, bevel up. Decreased resistance is felt as the needle passes from the more resistant dermis into the subcutaneous fat. At the dermal–subcutaneous junction, the 25-gauge 1-in needle is easily advanced parallel to the skin surface to the needle hub. To check for proper depth of needle, gently lift the syringe and



**Fig. 2.** Case 1. (A) 1.14.05, before Sculptra. (B) 1.14.05, before Sculptra. (C) 07.26.05, after Sculptra. (D) 7.26.05, after Sculptra. (E) 6.20.06, after Sculptra.

note the roll of skin overlying the needle (Fig. 6). When the needle is too superficial during advancement, the skin will tether or bunch—resistance due to intradermal location. When the needle is too superficial when the syringe is lifted, the skin appears tented over the needle. Withdraw completely and re-enter at the 30° to 45° angle, noting the resistance change, which signifies proper depth.

At proper depth, a retrograde injection is performed. As the needle is withdrawn from the skin, gentle pressure is applied to the plunger and a small volume (0.025–0.1 mL, depending on area) is injected. With initiation of the retrograde movement before injection, an intravascular injection becomes unlikely; however, when the area to be treated is highly vascular, like the temple, aspirate first, begin retrograde movement, and then inject as a precaution to avoid intravascular injection. Tunnel injections are terminated after removal of approximately three fourths of the 1-in needle to avoid superficial epidermal or dermal implantation (Fig. 7). As one approaches the tail end of the injection, less pressure is applied, tapering the trail of PLLA microparticles implanted. It is important to stay at the proper depth to avoid superficial implantation that may lead to a visible papule. Deeper

bolus may lead to nodule formation. On average, tunnels are spaced approximately 2 to 4 mm apart. This spacing allows for uniform distribution of PLLA throughout the areas of injection. Again, proper depth, small volumes (0.025–0.1 mL, depending on location), and uniform distribution with cross-hatching in a gridlike pattern ensure safe and efficacious treatment with Sculptra.

After a rhythm is established, these injections are performed quickly and in concert with steps to prevent clogs. Massage frequently post injection. Add ice and pressure when necessary. Some injectors may find it difficult to establish a rhythm of movement. These injectors may tend to “loiter” or “stall” (ie, inject without moving in a retrograde fashion), which is not a good thing for two reasons: (1) without movement, the implantation becomes a bolus injection and may lead to a superficial papule or deep nodule, depending on depth of implantation; and (2) intravascular injection may be more likely. Those who have a tendency to loiter or stall with injection or the newly trained injector should always aspirate before injection.

Tunneling may be modified by creating a fanning pattern in certain areas of the face, such as the temple, preauricular, midcheek, and lateral chin/



**Fig. 3.** Case 2. (A) 1.21.05, before Sculptra. (B) 1.21.05, before Sculptra. (C) 6.16.05, after Sculptra. (D) 6.16.05, after Sculptra. (E) 6.13.06, after Sculptra.

marionette areas. A single entry point and pivotal movement, fanning a series of retrograde tunnels, allows for fewer sticks and efficient placement of PLLA over a broad area. The volume of PLLA injected per tunnel when fanning is approximately 0.05 to 0.1 mL. This volume is injected in a tapering fashion within each arm of the fan to avoid excess accumulation at the point of pivot, avoiding formation of a deep nodule (Fig. 8). Fanning is considered a more advanced injection technique.

Depot injections in the author's practice and training sessions have become less common. Depot injections, by nature, are a small bolus. In areas such as thin periorbital and temporal skin, this type of injection seems counterintuitive and may account for the formation of small superficial papules or deeper nodules. Tunneling can replace the depot method around the periorbital and temporal areas. First, establish depth of injection. For example, in patients who have extremely thin skin, the needle will skirt the inferior aspect of the orbital rim, just above the periosteum. In patients who have thicker skin, the needle may remain within soft tissue at the dermal-subcutaneous junction.

Check depth as previously described. At the proper depth, with placement of the needle in the tear trough area, begin the retrograde movement first, then inject from medial to lateral, using approximately 0.025 to 0.05 mL. Icing immediately before and after this injection will stimulate vasoconstriction and minimize bruising. Massage post injection to facilitate uniform distribution of PLLA. Imagine that this small aliquot of Sculptra is implanted over approximately 0.75 in. This technique produces a safer trail or thread of PLLA implanted uniformly over greater distance than a focal depot injection of the same volume.

**Injection needles: 25-gauge 5/8-in and 26-gauge 0.5-in versus 25-gauge 1-in versus 25-gauge 1.5-in**

Using the retrograde injection technique, shorter needles such as the 25-gauge 5/8-in or 26-gauge 0.5-in require more sticks, more starts and stops, and are more likely to be associated with implantation of a small bleb or bolus of product compared with injection of the same volume of PLLA using



**Fig. 4.** Case 3. (A) 11.10.04, before Sculptra. (B) 11.10.04, immediately after Sculptra. (C) 7.15.05, after Sculptra. (D) 6.06.06, after Sculptra.

a longer, 25-gauge 1-in needle. A small bleb or bolus may be more likely to cause a papule or nodule. The author prefers the 25-gauge 1-in needle, which allows for a uniform tapered trail/tunnel of PLLA microparticles. The 25-gauge 1-in needle may require fewer sticks and is amenable to fanning of

PLLA microparticles for ease and efficiency of implantation. A 25-gauge, 1.5-in needle, on the other hand, may be difficult to navigate and to maintain a uniform proper depth of implantation. This longer needle bends easily and is harder to unclog.

#### Injection: 3-mL versus 1-mL syringes

Agitate the vial before filling syringes to suspend microparticles of PLLA. An 18-gauge needle allows



**Fig. 5.** Marking for PLLA distribution.



**Fig. 6.** Photograph shows 25-gauge 1-in needle lifted to illustrate proper depth.



**Fig. 7.** Terminate injection before removing needle.

easy movement of PLLA hydro-gel suspension into the syringe. Fill 3-mL B-D Luer-Lok syringes to 1-mL volumes. If multiple syringes are filled, leave a small airspace between the hub of the needle and syringe. Resuspend by shaking the syringe and expel air before injection. If PLLA sits in the hub, it will precipitate even before injection. This 3-mL syringe provides a uniform pressure gradient for injection, allowing placement of small aliquots of PLLA with less risk for bolus injection.

A 3-mL syringe filled to 1 mL fits comfortably in the hand. Injection volumes (0.025–0.1 mL per tunnel) may vary depending on area of treatment. After injecting approximately 0.5 mL total, pull back on the plunger, resuspend PLLA microparticles by agitating the syringe, and express air to avoid precipitation and clogging. A constant minimal drip with the syringe in a horizontal position may help keep the needle patent. The suspension sediments quickly and should be continuously resuspended for ease of injection.

A 1-mL Luer-Lok silicone-coated B-D syringe, on the other hand, may move product too quickly, and the likelihood for bolus injection increases. This syringe filled to 1-mL volume is difficult to handle in smaller hands. If used, the 1-mL syringe filled to 0.5 mL may be more manageable. If clogs occur, resuspension of PLLA may be more difficult given the decreased diameter of the syringe. For newly trained injectors, a 1-mL syringe offers a better visual quantification of small injection volumes (0.025–0.1 mL). With experience, control of small-volume injections becomes second nature, with visual skin movement and correction achieved by implantation serving as the guide.

#### **Injection volumes and guidelines for the lower two thirds of the face**

In moderate to severe cases, one vial per one-half face (~6 mL) or two vials total (~12 mL) may be required. Treatment volumes may change based on severity of volume loss, bony architecture, area or areas to be treated, and desired cosmetic result.



**Fig. 8.** Titrating volume.

The volumes expressed serve merely as a guideline. As experience with PLLA increases and as injectors become more advanced, the soft tissue response or skin movement following individual small volume injections becomes a visual guide for volume restoration. Massage should be done frequently post injection and patients are instructed to massage several times daily for up to 1 week.

1. Cheeks (nasojugal fold, medial cheek/lateral nasal wall, orbital rim, midcheek, lateral cheek at the zygomatic arch, and preauricular and temple areas): 2.5 to 3 mL per cheek.
2. Inframalar region/buccal fat pad: 1 to 1.5 mL fanned or tunneled over the atrophic area with cross-hatching for uniform distribution.
3. Perioral area (medial aspect of the nasolabial folds and marionette lines, lateral chin, mental crease, and prejowl regions): 2.5 to 3 mL total for moderate cases and 4 to 5 mL for severe cases.
4. Cutaneous upper and lower lip<sup>1</sup>: small trough-like, atrophic area just superior to the vermilion border of the upper lip or just inferior to vermilion border of the lower lip. These areas commonly have superimposed vertical rhytides. **DO NOT** inject the vermilion or body of the lips. Injection into the vermilion border or body of the lips may lead to formation of a papule or nodule. In the author's experience, fillers injected into the vermilion border may sometimes take the path of least resistance—dissecting superiorly into the vertical perioral rhytides of the cutaneous upper lip. This improper distribution and uncontrolled placement of PLLA may also lead to papule or nodule formation. Ice the perioral area before injection. A series of retrograde tunnels, beginning approximately 2 mm superior to the vermilion border of the upper lip, each approximately 2

mm apart, using approximately 0.025 to 0.05 mL per tunnel, is injected. This series of cutaneous upper-lip injections restores volume to the cutaneous portion of the upper lip and will transition into the nasolabial fold. Small volume of injection is accomplished with a quick retrograde movement and by placing gentle pressure on the syringe plunger. Watch the skin closely for a gentle rise in soft tissue. Use a newly filled syringe with homogenous suspension of PLLA, which is less likely to clog and provides a more uniform suspension for refined injections at the cutaneous lip or orbital rim. The steps may be repeated for cutaneous atrophy inferior to the lower-lip vermilion.

5. Orbital rim/eye rings/tear trough<sup>1</sup>: again using small volumes (0.025–0.05 mL), a retrograde tunneling injection is performed at the tear trough area just above the periosteum. In thicker-skinned patients, the depth of injection may remain at the dermal–subcutaneous junction. Ice before and immediately after injection to aid in vasoconstriction and minimize bruising. Often, there is a lateral complement to the medial tear trough that can be filled in a similar fashion at the depth of the orbital rim. The author does not like the depot method of injection in this area. Volume and depth, in the author's opinion, are difficult to control, making superficial or bolus injections more likely with the depot method.
6. Temples: 0.5 mL per temple. This area is highly vascular, so always aspirate before injection. A deep depot injection method just above periosteum at the level of the temporal fascia is commonly used; however, advanced injectors may accomplish uniform volume restoration with the fanning technique at the dermal–subcutaneous junction.
7. Oral commissure: the oral commissure is the only place the author occasionally uses the depot method of injection. Approximately 2 mm inferior and medial to the oral commissure, inject a small depot of 0.025 to 0.05 mL.

<sup>1</sup>Cutaneous upper and lower lip, orbital rim/eye rings/tear trough, and fanning are advanced injection techniques.

### Sculptra schedule

In patients who have HIV lipoatrophy, treatments are scheduled at 4- to 6-week intervals for 4 to 6 sessions, depending on the severity of atrophy. One vial per side of the face (6 mL) or two vials total (12 mL) for treatment of the lower two thirds of the face is usually required each session. Because

improvement occurs with successive treatments, the volume of Sculptra used may be titrated to lesser amounts or the distribution of Sculptra from one cosmetic unit to the next may be adjusted given clinical response. In most cases, the end point is 100% correction at the time of injection. The exception to this statement may be after the initial treatment of a severe case. In severe lipoatrophy, correction will come gradually with tincture of time if the injector concentrates on uniform distribution of PLLA. Do not overcorrect. Resist the tendency to overfill a severe concavity at any given injection session. Remember the mantra Treat, Wait, and Assess and the clinical guidelines of depth, volume, and distribution of product.

In cosmetic patients, the first and second treatments are separated by 4 to 6 weeks. In the author's experience, total treatment volumes in the first and second treatments are usually matched. Some patients may correct with two treatment sessions. The third treatment may be delayed up to 6 to 8 weeks after the second session, or postponed indefinitely if the patient is pleased with results. If a third treatment is performed, titrate volume as needed but proceed to an end point of 100% correction. Do not overcorrect. Except for severe cases, most cosmetic patients do well with two to three sessions.

The marketing and cost of Sculptra injections allows for further creativity. In the author's experience, patients who require less volume for a focal defect such as a premature familial tear trough appreciate pricing by the milliliter. Others who require far greater volume, such as global volumetric enhancement of the lower two-thirds of the face, may be given a cost per vial. When two vials are used per session, the second vial may be discounted further.

### Special considerations

In HIV patients, more atrophic areas are more difficult to inject. With progression of lipoatrophy, the atrophied fat becomes fibrotic. Fat extracted from a patient who has HIV has a cream to khaki color unlike the bright golden-yellow fat from the nonimmunocompromised host. Small aliquots (0.05–0.1 mL), injected in a grid pattern by cross-hatching, facilitate injection of severely atrophic areas and maintain a uniform distribution of PLLA. Examine and treat the patient's face as a whole. Do not treat a concavity as a focal defect. This disease is progressive, and areas of the face may be in different stages of lipoatrophy. Treat areas of mild, moderate, and severe lipoatrophy by titrating volumes of PLLA injected. Blend concave areas into areas that remain convex. In this fashion, the lower two thirds of the face is treated as a whole

using the concept of global volumetric filling while maintaining facial contour.

The safety and efficacy of injection correlate with volume, depth, and distribution of PLLA. Small volumes are placed at the dermal–subcutaneous junction, tunneled in a uniform distribution using the retrograde injection technique. With progression through the series of injections, new collagen is deposited in response to PLLA. With neocollagenesis, the increased skin thickness is fibrous, creating greater resistance at subsequent injection sessions.

### Expectations

Sculptra series or serial Sculptra injections require that informed consent should express varied results and the necessity of a serial injection technique. If you or the patient is looking for immediate gratification, then this serial global volumetric filler is not for you.

Most patients maintain approximately 20% correction 4 to 6 weeks after the initial treatment session. The appearance does not go down to baseline for most patients. A pretreatment photograph may help keep perspective and expectations realistic.

HIV lipoatrophy shows progressive gradual results with marked improvement in moderate to severe cases occurring after the fourth treatment session. For optimal results, the series is continued for a total of 5 to 6 treatment sessions based on severity and response.

Cosmetic patients may show a quicker response. Most will require 2 to 3 treatments. More severe cases may require a fourth session.

### Does Sculptra replace a face-lift?

Sculptra is not meant to replace a plastic surgeon's face-lift. Sculptra, however, may enhance what a surgeon can do with a face-lift. **Boxes 1 and 2** summarize treatment guidelines and indications for Sculptra. Postoperative swelling/edema adds volume to the middle third of the face. After 4 to 6 months, the edema dissipates and this pseudovolumization is lost, taking away the healthy, robust appearance of the cheeks. Sculptra may supplement and extend the longevity of a face-lift by restoring volume to the cheeks.

Frequently in patients who have a history of facial surgery, the lateral cheek/preauricular fat pad becomes atrophic, giving the profile a flat and unattractive appearance. Sculptra, as a 3-D filler, can re-establish the lateral anterior and superior movement of the skin, giving the cheek and preauricular areas volume while maintaining contour. Instead of a complication of surgery, this lipoatrophy becomes

### Box 1: Guidelines for injection of poly-L-lactic acid

#### Do's

1. Plan and individualize each case before injecting.
2. Obtain pre- and post-treatment photos.
3. Globally treat and inject the lower two thirds of the face as a whole.
4. Volumize, blending concavity into convexity to restore 3-D appearance.
5. Begin injections superiorly and move in a medial-to-lateral direction, and then progress to the inferior face, again injecting from medial to lateral.
6. Inject using retrograde tunnels and appropriate volumes (0.025–0.1 mL, depending on area)
7. Ice and massage.
8. Follow the mantra Treat, Wait, and Assess to guide through Sculptra series.
9. Think depth, volume, and distribution of PLLA for cosmetic success.

#### Don'ts

1. Don't fill lines or focal defects with a global volumetric filling agent.
2. Don't loiter or stall with injection.
3. Don't inject superficially.
4. Don't forget to aspirate, especially in highly vascular areas.
5. Don't overcorrect.
6. Don't bolus or inject large volume depot injections (>0.05 mL).

### Box 2: Indications: expanding Sculptra use to volumize and refine

Lipoatrophy (hereditary, disease/drug related, aging, and iatrogenic)  
 In place of cheek implants  
 Pad aging cheek implants that have eroded dermis/fat  
 Refine chin implant  
 Restore cheek volume 4 to 6 months post–face-lift  
 Volumize the aging post–face-lift patient  
 In male patients in whom a face-lift is not a good thing  
 Eye rings or hollow eyes post blephroplasty  
 Tear trough  
 Temporal atrophy  
 Prejowl area  
 Rebuild/re-establish or refine the jawline  
 Correct facial asymmetry  
 Mitigate lower eyelid hyperpigmentation (a vascular effect)  
 In nonsurgical candidates  
 No "down time"

a sometimes-expected side effect remedied by Sculptra.

### Post-treatment side effects, complications, and care instructions

Most patients have mild erythema post injection due to injection sites, massage, and ice packs that fades spontaneously. Most patients bruise to some extent, which is a likely side effect given the number of needle sticks and injection sites required to volumize the face. Bruising and hematoma formation may be minimized by cessation of common and unnecessary blood thinners such as alcohol, aspirin, nonsteroidal anti-inflammatory drugs, Saint-John's-wort, and vitamin E 1 to 2 weeks before treatment.

Small papules and nodules, although mostly only palpable and not visible, tend to be a source of concern for the patient and the physician. Formation of papules or nodules is most likely technique dependent. Too great a volume injected superficially or failure to terminate the injection before needle withdrawal may lead to a superficial papule. In the author's experience, superficial papules appear to be transient and most undergo spontaneously resolution by way of the phenomenon of transepidermal elimination. In the author's experience, topical retinoids (tretinoin 0.025%–0.1%) and superficial chemical peels (glycolic acid, lactic acid, mandelic acid, or salicylic acid) may also aid in resolution or even help prevent formation of papules. Nodules may also be technique dependent and result from a deeper bolus of product followed by an exaggerated inflammatory response. Nodules may occasionally be visible through thinner skin such as found in the temple or periorbital areas. If the nodule is palpable but not visible and not bothering the patient, then allow it to spontaneously resolve. If it is symptomatic or visible, then subcision with a 30-gauge needle and injection of 0.02 to 0.04 mL of triamcinolone acetonide (Kenalog) 2 mg/mL may be injected to help dissolve a nodule. This treatment may be repeated at 2- to 4-week intervals. Avoid overinjection or concentrated triamcinolone acetonide solutions to lessen steroid side effects (skin atrophy and hypopigmentation). This situation is an example of "less is more." Some experienced injectors advocate subcision followed by injection of 0.9% normal saline injection USP to aid in dissolution of nodules.

If proper retrograde injection technique is used and aspiration is performed before injection of highly vascular areas, then intravascular injection remains unlikely.

Adherence to proper "clean" sterile technique and the use of bacteriostatic sterile H<sub>2</sub>O injections

(USP) and preserved lidocaine makes infection unlikely.

Post treatment, patients are instructed to ice intermittently for 1 to 2 hours. Swelling and erythema dissipates over 3 to 5 days. Patients are required to massage or kneed the skin several times daily for 1 week to facilitate uniform distribution of product. Sun exposure and vigorous exercise should be avoided until erythema and edema resolve.

Patients on chronic immunosuppressive/anti-inflammatory therapy such as prednisone should be approached cautiously with PLLA. Suppression of the inflammatory response during prednisone therapy may lead to a subtherapeutic response to PLLA. Following discontinuance or interruption of prednisone therapy, an exaggerated or unpredictable response to PLLA may occur.

### Summary

Remember the mantra of Sculptra—Treat, Wait, and Assess—and the injection triad of depth, volume, and distribution of PLLA implantation. Be conservatively aggressive; that is, use appropriate volumes at times of treatment, titrating volume to correction, and spacing treatment intervals appropriately. The volume and number of treatment sessions may vary based on age, sex, bone structure or facial anatomy, facial symmetry, cost, and desired cosmetic result. Approach the lower two thirds of the face as whole for optimal effect. Sculptra is best used as a 3-D global volumetric filler, whether or not the patient has HIV.

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