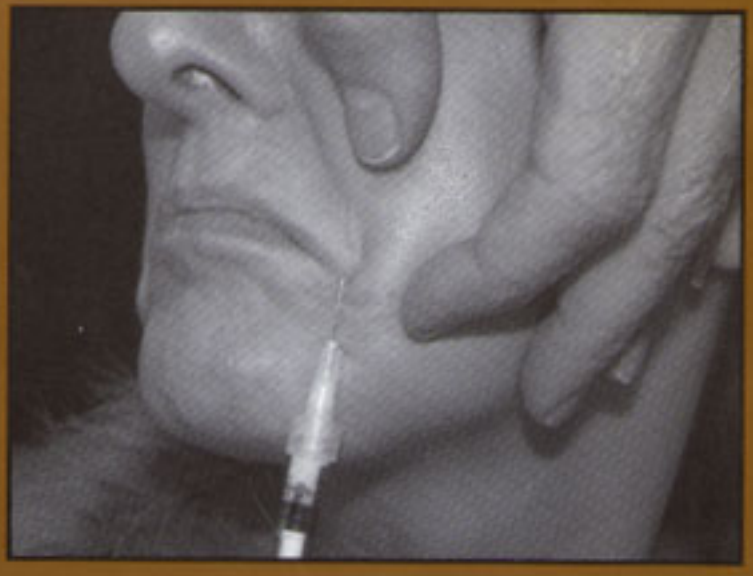
VOLUME 20, Number 2 MAY 2004 ISSN: 0736-6825

FACIAL PLASTIC SURGERY

Soft Tissue Augmentation with Facial Fillers



www.thieme-connect.com
www.thieme.com/fps

Thieme
New York • Stuttgart

Soft Tissue Augmentation Using Sculptra

Gail Humble, M.D.[1] and Douglas Mest, M.D.[1]

ABSTRACT

Sculptra (poly-L-lactic acid) as of August 2004 has been approved by the U.S. Food and Drug Administration as the first injectable facial volumizer in the treatment of lipoatrophy. Lipoatrophy is often seen in HIV-positive patients and is felt to be multifactorial. This article reviews European and U.S. clinical study data and summarize treatment technique for both on label and off-label use.

KEYWORDS: Poly-L-lactic acid, Sculptra, facial fat loss, lipoatrophy, volume replacement

As of August of 2004, the Food and Drug Administration (FDA) approved the first injectable filler to be targeted for the treatment of land replacement of volume in the facial wasting associated with HIV-positive patients. Lipoatrophy is felt to be multifactorial with contributing factors being the nucleoside reverse transcriptase and other antiretroviral medication used in the treatment of HIV. It is also felt to be due to the disease process as well as the aging process itself. All one has to do is to compare pictures of the robust young Rock Hudson to the gaunt aging man to realize the devastation this disease process has on one's face.

The history of Sculptra dates back to 1999 where it first received CE Mark certification for filling of small facial deficits in Europe under the trade name New Fill. Since that time it has been used in over 150,000 patients. In 2004 in Europe it received additional approval for filling larger facial deficits associated with lipoatrophy.

Sculptra's primary ingredient is polylactic acid. Polylactic acid was first synthesized by a French chemist in 1954. Because Polylactic acid is of synthetic origin, no animal sensitivity is involved. This means no animal testing of the patient is required. Polylactic acid is biodegradable, biocompatible, and immunologically inert. Polylactic acid has been used since the early 1960s in the human body. Polylactic acid is a component in absorbable sutures such as Vicryl and Dexon. It has also been used in fixation devices in orthopedic surgery, in urethral and tracheal stents, in dental implants, and as a vehicle for vaccines. There have been over 7000 published articles on uses of polylactic acid in humans. Polylactides have been shown histologically to break down to the lactic acid monomer. This process takes 12 to 18 months. Through further metabolism this is further broken down to CO_2. The clinical results of the aesthetic results of Sculptra are believed to last 2 years.[1–3]

Sculptra consists of microspheres of polylactic acid that are 40 to 60 μm in diameter. Each particle is up to 140,000 d. The irregular product shape as well as heavy molecular weight contributes to the slow absorption of Sculptra. Each kit of Sculptra comes as a powder and once reconstituted with 5 mL of sterile water consists of 150 mg of polylactic acid per 5 mL.

Sculptra has a dual mechanism of action. Initially there is a volume effect, secondary to the hydrogel volume injected. This effect lasts up to 1 week. The secondary delayed mechanism of action involves collagen synthesis. At 1 month, histology shows microparticle capsulization with an increase in vascularity. At 6 months capsule thickness has decreased and the surrounding

Soft Tissue Augmentation with Facial Fillers; Editors in Chief, Fred Fedok, M.D., Gilbert J. Nolst Trenite, M.D., Ph.D., Daniel G. Becker, M.D., Roberta Gausas, M.D.; Guest Editor, John P. Fezza, M.D. *Facial Plastic Surgery*, Volume 20, Number 2, 2004. Address for correspondence and reprint requests: Gail Humble, M.D., Blue Pacific Aesthetic Medical Group, 1301 Manhattan Avenue, Suite 201, Hermosa Beach, CA 90254. [1]Blue Pacific Aesthetic Medical Group, Hermosa Beach, CA. Tel: +1(212) 584-4662. 0736-6825,p;2004,20,02,157,164,ftx,en;fps00506x.

areas are composed entirely of collagen fibers. At 18 months the microparticles have been shown to still exist with collagen neogenesis and no signs of inflammation. Sculptra is one of the few soft tissue fillers that can be termed a "biocatalyst."[1]

Metabolism involves bioabsorption and gradual degradation. Polylactic acid is gradually hydrolyzed into mono or oligomers ($C_3H_6O_3$). These fragments are then phagocytized by macrophages before being eliminated in the form of CO_2 (Fig. 1).

Sculptra under the name original name of New Fill was originally synthesized by Biotech Industries in Luxemburg. It is now owned and distributed by Dermik Laboratories, which are a subsidiary of Aventis (Berwyn, PA).

The first European data was submitted by Amard and Saint Marc in September of 2000. Twenty-six lipoatrophy patients were treated with New Fill. Ultrasound measurement was used to measure dermal thickness. A 151% increase in dermal thickness was found at 3 months, 196% at 6 months, and 131% at 54 weeks.[4]

A 96-week study was presented at the 10th Conference for Retroviral and Opportunistic Infection in Boston in February of 2003. Researchers from this VEGA study presented the results of 50 HIV-positive patients after receiving Sculptra for correction of facial lipodystrophy. Change in dermal thickness was evaluated using ultrasound and color Doppler preformed by the same trained radiologists. They found a threefold increase in dermal thickness, which was sustained at 72 and 96 weeks.[5]

Another study presented by Lafaurie from St Louis Hospital in Paris, France involved treating 40 patients with lipodystrophy. In this study, the product was diluted with 3 mL of sterile water and the patients were treated with 150 mg per cheek every 15 days. Efficacy was evaluated at 2 months and after 6 months utilizing photos analyzed by digital surface photogrammetry software. Results showed a mean increase of dermal thickness of 2.4 mm after two injections. Results were maintained at 2 and 6 months.[6]

The Chelsea Westminster study was done in London. A total of 30 patients with lipoatrophy were treated with Sculptra. These patients were randomized into two groups. The first group was treated every 2 weeks for a total of three treatments. The second

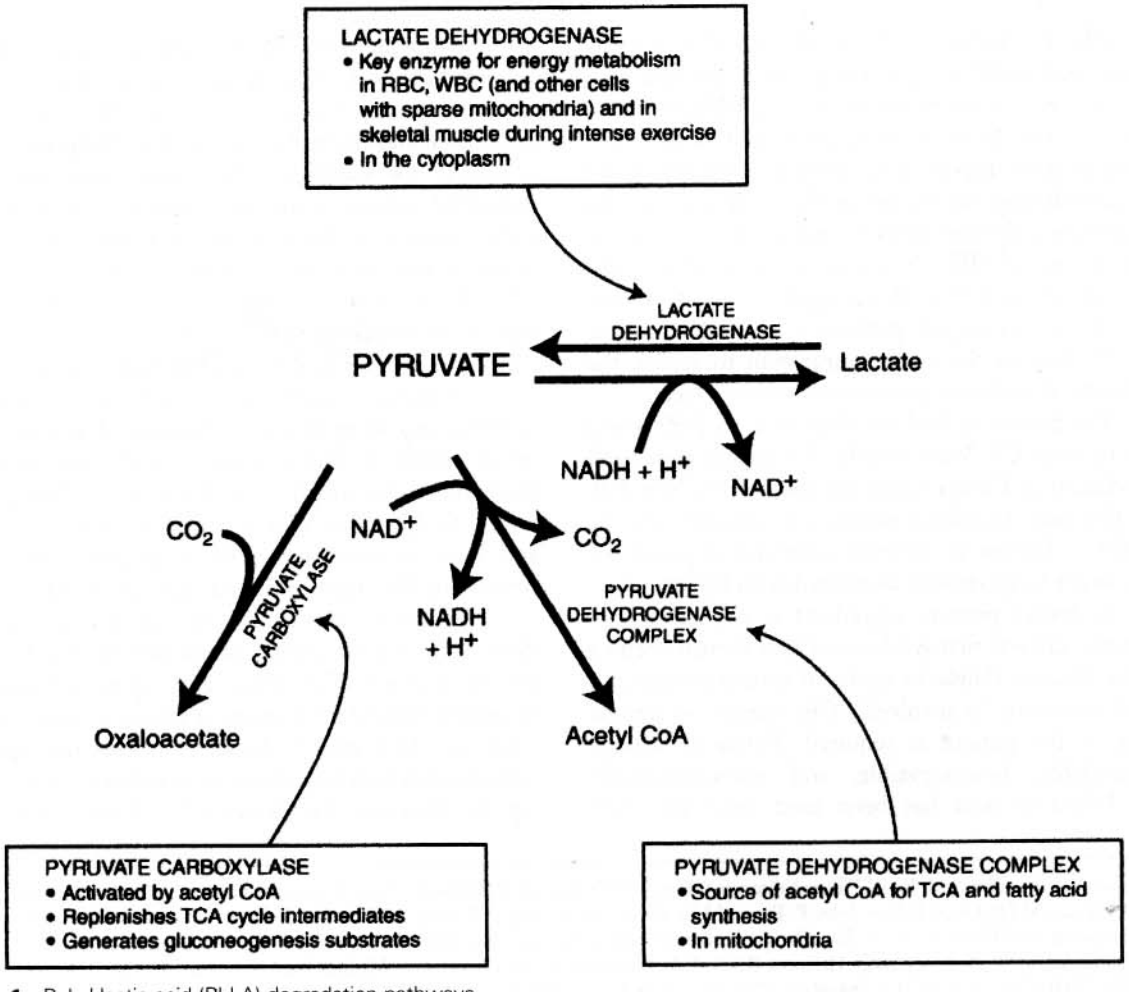


Figure 1 Poly-l-lactic acid (PLLA) degradation pathways.

Table 1 Treatment-Related Adverse Events at 2 Years

	VEGA Study	Chelsea and Westminster Study***	Mean Duration (Days)
Injection procedure-related			
Bruising	3 (6%)	11 (38%)	6
Edema	2 (4%)	2 (7%)	3
Discomfort	0	3 (10%)	3
Hematoma	14 (28%)	0	17
Inflammation	0	3 (10%)	3
Erythema	0	3 (10%)	3
Device-related			
Injection site subcutaneous papule*	26 (52%)	9 (31%)	Mean onset, 7 months**

*Subcutaneous papules refer to lesions of 5 mm or less, typically palpable, not bothersome, and not visible.
**Onset data available from VEGA study only. Duration not noted as most papules were ongoing at study's completion.
***Safety data collected post hoc for 27 of the patients at ~2 years from study start.

group had no treatment for the first 12 weeks and then received three treatments as well at weeks 12, 14, and 16, thus acting as a negative control. Both groups were evaluated at weeks 0, 12, and 24, utilizing ultrasound and serial photographs. Statistically significant increases in dermal thickness were noted in all patients with maintenance of clinically significant results to 2 years.[7]

In July 2002 an investigational device exemption (IDE) was submitted and accepted from Blue Pacific Aesthetic Medical Group in Hermosa Beach, California.[7] We enrolled 100 patients who received one to six treatments spaced 3 weeks apart. Caliper skin thickness was used to measure changes in transcutaneous thickness. Baseline laboratory values were taken and repeated every 3, 6, and 12 months to verify no change in lactic acid level. A well-being questionnaire was filled out prior to treatment, at the end of treatment, and at 6 and 12 months.[8]

As of October 2004, 100 patients were enrolled in the study, 99 completed treatment, 76 had completed the 6-month follow-up, and 54 completed the 12-month follow-up. A mean average of 57.8% increase in transcutaneous thickness was noted at the end of the study. At 6 months the increase in total cutaneous thickness (TCT) was 53.5% and this was shown to be maintained at 1 year with a 54.9% increase in thickness. Actual measurements were: initially (prior to treatment), 7.1 mm; end of treatment, 11.2 mm; 6-month follow-up, 10.9 mm; and 1 year, 11.0 mm. These results showed the augmentation not only held at 1 year but actually increased. Our study was used to establish clinical safety with Sculptra in submission to the FDA.

There was one additional U.S. study done by Peter Engelhart and colleagues in Florida. This was APEX 002, which was an investigator-initiated study. His results on efficacy and safety were similar to ours.[9]

In all studies, there were no serious adverse results. Although bruising and other injection related complications are always a possibility, the only device-related complication was that of subcutaneous nodules. These nodules are defined as being less than 5 mm, not visible but palpable. In our study nodule formation occurred with an incident of 9.2%. The average onset was 6 months and 46% spontaneously resolved (Tables 1 and 2). If spontaneous resolution does not occur, a subcision with a 25-gauge needle, followed by localized steroid or saline injection, may improve resolution. This may be repeated weekly and used in conjunction with massage. As a final treatment to any resilient nodules, a 5FU and steroid combination in very small quantities may be injected locally into the nodule. This may be repeated monthly as needed. Complete resolution may take 5 to 8 months.

In October 2003, we began the second protocol. The same 100 patients are being retreated as necessary with up to 12 treatments over 2 years and followed up 1 year following the final treatment. The only difference in the second protocol is that each vial will be mixed with 5 mL of sterile water and treatment intervals will be 5 weeks apart. The reason for the later change is that it had been surmised there may be less nodule formation with a more dilute solution.

Table 2 Treatment-Related Adverse Events at 1 Year

	APEX002 Study	Blue Pacific Study
Injection procedure-related		
Bruising	1 (1%)	30 (30%)
Edema	3 (3%)	17 (17%)
Discomfort	19 (19%)	15 (15%)
Erythema	0	3 (3%)
Device-related		
Injection site subcutaneous papule	6 (6%)	13 (13%)

The results in supplementation of facial volume loss have been quite impressive. Until recently, fat has been the only option for large areas of revolumization. Artecoll/Artefill and silicone have been used to treat lipoatrophy but have not had much success in these other areas. As an off-label use we find Sculptra useful for treating the lipoatrophy we see in our aging patients. The average volume loss in the face per year may be up to 4 to 5 mL per year. Although fat grafting and implants are available to camouflage this volume loss, none of them present with the ease of Sculptra injections. In our study our patients received up to six treatments. In cosmetic uses, most patients require only two to three treatments.

Inevitably one will be asked to verify how long Sculptra will last. Clinical studies have shown a threefold increase in dermal thickness that is maintained for up to 2 years.

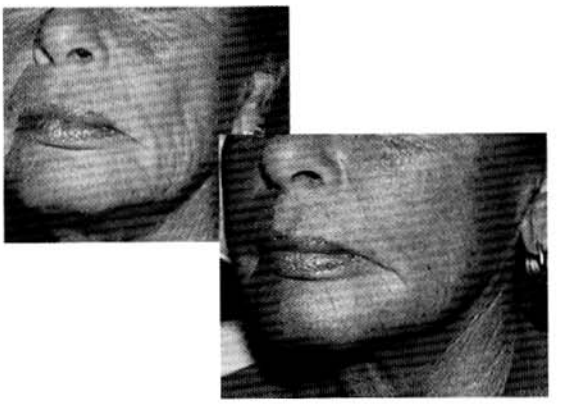


Figure 2 Sculptra off-label use. (A) Before and (B) after three treatments. Photos courtesy of D. Vleggar, M.D.

INJECTION TECHNIQUE

An 18-gauge needle is suggested in the reconstitution of Sculptra. Sterile water is used. After the reconstitution, the product must stand for 2 hours. It is then placed in an agitator. A 25- or 26-gauge needle is then used for the actual injection process. We find it easiest to draw the reconstituted Sculptra into individual 1-mL syringes with a luer lock top. No refrigeration is needed for this product at any time and in the powder form the product has a shelf life of 2 years. Once reconstituted the product should be used within 72 hours.[10]

The procedure itself is quite painless with the patient receiving an infraorbital block either intraorally or transcutaneously. Some peripheral infiltration is done with 1% lidocaine in the area not anesthetized with the block. Initially we primarily treated the malar and temple area. Now we are injecting the neck, infraorbital area, chins, perioral area, and hands in appropriate patients.

In all areas there is a distinct difference in injection technique. Primarily this is based on the depth and vascularity of the individual area. There are certain rules of thumb that govern most areas, however. The injections are done at about a 30- to 45-degree angle. In all areas massage should be used to establish uniform deposition of the product postinjection. The product is meant to be placed in the deep dermis. It should not be placed superficially. If blanching occurs, the injection must stop. For all areas we have the patient then massage the treated area once a day for 2 weeks at home. A lubricating lotion prior to massage makes palpation of any irregularities easier to feel while decreasing the irritation to the skin. Ice is also always used posttreatment.

A brief summary of injection technique for each area follows. There are two basic injection techniques. The first is tunneling, which is used primarily in the lower face. With this technique, a thin trail of Sculptra is deposited in the tissue as the needle is withdrawn, with the volume limited to 0.1 to 0.2 mL of Sculptra per injection. The second technique is the depot technique. With the depot technique, Sculptra is injected in a small bolus of 0.05 mL or less. This technique is used in the upper and midface.[11]

Malar Area

The injection is done at a 30- to 45-degree angle. A cross-hatching technique is utilized, and injection is done on withdrawal. A grid pattern is used. Injection of 5 mL is appropriate for each cheek area for lipoatrophy, less if the patient is being treated for cosmetic reasons only. Up to 30 injection sites can be used per cheek.

Temple Area

In the temple area the product is laid as deeply as possible, close to the periosteum. The injection is done from a lateral to medial direction. Because of the vascular nature of this area, reflux may be checked for bloody aspirate. The depot technique is used here, with 0.5 mL being injected per injection site. Up to 10 injection sites may be needed per temple area.

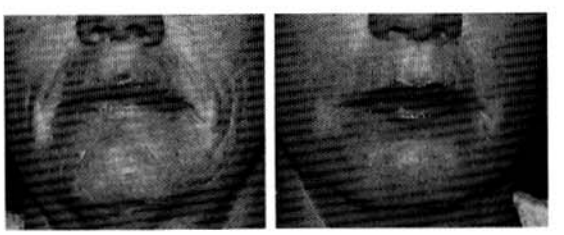


Figure 3 Sculptra off-label use. (A) Before and (B) after three treatments. Photos courtesy of D. Vleggar, M.D.

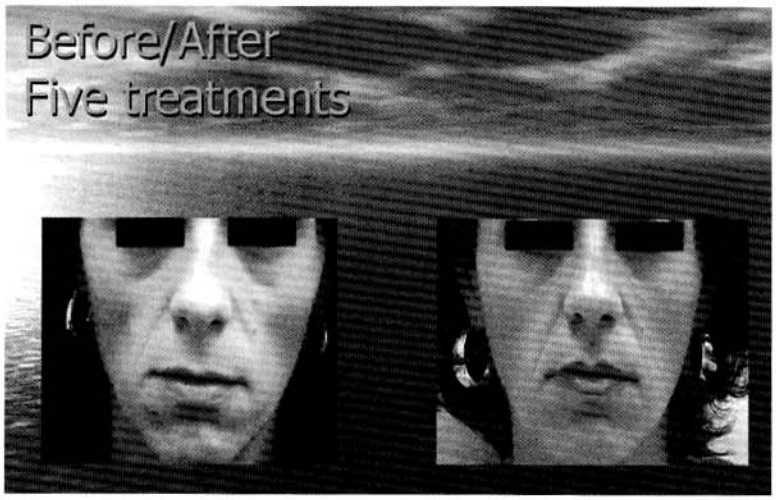


Figure 4 Lipoatrophy patient (A) before and (B) after five treatments with Sculptra.

Under Eye Area

Like the temples this is another highly vascular area. The product is again placed just above the periosteum, reflux may be checked, and massage may be used after placement of the product. The depot technique is used with 0.5 mL being used per injection site. A total of 0.5 to 1 mL is all that is needed per treatment for this area. It is best to stay out of the region below the inner canthus.

Glabella

Frown lines are treated with injections made in the direction of the wrinkle for middepth rhytids. For deeper wrinkles, cross-hatching can be used. This is the exception; here the tunneling technique here. This treatment is usually combined with a prior Botox treatment.

Chin

The chin is done with short cross-hatching injections. Volume is variable depending on how far out into the lateral contour of the face the injections are carried. These results are improved with a prior Botox treatment. Here the tunneling technique is used. Use no more than 1 mL for chin augmentation, and less than a total of 2 mL to fill marionette lines and revolumize the chin.

Neck

The neck necessitates a larger volume with the entire two vials being utilized. It is difficult to do a block in this area, although patients report minimal pain. Ecchymosis is almost certain, so we do prep our patients for this. Cross-hatching is used over the entire area. This area can be treated with Botox to lessen platysmal bands prior to treatment with Sculptra.

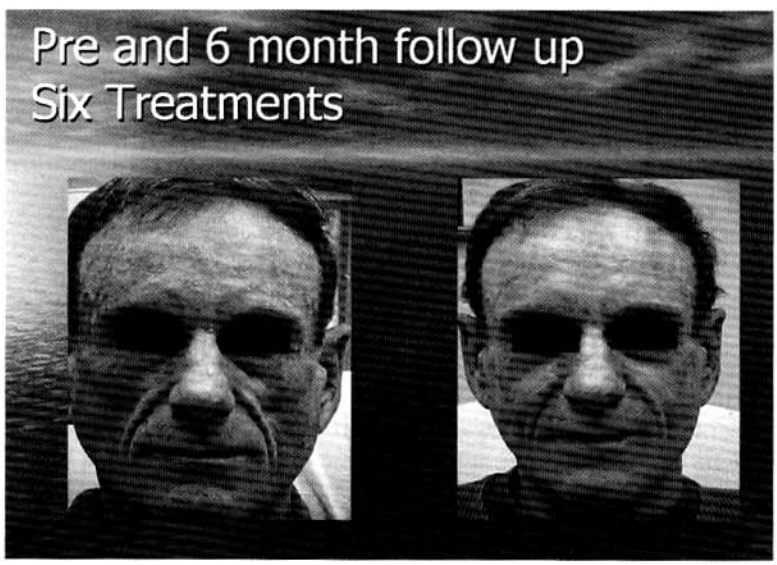


Figure 5 Lipoatrophy patient (A) before and (B) 6 months after six treatments with Sculptra.

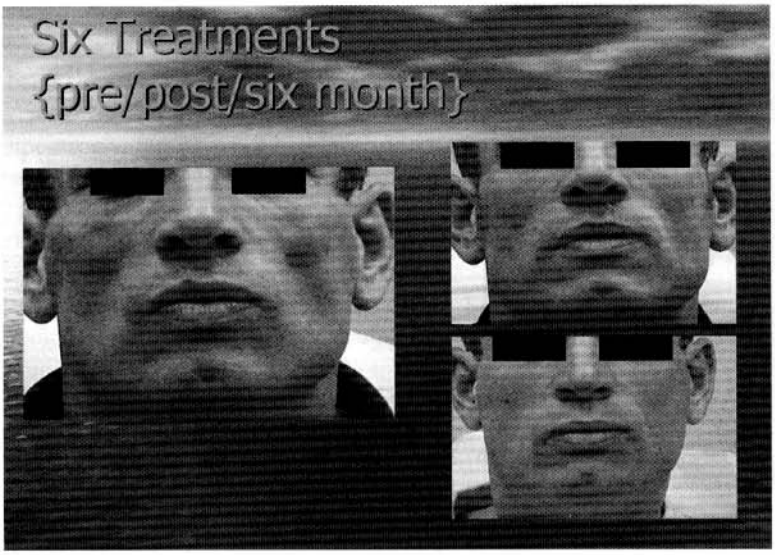


Figure 6 Lipoatrophy patient (A) before, (B) immediately after, and (C) 6 months after six treatments with Sculptra.

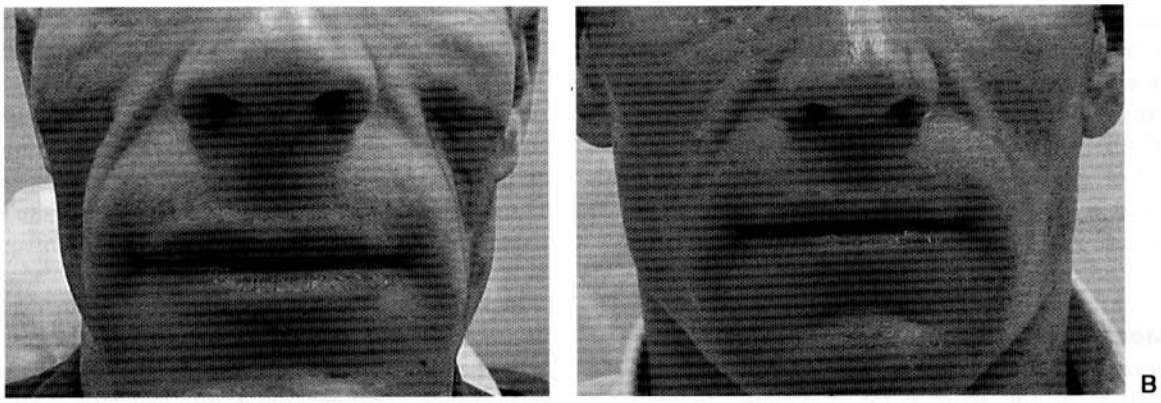


Figure 7 Lipoatrophy patient (A) before and (B) 1 year after five treatments with Sculptra.

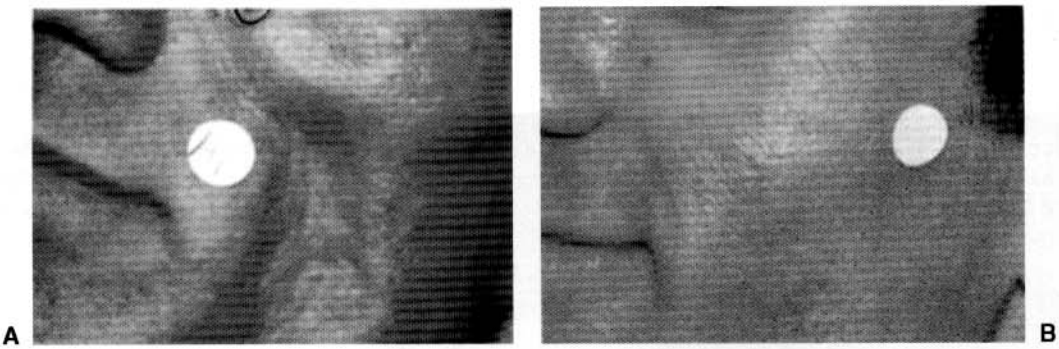


Figure 8 Lipoatrophy patient (A) before and (B) 1 year after six treatments with Sculptra.

Hands

We combine this treatment with prior sclerotherapy. A radial nerve block is used by placing a ring block of 1% lidocaine in the anatomic snuff box. Once anesthesia has been established, one reconstituted vial is used per hand. We place it between the veins and use finger massage afterward to mobilize it.

Perioral

Sculptra is not optimal for lip augmentation but may be used rather for support of the aging perioral area. Injections are done at the dermis–subcutaneous border and not in the lip mucosa. Injections are made superior to the vermillion border. Two to three sessions are required.

It is important to remember to undertreat an area. Managing patient expectation is important with this product. Patients should be prepared for the initial volumizing effect to diminish with days to weeks and no true dermal thickening to occur prior to weeks to months. Overall, patient and physician satisfaction is very high with this product. It has earned a place in our arsenal of injectables for soft tissue filling (Figs. 2–8).

REFERENCES

1. Brady JM, Cutright DE, Miller RA, Barristone GC. Resorption rate, route, route of elimination, and ultrastructure of the implant site of polylactic acid in the abdominal wall of the rat. J Biomed Mater Res 1973;7:155–166
2. Cutright DE, Perez B, Beasley JD III, Larson WJ, Posey WR. Degradation rates of polymers and copolymers of polylactic and polyglycolic acids. Oral Surg Oral Med Oral Pathol 1974;37:142–152
3. Sattler G. Long-lasting results with polylactic acid. Derm 2003;9:422–423
4. Amard & Saint Marc Polylactic acid in the treatment of HIV-associated lipoatrophy. Second Lipodystrophy Workshop, Toronto, Canada; September 2000
5. Mest DM, Humble G. Hermosa Beach, California, Current IDE#G020113
6. Lafaurie M. Dolivio, St. Louis Hospital, Paris, France. Treatment of lipoatrophy with injections of polylactic acid. Tenth Conference for Retrovirus and Opportunistic Infection February 2003
7. Moyle GJ, Lysakova L, Brown S, et al. A randomized open-label study of immediate versus delayed polylactic acid injections for the cosmetic management of facial lipoatrophy in persons with HIV infection. HIV Med 2004;5:82–87
8. Mest D, Humble G. Safety and efficiency of intradermal poly-L-lactic acid (Sculptura) injections for patients with HIV associated facial lipoatrophy. Antivir Ther 2004;9:L36
9. Engelhard P, Knies M. Safety and efficacy of New-Fill™ (polylactic acid) in the treatment of HIV-associated lipoatrophy of the face (HALF). XIV International AIDS Conference. Barcelona, Spain; July 7–12, 2002
10. Sommer B. Crystalline polyactic acid (New-Fill): current handling guidelines. Skin; 2004;15
11. Vleggaar D, Bauer U. Facial enhancement and the European experience with poly-L-lactic acid. J Drugs Dermatol 2004;3: 542–547

Soft Tissue Augmentation Using Silicone: An Historical Review

Gail Humble, M.D.[1] and Douglas Mest, M.D.[1]

ABSTRACT

Silicone has a long and colorful history in cosmetic medicine. We are once again seeing a resurgence of its use as a soft tissue filler. This article is a review of the historical past of silicone use and its appropriate off-label uses today in cosmetic medicine.

KEYWORDS: Silicone, soft tissue filler, lip augmentation, lipoatrophy, granuloma, migration

There are two distinct classifications of soft tissue fillers, those that are biodegradable and those that are not. The biodegradable class consists of hyaluronic acid, animal collagen, human allografts, synthetics such as polylactic acid, and autologous dermal tissue. The nonbiodegradable class consists of Artecoll/Artefill, Silicone, Gortex, Radiance, and perhaps one day Aquamid and Dermalive.

The popularity of the nonbiodegradable fillers, of course, is due to the duration of their results. The drawbacks to this class of fillers are the same, the permanence of the results. Fashions and styles change and we still search for the perfect filler with a 2-year longevity.

Of all of the fillers in the nonbiodegradable class, Silicone has the longest and certainly most colorful and controversial history.

HISTORICAL PERSPECTIVE

In the mid 1930s, Dr. J.F. Hyde, then working at Corning Glass Works, began an investigational study of silicone. In 1943, the Dow Corning Corporation was developed. The history of silicone use is closely tied to the development and studies of this company. Dow Corning produced the first silicone rubber in 1945 and other materials to be used by the military.

The fist country to utilize silicone oil in humans was probably Japan. Uchida[1] reported the use of liquid silicone to correct breast and cheek deformities. There was a "Sakuri Formula," which combined silicone oil with olive oil. This adulterated formula may have contributed to some of the complications seen with silicone in later years.

In 1962, Dow Corning established the medical products division to manufacture, distribute, and sell silicone oil for implantation. In 1963 a 350-centistokes viscosity agent was developed. This was the product used by Rees and his colleagues[2] to do one of the first studies in subcutaneous injections. Although minimal tissue reaction was noted, the possibility of migration became documented. The first siliconoma, reported as a complication, was in 1966. About this same time, the Food and Drug Administration (FDA) initiated its first investigation, and Dow Corning developed MDX4–4011. This was highly purified silicone oil expressly made for these studies. As a result of this study,[3] few adverse results were reported. There were two reports of migration and one of facial necrosis, and silicone was recovered in other organs.[3]

Outside this study there were numerous reports[4] of complications due to silicone injections into the breast area. Disfiguring silicone-induced inflammatory reactions were reported up to 20 years later.[4] Any physician

Soft Tissue Augmentation with Facial Fillers; Editors in Chief, Fred Fedok, M.D., Gilbert J. Nolst Trenite, M.D., Ph.D., Daniel G. Becker, M.D., Roberta Gausas, M.D.; Guest Editor, John P. Fezza, M.D. *Facial Plastic Surgery*, Volume 20, Number 2, 2004. Address for correspondence and reprint requests: Gail Humble, M.D., Blue Pacific Aesthetic Medical Group, 1301 Manhattan Avenue, Suite 201, Hermosa Beach, CA 90254. [1]Blue Pacific Aesthetic Medical Group, Hermosa Beach, CA. Tel: +1(212) 584-4662. 0736-6825,p;2004,20,02,181,184,ftx,en;fps00510x.

who recalls the subcutaneous mastectomies required to relieve the chronic pain and inflammation is warranted in their skepticism of silicone. As we know from ruptured breast implants today, silicone is in actuality one of the least reactive of all filler materials. In most patients, after implant rupture, the silicone stays soft and is encapsulated by only a very thin layer of fibroblasts.

I believe the reputation of medical-grade silicone has been damaged by several correctable factors. The first is injection of large quantities. Not only does this add to the incidence of migration (think of water droplets coming together), but it can result in an inflammatory nidus. This was the finding of a study by Dr. Gottfried Lemperle and colleagues in conjunction with the University of San Diego and published in 2003.[5] This study found that although silicone was chemically well tolerate, it became encapsulated as a foreign body and a chronic inflammatory reaction occurred. Giant cell invasion occurred and fibrous tissue surrounded and encapsulated the silicone. Because this capsule is avascular, it becomes a potential site of infection. It is the fibrous tissue that surrounds the silicone that may give rise to the reported delayed granulomas and palpable masses.

The other correctable factors that contribute to poor results and high complications associated with silicone treatment are the use of non–medical-grade silicone, unsterile technique, and nonphysician injectors. In the article by Jones and associates,[6] a personal communication with Wayne Richard at Richard James INC is referenced, which suggests what was considered "medical-grade silicone" in the past contained more elemental impurities than in the presently available silicone oils.

All of the above discussion on the history of silicone would have been simply rhetorical had the FDA not approved Adatosil (Bausch & Lomb, Rochester, NY), a 5000-centistokes silicone oil, in 1994. Silikon 1000 (Alcon Laboratories, Fort Worth, TX), a 1000-centistokes silicone oil, was approved in 1997. The FDA approved both of these for use as a long-term tamponade for complex retinal detachments. The FDA has not approved the marketing of silicone for injection for any cosmetic purposes. However, under the FDA Modernization Act of 1997, physicians were able to use medical devices for an off-label use. Silskin (Richard-James, Inc., Peabody, MA) has recently been approved by the FDA for investigational study in the treatment of nasolabial folds, marionette lines, midmalar depression, and facial lipoatrophy.

Still until Silskin is approved, with all of the controversy, why are patients and physicians still interested in liquid silicone? Why is silicone being included in this summary of soft tissue fillers, and why are we hearing lecturers speak on it for augmentation of lips and filling of facial rhytids? When it is used in microdroplet technique and in appropriate areas, it can give a beautiful, soft, and long-lasting result.

The microdroplet technique has gained popularity and has been the most popular and safest way for current injection. Duffy, a leading expert in liquid silicone, believes the incidence of complications with silicone are still 1% (this is even with strict adherence to protocol).[7–9] I believe before injections into any appropriate patient, the patient should be made aware that this is an off-label use. Any consent the patient signs should contain the possibility of migration and late-forming granulomas.

In my practice we use silicone off-label for lip augmentation only. We find the results to be reliable and consistent and complication rate to be very small. We find the lips to be the most appropriate place for silicone injection. This is true for several reasons. First, the injections are laid deep into the body of the lip. Silicone is not meant to be tracked along the vermillion border as with collagen. Second, if any untoward results occur, it is possible to do an excision of the actual tip tissue without resulting in significant deformity. I am not suggesting surgery is the treatment of choice for a complication of silicone; it is not. Rather, multiple steroid injections would be the preferred treatment for any inflammatory granulomas. The microdroplet technique helps in avoiding this as a complication.

Lip augmentation takes place after the patient receives an infraorbital block. This can be done transcutaneously or through the intraoral approach. Two injection techniques have been described for lip augmentation with silicone. The first is a multiple puncture technique where a 26-gauge short needle and no more than 0.01 per injection site are used.[10] The second is the tunneling technique. Tunneling is done with a longer 25-gauge needle and silicone microdroplets are placed as the tip of the needle is withdrawn and fanned from side to side within the body of the lip. Tunneling is technically harder to do correctly as each silicone droplet is laid down separately and discreetly. Individual injections can result in a bloodier procedure as the lips are extremely vascular and each injection can potentially lead to bruising. I find once bruising occurs, the treatment must be stopped as the aesthetics of the lips are altered. With this technique only a small aliquot of silicone is placed at each deposit site, 0.01 or 0.005 mL. It is best to use a 1-mL syringe with a luer lock tip. The pressure required for injection can be significant and this will keep the needle tip from coming off. Because of the small quantity deposited during each session, we make our patients fully aware that more than one treatment will be necessary. Treatment intervals are 30 days apart as maximal fibrosis occurs at 21 days and this leaves a few days for leeway. We are extremely careful with our patient selection and often encourage our patients to try a short-term filler first, so they can be sure they like the results. We also limit the size of augmentation we offer patients with silicone.

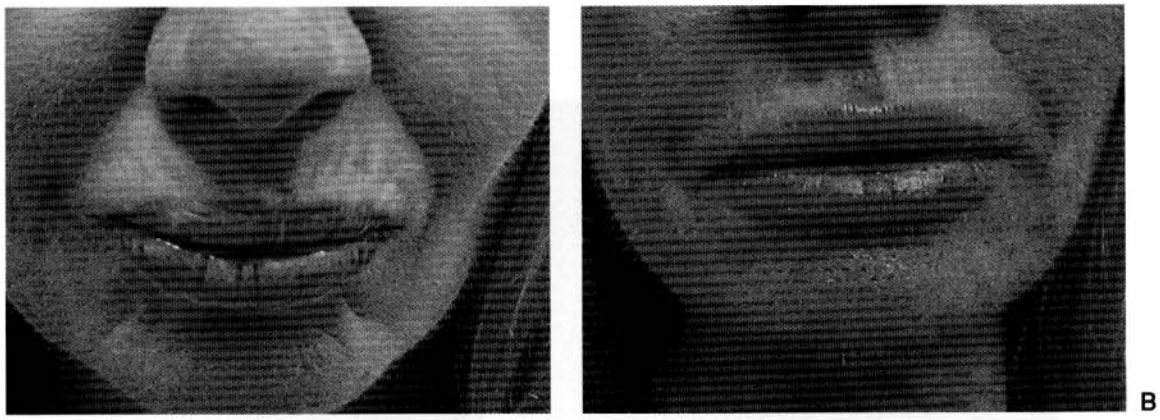


Figure 1 This patient was received three treatments with Silikon. (A) Her preoperative complaint was multiple lip rhytids. (B) After treatment her lips were revolumized without being augmented.

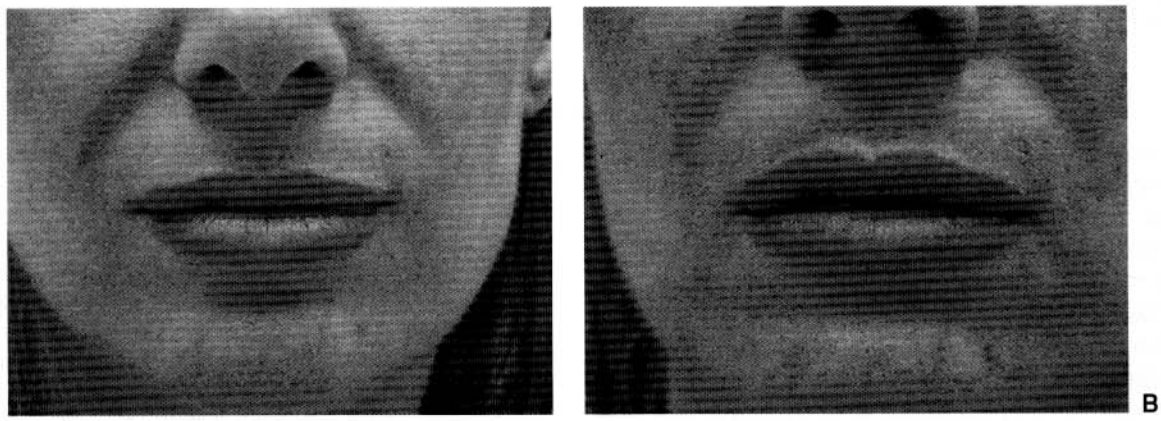


Figure 2 This patient previously had soft forms placed in her lips. (A) She was unhappy with the concavity she was left with in the Cupid's bow area. (B) After two treatments with Silikon, the patient achieved a fuller Cupid's bow.

We find with silicone there is only minimal swelling relative to some of the other fillers. We do have our patients use ice posttreatment to reduce swelling. We also tell all of our patients to massage their lips once a day for the rest of their lives. This involves having them press their lips together after brushing their teeth.

I am asked if I will add silicone to supplement other lip augmentation. On occasion I will, if the patient has soft form in and there is an area that the soft form has not filled, leaving a deficit. Silikon 1000 can be used to correct the deficit. In the lips the silicone cannot be placed too superficially as a yellow discoloration may remain.

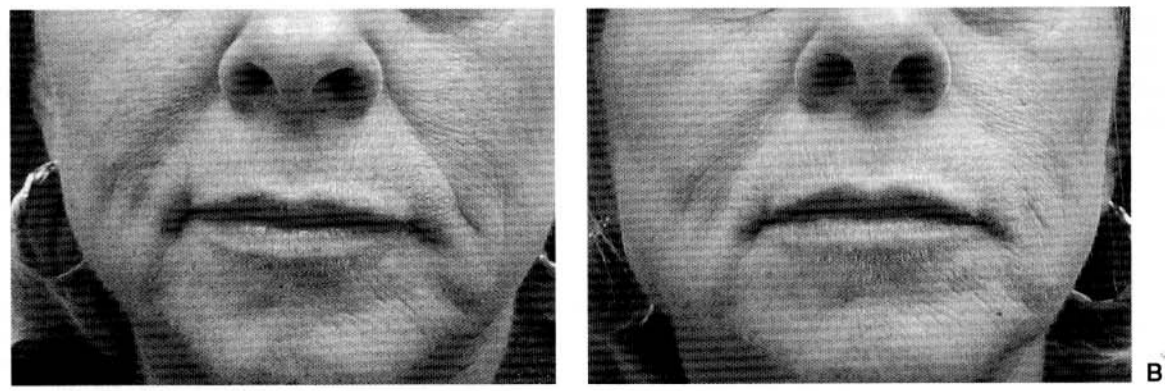


Figure 3 This 42-year-old woman had naturally uneven lips. (A) She desired correction of the deformity only. (B) After one treatment with Silikon the patient had the improvement she desired.

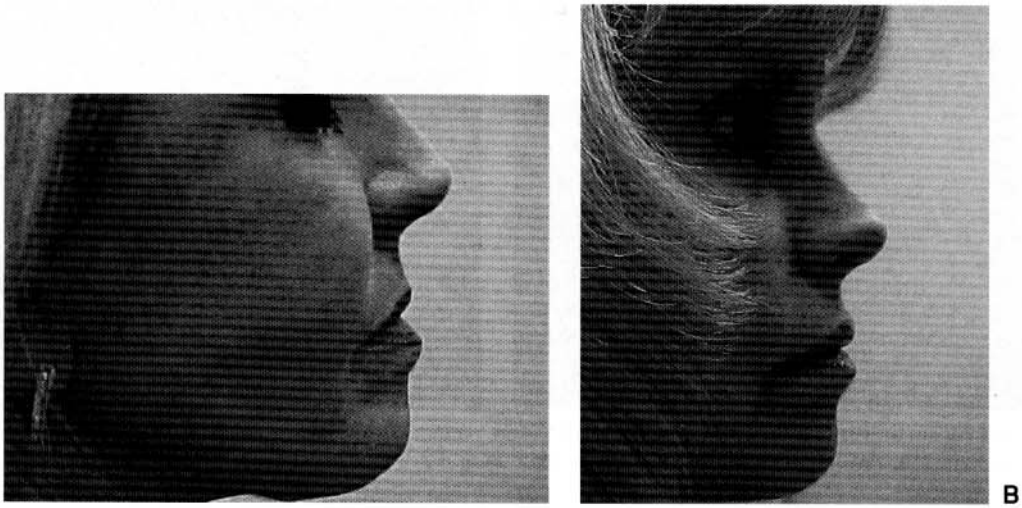


Figure 4 (A) This patient was unhappy with the prominence of her upper lip. (B) After two treatments with Silicone, she was much happier with her profile as well as her frontal view.

Silicone is being used by many other physicians to fill acne scars, augment facial rhytids, and correct facial lipoatrophy. Jones and colleagues studied 410 patients with lipoatrophy at four centers who were being treated with either Silikon 1000 or VitreSil 1000.[5] A subset of 77 were evaluated for clinical safety and efficacy. No significant adverse results were found, and it was the opinion of the authors of that study that highly purified centistokes oil is a safe and effective treatment for facial lipoatrophy. In this study up to 16.9 mL total were injected but this was over a period of an average of 59 weeks. Still the microdroplet technique was strictly adhered to.

We do not use it for any of these purposes in our office. We did a study on Sculptra in treatment of facial lipoatrophy in our office, so we have been using polylactic acid to treat this problem. I had thought the volume necessary to correct facial lipoatrophy may lead to problems with migration long term. However, I do hear many patients are ecstatic with the results. Acne scarring is another area of interest for the use of silicone. This technique requires the silicone to be placed rather superficially and on occasion a patient can be left with a small bump rather than a small depression. Many physicians has used it for this treatment with positive results (Figs. 1–4).

REFERENCES

1. Sakurai KH. Injectable silicone formula. Arch Otolaryng 1963;78:663–668
2. Rees TD, Platt J, Ballantyne DL Jr. An investigation of cutaneous response to dimethylpolysiloxane (silicone liquid) in animals and humans—a preliminary report. Plast Reconstr Surg 1965;35:131–137
3. Orthopharmaceutical Corporation. Investigation of new device clinical protocol. Protocol #H87-045. Silicone Investigation Meeting. New York, June 10 1987
4. Wilke TF. Late development of granulomas after liquid silicone injections. Plast Reconstr Surg 1977;60:179–188
5. Lemperle G, Morhenn VB, Pestonjamasp V, Charrier U, Gallo R. San Diego, California and Frankfurt, Germany. Plastic Reconstructive Surgery; 2003;112
6. Jones D, Carruthers A, Orentreich D, et al. J Dermatol 2004; in press
7. Duffy DM. The silicone conundrum: a battle of anecdotes. Dermatol Surg 2002;28:590–594
8. Duffy DM. Liquid silicone for soft tissue augmentation: background and current status. In: Klein AW, ed. Tissue Segmentation in Clinical Practice: Procedures and Techniques. New York: Marcel Dekker; 2003
9. Duffy DM. Silicone: a critical review. Adv Dermatol 1990;5:93–107; discussion 108–109
10. Wirtzer A. Twenty-eighth Annual Hawaii Dermatology Seminar 2004