DISCOVER WHY SO MANY AESTHETIC PROVIDERS ARE REDISCOVERING SCULPTRA® AESTHETIC



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Disclosures: Galderma: Speaker, Consultant, Trainer, Clinical Investigator, Advisory Board; Allergan: Consultant, Clinical Investigator, Advisory Board; Merz: Clinical Investigator magine a 401(k) for facial rejuvenation. In the words of facial plastic surgeon Jason Bloom, MD: "You put something in now for benefits in the future." That's exactly what Sculptra® Aesthetic (injectable poly-L-lactic acid, Galderma) is, he says. In fact, he uses the 401(k) analogy with many of his patients. "It's not like playing the stock market for short-term gains by using hyaluronic acid filler. This is long-term benefit. Sculptra Aesthetic is a long-acting product." The clinical trials for Sculptra Aesthetic followed patients out to 25 months. 12

After more than a decade on the market, Sculptra Aesthetic continues to grow in popularity with aesthetic providers like Dr. Bloom. "The popularity of Sculptra Aesthetic has grown tremendously, not only here in the US, but globally," observes dermatologist Melanie Palm, MD. "I think that's because there are so many applications that many of us discuss at meetings and that have appeared in published reports. We're recognizing the artistry and thinking structurally about the face and the ability of a collagen stimulator to provide very natural and gradual but meaningful results over time."

SOMETHING DIFFERENT

Douglas Mest, MD, who specializes in aesthetic treatments, clarifies that, among today's aesthetic offerings, "Sculptra Aesthetic should not be classified simply as a filler. It's an injectable. I tell patients that with Sculptra Aesthetic, I can address a number of the underlying aging processes with one product by replacing lost collagen, which gives them improved structural support to their skin."

Sculptra Aesthetic is best classified as a biostimulatory agent. A mouse study² that looked at tissue response after implantation of poly-L-lactic acid microparticles, "found at a month, there was a controlled inflammatory response with an infiltrate of lymphocytes, of macrophages, of mast cells, and fibroblasts. By three months, there was a fibrous cap-





Actual patient, Age: 50, Individual results may vary, Treated with 6 vials of Sculptra® Aesthetic, Shown before and 27 weeks after initial treatment. Results have not been retouched.

sule, so you were actually getting collagen stimulation. And by six months you saw degradation of the PLLA particle and new collagen—type one collagen—formation was increasing," Dr. Palm explains. "Biopsy data³ show that collagen formation occurs through at least 12 months after Sculptra Aesthetic placement and may even occur for a longer period of time."

Dr. Mest notes that Sculptra Aesthetic is provided as consistently sized (40-60micron), irregularly shaped microparticles.4 "It's more stimulatory than round microspheres. And poly-Llactic acid breaks down into lactic acid monomers, which are found naturally in the body," he adds.

Sculptra Aesthetic's novel mechanism of action is critical, says dermatologist Shino Bay Aguilera, DO. "I'd rather have my patient imitate the volume lost with their own collagen, rather than trying to have products occupy space in their face, instead of using a lot of injectable gels to imitate volume," he says.

Interestingly, Dr. Mest credits Sculptra Aesthetic with opening the way to discussions of volume replacement. He was lead author of the initial pivotal trials that supported FDA approval of Sculptra. "It was mind blowing how much volume correction was seen. And it honestly was the first time we talked about volume

loss in the aesthetics field," he says. "We used to just fill individual lines. Now it's all we really talk about: lipoatrophy of aging, bone loss, other aging changes."

"Sculptra Aesthetic has no volume in and of itself," Dr. Bloom says. "It's a powder. By stimulating the body's own collagen, you get a volumization effect; it's ramping up the production of collagen through a controlled inflammatory response."

Both Dr. Bloom and Dr. Mest liken treatment with Sculptra Aesthetic to the process of planting grass seed. "We mix the Sculptra Aesthetic with water to sprinkle it into the skin and then that water—which is just there to be able to sprinkle the 'seeds'—gets absorbed," Dr. Mest offers. "And for a couple of weeks, patients don't see much of anything. Around the third or fourth week, they start to see an improvement. I actually think that's a really good thing, because I think having patients gradually look better, so nobody has to know they had anything done, is really important."

Dr. Palm concurs, noting that the gradual onset of effect is especially popular among men, for whom cosmetic procedures may be stigmatized. "Sculptra Aesthetic is popular for many of my professional patients, people that are in the

public eye or people that are just really concerned about, 'Putting something foreign in their skin," she says.

Dr. Palm maintains that even though other injectable products—"many of which I use on a daily basis"—are safe, patients, "like the idea of harnessing their body's own biological machinery to produce 'their own filler.' That has been very appealing. For many of my patients, if appropriate, Sculptra Aesthetic is something I go to for foundational support."

WIDE APPEAL

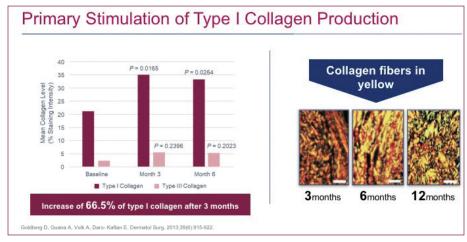
"As we get older, we see changes in volume from deeper tissues—as deep as the periosteum, the bone, the deep fat compartment—and also from the amount of collagen that we have in the dermis," Dr. Aguilera points out. "With the proper technique, with poly-L-lactic acid, we can, basically, give back the appearance of a more youthful face by imitating the volume of deeper tissues with one product."

Experts in the use of Sculptra Aesthetic say the product may be especially well suited for younger patients those in their 30s or early 40s who are just seeing the first signs of collagen depletion and volume loss.

Regardless of patient age, Dr. Aguilera advocates for Sculptra Aesthetic for most cases of volume loss. Some patients in their 30s can have significant volume loss—think exercise enthusiasts. "They look very gaunt and tired. For them, this product is incredible. The only drawback for a young patient is that they want everything immediately. But if they choose to do Sculptra Aesthetic and be patient—just wait about two months the result that they're going to get is going to be longer-lasting than if they use an injectable filler, like hyaluronic acid gel, because the durability of the results is going to last longer."

Dr. Bloom also uses Sculptra Aesthetic across a range of patient ages but especially in younger patients. He says Sculptra Aesthetic can be a good





alternative to fat grafting, especially for those with limited stores of body fat.

Regardless of the patient's age, Sculptra Aesthetic provides natural looking results, Dr. Bloom stresses. "HA filler is easy to overdo. You can put too much filler in a patient rather easily and make them look strange. It is, I would say, very difficult to overdo Sculptra Aesthetic."

Many patients require education about their aesthetic concerns and available interventions. When a patient complains about the appearance of the nasolabial fold, "It's often the loss of mid-face volume that's causing the fold, and you have to explain that to patients," Dr. Mest says. "Sometimes patients get it, sometimes they don't."

"If you educate your patients and tell them about the aging process, and you have graphics, where they see what aging on the skin looks like, what aging on the deep fat compartment looks like, what aging on the bone looks like, then they have a better idea of the aging process," Dr. Aguilera stresses, "Then, they will be more receptive to use a product that can help with volume loss on the face."

Clinical experience—and data—indicate high levels of patient satisfaction with treatment.⁵ Dr. Palm had early exposure to Sculptra Aesthetic during her fellowship and learned from mentors how to artfully and effectively provide treatment; at the time, she co-authored a retrospective study on patient satisfaction.6 "We found that up to 75 percent of patients were satisfied to very satisfied with the results of Sculptra Aesthetic treatment at 25 months after their last injection session," she says.

A GAME CHANGER

Patients educated on the aging process and the biostimulatory effects of Sculptra Aesthetic are primed for high levels of satisfaction, Dr. Aguilera asserts. "The only thing they need to do is wait a little bit of time—up to two months to enjoy the benefit of a product that is going to re-create volume loss with their own tissue, that's going to look natural, that is going to last longer. That's where Sculptra Aesthetic was a game-changer in my practice."

Patients treated with Sculptra Aesthetic may continue to maintain aesthetic improvements up to 25 months or more.* But, over that time, the aging process continues, Dr. Palm notes. "I want to keep them at that upper plateau once we've achieved correction." To that end, she advises patients to retreat before they begin to see a loss of volume. Dr. Palm notes that, because the injector's knowledge of anatomy and injection technique are critical, patients are willing

to pay a premium for Sculptra Aesthetic treatment. But once they are on maintenance, they will not require as many retreatments as they would with other injectables. She says patients are very pleased, and the vast majority continue to use Sculptra Aesthetic as a part of their maintenance, cosmetic treatment plan.

"It's cost-effective," Dr. Aguilera believes, based on his patient experience. He suggests that this adds special appeal for millennials, who are cost-conscious after the 2008 recession. "Now, with COVID-19, they get hit again with another recession and they may have lost their jobs. Sculptra Aesthetic, I think, is going to make more sense for the younger population, because they are looking for cost-effective things. They just want to know that it works."

All the experts note that they use a range of aesthetic injectables in their practices, and some patients who receive Sculptra Aesthetic may have cosmetic concerns that are addressed with HA fillers or other products.

"Sculptra Aesthetic is a winner when you add in wide area of treatment and then how long it lasts—because it does truly last," Dr. Mest says. "I've been doing it long enough that the longevity is definitely there. This lasts years, not months."

"It is my favorite injectable treatment by far," Dr. Bloom says. "I love the product, and I feel like those aesthetic injectors who know it, love it."

Please see Important Safety Information on the following page.

^{*} The clinical study ended at 25 months.

^{1.} Narins RS, Baumann L, Brandt FS, et al. A randomized study of the efficacy and safety of injectable poly-L-lactic acid versus human-based collagen implant in the treatment of nasolabial fold wrinkles. J Am Acad Dermatol. 2010;6(3):448-462.

^{2.} Gogolewski S, Jovanovic M, Perren SM, Dillon JG, Hughes MK. Tissue response and in vivo degradation of selected polyhydroxyacids: polylactides (PLA), poly (3-hydroxybutyrate) (PHB), and poly(3-hydroxybutyrate-co-3-hydroxyvalerate) (PHB/VA). J Biomed Mat Res. 1993;27:1135-1148.

^{3.} Goldberg D, Guana A, Volk A, Daro-Kaftan E. Single-arm study for the characterization of human tissue response to injectable poly-L-lactic acid. Dermatol Surg. 2013:39(6):915-922.

^{4.} Lowe NJ. Dispelling the myth: appropriate use of poly-L-lactic acid and clinical considerations. J Eur Acad Dermatol Venereol. 2006 May; 20(Supp 1):2-6. Sculptra Aesthetic: What You Should Know. Available at: https://www.realself.com/ sculptra-aesthetic. Accessed August 24, 2020.

^{6.} Palm MD, Woodhall KE, Butterwick KJ, Goldman MP. Cosmetic use of poly-l-lactic acid: a retrospective study of 130 patients. Dermatol Surg. 2010;36(2):161-170.

Important Safety Information

Indication: Sculptra[®] Aesthetic (injectable poly-L-lactic acid) is indicated for use in people with healthy immune systems as a single regimen for the correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grid pattern (cross-hatch) injection technique is appropriate.

Sculptra Aesthetic should not be used by people that are allergic to any ingredient of the product or have a history of keloid formation or hypertrophic scarring. Safety has not been established in patients who are pregnant, lactating, breastfeeding, or under 18 years of age.

Sculptra Aesthetic has unique injection requirements and should only be used by a trained healthcare practitioner. Contour deficiencies should not be overcorrected because they are expected to gradually improve after treatment.

Sculptra Aesthetic should not be injected into the blood vessels as it may cause vascular occlusion, infarction or embolic phenomena. Use at the site of skin sores, cysts, pimples, rashes, hives or infection should be postponed until healing is complete. *Sculptra Aesthetic* should not be injected into the red area (vermillion) of the lip or in the peri-orbital area.

The most common side effects after initial treatment include injection site swelling, tenderness, redness, pain, bruising, bleeding, itching and lumps. Other side effects may include small lumps under the skin that are sometimes noticeable when pressing on the treated area. Larger lumps, some with delayed onset with or without inflammation or skin discoloration, have also been reported.

Sculptra Aesthetic is available only through a licensed practitioner. Complete Instructions for Use are available at www.SculptraAesthetic.com.