Considerations for the Use of Injectable Poly-L-lactic Acid in People of Color

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ABSTRACT

With demand for minimally invasive cosmetic procedures rising in patients of color, it is becoming increasingly important for clinical dermatologists to be aware of specific needs of these patients. This article therefore reviews considerations for using cosmetic procedures on skin of color, and reports the authors' clinical experience with the use of injectable poly-L-lactic acid (PLLA, Sculptra®, Dermik Laboratories, a business of sanofi-aventis U.S. LLC) in this patient population. The authors' experience indicates that patients with skin of color may require an increased interval between treatments; however, with proper attention to patient selection and administration technique, injectable PLLA can be used effectively in this patient group. Controlled clinical studies that include more patients of color are needed to fully assess the benefits and risks of cosmetic products, such as injectable PLLA, in these populations.

INTRODUCTION

Demand for minimally invasive cosmetic procedures is rising in people of color.[1] According to data from the American Society for Aesthetic Plastic Surgery, over 10 million cosmetic procedures were performed in the United States (U.S.) in 2008, of which 83% were nonsurgical.[2] Racial and ethnic minorities accounted for approximately 20% of the cosmetic procedures.[2] Since 1997, the number of nonsurgical procedures in the U.S. has increased by 233%.[2]

The demand for cosmetic procedures is likely to increase further, given census bureau projections for population growth among nonwhite ethnic groups in the U.S. In 1990, 76% of the U.S. population was classified as white, and 12% was classified as black, 9% Hispanic and 2.8% Asian.[3] However, projections for 2050 indicate a very different picture, with approximately 53% of the total population likely to be classified as white, 14% black, 25% Hispanic and 8% Asian.[3] Thus, it is becoming increasingly important for clinical dermatologists to be aware of specific needs of their patients of color. As yet, this has not translated into differences in the demographics of the population of patients seen in the authors' practices.

There is no standardized definition or classification method for skin of color, but several systems have been used clinically.[4] One common method is the use of Fitzpatrick skin types IV through VI,[5] although this classification system was originally developed to define response to UV light in phototherapy rather than to define ethnicity.[4] Among dermatologists, it is generally accepted that an olive skin tone (beige or lightly tanned) is classified as type IV, brown skin as type V, and black skin as type VI.[3] The Taylor Hyperpigmentation Scale uses 15 cards of different skin hues—each with 10 increasingly darker gradations—to assess hyperpigmentation disorders.[6] In the U.S., racial or ethnic groups considered to have skin of color include African American and Caribbean black persons, Asian and Pacific Islanders, Native Americans, Latino or Hispanic individuals and the majority of Indians, Pakistanis and those of Middle Eastern origin.[3] For the purposes of this review, skin of color is defined as Fitzpatrick skin types IV, V and VI.[3] A new classification system has recently been developed based on the Fitzpatrick scale that includes additional assessments of hypopigmentation, photoaging and scar morphology.[7] This system seems to address the limitations of the Fitzpatrick system, as there are more elements to skin damage than photoaging.

Injectable poly-L-lactic acid (PLLA, Sculptra®, Sculptra Aesthetic; Dermik Laboratories, sanofi-aventis U.S. LLC) contains microparticles of PLLA, a synthetic, biocompatible, biodegradable polymer from the alpha-hydroxy-acid family. It was approved in 2009 by the U.S. Food and Drug Administration (FDA)[8] for use in immune-competent people as a single regimen for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which a deep dermal grid pattern injection technique is appropriate. It is also approved[9] for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus (HIV). Clinical experience with injectable PLLA in both HIV-associated facial lipoatrophy and in cosmetic facial volume restoration supports a gradual onset and sustained duration of action, with improvements shown to be maintained for up to two years.[10–12] Most clinical data, however, have been obtained in studies with predominantly white patient populations. Published data in patients of color are still lacking. The current article reviews specific considerations that need to be addressed when using cosmetic procedures on skin of color, and describes the authors' clinical experience with the use of injectable PLLA in a group of patients that is growing in importance in many clinical practices.

Overview of Considerations for Use of Cosmetic Procedures in Patients of Color

An important consideration for patients of color is that their skin has biological differences versus fair skin that affect cosmetic correction needs. First, photoaging-related facial signs begin to appear 10–20 years later in patients with darker skin compared to those with lighter skin tones.[13,14] Specifically, fine perioral lines and periorbital lines—common in aging white skin—tend not to occur in skin of color. The signs of facial aging in patients of color typically stem from volume loss from the deeper muscular layers of the face, rather than the dermal layers as in white patients. In blacks this is reflected in a tendency toward mid- and lower-face aging, including upper lid laxity, sagging of the malar fat pads toward the nasolabial folds, and jowl formation.[13,14] Compared with whites, blacks have a more marked bony structure of the face with greater lower face height, facial convexity, anterior dental height and soft tissue thickness, particularly of the lips and chin, and a longer lip length.[15] Therefore, the traditional surgical facelift procedure may not be the best option for most patients of color who desire a more youthful appearance. Minimally invasive procedures, such as botulinum toxin type A (Botox®, Allergan, Inc., Irvine, CA) injections and soft tissue augmentation are better suited to patients of color with mid- and lower-face aging who are not interested in more drastic surgical procedures.[13,16]

Other cosmetic issues of primary concern to many patients of color (African American, Hispanic and Asian patients) are uneven skin tone and hyperpigmentation disorders.[17,18] In a study specifically comparing skin conditions in white versus black patients, distinctive differences were observed between the two groups regarding texture and pigmentation. Whereas patients with lighter skin showed more marked fine lines, wrinkles, laxity and overall photodamage, the black patients showed much more hyperpigmentation and a tendency to a more uneven skin tone.[19]

In addition to biological differences, cultural differences in patients of color are important considerations that may impact the use and results of cosmetic procedures. For example, black patients are less likely to undergo surgical facial cosmetic procedures due to cultural attitudes that such procedures conflict with a healthy sense of racial identity.[13] Thus, viewed as an extension of the normal skin care regimen, nonsurgical procedures may be more acceptable to many of these patients. Black skin is also more likely to become dyschromic or scarred after surgical procedures than is white skin, further highlighting the importance of minimally invasive options for this group.[13] For Asian patients, who tend to have greater collagen and melanin content in a thicker dermal layer than do whites,[20] concerns about their appearance may be heightened by cultural attitudes placing great importance on physical beauty, equating physical traits with prospects for personal success in life.[13] However, there is little published literature on Asian preferences for cosmetic procedures—conservative treatment is recommended.[20]

Perceptions of what is aesthetically desirable in facial correction may vary among ethnic groups. As indicated above, the cosmetic goals of individuals with skin of color are generally not to emulate the Western standard of beauty or to mask distinctive ethnic features, but rather to enhance those features and correct the effects of aging to obtain a younger appearance.[13] In one study, many Hispanic patients emphasized the importance of preserving their ethnic identity; the ideal outcome for most patients seemed to involve fusion, in which ethnic identity is retained but with a trend toward the Western "aesthetic norm."[21] However, it is important to note that this norm is highly variable.[21] Definition of beauty is highly complex,[22] and wide cultural diversity in concepts of beauty[15] highlight the need for good communication with the patient regarding individual goals and desires.

Aside from patients' goals and expectations, factors that can affect the success of cosmetic procedures in skin of color include increased risk of keloid scar formation, hyperpigmentation and procedure technique. Keloids are more common in darker pigmented skin, although in our clinical experience keloids may also be seen in some Fitzpatrick type I patients (e.g., those of Irish or Baltic descent). Keloids tend to occur less frequently in older patients, and usually develop after some form of skin trauma—surgery, lacerations, vaccinations, body piercing, infection, burns, insect bites, tattooing or any cause of skin inflammation (e.g., acne, chickenpox, etc).[23] The rate of keloid formation as a result of acne scarring has been reported to be five to 15 times higher in the black than in the white population.[24] Generally, any tendency to form keloids should be recognized by the time a patient has reached adulthood,[24] and each patient should be asked about their personal and family history of keloids before selection of a procedure.

Hyperpigmentation is another concern in patients with Fitzpatrick skin types IV–VI. This occurs in response to inflammatory processes; causes generally include certain cosmetic procedures and mechanical trauma to the skin, as well as healing acne lesions.[4,25] Hyperpigmentation may resolve with protection from exposure to the sun for a period of time.[26] The authors have found that the incidence of hemosiderin deposition is increased when bruising occurs, giving the appearance of hyperpigmentation; the authors therefore take precautions to reduce bruising when performing cosmetic procedures.

In the use of soft-tissue augmentation in patients of color, proper injection technique is a critical factor to minimize adverse events associated with injectable facial soft tissue augmentation products (including injectable PLLA, hyaluronic acid derivatives and calcium hydroxylapatite). For example, in the authors' clinical experience, slower injection times in both patients with skin of color and in whites appear to be associated with less postinjection inflammation with traditional dermal fillers, which reduces the risk of inflammation-associated

effects. Steps that can reduce the risk of adverse events include proper product reconstitution, proper product placement, gentle massage of the injection area during or immediately after the treatment session, and, in the case of injectable PLLA, gentle postprocedure massage by the patient. However, it is important to note that overzealous manipulation of the injection area can cause bruising and should therefore be avoided.

Clinical Experience With Injectable PLLA in Patients of Color

In assessing patients prior to using injectable PLLA some experts choose to make slight modifications to the injection procedure documented on the product information,[8,9] including increasing the dilution volume, and/or adding a local anesthetic to the vial when reconstituting the suspension or prior to injection. One physician has recently reported reconstituting the injectable PLLA vials with 5 mL of sterile water for injection, using a topical local anesthetic one hour before the injection procedure; and using 2 mL of lidocaine 1% to block the infraorbital nerves.[27] An alternative approach is to reconstitute the vials with 6 mL of bacteriostatic water and 2 mL of lidocaine 2% (with or without epinephrine, added at the initial reconstitution) and inject deeper than the superficial subcutaneous layer but not into the deep dermis.

In assessing patients prior to use of injectable PLLA, the authors no longer review just the wrinkle but also consider the volume of tissue loss. Skin folds will usually correct with adequate filling and redraping of the sagging skin (sagging can be more marked in people with skin of color), so physicians look at the loss and descent of the malar fat pad and the decrease of maxillary bone volume. Treatment is aimed at replacing lost facial tissue volume in all layers. Volume loss occurs in all patients; however, in people with skin of color it tends to manifest as laxity of the skin in the mid- and lower face (Figures 1 and 2), whereas in white patients the result may be development of concavity. The patient in Figure 1 underwent two treatment sessions with injectable PLLA. In the first session two vials were used, each with a 5 mL dilution volume of bacteriostatic water; in the second solution, one vial of product was used with a 6-mL dilution volume. Topical lidocaine 4% was applied 45 minutes before injection; together with infraorbital and mental blocks of 1 mL of lidocaine with epinephrine at each site prior to injection for the mid and lower face. The treatment area was massaged for three to five minutes, and the patient was asked to massage twice daily when cleansing her have. The patient in Figure 2 received one vial on injectable PLLA (diluted with 6 mL bacteriostatic water and 2 mL 1% lidocaine with epinephrine) injected to the midface and temples, followed by one additional vial (same dilution) injected approximately 16 months later. The patient massaged the injection area for five minutes twice daily for one week after each treatment session.

FIGURE 1. A 70-year-old patient with Fitzpatrick skin type IV, **a)** before treatment, showing the laxity often seen in skin of color, and **b)** after treatment with injectable PLLA, showing restoration of the facial contours. Injectable PLLA was placed into the mid and lower face in two treatment sessions nine months apart. Used with permission from Saunders/Elsevier. *Facial Rejuvenation With Fillers Textbook*; PLLA Chapter 5. Pages 59-60.

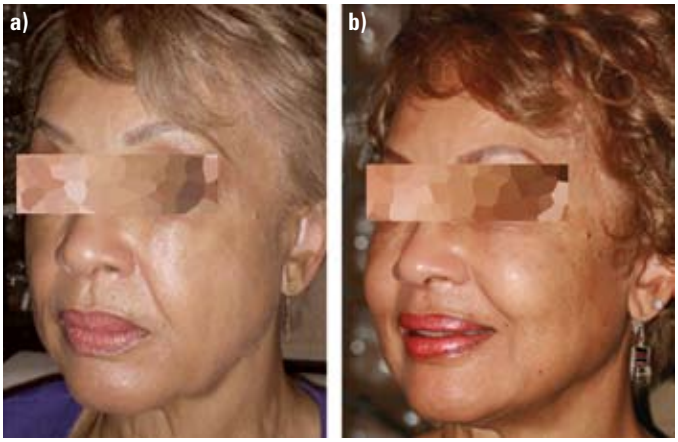
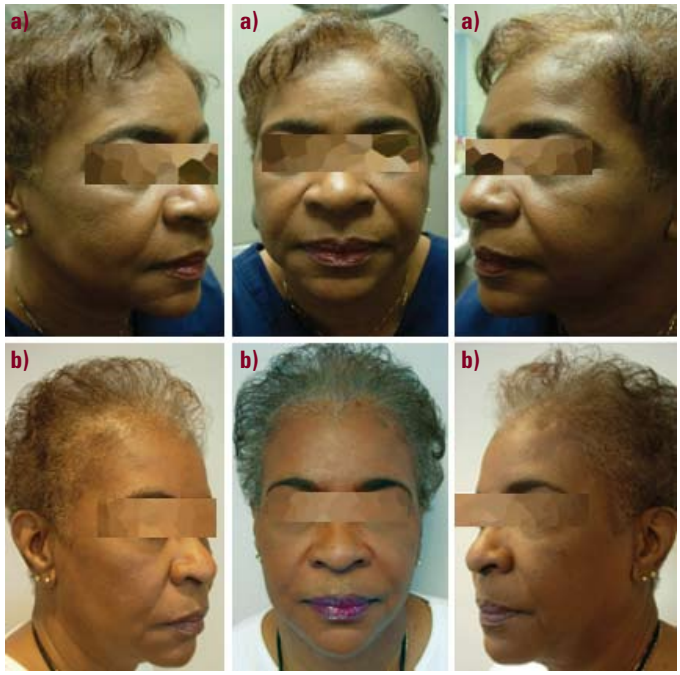


FIGURE 2. An African American patient with Fitzpatrick skin type V, **a)** before and **b)** after treatment with injectable poly-L-lactic acid placed into the midface and temples in two treatment sessions, 16 months apart. After-treatment photographs were taken 13.5 months after the final session.



Marked nasolabial folds have been noted in some of the authors' black patients. The patient in Figure 3 received a single vial of injectable PLLA (diluted with 6 mL bacteriostatic water and 2 mL 1% lidocaine with epinephrine). The patient massaged the injection area for five minutes twice daily for one week; the second photograph was taken seven months after the first. In all three patients, the facial volume loss was corrected with the PLLA injections. In contrast, the volume loss in the authors'

FIGURE 3. An African American patient with Fitzpatrick skin type IV, **a)** before and **b)** seven months after treatment of marked nasolabial folds with a single vial of injectable poly-L-lactic acid injected into the medial cheeks, zygpmatic cheek, temples and nasolabial folds.

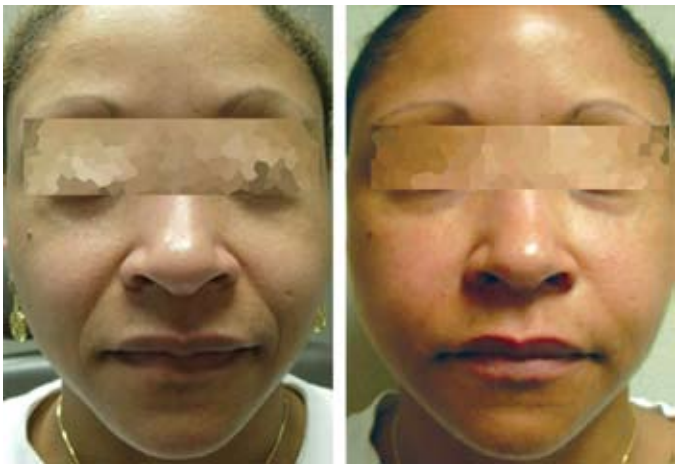
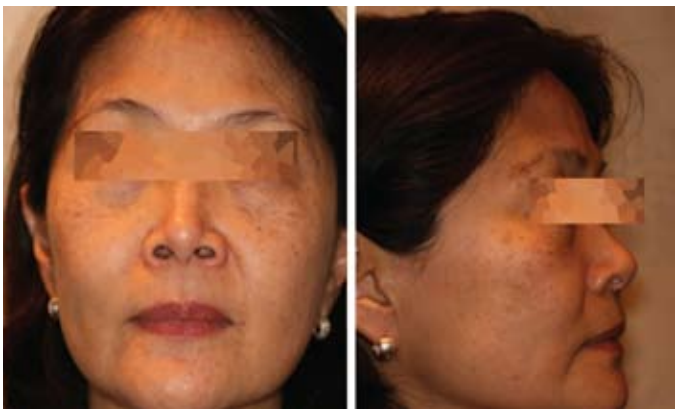


FIGURE 4. An example of an Asian patient, showing the facial flattening that occurs with age. No cosmetic procedures were performed on this patient.



Asian patients manifests as flattening of the facial convexities, as show, for example, in Figure 4; this patient did not undergo any cosmetic procedures.

Injectable PLLA is extremely useful for midface volume correction. Although the recommended cross-hatch and fanning techniques used to deposit injectable PLLA in the superficial SC layer can result in some improvement in the aging face, in the authors' experience, volume restoration in the SC layer alone does not result in optimal correction. In the authors' practice, injectable PLLA is deposited in multiple layers of the face to fully correct the multilayer volume loss of aging, thereby restoring the volume contained in the facial scaffold and redraping the redundant skin. This technique results in a natural, more youthful appearance. Multilayer correction is achieved by initially placing small aliquots of product above the bone along the maxilla and zygoma, starting at the nasofacial sulcus.

Submalar SC injection of PLLA can be performed; however, care must be taken not to overcorrect the submalar region without fully addressing the malar region. This will further accentuate the trapezoidal appearance of the face. By augmenting the malar cheek, canine fossa and piriform sinus regions, the nasolabial fold will be improved; however, additional product can be threaded perpendicular to the nasolabial fold to further enhance the correction. With adequate correction of the malar cheek region, very little correction of the lower cheeks is needed. The authors' advise the patient to perform a gentle but deep two- to five-minute massage of the treated areas twice daily for a week.

Having used injectable PLLA to treat a large number of patients with Fitzpatrick skin types IV–VI, the authors' find that these patients generally show minimal bruising, although it may be difficult to recognize deep bruising in patients of darker skin types. The extent of bruising seems to be lessened by the use of lidocaine with epinephrine. Hyperpigmentation is a rare side effect that can occur with any trauma to the skin and with all injectable devices, and may be associated with faster injection rates and bruising. Topical bleaching creams are helpful, but not if hemosiderin is considered to be present on clinical inspection. If marked hemosiderin deposition occurs, the use of a neodymium-doped yttrium aluminum garnet (Nd:YAG) laser may be required to remove persistent discoloration.

In the authors' experience, patients with skin of color tend to achieve the desired correction with fewer injection sessions of PLLA than do patients with types I–III; for this reason, the authors like to wait longer between sessions (typically one to two months) to avoid overcorrecting. A family history of keloids does not preclude correction procedures, but the authors do try to avoid correction in patients with a history of keloids. Overall, our patients with darker skin treated with injectable PLLA have had very positive results, experiencing cosmetic improvement that was maintained over approximately two years. In the authors' clinical experience, there have not been significant injectable PLLA-related adverse events in patients with skin of color; in particular the authors have not noted any keloid formation or abnormal scarring. The incidence of nonvisible small papules is similar to that seen in the patients with white skin (6% in one recent study).[28] Differences in skin type notwithstanding, however, other factors may contribute to the development of nodules or papules. For example, studies in which injectable PLLA was diluted with 4 mL or less reported nodule/papule rates of 31–44%.[11,29] In studies using dilutions of injectable PLLA of 5 mL or more the rates dropped to 13.1% or less.[10,30–32] Other factors that may contribute to the development of nodules and papules include injection into superficial dermal areas, lack of adequate post-injection massage, and injection into hyperdynamic areas of the face.[33–35]

Future Perspectives

Despite the favorable results with injectable PLLA use we have observed in our clinical practice treating patients of color, clinical trial

data regarding the use of facial volume replacement procedures in these populations are currently lacking. Controlled clinical studies are clearly needed to provide more concrete data regarding risks and benefits of treatment in these patient populations. Ideally, prospective trials of agents for facial rejuvenation should include substantial numbers of patients of color, in order to more accurately reflect changing demographics in the U.S. and to provide more data regarding the use of these agents in people of color. In fact, the ongoing FACES trial, assessing the long-term safety of injectable PLLA in HIV-associated lipoatrophy, includes an important number of non-white participants with HIV lipoatrophy. This and other studies should provide more information in the future regarding the efficacy and safety of injectable PLLA in patients of color.

CONCLUSION

It is important to note that skin of color has biological differences versus fair skin that affect cosmetic correction needs. Specifically, fine perioral lines, and periorbital lines—common in aging white skin—tend not to occur in skin of color. Cosmetic issues of primary concern to patients of color include an uneven skin tone, and hyperpigmentation disorders. Whereas patients with lighter skin show more marked fine lines, wrinkles, laxity and overall photodamage, black patients show much more hyperpigmentation and a greater tendency to a more uneven skin tone.

When using soft tissue augmentation in patients of color, proper injection technique is critical to minimizing adverse events associated with injectable facial soft tissue augmentation products. The authors' experience indicates that patients with skin of Fitzpatrick skin types IV, V and VI may require an increased interval between treatments; however, with proper attention to patient selection and administration technique, injectable PLLA can be used effectively in this group of patients. Overall, patients with darker skin treated with injectable PLLA have had very positive results, experiencing cosmetic improvement that was maintained over approximately two years.

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DISCLOSURES

Dr. Hamilton is a speaker and trainer for Dermik Laboratories, a business of sanofi-aventis U.S. LLC.

Dr. Burgess is a trainer for Dermik Laboratories, and has received honoraria from Allergan, Colbar, Medicis and Bioform. She has also conducted clinical research for Medicis and Allergan.

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