

Introducing Sculptra®: Global Restoration For The Aging Face

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Abstract

Changes in facial appearance with aging include increased prominence of lines and folds, dermal thinning and facial lipatrophy. Additionally, cheeks can flatten, jowls become prominent, temples hollow and nasolabial and marionette lines appear.

These changes can negatively impact self-esteem and, as such, cosmetic enhancement is often sought to re-establish a youthful appearance. There are several injectable agents currently available to help correct the signs of facial aging. Injectable poly-L-lactic acid (PLLA) is a biocompatible, biodegradable synthetic polymer device that, following injection, is hypothesized to elicit fibroblast production and subsequent collagen formation. Treatment with injectable PLLA has been observed to produce considerable increases in dermal thickness, with results lasting for up to 2 years, and longer in some cases. Furthermore, with correct reconstitution and administration, injectable PLLA demonstrates a favorable safety profile. This article reviews the use of injectable PLLA for global rejuvenation of the aging face, including reconstitution and administration techniques that can help optimize outcomes.

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INTRODUCTION

Recent surveys have confirmed that the demand for minimally invasive injectable procedures to restore a youthful facial appearance has escalated in recent years, and it is anticipated that this demand will continue to increase.^{1,2} Statistics published by the American Society of Plastic Surgeons (ASPS) reveal that, during 2006, injections of botulinum toxin type A (Botox[®]; Allergan, Inc., Irvine, CA) and the passive filler hyaluronic acid, were among the top five non-surgical cosmetic procedures performed in the US (4,090,517 and 778,285 procedures were performed respectively).² Botox helps restore youthful features by relaxing muscles to smooth individual fine lines and wrinkles,^{3,4} whereas passive fillers, such as hyaluronic acid and collagen, correct defects in the dermis (usually mild-to-moderate fine lines and wrinkles) with exogenous, inert, implanted material. News that the US Food and Drug Administration (FDA) is now considering injectable poly-L-lactic acid (PLLA; Sculptra[®], Dermik Laboratories, Bridgewater, NJ) for a cosmetic indication suggests that

practitioners may soon have access to a different type of injectable product that can be used for global rejuvenation of the aging face. Following injection, PLLA reshapes the face through volume restoration, thereby recreating youthful contours.

In this article, Dr. Paula Moynahan, a plastic surgeon with offices in Connecticut and New York, evaluates the use of injectable PLLA in effectively establishing a more youthful facial appearance. She will explain the unique benefits of injectable PLLA and her aesthetic enhancement protocol regarding its use.

THE AGING FACE

Intrinsic and extrinsic factors contribute to the aging process that affects all tissues of the body.⁵ Biological variability, combined with environmental influences, which include sun exposure, cigarette smoking, the use of alcohol and drugs, poor diet and stress, cause universal alterations in the appearance and function of the entire body.^{6,7} However, it is the visible signs of aging as they are manifested on the face that can impact most dramatically upon self-perception and self-esteem.⁸ A devaluation of one's worth will, ultimately, have a negative effect on self-confidence.

Cosmetic enhancement and the subsequent improvements in facial appearance have been associated with psychological benefits, such as improved self-esteem and quality of life.⁹

A myriad of changes in facial appearance are noted with aging. Wrinkles, prominent lines and folds, dyschromia, surface textural changes, diminished hydration, thinning of the dermis, slowing in the rate of cellular turnover, facial lipoatrophy and bone resorption can all combine to produce an aged, tired and dissipated look.^{8,10,11} Cheeks can flatten, jowls become prominent, temples hollow and nasolabial and marionette lines appear.¹⁰ Fat loss associated with aging produces a loss of facial volume, reducing support to the overlying skin, and creating a slow and inexorable transition from the visually pleasing aesthetically ideal contours of a youthful face, to an aged and undesirable appearance.

The sought-after appearance of youth has a long history stretching back to antiquity. However, advances in anesthesia and asepsis, combined with a broad acceptance of various anti-aging modalities, served as an impetus for the introduction of a number of effective and safe treatments. These treatments can help in the restoration of a more youthful and healthy appearance.

THE EVOLUTION OF THE GLOBAL APPROACH TO THE AGING FACE

THE MODERN FACELIFT

The 20th century defined the paradigm of the modern facelift as tightening and excising of excessive skin and the development of the Superficial Muscle Aponeurotic System (SMAS) flap technique.^{12,13} The modern facelift significantly reduces an aged facial appearance due to sagging skin and underlying tissues; however, the results are limited by the inability of the procedure to effectively restore lost volume. It is now recognized that further improvement, with optimization of youthful contours, is achievable through volume restoration that corrects lipoatrophy.

THE ROLE OF INJECTABLE AGENTS IN THE TREATMENT OF THE AGING FACE

BOTULINUM TOXIN

At present, the most popular minimally invasive treatment for anti-aging is the injection of clostridium botulinum type A neurotoxin (Botox®; Allergan, Inc., Irvine, CA).¹ A dramatic increase in the use of Botox has occurred since its approval by the FDA to smooth glabellar lines in 2002. In 2006, sales of Botox approached 1 billion dollars and the American Society of Plastic Surgeons' (ASPS) statistics

reveal the administration of over 4 million injections during that year.² This represents a 7% increase over the preceding year.²

As a neurotoxin, the mechanism of action of botulinum toxin is to reduce or eliminate wrinkles and furrows by weakening or paralyzing the injected muscles, with effects lasting up to 3–4 months.⁴ Although a rival product to Botox is not currently available in the US, it is thought that FDA approval of a similar neurotoxin for cosmetic indications, Reloxin® (Medicis Pharmaceutical Corp, Scottsdale, AZ), may be forthcoming during 2008.

PASSIVE FILLERS

Injectable passive fillers are essential agents for modern, non-invasive facial rejuvenation. These injectables can be used to correct individual lines and wrinkles and, in certain cases, for localized volume restoration. Among the earliest 'anti-aging' passive injectable to achieve widespread acceptance was purified bovine collagen (Zyderm®/Zyplast®; Inamed Corp, Santa Barbara, CA).^{14,15} Immediate softening of lines and folds of facial expression is achieved through the addition of inert material to the dermis to increase volume (i.e. passive filling), and the resultant correction persists for approximately 3–6 months.^{14,15} Although an improvement in appearance is evident following injection of collagen, further enhancement through the use of minimally invasive products with a long duration was sought, and has led to the introduction of other options.

Today, the most popular passive injectable filler is hyaluronic acid, which, when injected into the targeted areas, softens lines and folds and is also used to plump the lips.¹⁶ The benefits achieved generally persist for six months or longer, although are variable depending upon the density of the product injected.^{16,17}

In addition to injectable hyaluronic acid, an exhaustive list of additional new options of short-term and permanent passive fillers exists and continues to unfold, providing a vast array of non-surgical facial rejuvenation choices for the consumer.^{17,18} These agents will, however, not be discussed further in this article.

VOLUMIZING INJECTABLE

Injectable PLLA possesses unique characteristics that can provide a global approach to facial restoration, with predictable results and a favorable safety profile.

Injectable PLLA is a synthetic polymer that is a

biocompatible, biodegradable and immunologically inert member of the alpha-hydroxy acid family.^{19,20} Alpha-hydroxy acids, most notably glycolic acid, are well recognized for their anti-aging properties when applied topically, and several are used as facial chemical peeling agents to achieve cosmetic enhancement. Furthermore, they are major ingredients in skin rejuvenation treatment products.

Injectable poly-L-lactic acid

HISTORY OF POLY-L-LACTIC ACID

PLLA has an impressive safety record in its widespread use in various surgical specialties. It has been safely used in absorbable sutures (Vicryl® and Dexon®), orthopaedic plates and screws, and soft tissue implants for decades.^{21,22} The FDA approved the use of injectable PLLA for the restoration and/or correction of human immunodeficiency virus (HIV)-related facial lipoatrophy on August 3, 2004. Since that time, patients with HIV-associated facial fat loss have benefited from the use of injectable PLLA.^{23,24,25,26} Specifically, a reversal of the patient's wasted appearance, secondary to the restorative effects of PLLA injections, has resulted from the restoration of more wholesome and youthful contours.^{23,24,25,26} The creation of a healthier, more natural and attractive appearance has also been shown to result in significant psychological benefits, not the least of which is an increased sense of self-worth and an enhancement of quality of life.^{25,26}

POLY-L-LACTIC ACID FOR COSMETIC INDICATIONS

Injectable PLLA is currently approved in Europe, Canada, Australia and Brazil for cosmetic purposes, and is under FDA review in the US for a similar indication. In the cosmetic setting, injectable PLLA has demonstrated efficacy in the treatment of age-related lipoatrophy, with similarly promising results to those observed in HIV-related facial lipoatrophy.^{27,28,29}

The ability to provide global volume restoration by correcting hollows, flattening and concavities, developed secondary to aging, creates a youthful definition to facial contours. The aging face reveals lines, wrinkles and folds, resulting in tens of thousands of new facial planes. Additionally, the amount of soft tissue overlying 'boney prominences' diminishes and redistributes as lipoatrophy progresses. It is important to note here that it is not only the patient's bone structure, per se, that creates the aesthetically

ideal face, but also the distribution of soft tissue overlying the skeletal structure, which produces the contours of a youthful and 'beautiful' face. The global restoration of lost volume through the selective injection of PLLA can restore youthful curves, contours and convexities to the face (Figures 1, 2 and 3). Indeed, global restoration of volume loss is a necessary component in optimizing the rejuvenation of the aging face.

Figure 1

Figure 1: Patient (aged 47 years) before and after photographs (4 months post final injection) following four treatment sessions with injectable poly-L-lactic acid



Poly-L-lactic acid was reconstituted with 6 mL sterile water for injection and allowed to stand for 24–48 hours before injection. In total, four vials of poly-L-lactic acid were injected over the course of 10 months at intermittent times.

Figure 2

Figure 2: Patient (aged 46 years) before and after photographs (2 months post final injection) following three treatment sessions with injectable poly-L-lactic acid



Poly-L-lactic acid was reconstituted with 6 mL sterile water for injection and allowed to stand for 24–48 hours before injection. In total, three vials of poly-L-lactic acid were injected over the course of 10 months at intermittent times.

Figure 3

Figure 3: Patient (aged 55 years) before and after photographs (21 months post final injection) following two treatment sessions with injectable poly-L-lactic acid



Poly-L-lactic acid was reconstituted with 6 mL sterile water for injection and allowed to stand for 24–48 hours before injection. In total, two vials of poly-L-lactic acid were injected over the course of 21 months at intermittent times.

MECHANISM OF ACTION OF POLY-L-LACTIC ACID

The mode of action of PLLA is not completely understood. It is hypothesized that following injection, PLLA elicits the endogenous production of fibroblasts, which then combine with subsequent collagen production to produce a gradual overall thickening of the dermis in the injected region over time.^{20,30} Further improvement is obtained as additional treatments are rendered.

Biodegradation of the injected PLLA occurs through non-enzymatic hydrolysis within 6–24 months.^{19,20,30} The resultant lactic acid monomers are first metabolized into pyruvate, and subsequently carbon dioxide and water.¹⁹ However, volume restoration persists for approximately 2 years, and in some instances for a longer period of time.^{25,26,28} The long-term aesthetic benefits achieved through

injected PLLA-elicited global restoration of lost volume are desirable for significant reasons. The necessity of more frequent treatments to maintain semi-permanent correction is considerably less as compared to those required through the use of short-term passive fillers, such as collagen and hyaluronic acid. Furthermore, unlike other injectable agents that cause permanent changes, injectable PLLA offers a gradual and long-lasting increase in tissue volume that can be adapted over time as required.

POLY-L-LACTIC ACID USE FOR THE COSMETIC ENHANCEMENT OF THE AGING FACE

During the initial consultation for patients seeking cosmetic enhancement, patient expectations are evaluated, realistic goals are discussed and a treatment program agreed upon. Additionally, a facial analysis is performed, during which the shape, contours and proportions unique to each individual's face are evaluated. The restoration of the ideal structure of the face is determined.

Adherence to guidelines regarding the reconstitution and injection of PLLA is vital in order to minimize risks and complications (see box insert).^{19,29,31,33} Although most areas of the face are amenable to improvement through the use of PLLA injections, it is the enhancement of the malar prominence and the sub-malar region that are the key and cornerstone to facial rejuvenation. Forehead imperfections, tear trough deformities and hollows of the lower eyes can be improved by the judicious use of injectable PLLA, however, experience with advanced techniques is required. The nose and mucosa of the lips should be avoided.

AESTHETIC ENHANCEMENT PROTOCOL FROM THE AUTHOR'S EXPERIENCE

Although injectable PLLA has been well tolerated,^{28,34} proper reconstitution of the product, appropriate injection technique and patient adherence to post-treatment instructions (specifically massage) can help minimize the risk of treatment-related complications.

RECONSTITUTION

- Injectable PLLA is supplied as a sterile, freeze dried preparation (150 mg per vial) consisting of PLLA microparticles, sodium carboxymethylcellulose and mannitol
- Each vial is reconstituted with 6 mL of sterile water for injection (SWFI) or, optionally, 5 mL of SWFI and 1 mL of 1% lidocaine (see instructions below for addition of lidocaine)

- Reconstitution 24–72 hours prior to injection is recommended to ensure adequate hydration of the PLLA microparticles; however, if necessary, the diluent may be added at least 2 hours prior to injection. It is essential not to agitate the vial for this time period to ensure that all the PLLA microparticles are fully hydrated, and to decrease the risk of needle-clogging during injection
- While the product is being hydrated, do not agitate the vial; agitation is to be avoided until the time of treatment
- The reconstituted vial should be stored at room temperature
- Heating of the reconstituted vial is not recommended since solubility, safety and efficacy studies have not been conducted under these circumstances
- Pain management may be augmented by the addition of 1 mL of 1% lidocaine to the reconstituted vial at the time the treatment is rendered
- Additional pain control can be achieved through regional nerve blocks, topical anesthetic, application of cold compresses and by talking to the patient (talkesthesia)
- Immediately prior to injection, the vial is agitated until a uniform suspension is obtained

MAPPING OF THE FACE

- Using a water soluble eyeliner, a 1 cm x 1 cm grid is drawn over the facial areas that are to be injected. The facial mapping serves to focus the injector's attention on the exact amount of product to be deposited in a methodical and precise manner, thus avoiding overcorrection or under treatment
- Pre- and post-treatment photographs are taken before and after facial mapping. Photographs of the mapped face are an important part of the medical record, providing clear documentation as to the areas injected with PLLA. They also contribute to the evaluation of the patient's clinical course
- Universal precautions and aseptic technique should

be used throughout the procedure

THE INJECTION OF POLY-L-LACTIC ACID

- After the reconstituted vial is agitated, an 18-gauge needle is attached to a 1 mL or 3 mL syringe; the reconstituted PLLA is withdrawn into the syringe.
- A 26-gauge 1/2, 3/8 or 5/8 inch needle, or a 25-gauge 5/8 or 1 1/2 inch needle is then substituted for the 18-gauge needle; a 26-gauge needle is recommended by the manufacturer
- Injections are performed using either tunneling or depot techniques, with 0.1 to 0.2 mL deposited per cm
- The PLLA is injected in the submuscular plane in the upper third of the face and subcutaneously in the lower two thirds of the face
- Massage of the treated areas with a lubricant, such as a facial moisturizer, is done during or after the injections are administered
- Cold compresses should be applied for 5 minutes after the completion of the massage

POST-TREATMENT INSTRUCTIONS

- The immediate volume correction that is noted at the time of treatment is due to the water used for reconstitution. This effect dissipates within 24 hours; the volume enhancement due to injectable PLLA requires approximately 4–6 weeks to become evident
- The patient is advised to massage the treated areas with the lubricant for 3 minutes, five times a day, for 5 days post-injection
- Cold compresses may also be applied as needed to reduce swelling and for patient comfort
- The practice of treat, wait and assess (TWA) should be assiduously adhered to in order to avoid overcorrection
- The second and subsequent treatments should be conducted, as required, 4–6 weeks after the previous PLLA injections

RISKS AND POSSIBLE COMPLICATIONS

As with all injectable agents, there are possible risks associated with the use of PLLA. Transient, injection related adverse events relatively common to all injectable products include ecchymosis, edema and erythema.^{35,36,37} These conditions usually resolve within 1–7 days following treatment. Subcutaneous papules and nodules have also been reported in the short- and long-term following injection with PLLA.³⁷ However, subsequent reports from practitioners have suggested that the incidence of these can be dramatically reduced with correct reconstitution and appropriate administration of the product (see box insert).^{19,29,32,33} Additionally, it is important to ensure the even dispersion of the injected PLLA microparticles throughout the treated area at the time of the injections and not to over-correct. The patient should also be instructed to massage the treated area for several days after the treatment in order to achieve desired results.

SUMMARY

The re-establishment of youthful contours, curves and convexities is vital to reversing the visible signs of facial aging. Injectable PLLA gradually restores volume through hypothesized endogenous collagen production and provides a natural and more youthful appearance. Consideration by the FDA of injectable PLLA for a cosmetic indication in the US presents us with the potential for a minimally invasive procedure that is effective, well tolerated and has long lasting benefits for global rejuvenation of the face.

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