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Poly-L-lactic acid for global facial volumization

Introduction

Biostimulatory fillers, such as poly-L-lactic acid (PLLA), have been increasingly used to address facial volume deficiency in recent years. PLLA is an absorbable, semi-permanent soft tissue filler that restores volume by stimulating collagen formation. It is comparable to facial fat grafting.

PLLA is approved by Health Canada for facial fat restoration due to antiretroviral therapy-induced lipoatrophy.[1] It is also approved for increasing the volume of depressed areas due to skin creases, wrinkles, folds, and for skin aging. In real-world use, PLLA has also been used in off-label areas, including the neck, dorsal hands, abdomen, thighs, and the gluteus.[2] Multiple studies have confirmed the high patient satisfaction rate, excellent safety profile, and efficacy of PLLA for treating the aging face.[3]

Mechanism of Action

Injectable PLLA is a composed of crystalline microparticles of lactic acid polymers. PLLA is biocompatible, biodegradable, and biologically inert. It has various applications in medicine, such as suture material, pins, plates, and soft-tissue implants.[4] PLLA is metabolized along the same pathway as lactic acid to carbon dioxide and water, which is excreted through the respiratory system.[4]

The biostimulatory nature of PLLA differentiates it from other fillers: the particles induce a foreign body tissue response. This upregulates fibroblast and histiocyte response leading to increased collagen and elastin formation. This overall process leads to dermal thickening, and in turn, volumization.

Patient Selection

Appropriate patient selection for PLLA therapy is the first step in attaining aesthetically desirable and safe outcomes. Patients with global facial volume loss and mild skin laxity are ideal candidates. PLLA therapy is not appropriate for enhancing or contouring discrete sites; these patients are better served with hyaluronic acid fillers. PLLA cannot be used in the infraorbital region or lips due to the risk of nodule formation.

Patient expectations should be carefully evaluated. Patients must understand that volumetric expansion is a delayed and long-term process, taking approximately 3 months to appreciate initial effects.[1] This treatment should thus not be utilized for patients desiring immediate effect. On the other hand, gradual volume restoration may be of benefit to those wishing to be discrete about cosmetic treatments.

PLLA is contraindicated in patients with known hypersensitivity. Its safety in pregnant patients or those breastfeeding has not been studied. PLLA should not be injected at sites of active inflammation.[1]

Treatment Intervals and Planning

The number of total vials is guided by the degree of correction required and overall improvement. There are various factors involved in determining a patient's response

to PLLA, such as age, underlying comorbidities, and genetic patterns of aging. It is thus difficult to employ a generic formulaic approach to the total number of PLLA vials required. However, the "rule of decades" is a helpful guide: a patient's age in decades approximates the total number of vials of PLLA required.[5] For example, a 43-year-old patient likely requires a total of 4 vials, in contrast to a 78-year-old patient who will likely require 7 vials for global optimization.

Patients should be treated to full correction, not overcorrection, during each injection session. Thus only 1-2 vials are recommended at 4 to 6-week intervals, until the total number of vials is reached. The product monograph suggests a "treat, wait, assess" approach1. There should be a minimum of 4-week intervals between treatment and assessment to determine the effect of PLLA.1 This series of initial treatments is then followed by periodic maintenance, ranging from 1 to 2 vials on an annual basis.

Reconstitution

PLLA is marketed in Canada as SCULPTRA. It is packaged as a dehydrated powder of 150 mg of freeze-dried PLLA, 90 mg of sodium carboxymethylcellulose, and 127.5 mg of mannitol. The latter is a cryoprotectant, while the sodium carboxymethylcellulose is a product stabilizer and suspending agent.[6] Prior to reconstitution, it can be stored at room temperature. After reconstitution, SCULPTRA can be stored up to 72 hours at room temperature or refrigerated but should not be frozen.[1]

PLLA can be reconstituted with bacteriostatic water or normal saline; the former is preferred to prolong the sterility period.[5] The product monograph suggests reconstitution at least 2 hours prior to injection.1 More commonly used protocols range from overnight to 1 month prior to treatment; longer hydration periods may lead to more complete hydration of the microparticles.[3,5]

Initial studies on PLLA for HIV lipoatrophy used smaller reconstitution volumes, ranging from 3 to 5 mL.[7,8] Higher volumes (8 to 16 mL) are now used; this, in combination with longer hydration periods, decreases the viscosity of the product. A decreased velocity likely decreases clogging of the syringes, facilitates even distribution throughout the treatment areas, and likely reduces the risk of nodule formation.3 For increased volumes and prolonged time periods, the vial is initially reconstituted with 5 to 7 mL of bacteriostatic water. It can be stored at room temperature or in the refrigerator. Prior to injection, the product is further hydrated with additional bacteriostatic water or lidocaine with or without epinephrine.

Anesthesia

Pain management during aesthetic procedures is an important consideration. There are 2 potential sites of discomfort during PLLA injections: the dermal entry point of the needle/introducer and when the needle/canula touches the periosteum. Topical anesthesia or injections of local anesthetic at the needle/introducer entry point can also be utilized. If reconstituted with lidocaine, patients will experience some relief once small amounts of PLLA has been delivered to an area.

General Injection Pearls

There are various technique considerations. PLLA can be injected with either a needle or cannula. Larger sizes of needles (26 gauge) or cannulas (25 gauge) should be used. Reconstituted PLLA has a water-like consistency. As such, little pressure is required to distribute the product.

Prior to deposition, a reflux maneuver should be performed to reduce the risk of intra-arterial injections. PLLA must be injected in the deep dermis or subcutaneous layer. The use of needles can result in superficial placement of the product; great caution must thus be exercised with this approach. If product is injected too superficially the injected area will blanch immediately or shortly after injection. If this occurs, the needle should be removed and the treatment area gently massaged. In the event that the blanching does not disappear, the patient should not be re-injected.1 A deep depot and linear threading or 'fanning' techniques are most commonly used.[5]

One of the most challenging aspects of PLLA injections is clogging of the needle/cannula. Prior to drawing up the solution, it should be mixed vigorously to avoid clogging. The solution should also be drawn from the bottom of the glass vial to avoid bubbles in the syringe. The reconstituted product should be homogenous; however, it separates within minutes. It should thus be injected swiftly, or only one syringe should be prepared at a time.[5] If clogged, the needle or cannula can be flushed with normal saline.

To ensure uniform product distribution, the treatment area should be vigorously massaged during and immediately after injection.

Post Treatment Course and Care

If reconstituted with lidocaine, patients may experience numbness in the treated areas for 1 to 2 hours. Given the large volumes of liquid required for reconstitution and post-treatment edema, patients will experience immediate but temporary filling. As the water vehicle is resorbed over the following 1 to 4 days, patients will return to their baseline.[5]

Patients are also required to massage the areas in the days following treatment. The "5-5-5 rule" can be applied: in the 5 days following treatment, patients are to massage the treated areas for at least 5 minutes, and at least 5 times per day. This facilitates even distribution of the product.

Adverse Effects

In general, PLLA has a favourable safety profile.[5] Adverse effects are usually minor and mainly injection-related, such as erythema, ecchymosis, and edema. The development of noninflammatory nodules due to product accumulation has been associated with uneven distribution of the product. Adherence to regular post-treatment massages reduces the risk of nodule formation. Nodules can be treated with saline injections, to disperse the product.

In summary, PLLA is a safe and efficacious option for global facial volumization. It provides collagen stimulation, thereby promoting dermal remodelling.

References

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