SCULPTRA INJECTIONS

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Long-term aesthetic outcomes with injectable poly-L-lactic acid: observations and practical recommendations based on clinical experience over 5 years

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Summary

Background Facial rejuvenation techniques have evolved in recent decades driven by a paradigm shift to restoration of lost volume, and an increase in the number of available products. As clinical experience has increased, practitioners have further refined the use of these products.

Objectives To share observations and practical recommendations based on clinical experience with the aesthetic use of injectable poly-L-lactic acid (PLLA) in patients followed for up to 5 years.

Methods Literature review and retrospective case history review of the first 100 patients treated with injectable PLLA, many of whom have been followed for over 5 years.

Results Use of injectable PLLA, alone or in combination with other products, has provided excellent and long-lasting (up to 5 years) aesthetic results for most of the reviewed patients. Typically, patients have received one or two touch-up sessions between years 2 and 4 after initial full correction. There were minimal adverse events of papule formation; these eventually resolved.

Conclusions Injectable PLLA is a safe and effective option for achieving long-term patient satisfaction with soft-tissue augmentation.

Keywords: calcium hydroxylapatite, collagen replacement, calcium hydroxylapatite, dermal fillers, hyaluronic acid, injectable poly-L-lactic acid, soft-tissue augmentation

Introduction

Overview of Dermal Fillers for Facial Rejuvenation

Facial aesthetics and soft-tissue augmentation techniques to ameliorate the effects of ageing have evolved over recent decades, driven in part by development of newer agents that help restore a more youthful appearance.¹ As clinical experience has increased, administration techniques have evolved. It is now appreciated that although dermal fillers are best used for three-dimensional facial contouring and addressing static rhytides, they can be combined with use of neurotoxins for correcting dynamic rhytides.¹⁻³ We also have learned that less viscous dermal fillers are more appropriate for superficial defects and fine wrinkles, whereas more viscous longer lasting fillers work best for deeper contour deficiencies and adding volume.⁴⁻⁶ Less viscous products include the older collagen products (bovine and human) which are no longer available and hyaluronic acid-based fillers, whereas longer-lasting products include calcium hydroxylapatite (CaHA), injectable poly-L-lactic acid (PLLA), and permanent fillers (injectable liquid silicone or polymethylmethacrylate).⁷⁻⁸
Treatments with collagens (such as Zyplast, Cosmoderm, or Cosmoplast) typically lasted about 2 months in areas of high mobility (e.g., the lips) and 3–6 months in other areas. The hyaluronic acid–based fillers (such as Restylane® [Medicis, Scottsdale, AZ, USA] and Juvederm® [Allergan, Irvine, CA, USA]) have varying durations of effect; in general, they can be used for deeper folds or wrinkles compared with collagens, provided that the product is appropriately matched to the treatment site. Longevity of hyaluronic acid–based products has been estimated at 3–4 months for lips or oral commissures, 4–6 months for nasolabial folds, and 6 months or longer for tear troughs and the glabellar/forehead region whereas some formulations have been reported to have effects lasting for 9 months to 1 year.

Calcium hydroxylapatite (Radiesse® [Merz, San Mateo, CA, USA]) and injectable PLLA (Sculptra® Aesthetic, Sculptra® Northbridge, NJ, USA) are biodegradable and have long-lasting aesthetic effects of differing durations. They can both be used in a number of facial areas, but are recommended for deeper injection. The aesthetic effects vary from immediate (CaHA) to gradual (injectable PLLA). However, after achieving full correction, the results from both products can extend beyond those seen with hyaluronic acid products. Although the label states that the duration of effect is 1 year, some reports have indicated that CaHA has last 18 months or longer. Injectable PLLA has been reported to have effects lasting up to 25 months.

I have used injectable PLLA extensively as a long-lasting volume replacement agent of choice, often in combination with other products to meet patients’ individualized aesthetic needs. My experience with this device began in 2002, as I collaborated with international colleagues during visits to clinics in France and Mexico; US Food and Drug Administration (FDA) approval for aesthetic use occurred in 2009. The purpose of this article is to share the results of a retrospective review of our experience with the aesthetic use of injectable PLLA in the hope that this knowledge may assist other practitioners in improving clinical outcomes for patients desiring long-lasting soft tissue augmentation.

Eight years’ clinical experience with injectable PLLA: observations and practical recommendations

Over 8 years of using injectable PLLA in my practice, I have noted excellent results, with some patients returning after 2–4 years for touch-up treatments. Based on this experience, I have retrospectively reviewed the case histories of my first 100 consecutive patients for whom complete data were available with the objective of identifying common themes. As this was an informal assessment of outcomes with injectable PLLA, there were no entry criteria and no prespecified analysis was conducted. The examples presented here are representative of typical treatments and results in my office during the review period. Treatments were tailored to the individual needs of the patients.

Before (a) and after (b) correction of total facial lipoatrophy with injectable poly-L-lactic acid (PLLA; temples, buccal fat pads, cheeks, submalar, and mandibular areas) and hyaluronic acid (tear trough).
Duration of effect

The aesthetic effect of injectable PLLA has been reported as lasting for up to 25 months after the last treatment.\textsuperscript{16,17} In my clinical practice, I have seen durations of effect of up to 4 years after full correction was achieved, without touch-ups, especially in patients who are younger than 55 years of age. Reasons for variability in duration of effect do not appear to have been documented in the literature and require further investigation. The foundation of the tissue and bone structure is an important factor in determining final outcomes.

Figure 1 shows a 62-year-old woman before and 4 years after treatment with injectable PLLA (reconstituted with 5 mL of sterile water for injection [SWFI] plus 1 mL of lidocaine) to the temples, buccal fat pads, cheeks, and submalar and mandibular regions, in combination with 1 mL of hyaluronic acid for the tear trough. Four injection sessions at 1-month intervals were required for treatment with injectable PLLA; two vials were administered in the first session and one vial was administered over each subsequent session. Hyaluronic acid (1 mL) was also injected into each of the nasolabial folds annually, at the time of regular skin cancer screenings. This patient did not require re-treatment with injectable PLLA before the 4-year assessment.

Figure 2 (a) Before (2006) and (b) 1 year after (2007) correction of nasolabial fold wrinkles, cheeks, submalar, and mandibular areas with injectable poly-L-lactic acid (PLLA). The same patient is shown again (c) before (2009) and (d) after (2010) touch-ups in the preauricular, cheek, and submalar areas with injectable PLLA; the nasolabial folds did not require further correction.
Figure 2 shows a 54-year-old woman before (a) and after (b) treatment with four sessions of injectable PLLA at 1-month intervals (SWFI 5 mL + lidocaine 1 mL) to correct nasolabial fold wrinkles, bilateral cheeks, submalar, and mandibular body lipoatrophy. Temporal atrophy was noted at the time of the second photograph, and correction of this area was added to the treatment regimen. Two years after the original correction (c), the patient returned for a touch-up with injectable PLLA (SWFI 5 mL + lidocaine 1 mL) and treatment of the temples; the ensuing results were maintained for an additional 2 years without further treatments (d). Similarly, Figure 3 shows a woman treated with injectable PLLA for the correction of lipoatrophy of the submalar, nasolabial fold, and mandibular areas. The results have been maintained for 5 years since the time of the original correction, including a touch-up with a single vial of injectable PLLA after years 3, 4, and 5. The total reconstitution volumes at these times were 6, 8, and 10 mL (SWFI 4–6 mL; lidocaine 4–6 mL).

With hyaluronic acid, alone and in combination with botulinum toxin, it has been noted that the volume of product required for subsequent re-treatments is reduced compared with the volume required for the initial correction, because of residual collagen replacement over time. With injectable PLLA, as shown in Figures 2 and 3, although significant inter-individual variation can be expected. A number of patient-specific factors can influence the overall duration of effect of injectable PLLA, particularly age and foundation of tissue and bone structure prior to treatment. As noted above, younger (<55 years of age) patients tend to experience longer durations of augmentation for reasons that are not understood at present – further research is necessary to clarify this. My clinical observations suggest that patients with significant facial laxity and lipoatrophy are more challenging and tend to require more frequent re-treatment because of the larger volumes and broader soft-tissue areas that need replacement.

Modifications of injection technique and postinjection procedures

The manufacturer’s recommendation for reconstitution of injectable PLLA is to use 5 mL of SWFI, allowing the vial to stand for at least 2 h to ensure complete hydration, and agitating gently before injection. The contents of the single-use vial should be used within 72 h or discarded. In my practice, the reconstitution procedure has evolved with experience. Initially, although off-label, the vial of injectable PLLA was reconstituted with 4 mL of bacteriostatic water and allowed to stand for at least 2 h without shaking, and then 1–2 mL of lidocaine 1–2% was added just before injection (a total volume of 5–6 mL). Since 2004, this has changed to either 4 mL of SWFI and 2–4 mL of plain lidocaine or 6 mL of SWFI and 2 mL of plain lidocaine (for a total volume of 6–8 mL). Consistent with my experience, greater reconstitution volumes have been reported to be associated with easier injection, more even distribution of the product at the injection site, and a reduced risk of needle blockage as a result of coalescence in the syringe before injection.
Immediately before injection, the vial is vigorously shaken by hand or with a mixer, with continued shaking throughout the procedure. Injections are performed with 3-mL syringes and 26-gauge, ½- or 1-inch needles. Occasionally, a 25-gauge, 1⅛-inch needle can be used with a fanning technique, allowing product placement in a broader area. The manufacturer recommends using a 26-gauge needle, but the chart review suggests that it is helpful to select the length and gauge depending on the location of the injection, the depth of the skin, the volume of reconstituted product to be injected, and variations in reconstitution volumes. The areas for treatment are always mapped before injection, and aspiration performed; aspiration is a useful routine before injection of any filler to confirm that a blood vessel has not been penetrated. During injection, the patient is positioned upright at a 30° angle. Approximately 0.1–0.2 mL per injection is used for tunneling, 0.05–0.1 mL for depot injections, and 0.2–0.3 mL for fanning, avoiding over-correction. Injectable PLLA can be injected into the deep layers of the skin, including the deep dermis (as indicated in the package insert) and subcutaneous plane.

Location of injection sites and combination of dermal filler products

Location of injectable PLLA is an important consideration for patients undergoing facial volume enhancement; the product provides a gradual onset (up to 6–7 months for full effect), and long-lasting response (2 years or more) when used for cheek/midface augmentation. In my experience, injectable PLLA is ideal for full facial contouring, including the jowl line, chin, nasolabial folds, temple enhancement, redefining the mandible, and correction of marionette lines. Injectable PLLA may be combined with a CaHA or hyaluronic acid–based filler in this area, because the latter agents are known to provide immediate correction that complements the longer duration of effect of injectable PLLA. It should be noted that the use of combination dermal fillers is not approved by the FDA. In my experience, two products should never be placed in the same location on the same day because, for example, treatment with injectable PLLA requires post-treatment massage whereas CaHA does not. A 3–4-week interval is usually appropriate to allow tissue recovery after injection, however, the recovery period from the different types of dermal filler is variable depending on the patient’s response to the injections. Based on my clinical experience, injectable PLLA combined with a hyaluronic acid or CaHA are my treatments of choice for correction of nasolabial fold deficiencies, although to my knowledge, no combinations of facial augmentation products or procedures have been approved by the FDA. Thus, caution should be exercised with the use of any combination of dermal fillers. An example of the use of injectable PLLA for volume enhancement (e.g., correcting facial asymmetry secondary to an auto accident and age-related facial lipoatrophy) in combination with hyaluronic acid (Restylane®) for the lips and tear troughs is shown in Figure 4. In this patient, injectable PLLA was reconstituted with 4 mL of SWFI and 2 mL of lidocaine. The cheeks were then injected into the deep dermal plane and superficial fat. The temple was treated using deep, subperiosteal depot injections of 0.2 mL for each area. The lateral mental areas and prejowl sulcus were injected in the dermal plane. The corners of the mouth were injected with Restylane® in the superficial dermis.

Minimization of adverse events

An important issue with all dermal fillers is the potential for adverse events. These products generally are well tolerated, and adverse events are usually mild. Events that can be expected to occur in some patients following injection include discomfort, bruising and bleeding, erythema, and mild treatment asymmetry. Injection site reactions can be reduced by following the injection procedures, whereas asymmetry can be treated with a touch-up procedure using a small volume of the dermal filler in an additional treatment session. Uncommon or rare adverse events associated with dermal fillers include allergic reactions (specific to bovine collagens), infection, vascular events, hematomas, granulomas, papules or nodules, and migration or extrusion of the product; nodules usually are related to mechanical coalescence of material rather than granuloma formation. Nodule formation can be the result of suboptimal product reconstitution and/or product placement. In the case of injectable PLLA, the incidence of papule or nodule formation has decreased notably over time, as experience with the product has increased and higher reconstitution volumes, such as those described above, have been utilized; the mechanisms for the improvement are not known. In reviewing the case records of the first 100 patients treated in my practice, I have seen only one instance of papules (small, palpable, but nonvisible bumps) attributed to injectable PLLA (injected on its own, using the SWFI 5 mL + lidocaine 1 mL reconstitution outlined above) in the perioral area close to the oral commissure. The papules resolved within 3 months after treatment with...
two intralesional injections of 2.5-mg/mL triamcinolone acetonide 1 month apart and destruction with normal saline. The formation of papules in this case possibly was because of the location of the product in the perioral area, which is not recommended by the manufacturer, and the proximity of the orbicularis oris muscle. I no longer place injectable PLLA near the oral commissures and do not recommend placement of the product around constricting muscles (e.g., orbicularis oculi or orbicularis oris) given that these are the areas in which nodules or papules have been most frequently observed.15,26,27 I also recommend against combined use of long acting and permanent fillers, because of the risk of reactivation of granulomas28 that may occur in areas away from the site of injection of the permanent filler. I observed this in one patient who developed nodules on the forehead, glabellar area, and nasolabial folds following use of injectable PLLA in the cheek and jaw areas approximately 15 years after the use of silicone. The patient did not recall her prior treatment with silicone until after the nodules developed. The granulomas resolved after treatment with triamcinolone injections. One further patient recently treated with injectable PLLA developed a diffuse hardening of the

Table 1 General recommendations for use of dermal fillers for facial volume restoration

| Select the product based on the location of the area to be treated, the desired depth of augmentation, and the age of the patient |
| If combining two different fillers with complementary modes of action, I allow time between treatments for tissue recovery. I do not recommend combining biodegradable products with permanent products |
| Become familiar with multiple injection techniques and use the appropriate injection technique for the product selected |
| The initial recommendation was reconstitution of injectable PLLA with SWFI 5 mL; we now use SWFI 4–6 mL with plain lidocaine 2–4 mL |
| “Full correction” is complete correction of areas being treated (sufficient amount of product). Multiple treatment sessions are required at 4-week intervals for injectable PLLA. Allow up to 6 months for development of full aesthetic effect. Avoid overcorrection with injectable PLLA by allowing 3–4 months for the product to work |
| Educate the patient from the beginning of the program that injectable PLLA requires a series of injections |
| Follow the manufacturer’s recommendations regarding peri- and posttreatment care of the injection site, e.g., massage after treatment with injectable PLLA |

PLLA, poly-l-lactic acid; SWFI, sterile water for injection.

Figure 4 Before (a) and after (b) correction of the temples, cheeks, submalar, mandible, and orbital rim with injectable poly-l-lactic acid (PLLA) in a woman with facial asymmetry secondary to an automobile accident, with phenotypic and ageing-related facial lipoatrophy. This injectable PLLA treatment was combined with use of a hyaluronic acid (Restylane) for the lips and tear troughs.
injection area (cheeks). The hardening resolved over 3–4 months after treatment with intralesional steroids plus minocycline.

Conclusions

Use of procedures and techniques for aesthetic improvement evolve with the training and experience of the practitioner, together with periodic reviews of the case histories of patients in an individual practice. Dermal fillers have evolved into a full spectrum of products that can be matched to the specific needs of patients. Fillers with complementary properties may be combined in separate treatment sessions to optimize aesthetic results, although no combinations have been evaluated by the FDA.

Just as it is necessary to match the product to the patient’s needs, it is important to adapt the injection technique to the specific product being used. For injectable PLLA, proper injection technique and postinjection procedures are critical to obtaining optimal results with minimization of the risk of nodule or papule formation. This includes sufficient reconstitution, volume, and avoidance of superficial placement of product, followed by appropriate ice, massage, and follow-up visits, with good patient education. Optimal and sustained correction involves multiple treatments and patience on the part of the clinician and the patient, until the full effects of the treatment approach are realized. Once the desired aesthetic outcome has been achieved, the current case review suggests that, with occasional re-treatments, injectable PLLA may have aesthetic effects that may be readily sustained for extended periods. These recommendations are summarized in the Table 1.

References

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