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Review

The use of poly-L-lactic acid filler in facial volume restoration: A review

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Abstract

Introduction

Injectable poly-L-lactic acid is a biodegradable compound that has been widely used for the last 30 years throughout Europe and the USA in a wide range of medical devices. It is a soft tissue filler most commonly used to restore volume of depressed areas of the midface or temporal fossa by stimulating neocollagenesis, increasing dermal thickness, and enhancing volume. The aim of this review is to present an update on the uses, the techniques and the adverse events of poly-L-lactic acid filler in facial volume restoration.

Conclusion

The mechanism of action of poly-L-lactic acid requires techniques and patient management as incorrect injection technique can cause device-related adverse events by overstimulation of the fibroblasts.

Introduction

The armentarium of injectable devices for cosmetic applications is divided into two broad types: fillers and sculptors. Fillers are injectable devices that are only intended for the correction of lines and wrinkles.

These are normally of minimal viscosity and are usually introduced into the upper layers of the dermis directly filling the most superficial deficits. On the contrary, sculptors are not intended for the correction of superficial manifestations of ageing and they should not be used in the same way as fillers as they are intended for different applications.

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Sculptors are injected into the deep dermis or upper subcutaneous tissue. Moreover, they are either non-resorbable or elicit a thickening of the dermis.[1]

When volume deficits developing in the upper and mid-face involving the skin density and skin firmness, the most effective course of action is to use a facial volume enhancer such as autologous fat[2,3] or expanded polytetrafluoroethylene implants.[4]

Autologous fat provides augmentation of severe facial volume deficits; however, it requires several treatment sessions and spread over a long period of time. It is also a surgical procedure with considerable down-time and risks for the patient, and requires the careful removal of the fat tissue to avoid damage.[3]

Polytetrafluoroethylene implants are tailored to the concavity or depression to be corrected and provide an instant effect; however, they require exact fitting to the concavity in question and the failure to do so may lead to the irritation of the tissues by the edge of the implant, moreover, the implants can also lead to an unnatural appearance as the skin ages.[4]

Various synthetic polymers are also available for the correction of facial volume loss. These include devices based on poly-L-lactic acid (PLLA), polymethylmethacrylate, polyacryl-amide, poly-alkyl-imide, polymethyl-siloxane and silicone oils.[5,6] These polymers provide long-term to permanent correction of facial deficits.

All are injected into the skin and mechanically 'bulk' the skin out. PLLA is an exception to this as it provokes a foreign body reaction.[1] It is unique among sculptors as it gradually restores the volume lost as a result of ageing. Its novel mode of action can also remodel the shape of the face.[7]

The aim of this review is to present an update on the uses, the techniques and the adverse events of poly-L-lactic acid filler in facial volume restoration.

Discussion

Injectable PLLA is a biocompatible, nonimmunogenic, nonmutagenic and reabsorbable polymer that induces neocollagenesis as a dermal stimulatory agent. PLLA is not a filler because the full effects of injections are gradual and it must be injected into the deeper planes of the dermis. The exact mechanism by which PLLA particles stimulate fibroblasts to produce collagen is unknown, but this new collagen creates volume as the PLLA is resorbed and degrades, eventually being respired as CO2.[8]

PLLA does not require allergy testing or any type of special storage. It is in the form of a freeze-dried powder that is reconstituted (each vial containing 350 µg of PLLA) with 5 mL of sterile water in a suspension.

The product then gradually takes the shape of a suspension that must remain at room temperature for at least 24 hours before the injection. Immediately before the injection, 1 additional milliliter of Xylocaine (lidocaine) (Astra- Zeneca, Rueil-Malmaison, France) is added to this suspension, for a total dilution of 6 mL per vial. The suspension is vigorously shaken, it is taken in a 1 mL Luer-Lock syringe with an 18-G needle and it is injected using a 26-G needle. The syringes should be shaken and turned over before the injection to ensure a suspension as uniform as possible.[9]

The best technique is the retrograde injection performed in the subreticular dermis, particularly the needle is placed at the dermis-hypodermis junction.

Deposition of a smooth layer of polymerized lactic acid (0.01 to 0.02 mL) stimulates with a mild inflammatory reaction the fibroblasts of the dermis to produce skin conjunctive tissue including collagen over the

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ensuing 4 to 6 months. As the implant slowly resorbs, new collagen is laid down, creating a thicker dermis, histologically, and increased volume, clinically. So, it is essential not to overcorrect because the injection is followed by a delayed fibroblastic reaction. The possible overcorrection increases the risk of a delayed formation of bumps that should be massaged carefully throughout the following week.

After injections with PLA, the recommended care regimen includes application of ice and gentle massage. Many practitioners recommend that massage be performed by patients 5 times per day for 5 minutes per session for 5 days.[9]

As the volumizing effect of PLLA injected into the facial tissues is gradual, three to five treatment sessions will be required. The exact number depends on the degree of volume loss and the response of the tissues to the presence of PLLA particles. Treatment sessions should be separated by approximately 4–6 weeks as this allows the gradual effects to be realized without the risk of overcorrection.[10] Reports published in the European literature suggest benefit duration of 2 to 4 years. According to the experiment of Lowe[11] patients continue to present signs of improvement 2 years after PLLA injection.

The most commonly experienced side effects of PLLA include the risks of bruises and initial swelling, oedema and temporary erythema. If a patient presents a history of possible sensitivity to lidocaine, dilution should then be 5 mL of water without Xylocaine to avoid the risk of an allergic reaction. Patients can also experience minute, palpable albeit invisible, non-inflammatory reactive nodules at the injection sites. Previous studies have reported the incidence of these palpable nodularities to be anywhere from 6% to 50%. The incidence of these nodules is decreased when using a more dilute suspension of the product. When nodules do occur, they are easily dispersed with firm massage or may be disrupted by introducing a fine gauge needle into the nodule with intralesional steroids. Quite simply, there are a few areas that require special considerations when injecting PLLA. One of these is the lips because injections into this site results in a high probability of having nodules or papules form. The tear trough and periorbital areas also must be treated gently and not be over corrected because the injection of high volumes in an attempt to rapidly correct volume loss may result in visible papules in this site. Finally, it is important avoiding injections into the glabela and forehead because of the implied risk of necrosis of any particulate product into this site.[12]

Injectable PLLA was developed in Europe and approved by the European Union in 1999 as New-Fill™ (Medifill, London, UK; Biotech Industries SA, Luxembourg) for increasing the volume of depressed areas, such as skin creases, wrinkles, folds, and scars.[13,14] This indication was extended to include large volume corrections of lipoatrophy in 2004. In 2004 Injectable PLLA was introduced in the United States as Sculptra™ (Dermik Laboratories, Bridgewater, NJ) and cleared by the U.S. Food and Drug Administration in August 2004 for the restoration and/or correction of the signs of facial lipoatrophy in people with HIV. Clinical trial data have established the efficacy of injectable PLLA for this application.[1, 15,16,17,18,19] However, the use of Sculptra™ for cosmetic purposes has been considered off-label in the United States. Because the product is a suspension rather than a solution (meaning that the particles float through the diluent rather than disperse evenly into it), there are some physical factors that govern its injection for esthetic use.

One of the most important considerations governing the ease of injection of Sculptra™ is the concentration of the product. The more concentrated material will tend to clog the needle increasing more frequent needle changes and more frequent punctures through the skin, which can produce increased bruising and swelling. In addition, unlike other materials that are homogenous fillers, the temperature of the material governs the injection of Sculptra™.

PLLA should be injected at room or body temperature to maintain a homogenous product because injecting cold material may result in some parts of the injected areas receiving large amounts of PLLA whereas others are injected primarily with diluent.[20]

In 2009, the FDA approved Sculptra™ Aesthetic for use in treating facial wrinkles.

Conclusion

Despite its limitations Sculptra™ represents the first of a new generation of products that restores (rather than directly replaces) volume. Its mechanism of action is unique and it requires techniques and patient management, as incorrect injection technique can cause device-related adverse events by overstimulation of the fibroblasts.

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