ORIGINAL ARTICLE



A technical approach for redefinition and volumization of lip area with hyaluronic acid: A case series

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Abstract

Background and Aim: Non-surgical procedures using injectable filler products for perioral rejuvenation have emerged and evolved rapidly to become one of the most frequently performed aesthetic treatments. We report a case series describing the administration of two hyaluronic acid-based dermal fillers (HA filler) with excellent characteristics and formulation using a technique developed by the author.

Patient/Methods: We describe a series of nine female subjects who underwent perioral rejuvenation performed by a single physician in her private clinic. The HA filler (Alaxin® FL or Alaxin® LV) was injected into the lips using the specially developed Clodia technique. Patients were given post-treatment advice for optimal results. Patient- and investigator-perceived outcomes were rated using the Global Aesthetic Improvement Scale (GAIS) and adverse events (AEs) were collected.

Results: All subjects described the injection method as painless and well tolerated, as shown by the immediate post-treatment photographs. Mean GAIS scores for both the patients and the investigator were 4.8/5, indicating significant improvement 12 months after the treatment. No AEs were reported during follow-up. The HA filler showed a high degree of dermal integration in all subjects, and the investigator reported excellent handling and injection properties.

Conclusion: Perioral rejuvenation with an HA filler administered using the developed injection technique gave highly satisfactory results in all subjects and was not associated with AEs.

KEYWORDS

moisturizing, perioral rejuvenation, redefinition, volumization

| INTRODUCTION

Our whole body is affected by the passage of time, and facial aging in particular is the focus of cosmetic treatments. At the subdermal level, loss of collagen and adipose tissue cause structural changes characterized by fine lines, increased wrinkle formation, grooves,

and depressions. Facial aging is not only caused by loss of adipose tissue and skin defects, facial muscles, and bones also contribute to this natural process.¹

Loss of collagen is one of the characteristics of aging, but other important components of the skin, such as hyaluronic acid (HA), also undergo critical changes.² A deeper understanding of aging in each

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anatomical layer of the face has contributed to the development of HA filler rejuvenation strategies.³ These non-surgical techniques have evolved rapidly, and facial feature augmentation using injectable filler materials is now one of the most frequently performed aesthetic treatments.⁴

Perioral rejuvenation focuses on the lips, two structures formed by skin and muscle, which give entrance to the oral cavity. Their anatomical structure consists mainly of a skeletal core covered by skin (epidermis, dermis, and hypodermis) and constituted internally by a mucosa formed by a lining epithelium, a lamina propria, and a submucosa. Several approaches have been developed in recent years in parallel with the increased availability of HA products with different biochemical and rheological features. This has given practitioners a wide range of products, each indicated for a particular procedure and treatment. Filler injection in the lip is primarily focused on restoring or emphasizing the natural lip curves, reflating the lip to reduce vermillion creasing, and addressing rhytids in the white lip skin, but also on enhancing lip size. In order to achieve the best results, therefore, it is important to choose the product that is best suited to the technique used.

In this context, a procedure has been developed that fulfills the needs of each patient and achieves natural and moisturized lips. This procedure can be used with different HA fillers for a variety of outcomes (adding volume, moisturizing, correcting asymmetries, lip redefinition). The aim of this case series has been to confirm the beneficial effects of the developed rejuvenation technique (improved aesthetics with no adverse effects) and show the safety and good dermal integration of the HA filler administered.

2 | MATERIALS AND METHODS

We describe nine cases that show the results of the technique developed for lip volumization and redefinition using Aliaxin® FL $(A_{FL})^7$ or Aliaxin® LV $(A_{LV})^8$ (distributed by IBSA Farmaceutici Italia Srl; Table 1). The procedures were performed between 2020 and 2021 by a single physician in her private clinic. Following the principles of the Helsinki declaration, all patients received information about the product and procedure, and signed an informed consent form for the procedure and for their anonymized clinical data to be used for training and scientific purposes.

2.1 | Hyaluronic acid filler

For this procedure, the HA fillers A_{FL}^{7} and A_{LV}^{8} were used. These biotechnological (non-animal sourced) products are hyaluronic acid-based dermal fillers made of hydrogel microparticles made of cross-linked HA with 1,4-butandioldiglycidyl ether (BDDE). Their insoluble hydrogel concentration and degree of crosslinking are the key to their performance.⁷ The products contain different combinations of cross-linked HA molecules weights: 500 and 1000 kDa in the case of A_{FI} and 1000 and 2000 kDa in the case

of A_{LV} (Table 2). Selection of these products responded to their physicochemical characteristics. A_{FL} is indicated for general lip rejuvenation, and because of its low to medium viscosity it is suitable for patients needing hydration and definition of the lips. A_{LV} meanwhile, is indicated for harmonious volumization of the lips or asymmetry correction.

2.2 | Injection procedure

Clodia is a developed technique for perioral filling, rejuvenation, and correction. The name was inspired by Claudia, wife of Metellus, who hailed from one of the most important families in Rome, the Claudius', better known as Clodia, and whose lips were said to be attractive.

The procedure consists of applying the selected HA product to the perioral area using an ergonomic needle. Lip injections were into the mid dermis. The product was injected at four sites: two in the top lip and two in the bottom lip, using a multilinear, retrograde, fanning technique that allows us to work on the lip edge or vermillion border and mucosal/submucosal junction from a single injection site as depicted in Figure 1 (and Video S1). In addition, cupid's bow area could be treated performing a gentle finger pressure of the central lip area against the needle, or by performing a local puncture. This complementary procedure was not applied in this case series. Using a longer needle allows us to treat the entire half lip with a single injection. This minimizes the number of injections and is better tolerated by the patient.

In all patients the treatment area was swabbed with alcohol and 4% local anesthesia was administered before treatment. The technique described above was performed using 27 G/19 mm needles, and the area was massaged gently after the treatment.

2.3 | Assessments

Possible adverse events (AEs; mild, moderate, or severe bruising, edema, redness, itching, inflammation, etc.) were recorded immediately after the intervention and at various time points until the end of follow-up. Lip function and sensitivity were also recorded. Outcomes were rated by the patient and investigator using the Global Aesthetic Improvement Scale (GAIS). Each patient was contacted by phone and asked to rate the outcome on the GAIS approximately 12 months after the intervention. Photographs were taken using a Sony Cyber Shot DSC-HX60 camera at different time points (before the procedure [T0], immediately after the treatment [T0^{post}], 6 months [T6] and 18 months [T18] after the treatment).

3 | RESULTS

A total of nine female patients were treated with HA fillers at different doses, depending on their requirements needs (Table 1).

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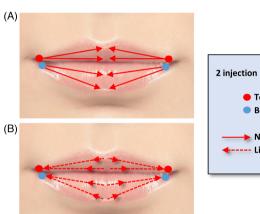
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Т0	3)			30	30)	31)	91			
Aim of treatment	Volumization	Volumization	Moisturizing	Moisturizing	Moisturizing	Volumization	Volumization	Volume correction	Moisturizing	
Dose (mL)	8.0	8.0	н	₩	Н	8.0	0.8	Н	1	(SIV-)
HA filler	Aliaxin® LV	Aliaxin® LV	Aliaxin® FL	Aliaxin® FL	Aliaxin® LV	Aliaxin® FL	Aliaxin® LV	Aliaxin® LV	Aliaxin® FL	+ 400
Patient request	More volume	More volume	Hydration and subtle volume	Hydration and subtle volume	Lip edge and hydration	Subtle volume	Subtle volume	Asymmetry correction	Hydration and subtle volume	source (210) of the transfer transfer to the transfer to the formation of the source o
Sex	ш	ட	ш	ட	ш	ш	ш	ட	ш	7
Age	32	33	55	43	35	42	22	35	45	
Subject	₽	7	ო	4	rv.	9	7	ω	6	Noto: Ago

Abbreviations: F, female; HA, hyaluronic acid; iGAIS, investigator global aesthetic improvement scale; pGAIS, patient global aesthetic improvement scale. Note: Age, HA filler type, and dose, aim of treatment, global aesthetic improvement scale (GAIS) scores.

TABLE 2 Hyaluronic acid physicochemical and rheologic characteristics.

	HA Molecular weight (kDa)	Cross-linked HA content (mg/mL)	Rheological values	Indications	Injection layer
A ^{FL}	500-1000	25	 Flow: 0.39 tan δ Lift: 45 G' (Pa) Plasticity (X): 0.23 	Lip contour redefinitionPerioral wrinklesLip rejuvenation/ Hydration	Mucous membrane and middle dermis
A ^{LV}	1000-2000	25	 Flow: 0.21 tan δ Lift: 107 G' (Pa) Plasticity (X): 0.15 	Restoring lip turgorHarmoniousVolumization	Middle and deep dermis

Note: Tan Delta value (δ) measures the elasticity/viscosity ratio, showing that elasticity under low shear stress is dominant over viscosity, achieving homogeneous tissue integration and a high resistance to mechanical stress. Elastic modulus (G') measures the elastic properties of the gel, and the ability of the gel to regain its original shape after deformation. Shear rate (X) measures the plasticity of the gel and it is an indicator of viscosity. Abbreviations: A^{FL} , Aliaxin® FL; A^{LV} , Aliaxin® LV; Da, Daltons; HA, hyaluronic acid; Pa, pascals.



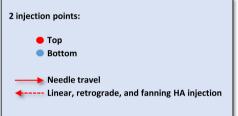


FIGURE 1 Schematic representation of the Clodia procedure. (A) Initial needle travel. (B) Multilinear, retrograde, and fanning hyaluronic acid injection.

All subjects were Caucasian, aged between 22 and 55 years (mean \pm standard deviation [SD] 38.0 ± 9.4 years). Four patients were treated for lip volumization, four patients were treated for lip moisturizing and one patient was treated for lip asymmetry. The mean volume of filler used was less than 1 milliliter (0.9 \pm 0.1 mL).

Patients were assessed before the procedure (T0), immediately after the treatment (TO^{post}), and at different time points thereafter (from 6 to 18 months). At TO^{post}, none of the patients presented edema or relevant AEs. Photographs taken immediately after the procedure show that the Clodia technique is minimally invasive and well tolerated (Table 1). This observation was further supported by the absence of any reported AEs in any patient during follow-up and illustrates the importance of the injection technique in preventing post-procedural discomfort. All subjects reported excellent lip sensitivity and integration of the HA filler in the labial mucosa. Mean patient-perceived GAIS score was 4.8/5 (SD=0.4), and shows the high degree of patient satisfaction with the cosmetic outcome 12 months after the intervention (Table 1). The investigatorperceived GAIS score was also 4.8/5 (SD=0.4). A_{FL} and A_{LV} showed consistent outcomes up to T18, as evidenced in the before and after photographs (Figure 2). The duration of effect was similar for both HA fillers used. Aesthetic improvement remained evident a minimum of 6 months after the treatment and at longer times (case 1-3, 5, 6, 8, and 9 had longer follow-up).

4 | DISCUSSION

Non-invasive aesthetic facial treatments are continuously evolving, creating a growing demand for high-quality products that can meet the needs of all types of patients. The injection technique used determines the quality of the cosmetic outcome, limits the appearance of small lumps and bumps (natural appearance), and reduces the risk of local AEs. ¹⁰ In this case series, we reported the safety and benefits of perioral HA fillers administered using the developed technique by the author.

The *Clodia* technique was originated to redefine the lips and volumize and hydrate lips in a natural way. The main objective was to maximize the cosmetic outcomes achieved while minimizing the incidence of adverse effects. Using a longer needle allowed us to perform the entire procedure using only two injections, thus minimizing patient discomfort. Mild to moderate complications are usually reported in this type of procedure, being the most frequent swelling, bruising, pain, redness, and itching, 11,12 but none were reported during follow-up of any of the nine patients included in this case series.

Fillers are selected based on their biophysical properties, target tissue depth, and type of correction planned. ¹³ The different degrees of HA crosslinking, hydrogel microparticles size, and gel concentration in HA fillers give each its particular rheological characteristics

FIGURE 2 Photographs of two patients before, post-immediate, 6 months and 18 months after treatment. Patient above treated with Aliaxin® LV. Patient below treated with Aliaxin® FL. Patients provided written informed consent for the use of the images for scientific research.

and resistance to degradation, all of which are key to their clinical performance. The capacity of the filler to integrate in the surrounding tissues is also essential for a natural effect. In this regard, as previously reported 7.8,14 and shown in this case series, Aliaxin® hydrogels are long-lasting, and their excellent plasticity and viscosity make them easier to administer and integrate into the tissue. Thanks to their rheology, the HA fillers used in this study provided good volume and hydration with excellent definition of the lips and perilabial area when one type of HA or another is injected into the same anatomical layer. Additionally, due to the characteristics of the HA used for lip volumization, the clinician injected a lower amount of product using this technique. Interestingly, there is evidence to suggest that HA fillers revitalize the extracellular matrix and stimulate dermal components and their functions, 15 but further clinical studies are needed to show this effect in the perioral mucosa.

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At the aesthetic level, the aim of the technique presented in this study was to harmonize and rejuvenate the perioral area and improve facial proportions; patient-perceived satisfaction determined by the GAIS showed the efficacy and excellent results of the procedure 12 months after the intervention. The comprehensive study of the patient, the choice of appropriate products, and the use of the developed technique were the keys to achieving overall patient satisfaction beyond the mere aesthetic improvement.

This study has the limitations inherent to case series. Follow-up was heterogeneous because the study was based on real clinical practice. Nevertheless, this is the first report of the *Clodia* injection technique for lip rejuvenation using HA products that shows promising results, no AEs, and good cosmetic outcomes.

In conclusion, the injection technique used is the key to obtaining excellent results, and *Clodia* method combined with Aliaxin® HA filler is a safe and effective approach to perioral rejuvenation.

AUTHOR CONTRIBUTIONS

The author has perform the study and has been involved in drafting and critically revising the mansucript for fundamental intellectual contribution.

ACKNOWLEDGMENTS

The author would like to thank Dr. Miriam Ejarque and Dr. Blanca Piedrafita from Medical Statistics Consulting S. L. (MSC) for medical writing services and IBSA Farmaceutici for the services provided. We would also thank Irene Giménez, assistant of the clinic, Dr. Natalia Ribe, for her help, and Dr. Jordi Campillo and Dr. Pau Valdés for their work as historical consultants about *Clodia*.

FUNDING INFORMATION

This study has not been funded by any public or private body.

CONFLICT OF INTEREST STATEMENT

The author has performed scientific consulting and lectures for Allergan Aesthetics, FillMed, Galderma, IBSA, Merz, Q-Med, and Teoxane.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

All patients have provided their written consent for the publication of anonymous and unidentifiable materials pertaining to themselves.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Ribé N. A technical approach for redefinition and volumization of lip area with hyaluronic acid: A case series. *J Cosmet Dermatol.* 2023;22:1739-1744. doi:10.1111/jocd.15749