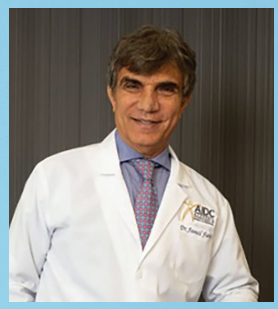

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> “Every professional must have a thorough knowledge of facial anatomy and adequate experience to evaluate the patient and make the correct treatment recommendations.”

A NEW HYALURONIC ACID FILLER WITH LIDOCAINE FOR NASOLABIAL FOLDS AND LIP CORRECTION

Drs Jamel Fares, Jenny Simancas, Carlos Vivas, and Carlos Arguedas share the results of their multicentre clinical study evaluating the safety and efficacy of the latest Fillderm® HA filler with lidocaine

ABSTRACT
The use of dermal filling techniques for soft tissue augmentation has greatly increased in recent years. Hyaluronic acid is one of the most used temporary dermal fillers in the treatment of facial wrinkles, furrows, and folds due to its effectiveness and safety.
Objective: To evaluate the efficacy and safety of Fillderm®, a new hyaluronic acid filler, for nasolabial folds and lip correction.
Methods: Open, multicentre study comprising 80 women. The Global Aesthetic Improvement Scale and the Wrinkle Severity Rating Scale evaluated efficacy. Efficacy was evaluated through observation and the reporting of side effects.
Results: One week after the filler injection, improvement in nasolabial folds and lips was observed in 89% and 86% of the women, respectively. Mild or moderate transient inflammatory reactions and ecchymoses occurred in 15% and 9% of patients, respectively, mainly in nasolabial folds. Two patients presented labial herpes simplex after treatment of the lips. The good results were maintained in 85% and 70% of women for nasolabial folds and in 80% and 65% of women for lips after 6 and 8 months, respectively.
Conclusion: Fillderm® was effective and safe for these indications.

WRINKLES ARE THE MOST apparent sign of facial ageing; they are dermo-epidermal depressions caused mainly by the sun (photo-ageing), intrinsic ageing, and the influence of factors such as gravitational force, repeated muscle movements of mimicry, disorganisation of collagen and elastic fibres and by the progressive loss of glycosaminoglycans[1].

At present, several treatment methods can be indicated according to the degree and type of patient ageing defined using the ageing classifications described in the literature (i.e. Fitzpatrick, Glogau).

Depending upon the degree of ageing on the patient's face, we can find lines, wrinkles, folds, grooves, hyperchromias, hypochromias, flaccidity, and premalignant and malignant lesions. All of these are typical during the ageing process, which can converge and form difficult, complex indications for treatment.

Ageing evaluation

The Glogau classification continues to be very useful for diagnosing the severity of ageing (Types I, II, III, IV).). As patients increasingly adopt preventive measures, their physical appearance may not necessarily reflect their actual age[2]. Consequently, it is important not to rely solely on chronological age when diagnosing ageing. Instead, a comprehensive clinical evaluation should consider the specific changes observed in each individual.

In all facial aesthetic treatments, the objective is to restructure the face and improve the so-called triangle of youth (open angle of the lateral and orbital wall, full cheek volume and the definition of the mandibular contour.)

There are limits to what facial fillers can do, which is directly related to:

- Type of skin
- Degree of ageing
- Type of wrinkle
- Skin flaccidity
- Profile of the patient (diet, physical activity, habits, profession, diseases)
- Age.

As there are several possible combinations causing the changes produced by ageing, it is recommended to combine filling techniques with one or more of the following treatment options: surgical procedures, peeling, laser, pulsed light, carbon dioxide, long wave, radiofrequency, infrared, and other procedures. Every professional must have a thorough knowledge of facial anatomy and adequate experience to evaluate the patient and make the correct treatment recommendations.

In our experience, patients with a round face shape and/or oily or acne-prone skin usually have poorer results or may have complications such as prolonged inflammatory processes, danger of infection by purulent lesions, or reactivation of intradermal cysts.

Procedures based on the use of filling materials are indicated in all patients, regardless of their age, that display marked signs of ageing in the region of the upper lip, lower lip, flattening of the upper lip with alteration of the pillars ▷

KEYWORDS
Hyaluronic acid, skin, wrinkles

Figure 1 (A) Before and (B) after injection of Fillderm in the nasolabial folds

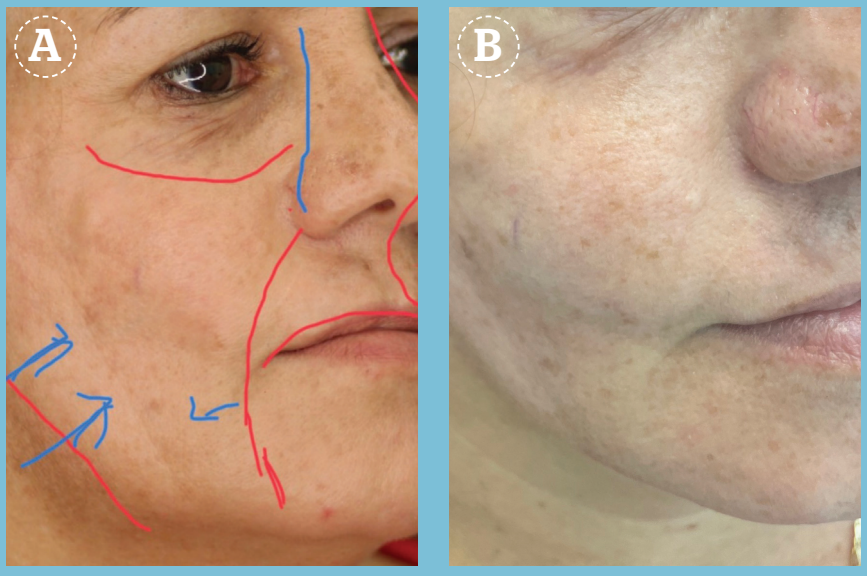

Figure 2 (A) Before and (B) after injection of Fillderm for volume in the cheeks and cheekbones

▷ of the philtrum, nasolabial folds (SNG) and labial commissures (CMS), with or without alterations to the mandibular contour. These signs appear especially in patients in grades I, II and III of the Glogau Standard. In ageing grades III and IV, when surgery is prescribed, it may also accompany filling techniques in these regions.

Presently, no optimum filling material possesses all the properties and characteristics necessary to treat all signs of ageing successfully. Instead, what exists are specific parameters we look for when we choose a product:

- Non-allergenic
- Non-pyrogenic
- Not teratogenic
- Does not migrate
- Does not require a previous test
- Has a duration of between 8 to 18 months
- That is not permanent.

When referring to the best facial filling material, we can firmly say that it is one that complies with the specific parameters described above and effectively fills the depressed region, be it a line, a wrinkle or a groove, and that also favours or does not intervene in the cutaneous metabolism.

The filling material should not alter the mobility of the mimic musculature. We often observe that permanent materials change the region's movement, limiting and altering the normal ageing process. Generally, when performing rhytidoplasty in patients in whom this type of permanent filling has been used previously, a fibrous process occurs that interferes with the surgical procedure, limiting the mobility of the facial structures.

Currently, several commercial injectable preparations are combined with lidocaine, which significantly increases the fluidity of the filler material. This combination allows for the product to pass more easily through fine gauge needles. The gentle pressure exercised by the plunger allows the injector to be very precise with the amount to be injected, in addition to offering comfort to the doctor and less discomfort for the patient.

Materials and methods

For the development of this clinical study, we used a product called FILLDERM®.

FILLDERM® is a range of dermal fillers consisting of biphasic gel formulations of hyaluronic acid (HA) with special patented double-cross link (DCL) technology, using no animal-stabilised HA.

The FILLDERM® (Eye contour, Derm, Deep, Face Shape, Body Shape) range of products consists of a soft gel with high flexibility that integrates into the tissue. The product comes in a SCHOTT syringe, along with Terumo needles and cannulas to reduce adverse effects.

Study design

The study is designed to evaluate the safety, effectiveness, and durability of FILLDERM® with lidocaine for injection in the nasolabial folds to correct wrinkles, lip augmentation, and to reduce the pain associated with such treatments.

FILLDERM® was assessed through an open clinical evaluation across Panamá, Costa Rica, Nicaragua, and the Dominican Republic, and the data collected for this study was collected from January 5, 2018, to December 5, 2018, and included 80 patients.

Inclusion and exclusion criteria

Inclusion criteria

Healthy females between 20 and 50 years of age, with an indication for filling in the nasolabial folds.

Exclusion criteria

- Use of medication that could interfere with coagulation (acetylsalicylic acid, anticoagulants, ginkgo biloba, vitamin E)
- History of hypersensitivity or allergy to the components of the product
- Presence of autoimmune diseases, pregnancy, or lactation.

Efficacy and tolerance

Results were evaluated immediately by the doctor, as well as at 4 and 8 months, according to the patient's photographs. Three follow-up visits were scheduled on days 0, 120 and 240.

The immediate efficacy was not observed; however, considering that there was no limit to the quantities used, it was deemed satisfactory in all cases.

The volume to be injected was chosen not only based on economic criteria but also on aesthetic criteria shared by the doctor and the patient. Over-corrections were avoided. The volumes used in each patient were noted, and an average volume was calculated per indication.

Finally, each patient performed their own evaluation of efficacy and tolerance at days 0 and 240.

Number and description of cases

Eighty cases were collected among the four clinical centres: 40 for nasolabial folds, 10 for lips and 30 for more extensive indications of volume deficiency, such as cheeks and cheekbones, in addition to the nasolabial folds.

Results

The three most important criteria for evaluating an aesthetic filler are its tolerance, effectiveness as a volumiser, and its duration.

Nasolabial folds (40 cases)

Immediate and late tolerance was not a problem. The efficacy at 120 days was very satisfactory in 30 cases and satisfactory in 10 cases. After 240 days, it was very satisfactory in 28 cases, satisfactory in 10 cases, and average in 2 cases.

Lip augmentation (10 cases)

Immediate and late tolerance was not a problem. The efficacy at 120 days was satisfactory in 6 cases, average in 3 cases, and low in 1 case.

After 240 days, it was satisfactory in 8 cases, average in 1 case, and low in 1 case.

Increase of volume in cheeks and cheekbones (30 cases)

Immediate and late tolerance was not a problem. The efficacy at 120 days was very satisfactory in 25 cases and satisfactory in 5 cases. At 240 days, it was satisfactory in 21 cases, average in 7 cases, and low in 2 cases.

A multicentre, non-randomised, prospective, observational study was conducted by 4 clinics in the countries of Panama, Costa Rica, Nicaragua, and the Dominican Republic for the intervention of FILLDERM® facial filler. The inclusion and exclusion criteria were categorised, and the patients signed the consent forms free and informed.

Discussion

The treatment of nasolabial folds, lip augmentation and cheek volume are the most frequent applications of hyaluronic acid-based fillers. The addition of lidocaine to the hyaluronic acid formula results in a more practical product in its use by incorporating a topic anaesthetic.

This trial confirmed that FILLDERM® is safe and effective for patients looking for augmentation of the middle part of the face. FILLDERM® added fullness to the left and right cheeks, providing statistically significant results and clinically relevant visible aesthetic results for at least 8 months.

Table 1 Efficacy in nasolabial grooves (40 cases)

Evaluation	Time	
	120 days	240 days
Very good	30 (75%)	28 (70%)
Good	10 (25%)	10 (25%)
Average	–	2 (5%)
Low	–	–

Table 2 Lip augmentation (10 cases)

Evaluation	Time	
	120 days	240 days
Very good	–	–
Good	6 (60%)	8 (80%)
Average	3 (30%)	1 (10%)
Low	1 (10%)	1 (10%)

Table 3 Increase of volume in cheeks and cheekbones (30 cases)

Evaluation	Time	
	120 days	240 days
Very good	25 (83%)	21 (70%)
Good	5 (17%)	7 (23%)
Average	–	2 (7%)
Low	–	–

Key points

- Increasing the middle part of the face to adjust facial proportions can create a more pleasing aesthetic and facial appearance.
- FILLDERM® added fullness to the left and right cheeks, providing significant results for at least 8 month.
- This study confirmed that FILLDERM® is safe and effective for patients looking for augmentation of the middle part of the face

▶ ***Declaration of interest*** *The authors have consulted for Fillderm*

▶ ***Figures 1-2*** *© Dr Fares*

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