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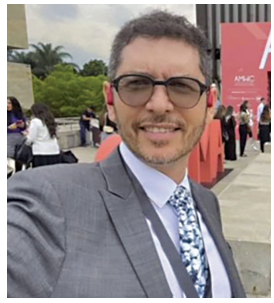
THE EFFICACY AND SAFETY OF DURAFORM® DERMAL FILLER

Drs Jamel Fares, Carlos Vivas, Yaribel Chan, and Juan Contreras share the results of their clinical study on a new long-lasting PCL dermal filler



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ABSTRACT
The demand for non-surgical procedures is on the rise as more people seek to maintain a youthful appearance. Patients are looking for safe and effective options that provide long-lasting results. Soft-tissue dermal fillers are able to meet these needs, and a new trend in collagen stimulators is showing promise in restoring and preserving facial contours. The use of long-lasting dermal fillers based on polycaprolactone (PCL) compounds is increasing among both patients and physicians. These collagen stimulators offer long-lasting effects, safety, and high patient satisfaction. Their use is expanding beyond just the face, with indications for volume loss, skin laxity, and lipoatrophy in HIV patients, as well as body areas such as striae and cellulite

KEYWORDS
Polycaprolactone, hyaluronic acid, dermal filler, collagen stimulator, face rejuvenation, skin laxity and body area

AS LIFE EXPECTANCY CONTINUES TO rise, there has been a consistent increase in the desire for non-surgical facial and body rejuvenation. Many individuals desire a more youthful appearance, leading to a global surge in the popularity of dermal fillers. These fillers effectively address concerns such as lost volume, wrinkles, and the enhancement of facial contours.

DURAFORM® is the first collagen stimulator with long-lasting effects using a new technology developed by Laboratoire GlobalSkin France called ICH (INNOVATION CONCEPT HYBRID). This technology combines microspheres ranging from 25 to 40 microns with a gel of hyaluronic acid, which acts as a transport to the skin using 25 gauge needles or cannulas. DURAFORM® is composed of polycaprolactone (PCL) and hyaluronic acid (HA), with PCL accounting for 30% and HA for 70%. Polycaprolactone is an FDA-approved, hydrophobic, biocompatible, and biodegradable polymer with good mechanical properties; therefore, it is used for a variety of applications[1]. A recently published study has shown that the PCL-based dermal filler induces neocollagenesis, a process associated with improvement in the appearance of the skin[2]. Its specific physicochemical and mechanical properties, viscoelasticity and ease of shaping led to the production of PCL-based products with various shapes and durations dependent on its biodegradation kinetics. PCL has been safely used in the biomedical field for more than 70 years, from sutures to tissue and organ replacement via 3D printing[3]. Based on the evidence, it can be inferred that PCL is a material that can be considered safe.

Methods

A clinical study was conducted at multiple centres to observe and describe the safety, effectiveness, and long-term effects of treatment on male and female subjects aged 30 to 55 years. The study involved 200 patients, 90% of whom were women and 10% men, who received treatments at different clinics and countries. The study followed good clinical practice guidelines, and all patients gave their informed consent.

Indications

Indications for the use of DURAFORM include skin laxity, nasolabial folds, facial contour, chin augmentation, nose, hands, depressed scars, and lipoatrophy in patients with HIV. ▷

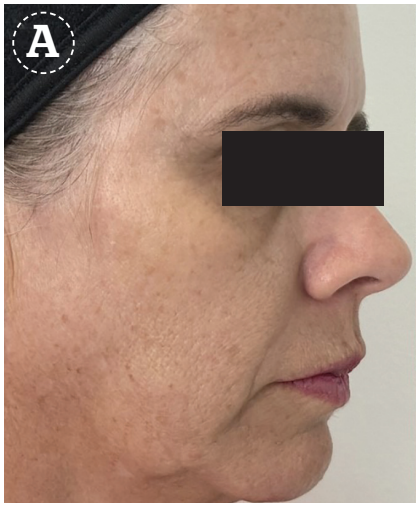
Table 1 Inclusion criteria

Sample	200 patients
Ethnicity	Hispanic and non hispanic
Control	720 days
Age	30-55 years
Gender	180 women, 20 men
Fitspatrick skin types	II, III & IV
Control days	0, 30, 90, 180, 360 & 720
Glasgou Wrinkle Scale®	Score 3: 60%, score 4: 40%

> “Out of the 200 patients, 160 patients (80%) expressed complete satisfaction with the Duraform implantation, citing long-lasting results and improved skin quality as the reasons for their satisfaction.”

Table 2 Injection sites

Temporal area	10 patients
Mid facial area: malar, nose, nasolabial folds	65 patients
Lower facial area: chin, jawline	15 patients
Other areas: scars, hands, neckline	10 patients



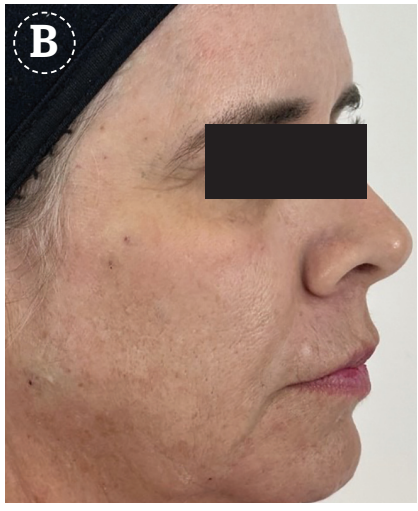


Figure 1 (A) Before and (B) 90 days after applying 2 ml Duraform for the nasolabial folds

Exclusion criteria

Exclusion criteria comprised skin disease, medical history (hypersensitivity to any ingredient in the study, including anaesthesia), history of allergies and scars, previous treatment with permanent dermal fillers or collagen stimulators, a non-permanent filler such as hyaluronic acid in the last 2 years, laser treatment or chemical peeling in the last year, pregnancy or any other facial treatment in the last year.

Evaluation and visit control

The physician utilises clinical evaluation and photographic evidence to manage and monitor the patient’s progress.

Follow-up was conducted over 720 days by the clinical practice with patients’ visits to the physician’s practice at 30, 90, 180, 360, and 720 days, clinically and with photos. Prior to the initial interview, the physicians assessed all the patients and gathered comprehensive information, including photographs. During the first interview, they evaluated the wrinkles, scales and laxity of the skin, as well as measured the severity of the wrinkles.

Injection techniques

Different techniques have been described for injecting dermal fillers, such as linear threading, fanning, serial puncture, and bolus injections. The volume of the

injection varies depending on the specific indication for the filler and can range from the subdermal (subcutaneous) to supraperiosteal layers. While dermal fillers were initially approved for use with needles, the use of cannulas is now considered the volume technique. The choice between injection techniques on cannula versus needle use is typically the injector's personal preference and experience.

The cannula technique minimises trauma and prevents bruising and intradermal ridges, especially in nasolabial folds. It requires only a single cannula penetration through a tiny hole made by a needle, in this case, 23 or 25 gauge.

The touch-up procedure can be done between 3 to 6 months after the initial treatment. Clinical practice has shown that approximately 30% of patients may require a second treatment in order to achieve full correction, especially those with lipoatrophy and scars.

Side effects

Collagen stimulators are widely acknowledged as both safe and efficient. All patients received treatment from skilled and experienced physicians across multiple facilities. Although some side effects may occur with dermal filler injections, they typically resolve within a few days. These include:

- swelling
- local pain
- bruising
- redness
- oedema
- discolouration.

Results

All the patients completed the trial without any treatment or post-treatment-related adverse effects.

Out of the 200 patients, 160 patients (80%) expressed complete satisfaction with the Duraform implantation, citing long-lasting results and improved skin quality as the reasons for their satisfaction. On the other hand, 20% of the patients reported that the treatment did not meet their expectations.

Conclusion

Collagen stimulators combined with PCL, a widely recognised polymer in the field of aesthetics, present a new perspective on skin rejuvenation using injection techniques. This unique method delivers lasting results for patients and physicians, as evidenced by the successful clinical trial of Duraform, which demonstrates exceptional outcomes even after more than 2 years.

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

▶ ***Figures 1-4 & tables 1-2*** *© Dr Fares*

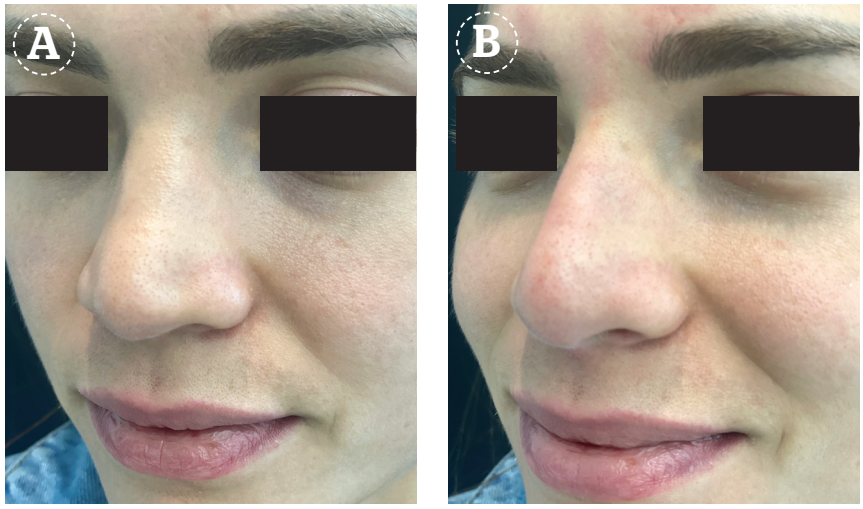
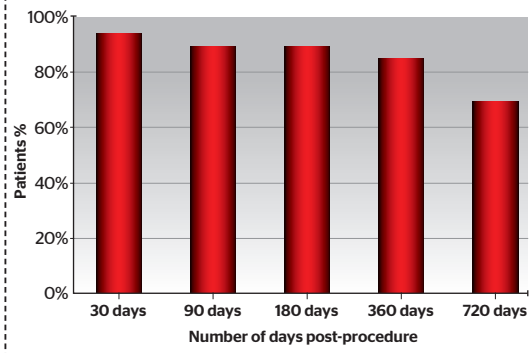


Figure 2 (A) Before and (B) 90 days after applying 1 ml of Duraform for the nose

Figure 3 Efficacy based on clinical observation



Key points

- Polycaprolactone is a FDA approved material
- By promoting neocollagenesis, DURAFORM dermal filler made from PCL, improves the overall appearance of the skin
- The trial revealed remarkable results that continue to be evident even after a period of more than 2 years

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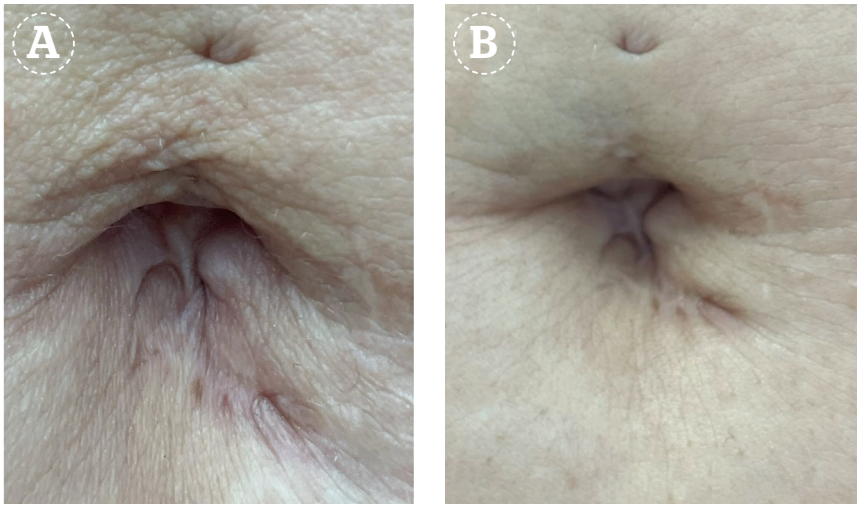

Figure 4 (A) Before and (B) 360 days after applying 2 ml Duraform, the results are still visible