

Case Report,

## A Periorbital Treatment Option Using a Polycaprolactone-based Dermal Filler for Infraorbital Volume Restoration: Case Series

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### **Abstract:**

**Background:** The polycaprolactone-based filler, (PCL-1, Ellansé-M) has been widely used for the treatment of various facial regions, both for volume enhancement and skin rejuvenation. Thus far, reports on the outcomes of PCL-based dermal fillers for the infraorbital area are limited.

**Objective:** To assess the aesthetic outcomes related to the infraorbital area using a PCL-based dermal filler over a one-year post-treatment period.

**Materials and Methods:** The study population consisted of 10 patients (100% women) aged between 45 and 65 years, undergoing infraorbital treatment with a PCL-based dermal filler in a private clinic. The authors employed the grading system based on the volume difference between pre- and post-injection photographs to evaluate its efficacy at 1- and 12-months post-procedure.

**Results:** The average evaluation scores at 1 and 12 months were 1.5 and 1.8, respectively. The mean improvement on the clinical GAIS scale was observed in all participants one year after the procedure. A clear increase in volume of the infraorbital area were observed in all patients at one year.

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**Keywords:** polycaprolactone (PCL), tear trough, Rejuvenation

### **Introduction:-**

The eyes are one of the first facial areas to show signs of aging. (1) While infraorbital hollows represent one of the most frequently targeted areas in facial aesthetic treatments, they are often regarded as difficult to address due to the complex periorbital anatomy, concurrent deformities, and the potential for complications. Various treatment options exist, including lower eyelid blepharoplasty, resurfacing laser and light therapies, radiofrequency treatments, chemical peels, and the use of fillers. (2)

Among the treatments available, both fat and filler injections aim to volumize periorbital regions. However, fat injections are time-consuming, costly, and carry the risk of irregularities and uncertain long-term volume retention. In contrast, Hyaluronic acid (HA) fillers, like Hyaluronic acid

gel (HAG), are recognized as safe and effective for volumizing infraorbital hollows since 2004. While HA fillers demonstrate efficacy in facial volume restoration, the need for repeated injections to maintain aesthetic correction poses a significant challenge. Additionally, there is a discernible limitation in their sustained long-term bio-stimulating effects, warranting consideration for alternative approaches in scientific research. (2-5)

The treatment of the infraorbital area is challenging due to its vascular supply and lymphatic drainage, which can lead to significant bruising and edema. Less invasive filler injection treatments have gained popularity. However, despite the convenience and safety associated with these minimally invasive methods, variable results, and an increased risk of complications,

such as the development of nodules, visible lumps, swelling, skin discoloration, or the occurrence of the 'Tyndall effect' optical discoloration, may occur. (6–8)

Dermal fillers have been continuously evolving to enhance their safety, effectiveness, and durability. (2,3)

The PCL-based filler is a novel collagen stimulator composed of PCL microspheres (30%) suspended in carboxymethyl cellulose (CMC) gel carrier (70%), which provides an immediate but temporary filling effect. Carboxymethylcellulose gel-based filler consisting non-HA bioresorbable polycaprolactone (PCL)-based filler (Ellansé®; Sinclair Pharmaceuticals) has been introduced to the esthetic market in 2009, representing a new class of collagen-stimulating fillers and has a proven safety profile, but rare potential complications such as nodules or granuloma can occur. (3,9,10)

Our retrospective study describes the approach and reports the results of infraorbital volume restoration one year after the injection of the dermal filler Ellansé M by a single clinician.

#### **Materials and methods:-**

The medical records of ten patients who underwent Ellansé® injection for volume correction of infraorbital area were reviewed. All the treatments described in the present article were carried out by a single medical doctor, Dr. Alexandre Adolfo, in his private practice. Written

and verbal informed consent was signed by each of the study participants. This study was accomplished in accordance with the Declaration of Helsinki.

#### **Patient Population**

This article retrospectively reviewed 10 patients' photographs at 1- and 12-months post injection from a private practice setting in Belo Horizonte, Divinopolis and Betim, Minas Gerais, of whom all were female. The ages ranged from 40 to 65 years.

#### **Treatment Procedure**

Each syringe (1 mL) of the material was premixed with 0.2 mL of 2% lidocaine prior to use.(11)

The product was then injected onto the supra-periosteal plane by vertical puncture using 22-G cannula. The amount was injected into the periorbital area using a microbolus technique, in the suborbicularis plane below the orbital rim (Fig. 1)

**Figure 1.** A 22G cannula is inserted below the point marked by the white circle, passing beneath the orbicularis muscle, and moving upwards until resistance is felt, located medially to the tear trough ligament and both centrally and laterally to the orbicular muscle. Each blue circle denotes the site of PCL injection, where 0.1–0.2 ml of PCL is strategically placed on each side in micro-bolus droplets along the length and beneath the base of the ligament, aiming to offer lift and support.



#### **Evaluation**

For each patient visit, frontal photographs, taken using standard head positioning and lighting, were collated. A grading system was used based on the volume difference between pre- and post-injection photographs (0 = no difference; 1 = effect present but not obvious; 2 = effect present and obvious)

Table 2. The authors evaluated and graded patients' photographs on a scale of 0-2 for each of the three parameters. (4) The pre-injection, immediate post-injection, 1-month and 12-month post-injection photographs were used for evaluation.

**Table 2.** Grading system used based on the volume difference between pre- and post-injection photographs.

Grade	Description
0	No Difference
1	Effect Present – Not Obvious
2	Effect Present - Obvious

**Results:-**

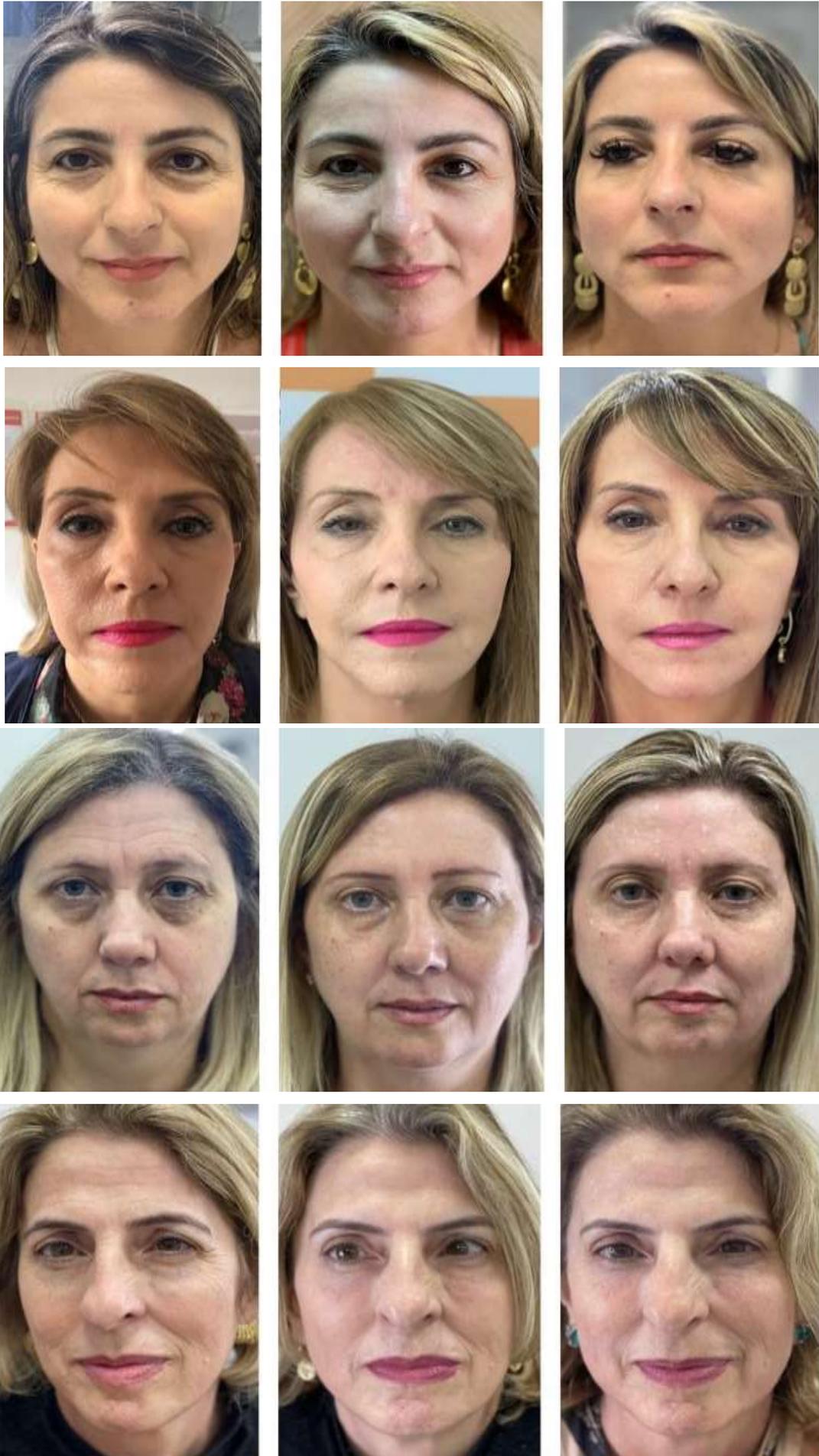
Table 1 represents the demographic and clinical visit data. The figure 2 shows the reviewed photographs before and after treatment. Written informed consent for the publication of images and details was obtained from each patient in the study.

**Table 1.** Demographic characteristics of study participants (N=10). All participants were female patients.

	Age (years)	Grade 1-month	Grade 12 months
<b>Patient 1</b>	44	2	2
<b>Patient 2</b>	41	1	2
<b>Patient 3</b>	62	2	2
<b>Patient 4</b>	56	1	1
<b>Patient 5</b>	54	1	2
<b>Patient 6</b>	79	1	2
<b>Patient 7</b>	47	1	1
<b>Patient 8</b>	60	2	2
<b>Patient 9</b>	51	2	2
<b>Patient 10</b>	61	2	2







### Efficacy

The 5 authors who evaluated the photos had 100% agreement in their assessments. There was a grade 1.5 improvement in the 1-month outcome in all cases. At 12 months, all cases showed improvement grade 1.8.

### Injected volumes

All patients had 1,2 ml of filler and lidocaine each side. All subjects were pre-treated with an infraorbital anesthetic nerve block (xylocaine +adrenaline).

### Safety

No complications were observed during the study evaluation.

### Discussion:-

Volume loss and contour irregularities at the transition between the eyelid and cheek are typical indications of the aging process. Nonetheless, the infraorbital area is often regarded as challenging to address. (2)

Hyaluronic acid (HA) fillers can be employed to treat infraorbital hollows safely and efficiently. Mustak et al. have documented malar edema, blue-gray dyschromia, and localized contour irregularities as primary concerns during both short-term and long-term patient follow-up following HA filler treatments. In contrast to blue-gray dyschromia and orbital rim fullness, malar edema typically manifests early, often after the initial injection. Nevertheless, in a minority of cases, malar edema was observed several years after the injection. According to their analysis, malar edema was detected in 11.5% of the patients they reviewed, with approximately 89% being mild cases. Only five cases required the dissolution of the hyaluronic acid gel (HAG) with hyaluronidase.(4)

When using high-viscosity products such as PCL-based fillers, the occurrence of malar edema can be minimized by restricting the injection volume, placing the product at or beyond the eyelid-cheek junction, and administering the filler deep to the malar septum at the supra-periosteal level. In our study, we consistently adhered to these practices.(9)

The PCL-based filler is a collagen stimulator composed of PCL microspheres (30%) suspended in an aqueous carboxymethyl cellulose (CMC) gel carrier (70%), which provides an immediate but

temporary filling effect. The PCL microspheres contribute to long- term volume by stimulating new type I collagen production. As the CMC gel is absorbed in the first 8 weeks, the loss in volume from the carrier gel is gradually replaced by the newly formed collagen because of the PCL-induced neocollagenesis. Considering the long half-life of type I collagen, it is logical to anticipate that PCL filler would eventually be substituted by the body's own soft tissue, leading to sustained long-term clinical effectiveness. (10,12)

The total bioresorption time of the product depends on the length of the PCL-polymer chain; in this regard, two product versions are available: S and M, which have bioresorption times of at least 1 and 2 years, respectively. In the present study, the M version was used, Clinical trials have shown that the PCL-based filler has a good safety profile, as has daily clinical practice and post market surveillance worldwide over 10 years. (9)

The filler based on PCL not only provides an instant increase in volume, due to the CMC gel component, and a sustained effect due to collagen stimulation. In most cases, only one session of the PCL-base filler is sufficient for effective volume augmentation. (10,13)

In our current investigation, we noted an enhancement in skin quality and thickness. While the initial increase in volume after 3 months was relatively smaller, the improvement reappeared six months post-injection and endured for a year, likely attributable to collagen formation. To our knowledge, it is for the first time that a PCL-based dermal filler has been documented for application in the periorbital region.

The complication rate of the PCL-based filler is low, and complications are mild in nature. Lin et al. didn't find any intravascular injection, nodules, and/or granuloma during the 3-year observation. (9) Our patients did not exhibit any nodules, swelling, or discoloration.

The present study was limited by its retrospective design and small number of patients. Further, only one clinician carried out the injections, although this may have improved the consistency and reproducibility of the technique and may be a good control variable. The study, however, does provide useful insight into the alternative volume restoration treatment for infraorbital area.

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