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Research Article

Concealing the Lower Eyelid Fat Bag Prolapse by Superficial Injections of Hyaluronic Acid-based Filler

Marina Landau[1*], Livia Prata[2], Matheus Rodrigues[3], Alessandra Santiago[4]

[1]Private clinic, Herzliya, Israel
[2]Private Clinic, Minas Gerais, Brazil
[3]Private Clinic, Sao Paulo, Brazil
[4]Private Clinic, Minas Gerais, Brazil

***Correspondence author:** Marina Landau, MD, Arena Dermatology, Private Clinic, Herzliya, Israel; Email: dr.marinaclinic@gmail.com

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Abstract

Purpose: The periorbital region plays a crucial role in facial aging perception, yet managing lower eyelid concerns remains challenging due to their complex etiology. This prospective exploratory case study reports a superficial injecting technique of Hyaluronic acid based-filler to target indentations caused by lower eyelid fat pad prolapse.

Methods: 50 participants aged between 18-80 years with infraorbital bulging received injections with ART FILLER® Fine Lines, a crosslinked HA filler. The injections were performed in subdermal plane using a BD syringe with a 31G needle. The Merz Infraorbital Hollowness Scale (MIHS) and Global Aesthetic Improvement Scale (GAIS) were used to assess the efficacy of the procedure. Additionally, palpebral-malar hollowness height using 3D images and dermal thickness via ultrasound were evaluated.

Results: 60 days post-injection, a significant MIHS improvement was observed, with 93% of subjects exhibiting at least one-grade enhancement. GAIS scores revealed high satisfaction, with 98% of subjects and 96% of clinicians reporting global improvement. Ultrasound imaging indicated a statistically significant increase in dermal thickness post-injection, confirming structural improvement. Only few minor adverse events were recorded, including edema (16%) and hematomas (14%), that resolved within days.

Conclusion: This study presents a novel HA-based technique effectively addressing lower eyelid fat bag prolapse depressions, supported by substantial aesthetic and structural improvement. Our findings brought important insights into non-surgical interventions for periorbital rejuvenation and treatment options for facial aging concerns.

Keywords: Hyaluronic Acid; Merz Infraorbital Hollowness Scale; Aging; Fat Bag

Introduction

The periorbital region is pivotal in the perception of facial aging, with recent advancements highlighting its significance. Notably, utilizing eye-tracking technology, a clinical study demonstrated that the periorbital region ranks as the second most crucial area in aging perception, beside the perioral region [1]. Despite this recognition, managing the lower eyelid region remains a challenging task due to its multifaceted and intricate etiology [2].

The presence of groove in the infraorbital regions that are commonly referred to as "dark circles", encompass several face anatomical regions including the nasojugal groove, tear trough deformity and palpebromalar groove. Various factors explain these anatomical characteristics including intraorbital fat herniation, skin and subcutaneous fat atrophy, muscle dynamics and malar bone resorption [3]. Current clinical classifications predominantly focus on hollowness rather than specifically addressing fat bag prolapses. However, the Merz Infraorbital Hollowness Scale offers a closer approximation because although it measures infraorbital hollowness, its different grades consider progressive degrees of fat bag prolapse [4]. The emergence of infraorbital bags is intricately linked to the aging process, characterized by progressive laxity of the support structures such as the Lockwood suspensory ligament and lateral canthal tendon. This laxity facilitates fat displacement and consequent bulging across the orbital

septum [5,6]. While aging contributes significantly, some individuals exhibit a constitutional predisposition exacerbating facial aging [7,8]. In contrast, youthful lower eyelids are characterized by a seamless transition between the eyelid and cheek [8,9]. This difference prompts the demand for aesthetic interventions, including both surgical and non-surgical interventions, to smooth this transition in aged subjects [10-12]. Among non-surgical interventions, hyaluronic acid-based fillers have gathered attention for addressing tear trough deformity, particularly via supraperiosteal filling techniques [13,14]. However, their efficacy diminishes in cases of lower eyelid fat bag prolapse, requiring surgical interventions like blepharoplasty [5,15]. While previous studies have explored superficial filling techniques for the infraorbital area, none have specifically targeted the correction of depressions associated with lower eyelid fat bag prolapse [14,16]. Therefore, this study aims to introduce a superficial hyaluronic acid filling technique aimed at concealing the indentation between prolapsed lower eyelid fat bags and the cheek.

Material and Methods

Test Products and Procedure of Injection

ART FILLER® Fine Lines from Fillmed Laboratoires is a crosslinked, hyaluronic acid of non-animal origin, slowly absorbable over time, colorless, sterile, non-pyrogenic, physiologically transparent, viscoelastic gel containing 0.3% by weight of lidocaine hydrochloride for its anesthetic properties [21]. This filler comes in a pre-filled 1.2 ml graduated disposable syringe that was transferred to a BD syringe 31G needle (BD, New Jersey - USA). The skin of the subjects was disinfected with 2% aqueous chlorhexidine and a topical anesthesia with Lidocaine 40 mg/g applied. The hyaluronic acid was injected in the subdermal plane along the palpebral-malar transition. The needle was inserted starting from the most medial part of the hollowness, with the first entry point about 4-6 mm away from the medial border, close to the deepest point of the sulcus. The total volume injected depended on the individual patient's need for correction. A delicate massage was done in regions with a punctual accumulation of product.

Population

Before their inclusion, all the subjects submitted to this study have signed a written informed consent. Included subjects were males or females between 18 and 80 years of age presenting infraorbital bulging (fat herniation) without midface volume loss (grades 2, 3 and 4 of the Merz Infraorbital Hollowness Scale [17]. Patients with history of previous injections in infraorbital area in the last 5 years were excluded from the study. The included subjects presented complete medical history and clinical data needed to interpret the clinical outcomes proposed in this study. The selected subjects were informed about the study process and completed a follow-up visit 60 days after the injection procedure.

Study Outcomes and Evaluation Criteria

The Merz Infraorbital Hollowness Scale (MIHS) was defined as the primary criteria of the study, a validated scale that stratifies the degrees of infraorbital hollowness into five grades: 0 No hollowness, 1 Mild hollowness, 2 Moderate hollowness, 3 Severe hollowness and 4 Very severe hollowness. This scale was selected, despite being called the Infraorbital Hollowness Scale, as it presents a scale of infraorbital hollowness secondary to prolapse of the lower eyelid fat pad. The primary outcome was evaluated before injection and 60 days post-procedure (+/- 15 days). The secondary outcome was the Global Aesthetics Improvement Scale (GAIS) [22], assessed by the dermatologist and by the subject to measure the degree of improvement observed after treatment. This scale has 5 points and is graded as follows: 1: Worsens, 2: Remains unchanged, 3: Slight improvement, 4: marked improvement, 5: Exceptional improvement. Another clinical outcome was the height of the palpebral-malar hollowness using the 3D images. This parameter was calculated with the profile image of the subjects by tracing a line between a point located on the eyelid (immediately before the skin inversion for the formation of the sulcus) and another point in the malar region (immediately before the skin inversion for the construction of the sulcus) - called line A; the height of the eyelid-brow-malar sulcus corresponds to the line that touches the lowest point of the sulcus and forms an angle of 90 degrees with line A. The images were taken at the level of the mid-pupillary line.

Dermatological Ultrasound Analysis

Subjects who had dermatological ultrasound analysis documented in their medical records were subjected to a reevaluation of this parameter at D60 post-injection. The measurements were conducted utilizing the CX50 analyzer (Philips Medical Systems, Bothell, WA, USA) equipped with a high-frequency transducer (7 to 15 MHz). Participants were positioned in a neutral seated posture, ensuring alignment of the head with the Frankfurt plane and the probe was positioned close to the skin, perpendicular to the craniocaudal line, with an orientation index in the upper direction.

Ethical Approval

This study will adhere to the items in the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) and was designed following its principles and guidelines [20]. This retrospective case study analyzing patients injected to conceal the indentation caused by a prolapse of the lower eyelid fat bag in Herzilya (Israel) and Divinópolis (Brazil), following the National Research Ethics Committees and following the Declaration of Helsinki (1964) guidelines.

Data Collection and Analysis

Data are given in their relative and absolute frequencies or in mean and standard deviation (or median and interquartile range). Numerical variables were tested for normality of distribution using the Kolmogorov-Smirnov test. Normally distributed variables were compared using Student's t-test for paired samples. The Chi-square test was used to compare categorical variables. All analyses were two-tailed, using a 95% confidence interval as a reference and tests showing a p-value < 0.05 will be considered statistically significant. The analyses were performed using SPSS 25.0.0 software (IBM, New York).

Results

Population and Procedure

For this retrospective case study, a cohort of 50 participants underwent treatment, encompassing a total of 100 lower eyelids (Table 1). Among the enrolled population, 22 subjects received treatment in Brazil, while 28 were treated in Israel. The majority of participants were female (92%). The mean age of the population was 48 years (range 21 to 76 years) and a mean Body Mass Index (BMI) of 24.71 (SD: 3.65) kg/m². Notably, the majority of patients had no prior surgical history (96%) or non-surgical interventions (92%). The efficacy of the procedure was evaluated at the 60-day post-injection, with no requirements for touch-up re-injections during the study period.

Evolution of the MIHS and the Success Rate

The primary objective of the study was to quantify the efficacy of the intervention utilizing the Merz Infraorbital Hollowness Scale (MIHS) for the lower eyelids of each subject. As presented in Table 2, 57% of the population exhibited severe or very severe hollowness prior to the injection, which decreased to 9% after 60 days post-injection. Similarly, 43% of the population displayed mild or moderate hollowness at baseline (D0), decreasing to 25% at the 60-day mark. Most notably, while mild hollowness was the minimal observed grade at baseline, 66% of the cohort exhibited an absence of hollowness at D60 following the injection. The observed improvement in MIHS for the whole population was statistically significant between D0 and D60 (Table 1). Representative photography of three enrolled subjects with different age at D0 and D60 post-injection is shown on Fig. 1. The success rate was determined by evaluating the frequency of MIHS grade variation in each lower eyelid. As shown in Table 3, 93% of the total population demonstrated an improvement of at least one grade, with 6% observing no change and only one subject experiencing worsening hollowness post-intervention.

Progression of the Infraorbital Hollowness

The efficacy of the procedure was also assessed by the evaluation of the palpebral-malar hollowness height using the 3D images. Fig. 2 shows the case of a patient treated with our injection procedure technique and how the depth of infraorbital hollowness was calculated before and after 60 days follow-up. At baseline (D0), the depth of infraorbital hollowness ranged from -0.01 to -2.3 mm, with a mean of -0.41 (SD 0.47) mm. By D60 post-injection, this parameter ranged from -0.27 to 1.33 mm, with a mean of 0.37 (SD 0.40) mm. A statistically significant difference of 0.78 mm in depth was observed, as evidenced by a paired samples t-test ($p < 0.001$). Fig. 3 presents a boxplot depicting the distribution of this data.

Benefits of the Intervention Confirmed by the GAIS

Subjects and investigators satisfaction were assessed using the 5-grade Global Aesthetic Improvement Scale (GAIS) score, ranging from 0 (worsened) to 4 (very much improved). Fig. 1 depicts the close alignment between the GAIS scores assessed by investigators and those self-reported by subjects, except for the category of best improvement, where 64% of subjects reported exceptional improvement compared to 48% as assessed by clinicians. Notably, 98% of subjects and 96% of clinicians reported a global improvement in the treated areas (Fig. 1).

Dermal Thickness Analysis by Ultrasound Imaging

Sixteen subjects had dermatological ultrasound imaging in their medical records, that were considered as baseline. Before injections, the dermal thickness measurements ranged from 0.12 to 0.34 mm, with a mean of 0.20 mm (+/- 0.048). At D60 post-injection, dermal thickness had notably increased, ranging from 0.19 to 0.43 mm, with a mean of 0.29 mm (+/- 0.06). This observed average increase of 0.09 mm in dermal thickness was found to be statistically significant, indicating a positive impact of the procedure on skin structure and integrity (Fig. 4,5).

Additionally, dermatological ultrasound assessments revealed precise filler distribution within the intradermal and immediate subdermal planes for all subjects examined. Notably, no evidence of filler migration into the eyelid fat bag was observed, highlighting the accuracy and safety of the injection technique in avoiding unintended tissue compartments.

Safety Assessment

The aspect and sensitivity of treated areas during and after injections were comprehensively evaluated. Overall, most of the observed events were typical occurrences associated with HA filling procedures, with the majority of local reactions resolving within a few days post-injection. A total of 20 subjects reported adverse events during the study period. Within the initial 21 days, 16% of patients experienced edema lasting an average of 7 days, while 14% presented hematomas with an average duration of 3.5 days. Additionally, overcorrection was noted in 6% of patients, with hyaluronidase required in 5% of cases to resolve it. No ischemic events were observed throughout the study's follow-up period.

Parameter	**Total**
Gender % (n)	
Female	92 (46)
Male	8 (4)
Age, mean (min, max)	48 (21 - 76)
BMI, kg/m^2 mean (SD)	24.71 (3.65)
Smoking, % (n)	
Yes	8 (4)
No	92 (46)
Previous surgical treatment, % (n)	
Yes	4 (2)
No	96 (48)
Previous non-surgical treatment, % (n)	
Yes	8 (4)
No	92 (46)
BMI: Body Mass Index; SD: Standard Deviation	

Table 1: Participant demographics and baseline characteristics.

Merz Infraorbital Hollowness Scale	D0 % (n)	D60 % (n)
No Hollowness	0 (0)	66 (66)
Mild Hollowness	20 (20)	14 (14)
Moderate Hollowness	23 (23)	11 (11)
Severe Hollowness	31 (31)	9 (9)
Very severe hollowness	26 (26)	0 (0)
Number of lower eyelid	100	100
Mean of MIHS (SD)	2,63 (1,07)	0,63 (1,00)
*p-value**	< 0.001	
MIHS Merz Infraorbital Hollowness Scale, SD Standard Deviation *p-value of the paired t-test for comparing the means of the MIHS D0 vs. D60		

Table 2: Merz infraorbital hollowness scale frequency on each lower eyelid at D0 and D60 post-injection.

Variation between D0 and D60 of Merz Infraorbital Hollowness Scale	N (%)
-1 (Worsen)	1 (1)
0 (Remained unchanged)	6 (6)
1	31 (31)
2	29 (29)
3	20 (20)
4	13 (13)
Success (At least −1grade vs. before)	93%

Table 3: Frequency of the variation of Merz infraorbital hollowness scale degree in each lower eyelid.

Figure 1: Representative images of 3 subjects of different age, depicting lower eyelid prolapse and hollowness at baseline D0 and D60 post-injection.

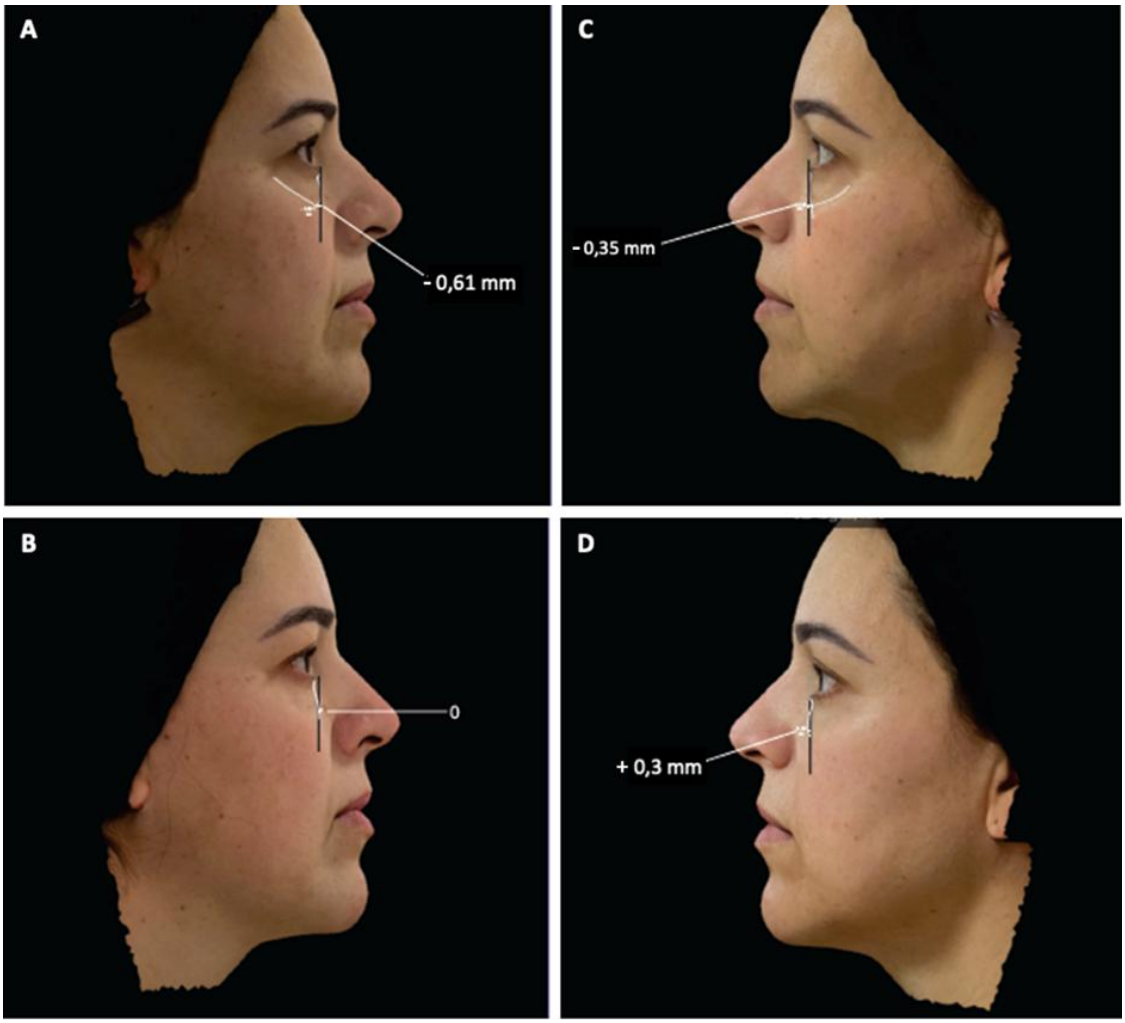

Figure 2: Calculus demonstration of infraorbital hollowness depth. (A) Right side at D0, exhibiting a depth of -0.61 mm measured at the level of the mid-pupillary line. (B) Post-treatment at D60, showing the filled region. (C) Left side at D0, revealing an infraorbital hollowness depth of -0.35 mm. (D) Left side at D60 highlighting an increase of +0.3 mm in the area compared to the previously established line.

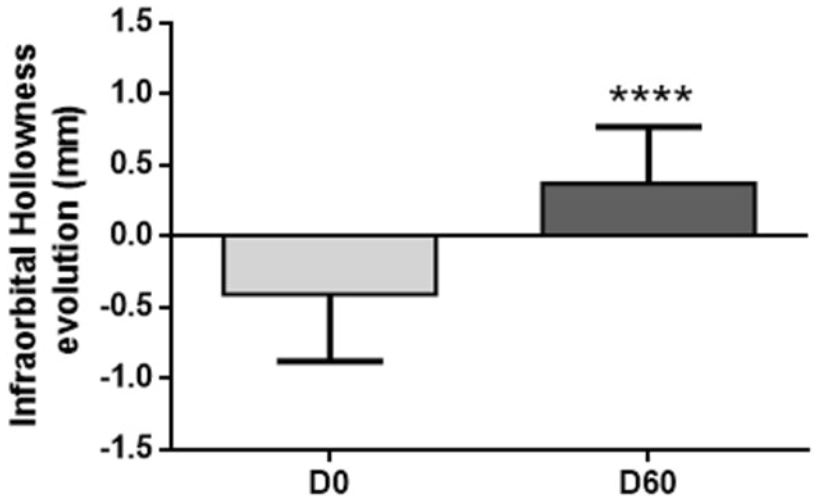

Figure 3: Boxplot showing the distribution of the depth infraorbital hollowness at D0 and D60 post-injection. Data are given as mean +/- SD, n=100; ****p<0.0001 vs. D0.

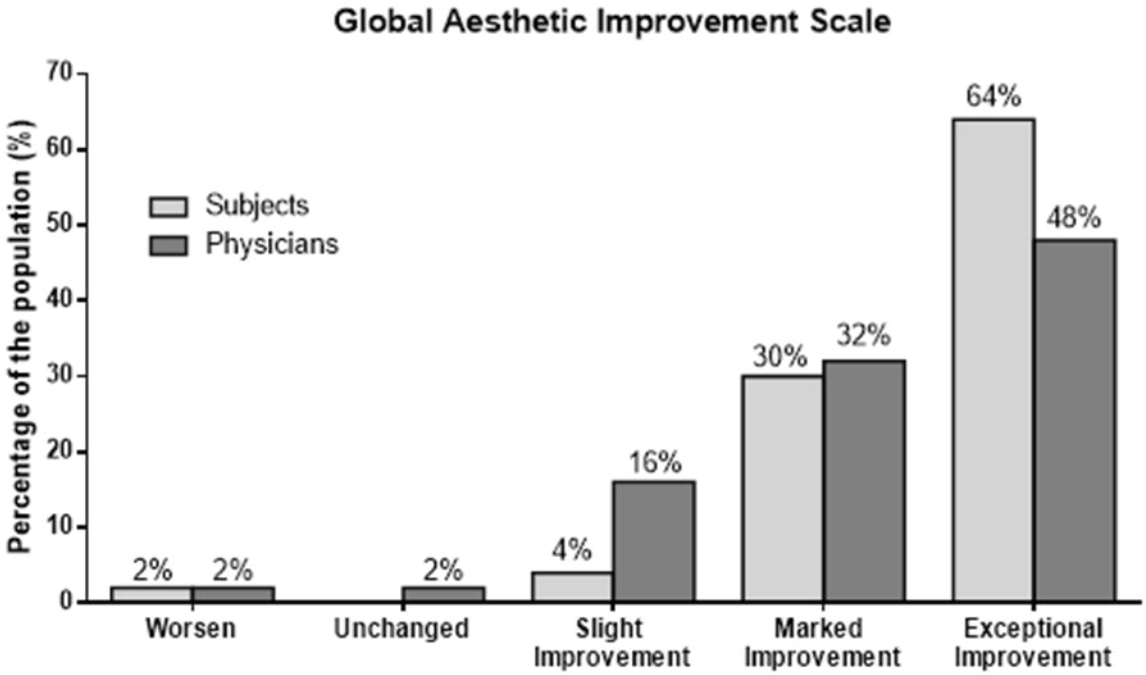

Figure 4: Evaluation of the 5 grades Global Aesthetic Improvement Scale by patients and physicians 60 days after treatment.

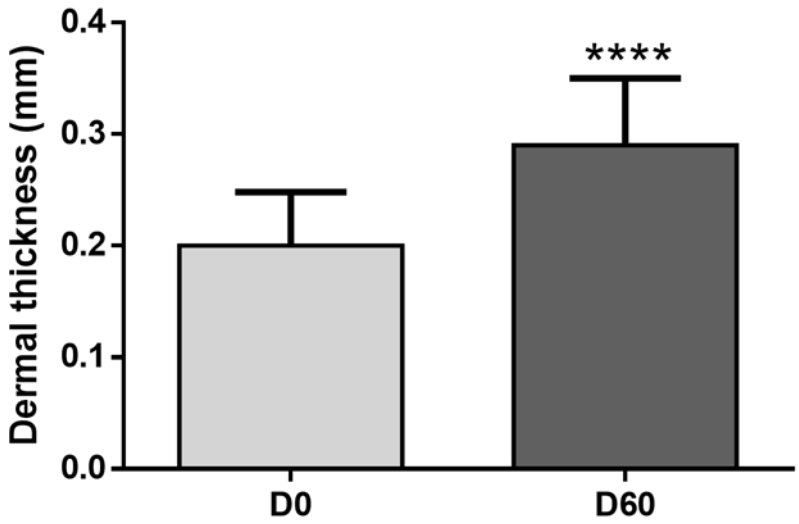

Figure 5: Evaluation of dermal thickness by dermatological ultrasound analysis. Data from 16 subjects collected in the medical records for D0 and measured at D60 post-injection. Data are given as mean +/- SD, n=16; ****p<0.0001 vs. D0.

Discussion

This study presents a comprehensive evaluation of a superficial Hyaluronic Acid (HA) filling technique aimed at concealing the prolapse of the lower eyelid fat pad, addressing a common aesthetic concern in the periorbital region. By employing Art Filler Fine Lines coupled with a needle injection procedure, the technique demonstrates efficacy in softening the appearance of lower eyelid fat pad prolapse, particularly suitable for subjects averse to or ineligible for surgical interventions. The presence of herniated infraorbital fat contributes to the prominence of tear troughs, accentuating the appearance of dark circles under the eyes [2]. Youthful lower eyelids exhibit a smooth transition between the eyelid and cheek, highlighting the aesthetic significance of this region [1]. As aging progresses, an accentuated groove develops along the eyelid-cheek junction, further emphasizing the need for effective aesthetic interventions [3].

Considering the delicacy of the region to be treated, the choice of injection device should provide smooth and precise injections, minimizing bruising and enabling the injection of microdroplets. The selection of the injection device was guided by the observations by Lee JH, et al., who delineated the distinct applications of cannulas and needles in lower eyelid filling procedures [3]. Their findings emphasized that when addressing hollowing in the lower eyelid without a pronounced lower eyelid fat pad protrusion, optimal outcomes are achieved with filler placement in the intramuscular or supraperiosteal plane using cannulas. Conversely, in cases where there is both indentation and prolapse of the lower eyelid fat pad, superior results are attained through subcutaneous injection with needles [3,12]. Deep fillers do not provide satisfactory results for the indentation between the lower eyelid and the cheek in the lower eyelid fat bag prolapse. By utilizing a BD syringe, our injection procedure ensures uniform and precise filler distribution, minimizing irregularities and hematoma formation. Moreover, this study pioneers the application of HA fillers to conceal lower eyelid fat pad prolapse, providing a novel solution to achieve smoother transitions and improved facial aesthetics.

The outcomes of this study, as assessed by the Merz Infraorbital Hollowness Scale (MIHS) and the Global Aesthetic Improvement Scale (GAIS), demonstrate notable improvements in hollowness severity and overall aesthetic enhancement. High patient and clinician satisfaction rates underscore the transformative impact of the technique, with marked and exceptional improvements reported by a significant proportion of participants. Dermatological ultrasound assessments revealed a notable increase in dermal thickness at D60 post-injection, indicating a localized stimulation of collagen production by Hyaluronic Acid. The Art Filler Fine Lines, featuring its Tri-Hyal technology, has demonstrated efficacy in promoting collagen synthesis and creating an optimal microenvironment for dermal fibroblasts. This facilitates enhanced tissue integration and improves aesthetic outcomes [17]. The observed thickening of the dermis holds significant promise for addressing indentations in this region, as one contributing factor to this issue is the disparity in skin thickness between the cheek and eyelid areas. Augmenting skin thickness in the transitional zone can lead to a smoother, more harmonious appearance. Transient adverse events such as bruising and edema were observed, consistent with expectations for needle-based injections in the periorbital region [18]. Notably, the absence of vascular occlusions and filler migration into eyelid fat bags highlights the safety and precision of the technique. The use of cannulas to fill the lower eyelid with hyaluronic acid has been shown to lower the risk of hematoma [18]. In our study, 14% of the enrolled subjects exhibit hematoma, a frequency comparable to the frequency described in the study of Berguiga and Galatoire, who treated the lower eyelid region with needles and observed a hematoma rate of 11.3% [19]. In addition, excellent tissue accommodation was observed with the product used, with no Tyndall effect or irregularities in the application. The free hyaluronic acid present in Art Filler Fine Lines (Fillmed, Paris, France) aids in the tissue accommodation process and may have been responsible for the excellent tissue integration observed [20].

The blue discoloration was not reported in any subject, whereas this adverse effect was present in previous studies using another hyaluronic acid needle within the supraperiosteal region. To reduce the likelihood of blue-grey discoloration, Mustak H, et al., recommended the supraperiosteal injection plan and minimize the amount of filler injected [21]. Despite a superficial injection plan in this study, we did not observe any Tyndall effect. We believe that this could be due to the excellent tissue integration of the filler and the micro-aliquots deposited by an extremely delicate device such as the 6 mm needle of the BD syringe. However, there is a potential risk to deliver the filler in multiple tissue layers using a needle, particularly getting the filler inside the fat bags. In our study, the dermatological ultrasound mapping carried out on 16 out of 50 patients showed that in all the cases, the filler was located in the dermis and subdermally and no filler was injected into the eyelid fat bags.

Study Limitations

The major limitations of this study are that it is not comparative study and has a relatively short follow-up period.

Conclusion

In conclusion, this study underscores the efficacy, safety and patient satisfaction associated with a superficial HA filling technique for concealing lower eyelid fat pad prolapse. By offering a minimally invasive alternative to surgical interventions, this technique presents a valuable addition to the aesthetic procedures targeting the periorbital region. Further research to assess long-term outcomes and refine the technique is warranted to optimize patient care and aesthetic outcomes.

Conflicts of Interest

The authors declare no conflict of interest in this paper.

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Disclosure
The products used in this study were provided by Fillmed laboratories, Paris, France.

Authors' Contributions
All authors contributed to conceptualization, treatment execution, manuscript writing and final approval.

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