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Research Article

Treatment of Periocular Skin Aging and Improvement of Skin Quality with NCTF 135® HA Polyrevitalization Injections

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Abstract

Introduction: Aging is a complex process in which different changes occur at cellular and macroscopic levels. Clinically, it can be seen as skin thinning, decreased elasticity, wrinkle formation and appearance of pigments, causing discomfort in patients. Skin boosters are resorbable drugs placed in the deep dermis to improve skin quality. NCTF 135® HA (FILLMED Laboratories, France) is a solution used in mesotherapy to improve skin aging.

Materials and Methods: This was a longitudinal, open-label prospective study. Patients older than 18 years of age who wished to improve their periocular skin quality were included. All patients received three injections during in-office procedures. The injections were performed at weeks zero, two and four. During each visit, the patients answered the Face-Q facial and eye appearance, skin quality questionnaires and follow-up photographs.

Results: Thirty-two participants were included in the study: 22 women and 10 men, with an average age of 40.5 years (29-56 years). The average score on the Face-Q questionnaire for satisfaction with full-face appearance at baseline was 44.22 points and after week six was 63.16 points (p=0.0001; 95% CI -26.86 to -11.0). Likewise, the baseline score of eye appearance was 41.22, with a score after week six of 57.00 (p=0.0001; 95% CI -22.62 to -8.938). For skin quality, the baseline assessment score was 11.52 and after week six, 5.31 (p=0.0001; 95% CI -4.55 to -7.02).

Conclusion: Periocular mesotherapy with NCTF 135 HA (FILLMED Laboratories, France) is safe and improves the skin quality. The patients were satisfied with their face and eye appearance after six weeks of treatment.

Keywords: Periocular Skin; NCTF 135 HA; Nanosoft Needles; Eyelid Dark Circles; Mesotherapy; Delivery; Safety Testing, Statistics

Introduction

Aging begins at birth and is a complex process, in which different changes occur at the cellular and macroscopic levels. Intrinsic aging is a programmed process by which cells undergo a natural and inevitable deterioration [1,2]. This process leads to a slower metabolic rate, diminishes collagen and elastin production and slows cell turnover. Extrinsic aging involves external factors that accelerate skin aging [2-4]. Ultraviolet (UV) radiation is the most important and consists of three components: UV-A rays with a Wavelength (WL) of 320-400 nm, UV-B rays, with a WL of 280-320 nm and UV-C rays with a WL of 100-280 nm. UV-A and UV-B are key to photoaging and cause the formation of Reactive Oxygen Species (ROS). UV-A rays penetrate deeper into the skin because of their longer WL [5,6].

In contrast, UV-B rays only damage the most superficial layers. Continued exposure to these factors causes tissue changes, such as elastosis, keratosis and hyperpigmentation and increases the risk of photo carcinogenesis. Other extrinsic factors associated

with skin damage include environmental pollution and smoking habits. Cigarette smoking induces a generalized decrease in capillary flow and deprives the tissues of adequate nutrition and oxygenation [2,6]. The skin is the bigger organ of the body. The epidermis is the superficial skin layer and keratinocytes are the chief cells. Fibroblasts, on the other hand, are cardinal dermis cells. Fibroblasts are responsible for collagen and elastin production in the Extracellular Matrix (ECMx) [1].

Skin aging and photoaging induce fibroblast senescence. These senescent fibroblasts, characterized by a lower metabolic rate, produce arrestin proteins that perpetuate the cell cycle and preclude apoptotic pathways. Consequently, ROS prevail and oxidative damage extends, resulting in collagen degeneration [1,2,4,5,7].

Clinically, the accumulation of these components results in atrophy of the epidermis, thinning, dryness, decreased elasticity, roughness, wrinkle formation, telangiectasias, erythema and appearance of pigments, generating discomfort in patients [8,9].

The Face-Q questionnaire is a scale used to assess the patients' perspectives on facial aesthetic treatments, with a Cronbach's alpha of ≥0.90. Some specific questionnaires inquired into the patients' satisfaction with their facial and eye appearances [10].

The Scientific Assessment Scale of Skin Quality (SASSQ) is a photo numeric scale that evaluates skin quality based on six parameters: elasticity, wrinkles, roughness, pigment, erythema and pore size. This scale has demonstrated an Intraclass Correlation Coefficient (ICC) of 0.81 for elasticity and 0.84 for wrinkles, while pigmentation and erythema had an ICC value ≥0.63, making it a tool with good validation to assess skin quality [11].

Treatments focus on reducing the stigmata associated with skin aging. Photoprotection is fundamental at every stage. Topical treatments, such as retinoids, antioxidants and alpha hydroxy acids, help increase collagen type I and III and reduce ROS damage. Alternatively, multiple energy transmission platforms have been developed to treat skin aging. Fractional carbon dioxide (CO_2) resurfacing techniques use energy at a predetermined WL to ablate the superficial layer and stimulate collagen synthesis, skin tightening and the removal of pigmented lesions [3,12-15].

Finally, injectable hyaluronic acid-based drugs are placed in the muscular or periosteal layers to improve the support of the superficial structures and skin quality. Moreover, skin boosters are resorbable drugs placed in the deep dermis to improve skin quality by fortifying the ECMx. Mesotherapy belongs to this field because it recovers the metabolic rate of the senescent fibroblasts. Some products mix hyaluronic acid with diverse components such as vitamins, minerals, coenzymes and amino acids [16-22].

NCTF 135® HA (FILLMED Laboratories, France) is a solution used for mesotherapy that contains a mixture of substances that provide fibroblasts with an ideal environment for their development. The manufacturer suggested five sessions in total, applying the first 3 with a separation of two weeks between each session, with two extra sessions separated by four weeks. Several authors have attempted to use different treatment schemes with favorable results [19].

Materials and Methods

This was an experimental, longitudinal, open-label, prospective study held at the Instituto de Oftalmología Fundación Conde de Valenciana I.A.P, Mexico City, Mexico, carried out between March 2023 and October 2023. This study adhered to the guidelines of the Declaration of Helsinki and was approved by local ethics (CEI-2021/09/04) and biosafety committees (CB-043-2021). All patients older than 18 years old, who wished to improve their periocular skin quality and signed an informed consent form, were included. Patients were enrolled between March and May and were followed up for six weeks. Patients were excluded if they had a history of known allergies to the product components, usage of dermal fillers or botulinum toxin six months before inclusion, pregnancy, lactation or a recent history of infections in the facial region. Patients were eliminated if they used botulinum toxin or other treatments to improve the skin quality in the periocular area.

Injection Technique

Patients received a drop of tetracaine in both eyes and the injection area was cleaned with an antiseptic solution. Sterile gloves and facemasks were used during the injection. The physician took 1cc of NCTF 135® HA (FILLMED Laboratories, France) in an insulin syringe and placed a Nanosoft needle (FILLMED Laboratories, France). Each eyelid received a 0.5cc of solution, forming

a series of papules and leaving a spacing of 0.5 cm between each injection site. At the end of the procedure, we applied NEOCICA cream (FILLMED Laboratories, France) as a healing moisturizer. All patients received three injections during in-office procedures. The injections were performed at weeks zero, two and four. During each visit, the patients answered the Face-Q facial and eye appearance, SASSQ questionnaires and follow-up photographs.

Statistical Analysis

The investigators used descriptive statistics to analyze the demographic variables and compared intragroup results over time and conducted a repeated measures ANOVA test for continuous variables. We used SPSS Version 20 (Chicago, IL, USA) for analysis and considered a value of $p<0.05$ as statistically significant.

Results

Thirty-one participants were included in the study, 22 women and 10 men, with an average age of 40.5 years (29-56 years) (Table 1). The average score on the Face-Q questionnaire for satisfaction with full-face appearance at baseline was 44.22 points and after week six was 63.16 points (p=0.0001; 95% CI -26.86; -11.0) (Fig. 1). Likewise, the baseline score of eye appearance was 41.22, with a score after week six of 57.00 (p=0.0001; 95% CI -22.62; -8.938) (Fig. 2). Taken together, these results demonstrate an increase in patients' perception of their post-treatment appearance.

For skin quality, the baseline assessment score was 11.47 and after week six, 5.31 (p=0.0001; 95% CI 4.749; 7.564) (Fig. 3). This reflects a significant improvement the skin quality (Fig. 4,5).

	N = 31	P
AVG AGE (RANGE), YEARS	40.5 (29-56 years)	
SEX, (%)		
MALE	10, (25%)	
FEMALE	21, (75%)	
FACE-Q - FACE		
Baseline	44.22	
Week 2	50.97	**(p=.007)**
Week 4	60.03	**(p= <0.0001)**
Week 6	63.16	**(p= <0.0001)**
FACE-Q - OJOS		
Baseline	41.22	
Week 2	46.50	**(p=0.059)**
Week 4	55.44	**(p=<0.0001)**
Week 6	57.00	**(p=<0.0001)**
SASSQ		
Baseline	11.46	
Week 2	8.16	**(p=<.0001)**
Week 4	5.91	**(p=<.0001)**
Week 6	5.31	**(p==<0.001)**

Table 1: Baseline demographics and follow-up scores. SASSQ: Scientific Assessment Scale for Skin Quality.

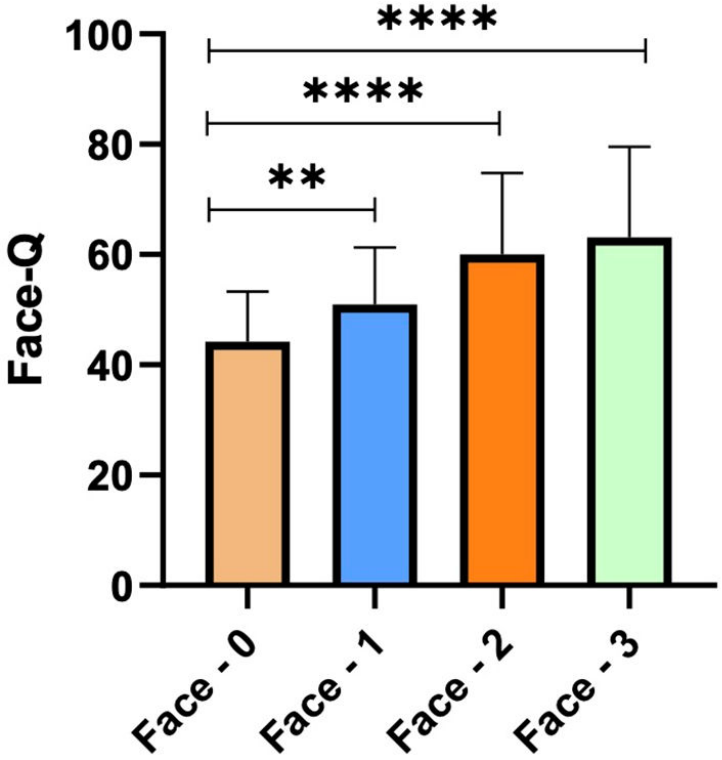

Figure 1: Face-Q Face appearance satisfaction scores at baseline (0), week 2 (1), 4(2) and 6(3). ** 0.007, **** <0.0001.

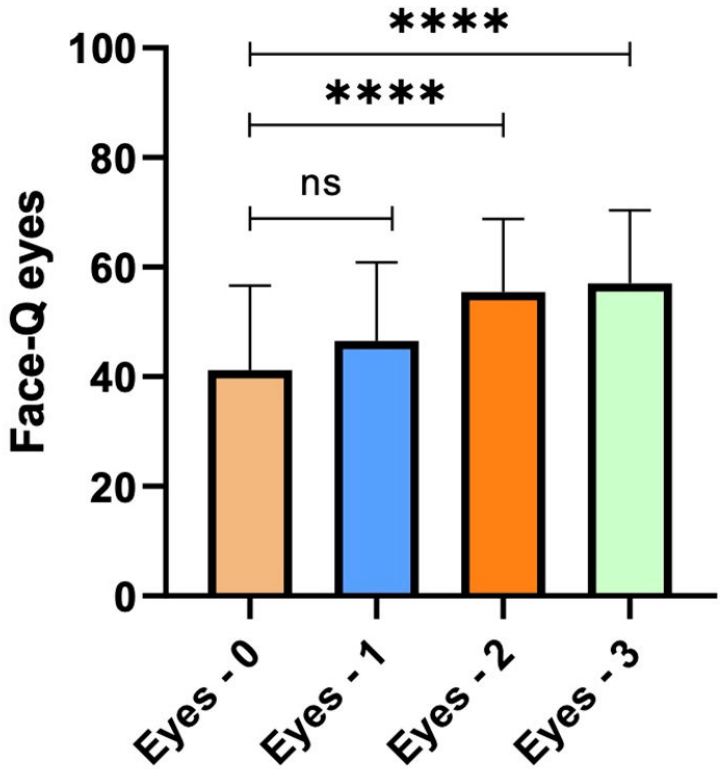

Figure 2: Face-Q Eyes appearance satisfaction scores at baseline (0), week 2 (1), 4(2) and 6(3). **** <0.0001.

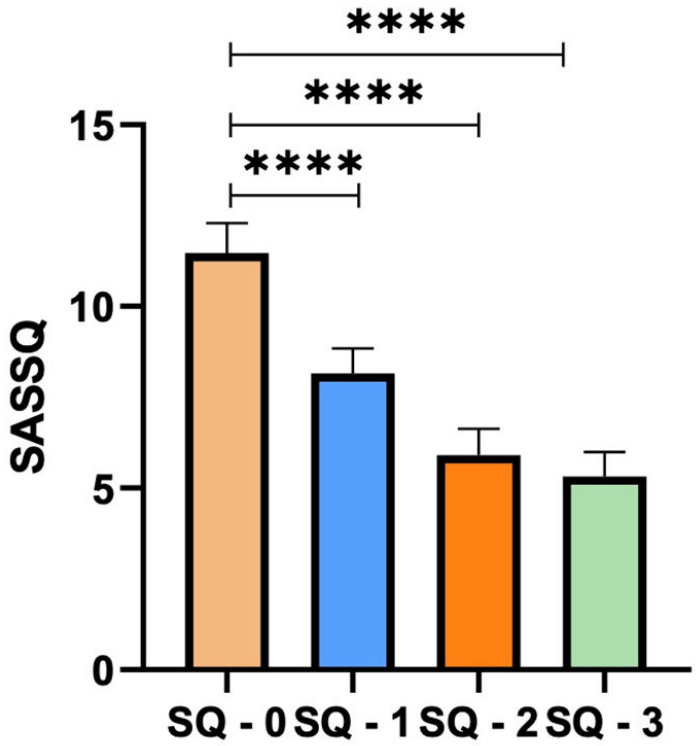

Figure 3: SASSQ (Scientific Assessment Scale of Skin Quality) scores at baseline (0), week 2 (1), 4(2) and 6(3). **** <0.0001.

Figure 4: Clinical photograph of a 29 years old female patient (A) at baseline. Note the erythema and roughness of the medial and central skin at the tear trough and fine lower lid wrinkles. After week six, these signs have satisfactorily improved (B).

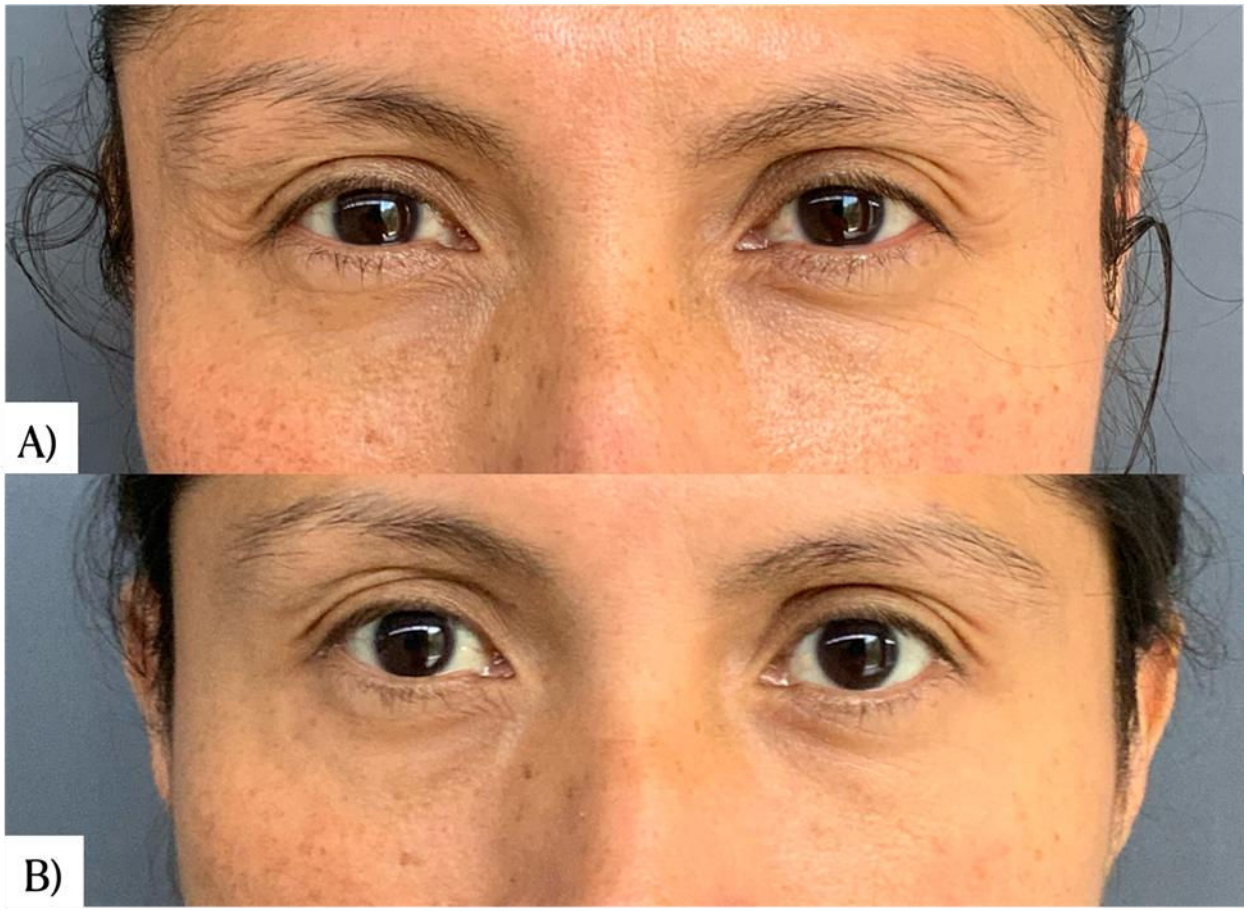

Figure 5: Clinical photograph of a 48 years old female patient (A) at baseline. Note the erythema and roughness of the medial and central skin at the tear trough, diffuse malar pigmentation and deep periocular and lower eyelid wrinkles. After week six, these signs have satisfactorily improved (B).

Discussion

This prospective, non-randomized study demonstrated an improvement in periocular skin quality after NCTF 135® HA injections using nanosoft needles in both men and women with a mean age of 40.5 years. Aging begins at birth and is a complex process in which different changes occur at the cellular and macroscopic levels. The effect of skin-boosters and mesotherapy in photoaging has been a topic of recent research, given their increasing popularity. Mesotherapy improves skin quality by applying a mixture of components applied to the dermis. Some *in-vitro* studies have reported increased production of type 1 collagen associated with hyaluronic acid, as well as an increase in the thickness and number of collagen fibers [23]. These findings suggest that in an ideal environment, senescent fibroblasts can improve their metabolic rate and be clinically reflected in skin quality.

Grand-Vincent, et al., demonstrated the efficacy of mesotherapy with NCTF 135® HA for the improvement of facial skin elasticity and elasticity [19]. Five injection sessions were performed on days 0, 15, 30, 60 and 90. In contrast, in a study by Fanian, et al., only three sessions were performed on days 0, 21 and 42 [24]. In our study, three mesotherapy sessions were conducted 15 days apart each and a final evaluation was performed at week six. Our findings are consistent with those of other studies, however, given the difference in treatment schemes, a comparison of the results should be performed with caution. This study demonstrated an improvement in periocular skin quality using two scales. The Face-Q evaluation scores showed an improvement in facial and eyelid appearance satisfaction. Moreover, the skin quality according to the SASSQ scale improved significantly at week six. For all, mesotherapy treatment improved the appearance of wrinkles, pigmentation, palpebral erythema and skin luminosity [19,23,25]. The use of the nanosoft needle allows for a painless application of the product and allows the product to reach the layer of the skin where the fibroblasts are located, which are the target cell that we want to stimulate. The only reported adverse effects were mild and associated with the product application procedure. Only one patient showed mild periocular erythema.

Conclusion

Mesotherapy with NCTF 135® HA improved periocular skin quality in the population studied in this study, which is of Hispanic origin. There is no established pattern of injection or patient follow-up. Further studies are needed to explore some undefined aspects, such as a larger sample size and a longer follow-up period.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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Acknowledgement

None

Data Availability Statement

Not applicable.

Ethical Statement

The project did not meet the definition of human subject research under the purview of the IRB according to federal regulations and therefore, was exempt.

Informed Consent Statement

Informed consent was taken for this study.

Authors' Contributions

All authors contributed equally to this paper.

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