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LETTERS TO THE EDITOR

Facial rejuvenation using a microneedle-based device with a revitalizing solution and free hyaluronic acid

To the Editor,

Treating delicate areas for facial rejuvenation is always a challenge as the procedure must be effective but not too aggressive because of side effects as pain. Here, we illustrated the preliminary results on the performance and tolerability of a protocol that combines an innovative device with a commercially available revitalizing solution in a real-life setting. This was a multicenter study, carried out by a panel of eight independent clinicians with different specialties in esthetic medicine.

Skin aging can largely be attributed to dermal fibroblast dysfunction and decrease in their biosynthetic activity. Injection treatments are the most performed procedures in the cosmetic dermatology practice.[1] Accurate injection is fundamental for optimum results, and therefore, standardized procedures would be beneficial.[2] The innovative technology (Fillmed Nanosoft^{tm}) is designed to inject the product with standardized intradermal delivery allowing reliability and accuracy of injections, reduced pain and minimal bruising, mainly in delicate areas. It is characterized by 3 Silicone Pyramid-shapes micro-needles (0.6 mm) and can be adapted to all syringes. A blue line determines the correct device orientation, which should be placed at 45° angle with respect to the skin (Figure S1). In our protocol, the device is combined with a poly-revitalizing solution (NCTF® 135HA) of 59 ingredients and free non-cross-linked hyaluronic acid with a well-known efficacy and safety profile.[2,3] After the injection, the development of papules, that last no longer than 24 h, is an indication of the correct positioning of the product into the dermis (Figures S2 and S3).

Clinicians retrospectively collected data on their patients, aged between 35 and 50 years, who were treated for the first time with the solution using the Nanosoft^{tm} device. Previous injections of the product with a standard needle were allowed. The treatment must envisage fullface including upper/lower eyelids. Each patient was handled with the same needle and one vial of product for the entire treatment and underwent three sessions every 30 days and a final evaluation after 90 days. We analyzed patient's profile at baseline, post-treatment changes, and side effects. Methods were detailed in the Appendix S1.

Overall, 33 records were collected and summarized in Table S1.

Figure S4 illustrates the magnitude of the post-treatment changes. Approximately two-thirds of subjects showed a remarkable/truly remarkable improvement in wrinkles and degree of elastosis (S4-A). The effect of the intervention on lower (S4-B) and upper (S4-C) eyelids was comparable ($p = 0.177$) and clearly perceivable in the short term (Figures 1 and 2). Patients and clinicians substantially agreed on the effect of the protocol on the overall skin quality: Almost 70% of them simultaneously declared to observe a remarkable/truly remarkable (64%) or moderate (6%) improvement. When in disagreement, the patient's perception of the intervention (S4-D) was significantly better compared to the clinician's judgment (S4-E) ($p = 0.037$).

The complications included moderate edema ($n = 3$) and/or erythema ($n = 11$); pain experience was observed in only 3 patients and was correlated to the product but not to the injection device. Almost all the side effects were transient and resolved within few hours (1 erythema and 2 pain experience), a day (2 edema, 10 erythema, and 1 pain experience), or 2 days (1 edema).

All patients declared being satisfied, and almost all of them (97% = 32/33) were willing to continue the treatment.

In conclusion, our preliminary results are encouraging in supporting the use of microneedle-based devices as patient-centered technology in the everyday clinical practice. The combined protocol is effective and safe for treating facial wrinkles and delicate areas like eyelids, and its performance seems to be independent from the skin patient's profile. Larger and controlled studies are necessary to provide the best evidence.

KEYWORDS

esthetic medicine, microneedles, nanosoft

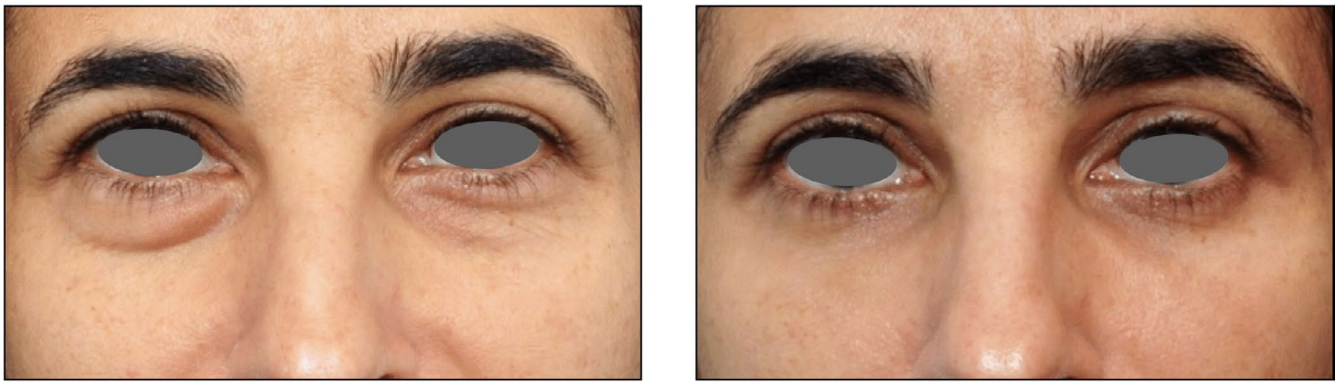

FIGURE 1 Before and after photographs at baseline (left) and at 90 days (right) showing eyelids wrinkle severity in a representative subject who underwent three monthly intradermal injections using an innovative microneedles medical device [Color figure can be viewed at wileyonlinelibrary.com]

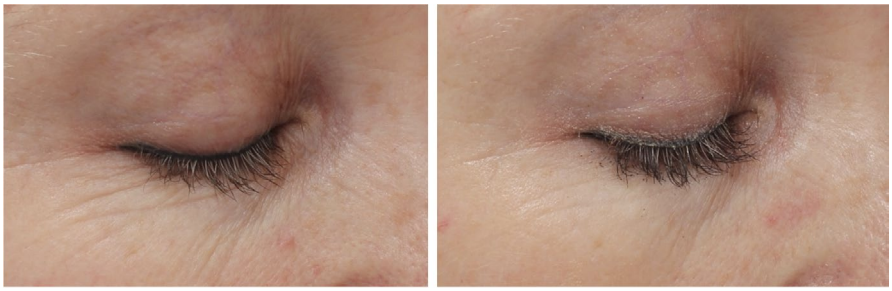

FIGURE 2 Before and after photographs at baseline (left) and at 90 days (right) showing eyelids wrinkle severity in a representative subject who underwent three monthly intradermal injections using an innovative microneedles medical device [Color figure can be viewed at wileyonlinelibrary.com]

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All listed authors have provided a significant contribution in the study by participating in design and conduct, data entering, data analysis, patient enrollment and assessment, and manuscript preparation.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

R.D. designed the research study, analyzed the data, and wrote the paper. R.D., A.G., E.V., M.B., F.M., L.L, A.R., and M.V. performed the research. All authors have read and approved the final manuscript.

ETHICAL APPROVAL

It's a multicentric study from different cities and doctors in Italy. The retrospective data analysis requires no ethical commitment.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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