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ORIGINAL ARTICLE

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Effects of a Topical Growth Factor Regimen Following Pre-elected Cosmetic Facial Injection Procedures

Mitchel P. Goldman MD,[a] Monica Boen MD,[a] Jennifer Deaver MD,[b] Elizabeth T. Makino BS CCRA MBS,[c] Rahul C. Mehta PhD[c]

[a]Cosmetic Laser Dermatology: A West Dermatology Company, San Diego, CA
[b]The Pearl Dermatology, Houston, TX
[c]Allergan Aesthetics, an AbbVie Company, Irvine, CA

ABSTRACT

Background: There are limited studies evaluating topical cosmetic skincare products following cosmetic facial injections.
Objective: An open-label study assessed a novel medical-grade topical skincare regimen following cosmetic facial injections.
Methods: The study enrolled 20 women with moderate to severe facial photodamage who used non–physician-dispensed skincare products and pre-elected to receive facial neuromodulator and hyaluronic acid (HA) dermal filler injections. All subjects continued regular skincare through week 4 after facial injection, then switched to the novel regimen (growth factor product, TNS Advanced+; day/night antioxidant serum system, Lumivive; HA-based hydrator, HA5; and basic skincare components) through week 16.
Results: At week 4, significant ($P \leq 0.05$) improvements from baseline were seen for multiple investigator-graded skin quality parameters, including overall photodamage, tactile roughness, and skin tone evenness, as well as fine and coarse lines/wrinkles. After switching to the novel regimen, additional significant improvements in overall skin quality and forehead, cheek, and perioral fine lines/wrinkles were observed at week 8 (all $P \leq 0.05$ vs week 4), which continued through week 16.
Conclusion: This study highlights the importance of topical skincare in conjunction with cosmetic facial injections to holistically optimize overall skin quality and appearance.

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INTRODUCTION

Cosmetic facial injections are one of the most common in-office procedures used to improve the signs of skin aging, including deep wrinkles and volume loss. Topical cosmetic skin products have also been shown to improve the appearance of fine and coarse lines/wrinkles, skin tone unevenness, and skin texture and radiance.[1,2] There are a wide range of topical anti-aging skin products available, including sunscreens,[2,3] antioxidants,[4] retinoids,[5,6] alpha hydroxy acids,[7,8] and various growth-factor containing products.[9,10] Facial rejuvenation products containing growth factors from a variety of sources, including plants, animals, and human tissues (including mesenchymal stem cells from adipose tissue, red deer umbilical cord lining, and human fibroblasts) have been developed.[11,12] Although products may provide benefits through differing mechanisms, those containing human fibroblast-derived growth factors have shown considerable effects on stimulating dermal extracellular matrix (ECM) components considered key to the reversal of signs of skin aging.[9,13]

Numerous studies have demonstrated the clinical efficacy of specific skincare products for facial rejuvenation, but data on the effects of skincare following cosmetic facial injection procedures are limited.[1,14-16] Therefore, we conducted an open-label study to assess the efficacy and tolerability of a novel medical-grade topical skincare regimen (including a growth factor–based product: TNS Advanced+) on female subjects with moderate to severe facial photodamage following pre-elected facial neuromodulator and hyaluronic acid (HA) dermal filler treatments. The physician-dispensed topical skincare regimen assessed in this study included basic skincare components (facial cleanser, moisturizer, and sunscreen; SkinMedica, Allergan, an AbbVie Company, Irvine, CA, USA), an HA-based rejuvenating hydrator, and an investigational antioxidant dual serum system in addition to TNS A+.

TNS A+, the novel hypoxic conditioned culture medium (HCCM)-based growth factor-based product used in the current study, was combined in a treatment regimen with a circadian-based antioxidant dual serum system (LumiVive® System [LVS]; SkinMedica; Allergan Aesthetics, an AbbVie Company, Irvine, CA, USA), designed to protect against environment skin aggressors during the day and protect against metabolic oxidation to support cellular recovery at night,[17,18] and an HA-based serum (HA5 Rejuvenating Hydrator; SkinMedica; Allergan Aesthetics, an AbbVie Company, Irvine, CA). The HA-based

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serum contains a proprietary blend of *Vitis vinifera* flower stem cell extract, marine microorganism polysaccharides, and a peptide complex to support the replenishment of endogenous levels of HA and epidermal homeostasis; 5 forms of HA are also included in the formulation to provide immediate hydrating effects on the skin.[1,19] Preclinical studies showed that this innovative combined regimen targets hallmarks of aging skin, offering skin rejuvenation benefits including effects on ECM components, skin repair, and improved barrier formation and function. The efficacy and safety of the TNS A+-containing regimen has also been demonstrated in a recent randomized, placebo-controlled study.

MATERIALS AND METHODS

Subjects

This study enrolled females aged ≥30 years of age with Fitzpatrick skin types I to VI who had moderate to severe overall facial photodamage (defined as a score of 4–9 on the modified Griffiths scale) and who had pre-elected to receive on-label facial neuromodulator or dermal filler injections. Eligible women were also required to have had prior experience with cosmetic facial injections (ie, had at least 1 facial injection of on- or off-label neuromodulator or filler in the past 2 years) and to be a current user of non–physician-dispensed brand skincare products (using only products that are available at drugstores or department stores) with established tolerance for at least 1 month. All subjects signed written informed consent forms and were willing to follow all study requirements and instructions. The principles of the 1975 Declaration of Helsinki were followed.

Individuals were excluded from the study for active symptoms of allergy, cold sore or warts, active psoriasis or eczema, rosacea, sunburn, open wounds, neurotic excoriations, excessive scarring, tattoos, or other skin conditions in the test areas that would interfere with study assessments; pre-existing or dormant dermatologic conditions such as psoriasis, atopic dermatitis, rosacea, or skin cancer; uncontrolled disease such as diabetes, hypertension, hyper- or hypothyroidism, active hepatitis, immune deficiency, or autoimmune disease; or any condition that would make study participation unsafe, such as conditions that require concurrent use of anticoagulants, bleeding coagulopathies, or photosensitivity diseases. Individuals were also excluded who had routinely used the following products or had procedures within the given time frame prior to study entry: chemical peel or microdermabrasion within 4 weeks; physician-dispensed skincare products within 1 month; Retin-A®, Retin-A Micro®, Renova®, Avita®, Tazorac®, Avage®, Differin®, or other similar prescription drugs or neuromodulator facial injection within the intended treatment area within 3 months; non-ablative laser or fractional laser resurfacing, skin tightening device, or dermal filler facial injections within the intended treatment area within 6 months; or Accutane® or another oral retinoid, or ablative procedures (ie, laser, chemical, cosmetic surgeries) within the past 12 months.

Study Design

This was a 16-week, multicenter, open-label study. All subjects received pre-elected cosmetic facial injections of dermal fillers and/or neuromodulators at baseline, performed only for FDA-approved on-label facial areas. Subjects then continued their regular, non–physician-dispensed skincare through week 4 to assess just the effect of the injections. At week 4, following cosmetic facial injection, subjects switched their skincare to a novel TNS A+ regimen through week 16 to assess the benefits of the new skincare regimen in addition to the effects seen from the injections. All subjects were instructed to use the novel topical regimen twice daily on facial skin. Assessments were made at baseline and weeks 4, 8, 12, and 16.

Outcome Measures

Investigators performed clinical grading of the full face at all study visits using the Griffiths modified 10-point scale, where lower scores indicate improvement (0 = none, 1-3 = mild, 4-6 = moderate, 7-9 = severe), for overall photodamage, tactile roughness, radiance, skin tone evenness, fine line/wrinkles, and coarse lines/wrinkles. Standardized digital photographs were taken of the subject's left, right, and frontal facial views using the Canfield Vectra XT 3D and Canfield VISIA CR cameras or Canfield Complexion Analysis camera system (Canfield Scientific Inc., Fairfield, NJ, USA). In addition, subjects were asked to complete multiple questionnaires regarding self-perceived efficacy, product attributes, and overall satisfaction at baseline and weeks 8, 12, and 16; tolerability was assessed using subject-reported adverse events.

Statistical Analysis

The intent-to-treat (ITT) population included all subjects who received treatment and participated in at least 1 post-baseline assessment. Number of subjects and mean of scores/values were provided at all applicable time points for all efficacy grading parameters. Mean change in efficacy assessments were compared as follows: week 4 vs baseline, and weeks 8, 12, and 16 vs week 4 (the start of novel skincare regimen use), using a paired *t* test. Significance was defined as $P \leq 0.05$.

RESULTS

Subject Demographics, Baseline Characteristics, and Injectable Treatments

This study enrolled 20 women aged 34 to 65 years of age (mean age, 50 years) with Fitzpatrick skin types II to V (Table 1). A total of 18 subjects completed the study; 1 subject withdrew between weeks 4 and 8 because of availability issues, and 1 discontinued between weeks 8 and 12 for an adverse event (see "Safety and Tolerability"). At baseline, all subjects received injections of neuromodulator (Botox®) and either 1 (n = 4) or 2 (n = 16) dermal fillers (including Juvéderm® Voluma XC, Volbella XC, Ultra XC, Ultra Plus XC, and Vollure XC; and Restylane-L®/Restylane® Silk).

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TABLE 1.

Subject Demographics and Baseline Characteristics	
Subject enrolled	**20**
Gender, female, n (%)	20 (100)
Age, years	
Mean	50
Range	34–65
Ethnicity, n (%)	
Caucasian	14 (70)
Hispanic	6 (30)
Fitzpatrick skin type, n (%)	
I	0
II	9 (45)
III	5 (25)
IV	5 (25)
V	1 (5)
VI	0

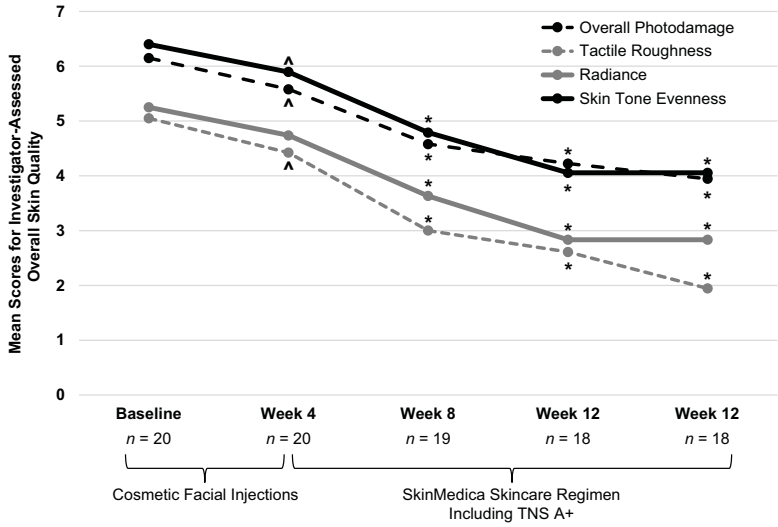
Neuromodulator injections were performed for crow's feet (n = 19), glabellar (n = 19), and forehead (n = 18) lines; dermal fillers were injected in the cheeks, nasolabial folds, marionette lines, lips, perioral oral commissures, chin, and midface. Most commonly used non–physician-dispensed skincare products used at baseline (and through week 4) included Neutrogena (n = 16), Olay (n = 7), No7 (n = 4), and Aveeno (n = 3).

Efficacy

At week 4, significant ($P \leq 0.05$) improvements from baseline were seen for multiple investigator-graded skin quality parameters, including overall photodamage, tactile roughness, and skin tone evenness, as well as fine and coarse lines/wrinkles, as a result of the baseline cosmetic facial injections with continued use of usual non–physician-dispensed skincare regimens (Figures 1 and 2). With the switch to the SkinMedica skincare regimen including TNS A+ at week 4, additional significant improvements in overall skin quality ($P \leq 0.05$ vs week 4) were observed after 4 weeks of use (ie, study week 8) and continuing through 12 weeks of use (ie, study week 16; Figure 1). Across all skin quality assessments, the addition of the SkinMedica skincare regimen with TNS A+ at week 4 resulted in >1-point improvements by week 8. The improvement in tactile roughness was the most profound, with a nearly 2.5-point decrease from week 4 to week 16. The SkinMedica regimen also provided additional significant improvements in forehead, cheek, and perioral fine lines and wrinkles after 4 weeks of use (Figure 2A) and maintained original (week 4) improvement in coarse lines and wrinkles (Figure 2B). Periocular fine lines and wrinkles were significantly reduced following cosmetic injections by week 4; these improvements were maintained by the SkinMedica skincare regimen for the remainder of the study (Figure 2A). Representative photographs of 2 subjects in the study are shown in Figure 3, demonstrating the improvements in facial appearance obtained from baseline to week 4 as a result of the cosmetic facial injections and the further enhancement of benefits observed over time (weeks 8 and 16) with the addition of the SkinMedica skincare regimen containing TNS A+.

Subject self-assessment questionnaires revealed that 75% of subjects at baseline thought their current non–physician-

FIGURE 1. Investigator-Graded Assessment of Overall Skin Quality. Overall photodamage, tactile roughness, radiance, and skin tone evenness were graded on a scale from 0 to 9, where lower scores indicate improvement.



^Statistically significant compared with baseline (all $P \leq 0.05$; paired t test). *Statistically significant compared with week 4 (all $P \leq 0.002$; paired t test).

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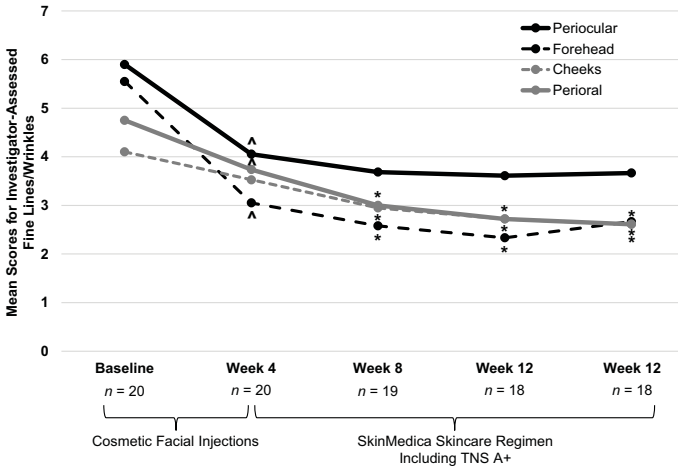
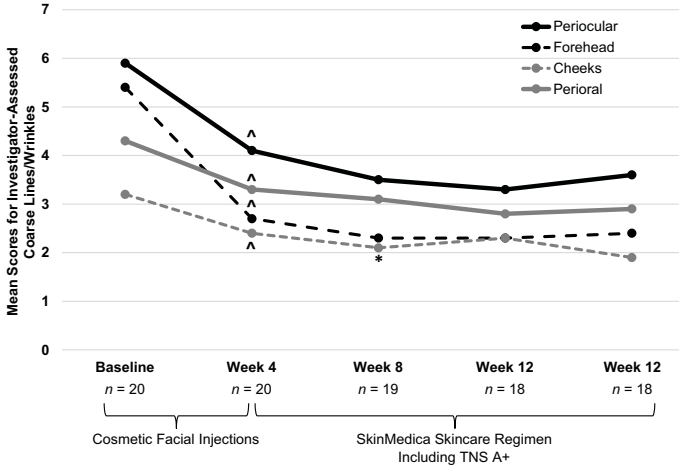
FIGURE 2. Investigator-Graded Assessment of Fine (A) and Coarse (B) Lines/Wrinkles. Graded on a scale from 0 to 9, where lower scores indicate improvement, for periocular, forehead, cheek, and perioral regions.

(A)



^Statistically significant compared to Baseline ($P \leq 0.005$; paired *t*-test)
*Statistically significant compared to Week 4 ($P \leq 0.03$; paired *t*-test)

(B)



^Statistically significant compared to Baseline ($P \leq 0.009$; paired *t*-test)
*Statistically significant compared to Week 4 ($P \leq 0.05$; paired *t*-test)

dispensed skincare regimen provided some added benefit on top of current injectable therapies. At weeks 12 and 16, there was a 1-point improvement in mean score (from 7 at baseline to 8, on a scale from 0 to 10) regarding the likelihood of continuing to use physician-dispensed skincare products. Half of subjects responded that they expected to see improvements in the appearance of their skin using the study skincare regimen within 2 weeks (10%, 1 week; 40%, 2 weeks); 69% of subjects reported first starting to notice improvements in the appearance of their skin within that 2-week time frame. Overall subject satisfaction with the regimen was 84% at week 8 and 94% at week 16.

Responses to specific questions concerning subject-perceived efficacy of the study's skincare regimen are shown in Figure 4; this skincare regimen was highly rated by most subjects across questions. Responses indicate a holistic benefit of the skincare regimen on improving overall health and look of the skin, subjects' confidence and self-esteem, feelings of attractiveness, and receiving compliments on their skin. Notably, 90% to 100% of subjects responded that the regimen "makes my skin look and feel better than any previous skincare regimen" and "is something I would recommend to my friends/family."The tested regimen was also highly rated for texture and application: 89% to 95% of subjects responded that the products were convenient to use as a daily skincare regimen, layered well together, and felt like they were formulated to work well together; 100% of subjects agreed that the products were simple to use and easy to apply.

FIGURE 3. Skin appearance over the 16-week study in subjects treated at week 4 with a SkinMedica physician-dispensed daily skincare regimen including TNS A+ in (A) a female Caucasian subject, 45 years of age, Fitzpatrick skin type III, treated postbaseline with a Botox, 50 units total (forehead, glabellar, and crow's feet); Juvéderm Ultra XC, 1 cc (nasolabial folds and marionette lines); Restylane, 1 cc (midface enhancement), and (B) a female Caucasian subject, 40 years of age, Fitzpatrick skin type II, treated postbaseline with Botox, 50 units total (forehead, glabellar, and crow's feet); Juvéderm Ultra XC, 1 cc (nasolabial folds); Restylane, 1 cc (midface enhancement and marionette lines).

(A)

(B)

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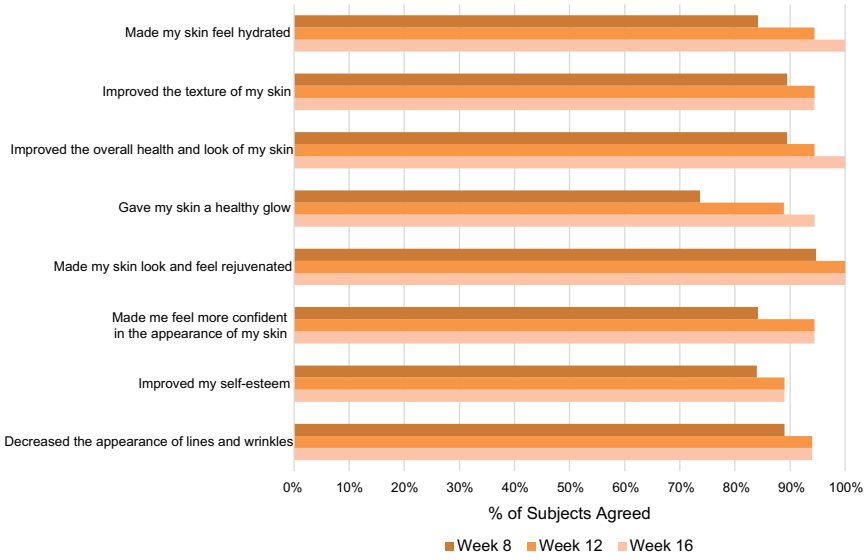
FIGURE 4. Subject-perceived efficacy of a SkinMedica physician-dispensed skincare regimen containing TNS A+ applied beginning 4 weeks after cosmetic facial injection.



Safety and Tolerability

The novel skincare regimen containing TNS A+ was generally well tolerated over 12 weeks of use in this study. No serious adverse events were reported. A total of 4 subjects experienced mild adverse events considered possibly product related: there were 2 subjects with resolved acne (1 with a history of hormonal acne and 1 who reported breakouts when her "makeup gets old"), 1 with ongoing acne, and 1 subject with contact dermatitis that resolved without sequelae upon discontinuation of the regimen (resulting in early discontinuation from the study).

DISCUSSION

This study further extends the clinical research base for the efficacy and tolerability of a novel physician-dispensed skincare regimen including TNS A+, which uses next-generation growth factor technology of conditioned media from human neonatal fibroblasts cultured under hypoxic conditions (HCCM) to mimic the embryonic environment. This next generation of growth factors can be used in topical skin products that promote skin rejuvenation by supporting stem cell proliferation and differentiation in addition to enhanced tissue function and regulation.[11] The efficacy results of the current study are consistent with those reported previously in a randomized controlled trial of TNS A+, and build on the benefits reported in clinical studies of a prior formulation of neonatal fibroblast-derived growth factors (TNS Essential Serum).[9,20,21] Other components of the regimen used in the current study have also demonstrated clinical efficacy when tested individually in prior studies. The dual (day/night) antioxidant serum system (LVS) was shown to significantly reduce pollution-induced skin damage in 3 randomized controlled trials.[17,18] In addition, the HA5 Rejuvenating Hydrator has previously been shown in open-label studies to provide significant improvements in fine lines/wrinkles and tactile roughness, and increase intrinsic skin moisture content, both immediately after use and over time with 8 weeks of twice-daily application.[1,19]

The current study on the combined skincare regimen, including a growth factor blend (TNS A+), antioxidant serum (LVS), and HA-based hydrating serum (HA5), provides important new information on the clinical benefits of this regimen in people undergoing cosmetic facial injections for facial rejuvenation. In our study, switching to the physician-dispensed skincare regimen at week 4 following cosmetic facial injections provided additional benefits to investigator-assessed skin quality and appearance, resulting in significantly better overall improvement compared with regular use of non–physician-dispensed skincare, which was continued for the first 4 weeks following injection. These benefits were seen in a study population who were already regular users of non–physician-dispensed skincare products prior to study enrollment, thus further emphasizing the added value of high-quality, clinically proven skincare regimens to optimize facial appearance and skin quality. Given the expectation that the primary benefits from facial cosmetic injections would be apparent within the first 4 weeks after the procedure, our data also indicate significant observable improvements in overall photodamage, tactile roughness, radiance, and skin tone evenness beyond those afforded by the cosmetic injections themselves.

Thus, the use of effective, physician-dispensed skincare products in combination with cosmetic facial injections has the potential to improve the overall aesthetic appearance resulting from facial rejuvenation procedures and to increase subject satisfaction

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with their appearance. In our study, overall subject satisfaction with the novel skincare regimen was high, and the majority of subjects (69%) reported noticing the effects of the skincare regimen within the first 2 weeks of its use. This exceeded the subjects' expectations, as only 50% indicated on initial questionnaires that they expected to see improvements within 2 weeks. Providing patients receiving cosmetic facial injections with topical physician-dispensed skincare products offers them the opportunity to continue to improve the quality of their skin at home, representing a continuation and augmentation of the benefits they can expect to achieve from the injectable treatments. In fact, the regular use of physician-dispensed skincare may have synergistic effects with cosmetic injections for improving a patient's overall aesthetic appearance, as the different treatment modalities have their specific targets: ie, neuromodulators affect the facial muscles, stopping dynamic wrinkles from occurring, while fillers provide tissue volume beneath the surface, and effective skincare regimens improve the quality of the overall facial surface.

This study was limited by its open-label, non-blinded design with a small number of subjects. The decision not to conduct a split-face study, in this case, was based on concerns that the products applied to half of the face may migrate to the other side and, more importantly, growth factors and antioxidants in the physician-dispensed regimen may have effects more generalized to the entire face rather than localized to the site of application.

CONCLUSION

In conclusion, the results of this study highlight the importance of high-quality, effective topical skincare products in conjunction with cosmetic facial injections to optimize overall skin quality and appearance. Effects of the novel regimen tested in this study were observed within 2 weeks of use, provided benefits beyond those obtained from previous regular use of non–physician-dispensed skincare products, and had a high degree of patient satisfaction.

DISCLOSURES

Allergan Aesthetics, an AbbVie Company, funded this study and participated in the study design, research, analysis, data collection, interpretation of data, reviewing, and approval of the publication. All authors had access to relevant data and participated in the drafting, review, and approval of this publication. No honoraria or payments were made for authorship. Monica Boen has no disclosures. Jennifer Deaver performs research studies and/or serves as a consultant for Allergan Aesthetics, an AbbVie Company, Galderma, Merz Therapeutics, Colorescience, and Lumenis. Mitchel P. Goldman performs research studies and consulting for Allergan Aesthetics, an AbbVie Company, Galderma, Merz Therapeutics, CellResearch Corp, Topix Pharmaceuticals, Inc., Lumenis, and Solta Medical. Elizabeth T. Makino and Rahul C. Mehta are employees of AbbVie and may hold AbbVie stock.

Data Sharing: AbbVie is committed to responsible data sharing regarding the clinical trials we sponsor. This includes access to anonymized, individual, and trial-level data (analysis data sets), as well as other information (eg, protocols and Clinical Study Reports or analysis plans), as long as the trials are not part of an ongoing or planned regulatory submission. This includes requests for clinical trial data for unlicensed products and indications.

This clinical trial data can be requested by any qualified researchers who engage in rigorous, independent scientific research, and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). Data requests can be submitted at any time after approval in the United States and Europe and after acceptance of this manuscript for publication. The data will be accessible for 12 months, with possible extensions considered. For more information on the process, or to submit a request, visit the following link: https://www.abbvie.com/our-science/clinical-trials/clinical-trials-data-and-information-sharing/data-and-information-sharing-with-qualified-researchers.html

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AUTHOR CORRESPONDENCE

Mitchel P. Goldman MD
E-mail:..... mgoldman@CLderm.com