

Open-label study assessing the efficacy and tolerability of topical skincare and sun protection products following intense pulsed light treatment

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Summary

Background: The visible signs of photodamage can be improved by intense pulsed light (IPL). Active ingredients in cosmeceuticals also have effects on skin quality and pigmentation, and can camouflage post-treatment side effects. Combination therapies utilizing different treatment modalities have been shown to optimize clinical outcomes for skin rejuvenation and patient satisfaction.

Aim: To evaluate the efficacy of a combination of IPL with a daily topical skincare and sunscreen regimen for the treatment of facial photodamage and for the improvement of IPL treatment tolerability.

Patients/Methods: Twenty female subjects with moderate-to-severe facial photodamage, with past history of IPL treatments, received one IPL treatment followed by the use of the topical skincare regimen for 8 weeks. An investigator assessed facial photodamage and hyperpigmentation at baseline, week 4, and week 8, and postprocedure erythema. Subject questionnaires were also administered at each visit.

Results: Compared to baseline, there was a significant improvement in photodamage and hyperpigmentation of bare facial skin. The application of the skincare regimen resulted in a significant reduction in post-IPL erythema, stinging/burning, and itching. The majority of patients were very satisfied or satisfied and felt the treatment regimen improved various aspects of skin quality and the tolerability of the procedure.

Conclusions: The addition of a topical skincare regimen after IPL treatment to the face resulted in significant improvements in facial photodamage and pigmentation, decreased post-treatment side effects, and increased tolerability.

KEYWORDS

cosmeceutical, intense pulsed light, sunscreens

1 | INTRODUCTION

Intense pulsed light (IPL) treatments were introduced in 1990s as a safe and effective treatment for photoaged skin.^{1,2} Contrary to lasers, which concentrate light at a monochrome frequency, IPL treatments deliver noncoherent light at a broader range of wavelengths.³ With

this increased range, IPL treatments have greater chance of targeting different chromophores in the tissue, such as melanin, hemoglobin, and water.⁴ Because of its effect on pigment, vasculature, and dermal collagen, IPL has been demonstrated to improve many of the signs of photoaging, which include lentigines, persistent hyperpigmentation, roughness, telangiectasia, wrinkling, elastosis, and inelasticity.⁵⁻⁷

Product skincare lines have also been shown to target the unwanted appearance of photoaging and protect from further damage, and can be beneficial after the application of light-based therapies to the skin. These products can function by blocking ultraviolet (UV) radiation or by mitigating some of the effects of extrinsic and intrinsic sources of aging.⁸ By far the most important component in a skincare regimen is a sunscreen, which provides coverage against UVA, UVB, and even infrared (IR) radiation.⁹ Additionally, sunscreens that contain active ingredients that function as antioxidants or decrease inflammation and melanin production further protect the skin from radiation and enhance the effects of cosmetic treatments.¹⁰ Finally, skincare products can make cosmetic treatments more tolerable by camouflaging post-treatments side effects like erythema, thereby improving the patient experience.

In this study, we evaluate the effect of a product regimen after an IPL treatment in improving facial skin and creating a better experience for patients who have had prior IPL treatments without topical regimens. The first product was a broad-spectrum physical sunscreen with antioxidants, an anti-inflammatory agent, and tint for cosmetic correction, while the second product was a mineral-based sunscreen powder.

2 | MATERIALS AND METHODS

The study was approved by a centralized Institutional Review Board (Chesapeake Associates IRB, Inc., Columbia, MD, USA) and conducted in accordance with Good Clinical Practices conforming to the ethical guidelines of the 1975 Declaration of Helsinki.

2.1 | Participants

Twenty subjects were enrolled. Subjects were eligible female patients 18-65 years of age with Fitzpatrick skin phototype I-IV with moderate-to-severe facial hyperpigmentation, defined as a grade of 4-9 on the Investigator's Overall Hyperpigmentation scale. Patients must have undergone a minimum of 2 IPL treatments to the full face in the prior 24 months and must have been willing to continue use of regular facial products without the addition of any new products aside from the study materials. Written informed consent was obtained from all participants before study entry.

Exclusion criteria included subjects with known allergies or sensitivities to the ingredients in any of the study products; open wounds, excessively sensitive skin, neurotic excoriations, dermatitis or inflammatory rosacea in the treatment area; active psoriasis, eczema, sunburn, excessive scarring, tattoos, or other skin condition on the facial area that would interfere with study assessments; current skin cancers or suspicious lesions on the treatment area; use of systemic retinoids within 60 days prior to the study; ablative laser resurfacing within 6 months preceding the study; facial peel or microdermabrasion of the face within 30 days prior to enrollment in the study; uncontrolled disease such as diabetes, hypertension,

hyper- or hypo-thyroidism, active hepatitis, immune deficiency, or autoimmune disease; concurrent therapy that, in the investigator's opinion, would interfere with evaluation of the efficacy or safety of the medication; a female subject who is pregnant, nursing an infant, or planning a pregnancy during the study; and participation within 30 days prior to the start of the study in a drug or other investigational research study.

2.2 | Intervention

On the first visit, patients received a full face treatment with IPL (Lumenis One system and Lumenis One M22™, Lumenis Inc., San Jose, CA, USA) using a cut-off filter of 560 nm, a double-pulsed technique with a 3 or 3.5 ms pulse duration for both pulses, a pulse delay ranging from 20 to 30 ms, and fluence range of 17-19 J/cm². After the IPL treatment, a study staff member applied a tinted broad-spectrum SPF 50 physical sunscreen (Colorescience Even-Up, Colorescience Inc., Carlsbad, CA, USA) to the patient's face. This was followed by the application of a layer of a SPF 50 mineral powder, in either a fair, tan, or deep shade (Colorescience Sunforgettable SPF50 brush, Colorescience Inc.). Key active ingredients are listed in Table 1. For the duration of the study (8 weeks), patients were instructed to apply a single pump of the mineral sunscreen every morning in a thin layer to the entire face after performing their regular skincare routine. Foundation and other cosmetics were applied after the sunscreen. Following the application of any cosmetics, subjects were asked to apply a layer of the mineral powder sunscreen to the full face and re-apply every 1-2 hours. Patients returned for follow-up visits at weeks 4 and 8 post-treatment. VECTRA 3D photography (Canfield Scientific Inc., Parsippany, NJ, USA) was performed at baseline pre-IPL, baseline post-IPL but before product application, post-IPL after product application, and then at weeks 4 and 8. A frontal, left oblique, right oblique, left lateral, and right lateral view were captured at each session.

2.3 | Study endpoints

2.3.1 | Primary endpoint

The investigator assessed overall hyperpigmentation and photo-damage on a 10-point scale (where 0 = none, 1-3 = mild,

TABLE 1 List of key active ingredients

Ingredient	Function
Titanium dioxide and zinc oxide	Sunscreen actives, UV protection
Thermus thermophilus ferment	Photoprotection, improve skin barrier, antioxidant
Tocopheryl phosphate	Antioxidant, skin calming
Bidens pilosa extract	Antioxidant, decrease melanin synthesis
Acetylated Rheum rhaponticum root extract	Tyrosinase inhibition, decrease melanin transfer

4-6 = moderate, 7-9 = severe) prior to treatment at baseline, and at weeks 4 and 8. The investigator also assessed for the global improvement in overall hyperpigmentation and photodamage at week 4 and 8 (where 0 = no change or worsening, 1 = 25% improvement, 2 = 50% improvement, 3 = 75% improvement, and 4 = over 95% improvement).

2.3.2 | Secondary endpoints

Erythema of the treatment area was measured by the investigator on a 4-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe) at baseline pre-IPL, post-IPL but before product application, and post-IPL after product application.

2.3.3 | Subject assessments

Subject burning/stinging and itching were assessed on a 4-point scale after IPL prior to product, and after IPL postproduct. Patients were also given a baseline questionnaire after IPL prior to product, and after IPL postproduct, where questions were answered as “not at all,” “somewhat,” “very,” and “extremely” (Table 2). At weeks 4 and 8, subjects assessed overall improvement and satisfaction with the treatment regimen. Patient overall improvement in skin condition was rated as 0 (no change or worsening), 1 (25% improvement), 2 (50% improvement), 3 (75% improvement), and 4 (over 95% improvement); patient satisfaction with the treatment regimen was rated as 1 (excellent/very satisfied), 2 (good/moderately satisfied), 3 (fair, slightly satisfied), or 4 (poor/not satisfied at all). Finally, at weeks 4 and 8, the experience with the treatment regimen (IPL and skincare products) was evaluated through 13 questions, answered as “agree strongly,” “agree,” “disagree,” and “disagree strongly.”

2.4 | Statistical analyses

Statistical analyses were conducted on an intent-to-treat basis (ie, all randomized subjects with at least 1 follow-up visit were included). All statistical tests utilized ANOVA or Student's *t* test interpreted at a 5% significance level. Continuous variables are reported as mean \pm SD (range).

TABLE 2 Subject baseline questionnaire

Upon seeing yourself in the handheld mirror and WITHOUT the topical products applied, how self-conscious would you be to go straight out in public?

Upon seeing yourself in the handheld mirror post IPL treatment and WITH the topical products applied are you now less self-conscious to go straight out in public?

Does your skin feel more comfortable post application of the topical products?

Do you feel the application of the topical products made your skin look immediately better?

3 | RESULTS

Twenty (20) female patients aged 42-62 (mean \pm SD age of 46.6 ± 8.6) presenting with a mean \pm SD score of 5 ± 0.86 for facial hyperpigmentation and a mean \pm SD score of 5.6 ± 1.4 for facial photodamage were enrolled. Nineteen patients completed the 4-week follow-up and eighteen the 8-week follow-up; two patients were lost to follow-up.

3.1 | Primary endpoints

The mean investigator score for hyperpigmentation and photodamage significantly improved from baseline at weeks 4 and 8, with $P < .01$ for all time points (Figures 1-4). Global improvement in hyperpigmentation was rated as a mean \pm SD of 1.95 ± 0.9 at week 4 and 1.44 ± 1.0 at week 8. For photodamage, the mean \pm SD global improvement score was 1.9 ± 0.9 at week 4 and 2 ± 0.9 at week 8.

3.2 | Secondary endpoints

There was a significant increase in investigator-assessed erythema from baseline to after IPL, prior to product ($P < .01$), and then a significant decrease in erythema with product application after IPL ($P < .01$) (Figures 5 and 6). There was no difference in erythema from baseline to post-IPL, postproduct application.

3.3 | Subject questionnaires

Most patients rated their overall satisfaction with the treatment as either “good” or “excellent” (66.7% at week 4 and 64.7% at week 8), and their overall improvement as either “moderate,” “marked,” or “complete” (55.6% at week 4 and 76.5% at week 8).

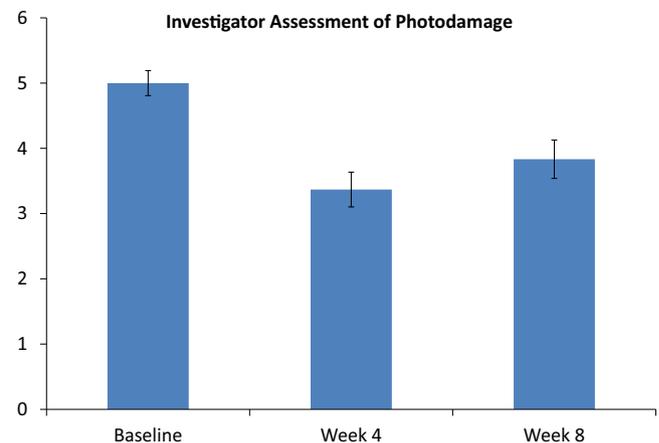


FIGURE 1 Mean investigator-assessed photodamage score. There was a significant improvement in scores from baseline at weeks 4 and 8

There was a trend toward a significant decrease in burning/stinging and itching with the application of product after IPL ($P = .09$ and $.07$, respectively). The subject baseline questionnaire showed that

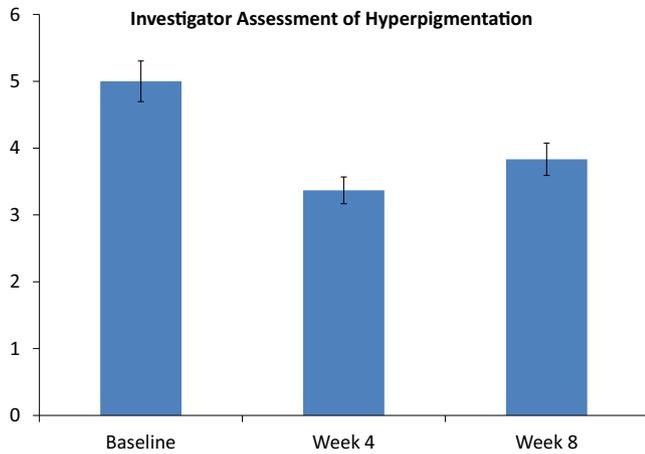


FIGURE 2 Mean investigator-assessed hyperpigmentation score. There was a significant improvement in scores from baseline at weeks 4 and 8

the majority of patients (55%) were at least somewhat self-conscious to go out in public after IPL without any product. With the application of product, 75% stated that they felt less self-conscious to go out in public. Ninety (90) percent felt product application made their skin feel more comfortable, and 100% felt product application made their skin look immediately better.

The 13-question questionnaire revealed that at all time points, at least 75% of patients either “strongly agreed” or “agreed” that the treatment regimen helped fade brown spots, improved evenness and skin tone, brightened darker patches, increased radiance, made the skin look brighter and healthier, and decrease the appearance of uneven skin tone. At least 70% of patients either “strongly agreed” or “agreed” that the treatment regimen improved overall skin tone, improved the overall skin condition and appearance, and increased self-confidence. Seventy-eight (78%) of patients at week 4, and 65% at week 7 felt that the regimen made the skin look more youthful. Finally, at least 70% of patient would continue using the treatment regimen and would recommend the regimen to others.

The treatment and skincare regimen were well tolerated, as none of the patients experienced complications or adverse events relating to IPL or to the use of the skincare regimen.



FIGURE 3 A patient at baseline prior to IPL (A-B), week 4 (C-D), and week 8 (E-F)



FIGURE 4 A patient at baseline prior to intense pulse light (IPL) (A-B), week 4 (C-D), and week 8 (E-F)

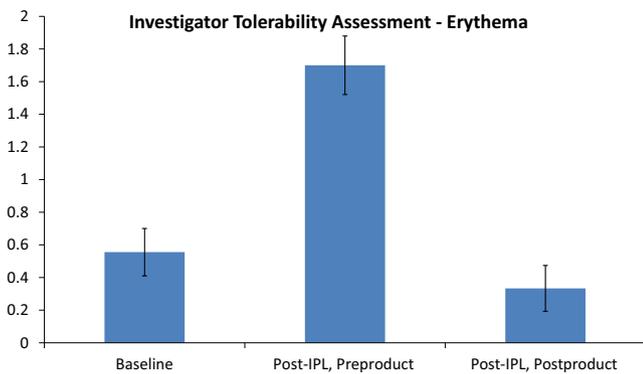


FIGURE 5 Mean investigator-assessed erythema. There was a significant increase in erythema after intense pulse light (IPL) treatment, and a significant decrease in erythema after product application

4 | DISCUSSION

Intense pulsed light, in conjunction with the use of skincare and sun protection products for 8 weeks, significantly improved the appearance of facial photodamage and hyperpigmentation in our trial. Multiple studies have established the efficacy of IPL alone for the treatment of the signs of photoaging. By far the largest review was conducted by Ping et al, who analyzed 2534 patients who received

at least 3 IPL treatments over a span of 12 years.¹¹ Response rates for photodamage were found to be between 88.2 and 96.4%. Bitter et al showed that after a series of four or more sessions, more than 90% of 40 patients showed visible improvement in the signs of photoaging.⁵ A retrospective review of 80 patients demonstrated that 79% still had an improvement in facial pigmentation 4 years after a series of 3 IPL treatments.⁶

The topical products used in this study have been previously shown to independently improve skin quality. Patients in our trial also benefitted from the effects of the skincare regimen. Roberts et al examined the effect of the same line of products on facial dyschromia and fine lines associated with photodamage. Twenty-eight patients used the regimen for a total of 12 weeks. The regimen not only camouflaged hyperpigmentation after 1 application, but its continued use enhanced bare skin, shown as significant improvements in pigmentation, smoothness, fine lines, pore size, and overall skin appearance.¹² This was thought to be due to the various active ingredients in the products, which in total can block UV and infrared radiation, inhibit steps in melanogenesis, increase cell turnover, and reduce inflammation.

The combination of IPL with the skincare regimen used in this trial likely has synergistic effects on photodamage. Other studies have shown that topical products, either prescription strength or as actives in over the counter products, can enhance clinical results.

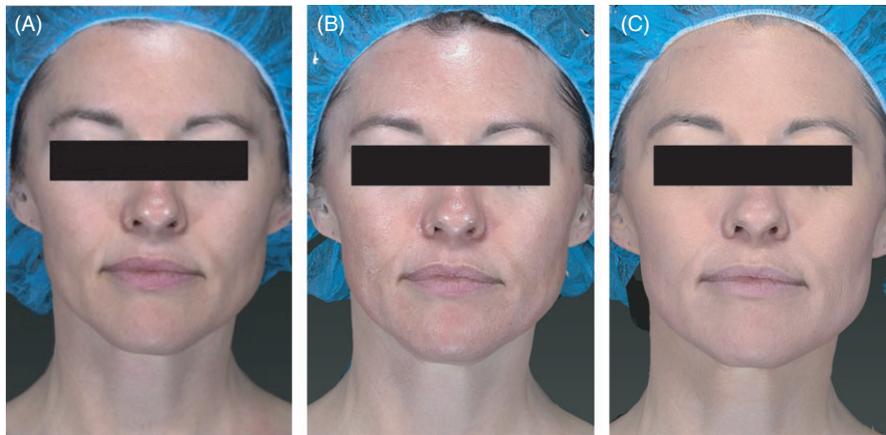


FIGURE 6 A patient at baseline (A), after intense pulse light (IPL), prior to product (B), and after IPL, after product application (C)

For melasma, the combination of IPL and triple combination (TC) cream (fluocinolone, hydroquinone, and tretinoin) has been shown to be superior to IPL or TC cream alone.^{13,14} Hydroquinone and tretinoin can also enhance the effects of IPL on hyperpigmentation and skin laxity.¹⁵ Garcia et al showed that adding an active skincare product containing niacin (NIA 24, Niadyne, Inc, Research Triangle Park, NC) after IPL treatments resulted in an accelerated overall rate of improvement in skin characteristics (wrinkles, fine lines, hyperpigmentation) when compared to IPL alone.¹⁶ Finally, Freedman demonstrated that compared to IPL alone or antioxidant use alone, using a pneumatically applied polyphenolic antioxidant solution before IPL resulted in clinical improvement in fine lines, texture, pore size, overall skin appearance, and histological improvement in skin architecture.¹⁷

Aside from impacting skin quality, topical products can make IPL treatment more tolerable to patients. In our study, the skin product regimen significantly reduced erythema, burning/stinging, and itching after IPL. It has been shown that phenolic antioxidants can decrease the incidence of erythema and the concentration of lipid peroxidase after IPL.¹⁷ Narurkar et al studied a five-product system (Clinique Medical Optimizing Regimen; Allergan, Inc., Irvine, CA, USA) that contained ingredients that were anti-inflammatory, antioxidants, prevented hyperpigmentation, and protected against UVA and UVB.¹⁸ The degree of erythema, edema, and burning/stinging returned to preprocedure scores at day 2 with the use of the regimen. However, four of 48 patients (27 with IPL and 21 with fractional nonablative laser) developed adverse reactions (acne and rash). None of the patients in our study developed adverse events.

Importantly, patient questionnaires revealed the topical regimen improved the ability of patients to return to their daily lives by making them less self-conscious and their skin more comfortable, thereby optimizing patient outcomes. Better results and perceived experience may translate to higher patient satisfaction, resulting in increased patient retention. This is the first kind of study to intricately measure patient experience with IPL and a topical regimen.

Limitations to this study include the small sample size, lack of blinding and randomization, and the absence of a control group.

5 | CONCLUSION

Intense pulsed light in conjunction with a topical regimen containing active ingredients was safe and effective in improving facial pigmentation and photodamage, decreasing post-treatment side effects, and enhancing tolerability.

DISCLOSURES

IT Jones and I Guiha have no disclosures. SG Fabi is a consultant for Allergan, Merz, Galderma, Alastin, Revance, and Thermi. SG Fabi has served as an investigator for Allergan, Merz, Galderma, Alastin, Revance, and Colorscience and is on the Speakers Bureau for Allergan, Merz, and Galderma.

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