doi:10.36849/JDD.8835

Neurocosmetic Post-Procedure Cream for Reducing Patient Discomfort and Enhancing Lower Eyelid Recovery After Ablative Treatments

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ABSTRACT

Contour Tunable Resurfacing Laser (TRL™) is an erbium: yttrium aluminum garnet (YAG) fully ablative laser commonly used to treat the delicate lower eyelid skin for undereye rejuvenation. Post-treatment patients experience discomfort and extensive downtime. This pilot study incorporated an innovative post-procedure treatment that addresses patient concerns to skin rejuvenation procedures to improve patient relief and recovery, while improving patient retention. The evaluated neurocosmetic Post Procedure Cream (PPC) was safe and tolerable for the thin delicate lower eyelid skin. Following Contour TRL™ under-eye rejuvenation, the PPC ameliorated discomfort by reducing erythema, edema, stinging, and itch post-treatment, while enhancing recovery. Tested alongside the commonly used anhydrous topical, the PPC reduced erythema in the treatment area better than the comparator after 3 days and restored skin tone evenness to pre-procedure condition as early as 7 days post-procedure and maintained skin health for 31 days. The PPC offers physicians a topical solution for post-laser rejuvenation, addressing an unmet need by reducing patient discomfort and enhancing skin recovery.

J Drugs Dermatol. 2025;24(9):952-955. doi:10.36849/JDD.8835

INTRODUCTION

A global survey exposed that "fear of needles/injections/pain", and "safety and side effects" were patients' main barriers when seeking aesthetic procedures, while aesthetic physicians underestimated these as patient concerns.[1] Skin rejuvenation procedures provide notable and desirable aesthetic results; however, patient discomfort and downtime reduce the likelihood that patients seek and/or complete the recommended treatment series.

The lower eyelid skin is a common area of concern as photoaging, visibly manifested as laxity, wrinkles, and pigmentation, appears earlier on the eyelids versus adjacent facial skin. Contour Tunable Resurfacing Laser™ (TRL) (Sciton, Inc., Palo Alto, CA) is an erbium: yttrium aluminum garnet (YAG) fully ablative laser that offers control over the depth of ablation and coagulation.[2,3] Recommended Contour TRL™ post-procedure care includes a 48-hour application of petroleum jelly. A study on 7 subjects revealed that the average pain score post-Contour TRL was 4.0 out of 10 (0 = none, 10 = intolerable), with a downtime of 7 to 10 days and adverse effects included edema, erythema, and flaking.[4]

A topical skincare treatment that can be incorporated immediately post-procedure to alleviate patient discomfort, while enhancing skin recovery and reducing downtime is an unmet need. Addressing patient barriers to skin rejuvenation procedures may improve patient compliance while improving recovery time.

The skin is highly innervated with sensory receptors expressed on keratinocytes and sensory neurons that detect chemical, mechanical, and thermal stimuli, and relay this information to the brain through the skin-brain axis.[5] Neurocosmetic ingredients modulate communication by activating or reducing the transmission of sensory information from the skin to the brain.[6] A breathable, semi-occlusive, gas-permeable, skin lipid-based post-procedure cream (PPC) was formulated with phytocompounds that directly stimulate communication between the nervous system and the skin. The PPC, containing proprietary unique neurocosmetic technology, a postbiotic, and lipophilic and hydrophilic hydrators was developed to address and ameliorate patient barriers in seeking and completing aesthetic rejuvenation procedures.

In an ex vivo study, the PPC significantly decreased transient receptor potential vanilloid 1 (TRPV1) and increased beta endorphin in stressed, post-procedure (PP) skin explants, indicating that the PPC alleviates discomfort by targeting biomarkers involved in the skin-brain axis.[7] Furthermore, the PPC provided patient relief from erythema, edema, and itching, and enhanced recovery following mechanical and thermal procedures, including radiofrequency microneedling, fractional ablative carbon dioxide laser, and hybrid fractional laser treatments.[8,9,10]

This randomized, double-blinded, split-faced pilot study hypothesized that the PPC would be safe, tolerable, and enhance recovery after full ablative Erbium: YAG laser for under-eye rejuvenation.

MATERIALS AND METHODS

A double board-certified head and neck surgeon and facial plastic surgeon performed ContourTRL™ of the under-eye on 2 female patients aged 64 and 69 with Fitzpatrick skin type (FST) III, and moderate-severe overall facial photodamage. Patients were prescribed an antiviral (Valtrex 500 mg BID), an antibiotic (Doxycycline 100 mg BID), and an oral steroid (Prednisone QD) for 5-, 5-, and 3-days post-treatment, respectively. Approximately 30 minutes pre-procedure, patients' bilateral under-eye was numbed with lidocaine 23% / tetracaine 7% cream and received a 2.5 cc nerve block (1.5 cc 2% lidocaine and 1.0 cc bupivacaine) and 0.5 cc bicarbonate injection. The bilateral under-eye areas were then treated with 2 passes of 70 µm ablative and 40 µm coagulation.

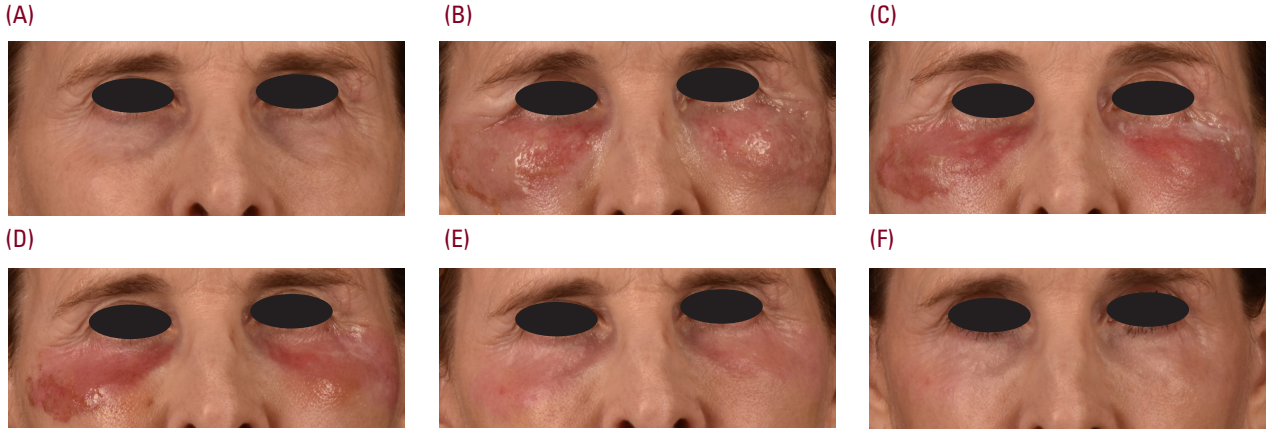
For the first 2-days PP, patients applied a standard of care ointment (Aquaphor; Beiersdorf, AG; Germany) to treatment areas with reapplication as needed to maintain moisture, and Refresh Tears Lubricant Eye Drops (Allergan; NJ) hourly while awake. Between days 2 and 7 PP, patients continued to apply Refresh Tears Lubricant Eye Drops as needed, and vinegar soaks to treated areas up to 6 times daily. Patients' left and right eyes were randomized to apply a neurocosmetic Post Procedure Cream (PPC; Revision Skincare®; TX) or Comparator Anhydrous Cream (CAC; Galderma; CA) twice daily. The treatment packages were labelled "R" for the right eye and "L" for the left eye. The ointment was then applied on top. Between days 7 and 31 PP, patients discontinued ointment application and vinegar soaks and continued with the PPC or CAC application.

Patients visited the clinic on days 1, 2, 3, 7, and 31 PP. Subject tolerability (burning, stinging, itching) and objective tolerability (erythema, edema, dryness) of the bilateral under-eye regions were evaluated separately using a 4-point tolerability scale at all timepoints (0=none, 1=mild, 2=moderate, 3=severe).

Clinical photography was captured at all timepoints with a Nikon D5600 (Nikon Corporation, Tokyo, Japan) and QuantifiCare LifeViz® mini (QuantifiCare®, GA). The under-eye regions were cropped with standardized templates and analyzed with ImageJ software (NIH, MD) to measure skin tone evenness and redness. Improvement was indicated by increased pixel intensity in the regions analyzed.

Statistical analysis was not performed due to a small sample size. Average values were calculated for tolerability and ImageJ measurements of skin tone evenness and redness at all timepoints. All patients signed an informed consent form and a photography release form.

FIGURE 1. Nikon D5600 clinical photographs of a 69-year-old female with Fitzpatrick skin type III. The CAC was applied to the right under-eye area and the PPC to the left under-eye area. Images shown are (A) preprocedure, (B) day 1 postprocedure, (C) day 2 postprocedure, (D) day 3 postprocedure, (E) day 7 postprocedure, and (F) day 31 postprocedure.



RESULTS

The PPC was safe and tolerable for the thin under-eye skin after fully ablative erbium:YAG laser rejuvenation. No adverse events or serious adverse events occurred throughout the pilot.

Immediate PP, ointment application, bilateral burning, stinging, and itching were reported. After day 2 PP, subjects applied the PPC and CAC per randomization until day 31. Both treatments resolved burning by day 3 PP. Subjects reported stinging and itching on day 3 PP with both treatments. Notably, stinging resolved by day 7 bilaterally, and itching decreased by 50% at days 7 and 31 with the PPC when compared to immediate PP. In contrast, itching persisted with the CAC at days 7 and 31.

Immediately, PP, bilateral dryness, edema, and erythema were reported by the investigator. Interestingly, the standard of care ointment led to a threefold increase in bilateral edema and erythema, 1- and 2-day PP when compared to immediate PP. Following PPC and CAC application, edema progressively improved after 3 days PP (Figure 1). Overall, the PPC reduced erythema 0.66x better than the CAC after 3 days. For example, a patient aged 69 with FST III saw a 2-fold reduction in erythema with the PPC compared to the CAC after 7 days (Figure 2).

The improvement in erythema was further supported by Nikon D5600 and QuantifiCare LifeViz® clinical photography and analysis. The PPC enhanced skin recovery and restored skin health after 31 days, while residual erythema persisted with the CAC even after 31 days (Figure 1). Quantificare LifeViz® photography demonstrated that the PPC reduced erythema more than the CAC after 31 days (Figure 2).

FIGURE 2. QuantifiCare LifeViz® Mini clinical photographs of a 69-year-old female with Fitzpatrick skin type III. The CAC was applied to the right under-eye area and the PPC to the left under-eye area. Images shown are (A) preprocedure, (B) day 1 postprocedure, (C) day 2 postprocedure, (D) day 3 postprocedure, (E) day 7 postprocedure, and (F) day 31 postprocedure

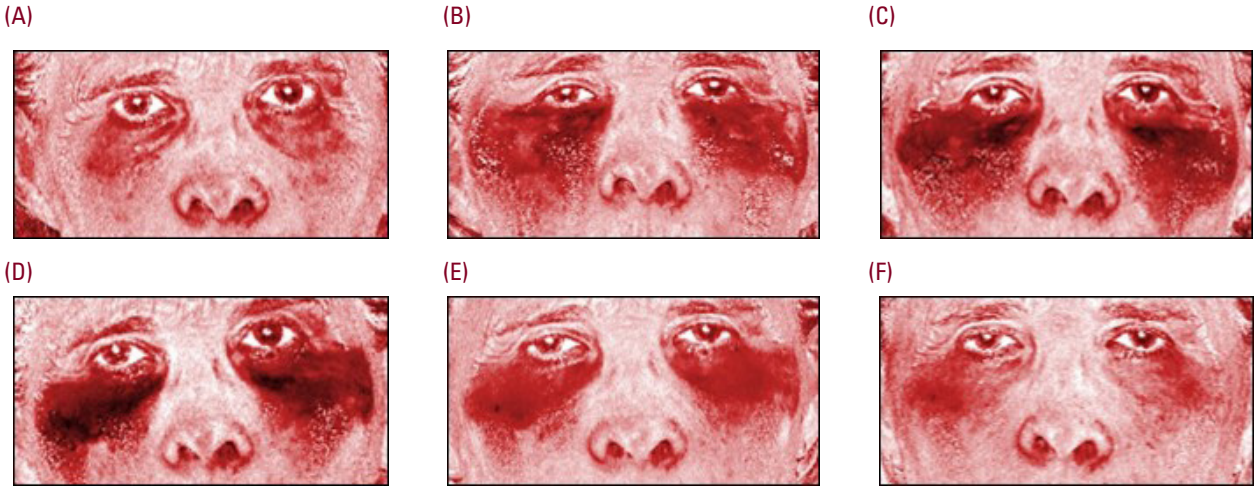
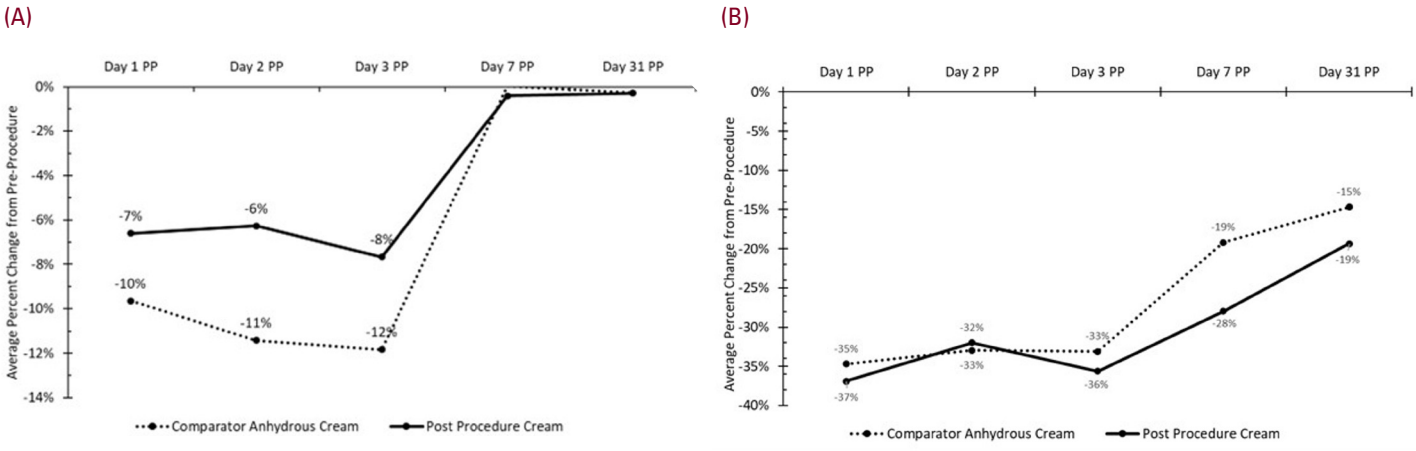


FIGURE 3. Average percent change from baseline was calculated with ImageJ software analysis of (A) skin tone evenness in the Nikon D5600 camera images and (B) skin redness in the Quantificare LifeViz® mini images. Pixel intensity analysis provided insight into barrier recovery at post-procedure (PP) timepoints. An average percent change approaching 0% indicates improvement, and a 0% change indicates no change from pre-procedure skin condition.



ImageJ analysis of clinical photography illustrated that the ointment alone was insufficient at enhancing skin recovery as indicated by the plateau line from 1 to 3 days PP (Figure 3). Both treatments, incorporated at day 2, restored skin tone evenness to pre-procedure condition as early as 7 days PP, indicating enhanced skin recovery, and maintained skin health for 31 days (Figure 3A). Both treatments reduced skin redness after 7 and 31 days (Figure 3B). These results indicate that the PPC enhanced skin recovery following Contour TRL under-eye rejuvenation, while ameliorating tolerability post-procedure.

DISCUSSION

A breathable, semi-occlusive, gas-permeable, skin lipid-based post-procedure cream (PPC) containing unique proprietary neurocosmetic technology, a postbiotic, and lipophilic and hydrophilic hydrators was developed to address and ameliorate patient barriers in seeking and completing aesthetic rejuvenation procedures. Tested against the current commonly used anhydrous topical, there were no reports of adverse events. Additionally, comparable and consistent healing supported the tolerability and efficacy of the PPC after ContourTRL™ treatment in 2 patients investigated. The neurocosmetic PPC addresses a current unmet need in rejuvenation procedures by improving patient discomfort and enhancing recovery time.

This pilot study provided preliminary insights on how to incorporate the PPC post fully ablative laser procedures. The pilot is limited by a small sample size and a narrow FST range. A future study incorporating a larger study population with a diverse skin type and ethnicity, along with a robust statistical analysis to assess the significance of results, can be implemented.

DISCLOSURES

The study was sponsored by Revision Skincare®. Dr Karimi has performed clinical trials and consulting for a variety of organizations and serves in multiple leadership capacities. Dr Karimi served as the clinical investigator for this trial and assisted in drafting the manuscript. Ms Iglesia and Dr Zahr are employees of Revision Skincare® and analyzed the images, statistical data, and drafted the manuscript. Ms Waldon and Ms Cong are employees of Rejuva Medical Aesthetics and assisted in drafting the manuscript. Ms Kononov is a consultant for Revision Skincare®.

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