A Split-Face Design Clinical Trial to Evaluate the Efficacy of a Masque when Used Post-Full Face Fraxel[®] Laser Treatment

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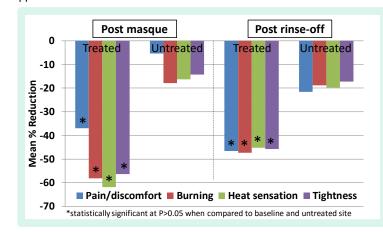
INTRODUCTION

Factors such as dermatological or aesthetic procedures, sun or wind exposure, and environmental aggressors can catalyze a state of temporary skin reactivity which leads to the appearance of redness, heat sensations and general discomfort. The goal of the present study was to evaluate the clinical effects of a facial masque designed to comfort and soothe skin following a popular aesthetic procedure.

METHODS

- This single center, split-face clinical trial was conducted over the course of 1 day on thirty (30) female subjects between the ages of 32-60.
- Each subject was treated with a Fraxel® laser treatment. The tested masque was applied by a clinician on the assigned side of the face according to a predetermined randomization.
- Clinical evaluations of the appearance of redness, dryness, flaking/peeling and swelling were conducted pre-laser, post-laser, postproduct application and post-product rinse off.
- Local cutaneous tolerability was evaluated by subject assessment of signs and symptoms of pain/discomfort, itching, burning, heat sensation and tightness separately for the facial halves.
- Digital images were taken at each of the designated study time points using a thermal camera and VISIA CR[™] system.
- Subjects also completed a questionnaire in regards to the cooling/calming/soothing effects post masque application.

Graph 1: Signs and symptoms as reported by the subjects after masque application and rinse-off.



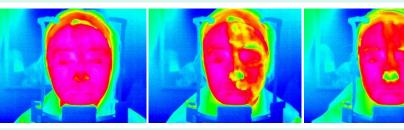
Baseline/Post Fraxel®

RESULTS

- The results indicated that the tested masque was effective in improving the appearance of redness (Figure 2) and reducing pain/discomfort, burning, heat sensation, and tightness on the treated side post-product application and/or post-product rinse off when compared to baseline and between the treated and untreated sides. (Graph 1)
- Results of thermal imaging showed a statistically significant reduction in skin surface temperature on the cheek of the treated side at post-product application and rinse off when compared to baseline (post-laser) and when compared to the untreated side of the face. (Figure 1)
- Subjects indicated feeling cool and feeling calmed/soothed immediately upon masque application.

Post masque application

Post masque rinse-off



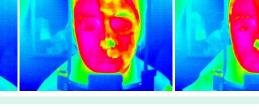




Figure 2: Subject showed similar improvement in the appearance of redness to those of the entire panel at post masque rinse-off.

Figure 1: Thermal imaging of the

treated (subject's left) and untreated

(subject's right) sites at baseline (post-

laser), post-product application and

rinse off.



CONCLUSIONS

The tested masque was effective in improving the appearance of redness following masque application and after rinse-off, reduced skin temperature and soothed signs of discomfort such as pain, burning, heat sensation, and tightness immediately upon masque application, following a Fraxel[®] procedure.