Advanced, Physician-Strength Retinol Peel Improves the Appearance of Fine Lines, Wrinkles, Skin Firmness and Overall Complexion Brightness

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Introduction

Physician-strength chemical peels are consistently the third most common cosmetic procedure next to neurotoxin and soft-tissue filler injections.¹ Among physicians, retinol continues to be a proven ingredient for the management of acne² and/or adjunctive care of photodamage³ due to its ability to enhance exfoliation, increase epidermal thickness and reduce matrix metalloproteinase (MMP) activity (collagenase) while increasing collagen.⁴

An advanced, physician-strength peel, containing 3% Retinol plus Retinol Boosting Complex™, was developed to exfoliate and improve the appearance of fine lines and wrinkles, and plump and firm skin while promoting a bright, even complexion. Formulated with bisabolol to help calm the skin, this peel provides additional benefits to overall skin appearance with the addition of Aminofil® and NeoCitriate® to enhance the skin's matrix for plumping and firming effects,⁵,⁶ as well as Vitamin E for antioxidant benefits.

This poster presents a summary of a 5 month, single center, prospective clinical study evaluating the tolerability and effectiveness of a cosmetic retinol peel, in conjunction with a homecare regimen, to improve the appearance of fine lines, wrinkles, skin firmness and overall complexion brightness on subjects with mild to moderate photodamage and/or acne with direct comparison to baseline parameters.

Clinical Photography

Figure 1. Improved Lines on Forehead With Better Skin Texture and Clarity Overall

![Baseline](image1.png) ![Week 12 (after 2 peels)](image2.png)

Figure 2. Improved Texture and Diminished Pigmentation on Cheek

![Baseline](image3.png) ![Week 12 (after 2 peels)](image4.png)
Study Methodology

Population

Key Inclusion:
- Photodamage, n=14
  - Males & Females, ages 35-65 years
  - Mild to moderate photodamage on the face: fine lines, wrinkles, mottled pigmentation, noted by a grade of 3-6 on the 0-9 Griffith's scale
- Acne, n=5
  - Males & Females, ages 18-35 years
  - Moderate facial acne (global assessment) as noted by a grade of 3 on a 0-4 scale

Key Exclusion (Photodamage & Acne):
Use of antiaging products or procedures, including:
- Rx topical retinoids within 8 weeks
- Topical hydroxyacids, retinol and other antiaging cosmetics within 4 weeks
- Resurfacing cosmetic procedures (e.g. peels, laser, light treatments, microdermabrasion) or oral retinoids within 6 months

Pregnant, nursing or planning to become pregnant

Statistics

- Clinical improvements were analyzed using the Wilcoxon signed-rank test (p<0.05)
- Self-assessed improvements utilized t-tests (p<0.05)

Evaluation Tools
(Visits at Week 0, Day 3, Day 7 and Weeks 6, 12, 18, 20)

Clinical Measures
Visual grading by dermatologist at each visit
- Photodamage (0-9 modified Griffith's scale)
  - Lack of Clarity/Radiance, Mottled Pigmentation, Fine Lines, Wrinkles, Pore Size, Laxity, Overall Photodamage
- Overall Acne Severity (0-4 scale)

Subjective Measures
- Self-Assessment questionnaires were completed by subjects at each visit

Digital Photography (VISIA-CR & Omnia Cameras)
- Conducted at baseline, Days 3 and 7, & prior to each peel at Weeks 6, 12 and 18, and 2 weeks after the final peel (Week 20)

Safety
- Objective and subjective grading included erythema, peeling, dryness and roughness
- Adverse events were recorded and tabulated

Test Products

3% Retinol Peel – Administered by physician approximately every 6 weeks (NeoStrata® ProSystem Retinol Peel)
- Applied and left on skin for at least 8 hours or overnight, then washed with cleanser

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Classification</th>
<th>Mechanism</th>
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<tbody>
<tr>
<td>Retinol 3%</td>
<td>Peeling Agent</td>
<td>• Precursor to retinoic acid (aka Retin-A) with better tolerance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Increases epidermal thickness &amp; reduces MMP activity (collagenase) while enhancing collagen</td>
</tr>
<tr>
<td>Triethyl Citrate</td>
<td>Firming Agent</td>
<td>Enhances collagen, plumps matrix to lift and firm</td>
</tr>
<tr>
<td>Acetyl Tyrosinamide</td>
<td>Volumizing Agent</td>
<td>Novel amino acid derivative targets collagen and hyaluronic acid to plump and firm skin</td>
</tr>
<tr>
<td>Bisabolol</td>
<td>Soothing/Calming Agent</td>
<td>Botanical derived from chamomile</td>
</tr>
<tr>
<td>Vitamin E Acetate</td>
<td>Protectant (skin &amp; retinol)</td>
<td>Antioxidant/free radical scavenger</td>
</tr>
<tr>
<td>Vehicle</td>
<td>Alcohol Solution Vehicle</td>
<td>Contains photostabilizer to protect retinol; Preservative free (alcohol), fragrance free, oil free, color free; Packaged in opaque unit dose vial</td>
</tr>
</tbody>
</table>

Homecare Regimen:
- Twice daily use of a cleanser followed by Day Cream SPF 23 or Night Cream
  - 4% PHA Cleanser (AM / PM) (NeoStrata® Facial Cleanser)
  - 10% Bionic/PHA Day Cream SPF 23 (AM) (NeoStrata® Daytime Protection Cream SPF 23)
  - 4% PHA/Bionic Physical SPF 50 provided as a high SPF alternative (NeoStrata® Sheer Physical Protection SPF 50)
  - 10% PHA Night Cream (PM) (NeoStrata® Ultra Moisturizing Face Cream)

Post-procedure Homecare:
- Used up to 1 week post-peel
  - 12% Bionic/PHA Cream or 10% Bionic Face Serum (until other products could be tolerated) (NeoStrata® Bionic Face Cream or Bionic Face Serum)
  - Sunscreen use was imperative; SPF 23 or SPF 50 as tolerated (see above)
Results

Dermatologist Clinical Grading
- All photodamage parameters significantly improved after four peels, *p<0.05 (n=14) (Figures 1–3)
- Overall photodamage significantly improved after 1 peel, and fine lines and pore size after 3 peels, *p<0.05 (n=14) (Figures 1–3)
- Overall Acne Severity trended towards a significant improvement after 4 peels, †p=0.06 (n=5) (Figures 4 & 9)

Self-Assessment
- Self-assessment supports dermatologist grading
  - Subjects rated improvements in lines, tone, pores, texture and blemishes (Figure 5)
  - Skin sensitivity was minimal throughout the study (Figure 5)

Mean Scores on 0-3 Scale

<table>
<thead>
<tr>
<th>Visit</th>
<th>Rough Skin Texture</th>
<th>Uneven Skin Tone/Coloring</th>
<th>Fine Lines</th>
<th>Visible Pores</th>
<th>Acne Blemishes</th>
<th>Skin Sensitivity (sting, itch, burn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>1.1</td>
<td>1.9</td>
<td>2</td>
<td>2.3</td>
<td>1.5</td>
<td>0.6</td>
</tr>
<tr>
<td>Week 6 (after 1 peel)</td>
<td>1.0</td>
<td>1.6</td>
<td>1.5</td>
<td>1.7*</td>
<td>1.2</td>
<td>0.4</td>
</tr>
<tr>
<td>Week 12 (after 2 peels)</td>
<td>1.2</td>
<td>1.7</td>
<td>1.5*</td>
<td>1.7*</td>
<td>1.4</td>
<td>0.6</td>
</tr>
<tr>
<td>Week 18 (after 3 peels)</td>
<td>1.0</td>
<td>1.3*</td>
<td>1.6</td>
<td>1.7*</td>
<td>1.3</td>
<td>0.6</td>
</tr>
<tr>
<td>Week 20 (after 4 peels)</td>
<td>0.7* (36%)</td>
<td>1.3* (32%)</td>
<td>1.5* (25%)</td>
<td>1.3* (43%)</td>
<td>0.9* (40%)</td>
<td>0.3* (50%)</td>
</tr>
</tbody>
</table>

Grading Scale: 0=none, 1=mild, 2=moderate, 3=severe with half point increments
*Significant improvement from baseline (p<0.05)

Tolerability

Objective and Subjective Irritation

Immediate response to Retinol Peel (in office)
- Almost no erythema or other signs of irritation noted while the peel was on the skin, in the office
  - Out of 56 peels administered:
    - 1 instance of mild erythema (week 12 peel)
    - 3 instances of mild stinging/burning during the peel (1 at baseline peel, 2 at week 12 peels)

Response in Days after Retinol Peel (Figures 6–8)
- A visible skin response was observed in the days following Retinol Peel
  - Increased dryness, peeling, roughness and tightness were observed on Days 3 and 7 (moderate or less)
  - Increased erythema for 9 out of 14 subjects on Day 3 (moderate or less) which decreased by Day 7
- Skin sensitivity was rated mild at Day 3 by 6 out of 14 subjects which decreased by Day 7
  - 10 out of 14 subjects felt no stinging/burning; only 4 subjects reported mild stinging/burning on Days 3 or 7

Adverse Events
- 1 subject had eye area irritation post-peel (swelling, erythema of skin), but continued with the study avoiding application of the peel too close to the eye
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Conclusions

- The unique, high-strength Retinol Peel was well-tolerated under physician direction
  - 8 hour and Overnight application was well-tolerated
  - Physician must manage patient expectations for peeling and redness
    - Peeling was observed within the first few days and resolved within approximately one week

- Clinical benefits were observed for Photodamage and Acne
  - Significant improvements in dermatologist grading for overall photodamage, fine lines, wrinkles, clarity/radiance, mottled pigmentation, pore size and laxity were observed
  - Improvement to overall acne severity was observed
  - Patient self-assessment and digital photography support clinical benefits

- PHA/Bionic homecare products were well-tolerated when used in conjunction with the Retinol Peel

- The Retinol Peel was found to be safe and effective delivering clinically significant improvements on acne-prone and photodamaged skin along with its noticeable peeling effects

References