# 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, <sup>5,6</sup> 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

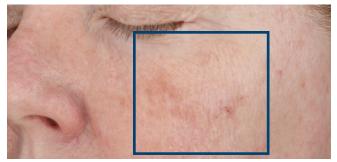


Baseline



Week 12 (after 2 peels)

Figure 2. Improved Texture and Diminished Pigmentation on Cheek



**Baseline** 



Week 12 (after 2 peels)

# **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

## **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

### **Statistics**

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

# **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

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

# **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<sup>®</sup> Ultra Moisturizing Face Cream)

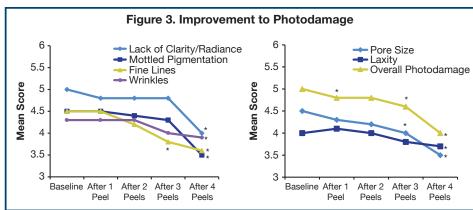
# Post-procedure Homecare:

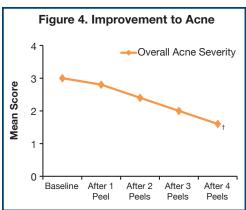
- Used up to 1 week post-peel
  - 12% Bionic/PHA Cream or 10% Bionic Face Serum (until other products could be tolerated) (NeoStrata® Bionic Face Cream or Bionic Face Serum)
  - Sunscreen use was imperative; SPF 23 or SPF 50 as tolerated (see above)

# 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)





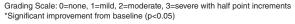
Decrease = Improvement

#### **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

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



#### Figure 5. Percent Improvement From Baseline 60 50 40 Percent 30 20 10 Rough Skin Uneven Skin Fine Acne Tone/Colorina Lines Pores Blemishes Sensitivity

# **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:

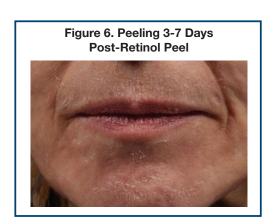
- 1 instance of mild erythema (week 12 peel)
- 3 instances of mild stinging/burning during the peel (1 at baseline peel, 2 at week 12 peels)

# 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

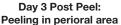


# **Clinical Photography**

Visible Peeling on Days 3 & 7 Post-Retinol Peel

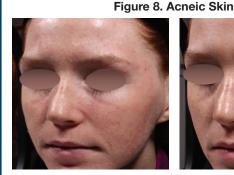
Figure 7. Photodamaged Skin







Day 7: Peeling has subsided



Day 3 Post Peel: Peeling on forehead and perioral area



Day 7: Peeling has mostly subsided; slight peeling on cheeks

> Benefits to Photodamaged Skin are shown in Figures 1 & 2 and Improvements to Acne-prone skin in Figure 9





Week 0



Week 6 (after 1 peel)



Week 12 (after 2 peels)

# **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

- 2015 Plastic Surgery Statistics Report. American Society of Plastic Surgeons. https://d2wirczt3b6wjm.cloudfront.net/ News/Statistics/2015/plastic-surgery-statistics-full-report-2015.pdf
- Yeh L, Bonati LM, Silverberg NB. Topical retinoids for acne. Semin Cutan Med Surg 2016; 35(2):50-6.
- Tucker-Samaras S, et al. A stabilized 0.1% retinol facial moisturizer improves the appearance of photodamaged skin in an eight-week, double-blind, vehicle-controlled study. J Drugs Dermatol 2009;8(10):932-6.
- 4. Kafi R, et al. Improvement of naturally aged skin with vitamin A (retinol). Arch Dermatol 2007;143:606-612.
- Bernstein EF, et al. Citric Acid increases viable epidermal thickness & glycosaminoglycan content of sundamaged skin. Dermatol Surg 1997;23:689-94.
- Farris PK, et al. A novel, volumizing cosmetic formulation significantly improves the appearance of target glabellar lines, nasolabial folds, and crow's feet in a double-blind, vehicle controlled clinical trial. J Drugs Dermatol 2014;13(1):41-6.