

# A New High-Potency, Multi-Mechanism Skincare Regimen for Photodamaged Skin: Results From a Vehicle-Controlled Clinical Trial







Barbara A. Green RPh MS<sup>1</sup>, Irina Brouda MA<sup>1</sup>, Brenda L. Edison BA<sup>1</sup>, Ronni L. Weinkauf PhD<sup>1</sup>, Patricia K. Farris MD<sup>2</sup>

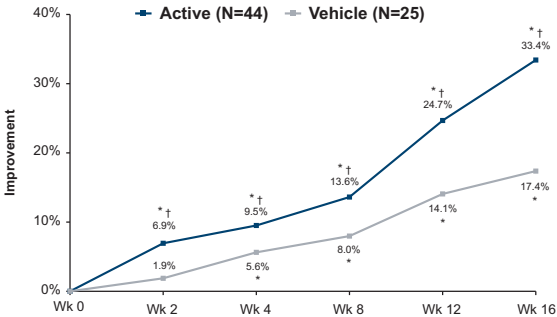
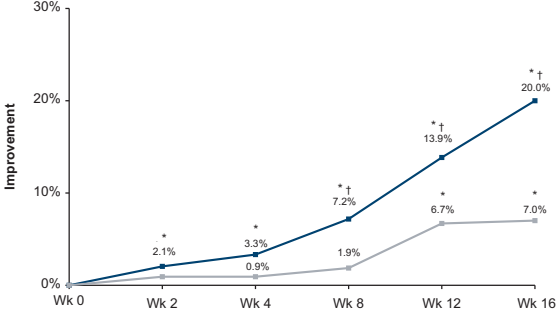
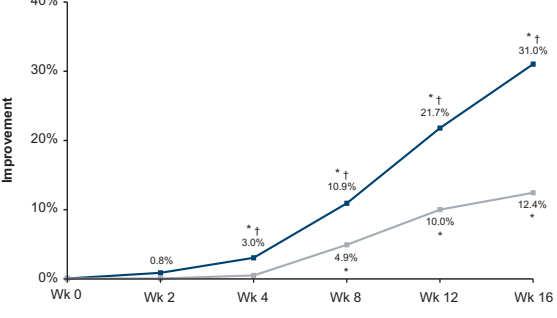
<sup>1</sup>NeoStrata Company, Inc, Princeton, NJ USA; <sup>2</sup>Department of Dermatology, Tulane University School of Medicine, New Orleans, LA, USA

Introduction	
Skin aging is a multi-faceted biological process that cannot be fully addressed by any single skincare ingredient. A high-potency skincare regimen that delivers over 35% active benefit ingredients daily was developed to provide anti-aging benefits across all skin layers via multiple mechanisms. Tolerability and effectiveness of the regimen were evaluated in a randomized, double-blind, vehicle-controlled clinical trial.	
Study Methodology	
Design	Double-blind, vehicle-controlled, randomized, parallel groups clinical trial (2:1 ratio, N=44 active group, N=25 vehicle group)
Population/ Inclusion	Caucasian women, aged 45-65, with mild to moderate general facial photodamage (4-7 on a 0-9 grading scale for fine lines and coarse wrinkles in the eye area and mottled pigmentation on the face) and willing to use higher strength skincare products
Exclusion	Known allergies to skincare products, skin/eye conditions or uncontrolled chronic diseases that could interfere with evaluations, current use of medications for skin or eye conditions, routine use of anti-aging topical products including prescription retinoids within 6 months, hydroxyacids, retinol and other anti-aging cosmetics within 2 months, and/or cosmetic procedures (e.g., peels, laser, light treatments) within 6 months
Duration	16 weeks
Treatment	Active group used Facial Cleanser, Day Cream, Night Cream, and Eye Cream, while Vehicle group used the four formulation vehicles
Evaluation Visits	Weeks 0, 2, 4, 8, 12, and 16
Evaluation Tools	<div><div><div><div>Clinical Measures</div><div>Visual grading by a trained clinician using a standardized grading scale</div></div><div><div>Objective Measures</div><div>Silicone replicas of the right or left crow's feet area (same side as was chosen for clinical grading) in half of the subjects in each group</div></div><div><div>Subjective Measures</div><div>Self-assessment questionnaires were completed by subjects</div></div><div><div>Photography</div><div>Digital photographs of faces were taken at Weeks 0, 8 and 16</div></div></div><div><div>Irritation / tolerability parameters: Erythema, Dryness, Burning, Stinging, Itching, Tingling, and Tightness were graded using a 0.5 incremental scale from 0 (none) to 3 (severe)</div></div></div>
Safety	Adverse events were recorded and evaluated

Test Products	
Product and Usage	Key Benefit Ingredients
<b>Facial Cleanser</b> (NeoStrata® Skin Active Exfoliating Wash) <ul style="list-style-type: none"><li>Day + night use</li></ul>	8.5% Polyhydroxy/Bionic acids (gluconolactone + maltobionic acid), botanical complex (extracts of aloe, chamomile, cucumber, althaea and rosemary), and soap-free surfactants
<b>Day Cream</b> (NeoStrata® Skin Active Matrix Support SPF 20) <ul style="list-style-type: none"><li>Day use</li></ul>	8% N-acetylglucosamine, 0.1% retinol, palmitoyl oligo- and tetrapeptides, vitamin E, pomegranate and coffee bush berry extracts, UVA/UVB sunscreens
<b>Night Cream</b> (NeoStrata® Skin Active Cellular Restoration) <ul style="list-style-type: none"><li>Night use</li></ul>	15% Alpha-hydroxy/Polyhydroxy/Bionic acids (5% each of glycolic acid, gluconolactone & maltobionic acid), palmitoyl oligo- and tetrapeptides, chardonnay grape seed extract, apple stem cell extract, extracts of acai fruit, pomegranate and blueberry, vitamin E
<b>Eye Cream</b> (NeoStrata® Skin Active Intensive Eye Therapy) <ul style="list-style-type: none"><li>Day + night use</li></ul>	6% N-acetylglucosamine, palmitoyl oligo- and tetrapeptides, apple stem cell extract, caffeine, sodium hyaluronate, vitamin E, optical blurring agents
<b>Vehicles (4)</b> <ul style="list-style-type: none"><li>Same daily regimen use as Active product</li></ul>	No key benefit ingredients; base formulations were provided in identical packaging as active products; the vehicle day cream was formulated with identical UVA/UVB sunscreens

Results	
<b>Active products outperformed Vehicles</b> <ul style="list-style-type: none"><li>The Active group began improving significantly more than the Vehicle group as early as week 2 and outperformed the Vehicle group on all aging parameters by week 12, <i>P</i>&lt;0.05. Differences in improvement were first observed at:<ul style="list-style-type: none"><li>Week 2 for Fine Lines, Clarity, Laxity, Tactile Roughness, Eyelid Crepiness, and Overall Appearance</li><li>Week 4 for Dyschromia and Sallowness</li><li>Week 8 for Wrinkles and Visual Roughness</li><li>Week 12 for Pore Size and Eyelid Lifted Appearance</li></ul></li></ul>	
<b>Active products and Vehicles were equally well tolerated</b> <ul style="list-style-type: none"><li>Mean tolerability scores were better than mild (&lt;0.5 score on a 0-3 scale) for all graded parameters and adverse events were minimal (mild to moderate irritation N=4 (Active), N=2 (Vehicle))</li></ul>	
<b>Anti-Aging effects of the Active products were apparent to subjects</b> <ul style="list-style-type: none"><li>After 16 weeks, Active group participants agreed:<ul style="list-style-type: none"><li>95%: skin was more firm and radiant</li><li>91%: skin looked younger and wrinkles were less noticeable</li><li>98%: skin texture was smoother</li><li>79%: brown spots were less apparent</li></ul></li></ul>	

Clinical Photography: Active Products	
<b>Improvement in Crow's Feet and Eyelid Crepiness</b> <div><div></div><div><div>Week 0</div><div>Week 16</div></div></div>	
<b>Improvement in Forehead Wrinkles</b> <div><div></div><div><div>Week 0</div><div>Week 8</div></div></div>	
<b>Reduced Pigmentation</b> <div><div></div><div><div>Week 0</div><div>Week 16</div></div></div>	

Clinical Grading Results	
<b>Improvement in Fine Lines</b> <div><div></div><div><div>Week 0</div><div>Week 2</div><div>Week 4</div><div>Week 8</div><div>Week 12</div><div>Week 16</div></div></div>	
<b>Improvement in Wrinkles</b> <div><div></div><div><div>Week 0</div><div>Week 2</div><div>Week 4</div><div>Week 8</div><div>Week 12</div><div>Week 16</div></div></div>	
<b>Improvement in Dyschromia</b> <div><div></div><div><div>Week 0</div><div>Week 2</div><div>Week 4</div><div>Week 8</div><div>Week 12</div><div>Week 16</div></div></div>	
<div><div>*Significantly better than baseline, <i>P</i> &lt; 0.05</div><div>†Significantly better than vehicle, <i>P</i> &lt; 0.05</div></div>	
<b>Conclusion</b> <ul style="list-style-type: none"><li>The new high-potency, multi-mechanism skincare regimen delivers advanced comprehensive anti-aging benefits to photodamaged skin through the synergistic actions of multiple benefit ingredients and is well tolerated.</li><li>These anti-aging effects are clinically measurable and statistically significant above and beyond the effect of the cosmetic vehicles and can be used to help restore the look and feel of youthful skin.</li></ul>	
<div><div>Poster presented at the 20th Congress of the European Academy of Dermatology &amp; Venereology, Lisbon, Portugal, 20-24 October, 2011.</div><div>Study sponsored by NeoStrata Company, Inc., Princeton, NJ, USA.</div></div>	

## Introduction

Skin aging is a multi-faceted biological process that cannot be fully addressed by any single skincare ingredient. A high-potency skincare regimen that delivers over 35% active benefit ingredients daily was developed to provide anti-aging benefits across all skin layers via multiple mechanisms. Tolerability and effectiveness of the regimen were evaluated in a randomized, double-blind, vehicle-controlled clinical trial.

## Study Methodology

<b>Design</b>	Double-blind, vehicle-controlled, randomized, parallel groups clinical trial (2:1 ratio, N=44 active group, N=25 vehicle group)
<b>Population/ Inclusion</b>	Caucasian women, aged 45-65, with mild to moderate general facial photodamage (4-7 on a 0-9 grading scale for fine lines and coarse wrinkles in the eye area and mottled pigmentation on the face) and willing to use higher strength skincare products
<b>Exclusion</b>	Known allergies to skincare products, skin/eye conditions or uncontrolled chronic diseases that could interfere with evaluations, current use of medications for skin or eye conditions, routine use of anti-aging topical products including prescription retinoids within 6 months, hydroxyacids, retinol and other anti-aging cosmetics within 2 months, and/or cosmetic procedures (e.g., peels, laser, light treatments) within 6 months
<b>Duration</b>	16 weeks
<b>Treatment</b>	Active group used Facial Cleanser, Day Cream, Night Cream, and Eye Cream, while Vehicle group used the four formulation vehicles
<b>Evaluation Visits</b>	Weeks 0, 2, 4, 8, 12, and 16
<b>Evaluation Tools</b>	
<ul style="list-style-type: none"><li>• <b>Clinical Measures</b> Visual grading by a trained clinician using a standardized grading scale</li></ul>	<ul style="list-style-type: none"><li>– Clinical parameters: Fine Lines, Wrinkles, Clarity, Laxity, Visual Roughness, Tactile Roughness, Dyschromia, Pore Size, Sallowness, Eyelid Crepiness, Lifted Appearance of Eyelid, and Overall Appearance were graded using a 0.5 incremental scale from 0 (none) to 9 (severe)</li><li>– Irritation / tolerability parameters: Erythema, Dryness, Burning, Stinging, Itching, Tingling, and Tightness were graded using a 0.5 incremental scale from 0 (none) to 3 (severe)</li></ul>
<ul style="list-style-type: none"><li>• <b>Objective Measures</b></li></ul>	Silicone replicas of the right or left crow's feet area (same side as was chosen for clinical grading) in half of the subjects in each group
<ul style="list-style-type: none"><li>• <b>Subjective Measures</b></li></ul>	Self-assessment questionnaires were completed by subjects
<ul style="list-style-type: none"><li>• <b>Photography</b></li></ul>	Digital photographs of faces were taken at Weeks 0, 8 and 16
<b>Safety</b>	Adverse events were recorded and evaluated

## Test Products

Product and Usage	Key Benefit Ingredients
<b>Facial Cleanser</b> (NeoStrata® Skin Active Exfoliating Wash) • Day + night use	8.5% Polyhydroxy/Bionic acids (gluconolactone + maltobionic acid), botanical complex (extracts of aloe, chamomile, cucumber, althaea and rosemary), and soap-free surfactants
<b>Day Cream</b> (NeoStrata® Skin Active Matrix Support SPF 20) • Day use	8% N-acetylglucosamine, 0.1% retinol, palmitoyl oligo- and tetrapeptides, vitamin E, pomegranate and coffee bush berry extracts, UVA/UVB sunscreens
<b>Night Cream</b> (NeoStrata® Skin Active Cellular Restoration) • Night use	15% Alpha-hydroxy/Polyhydroxy/Bionic acids (5% each of glycolic acid, gluconolactone & maltobionic acid), palmitoyl oligo- and tetrapeptides, chardonnay grape seed extract, apple stem cell extract, extracts of acai fruit, pomegranate and blueberry, vitamin E
<b>Eye Cream</b> (NeoStrata® Skin Active Intensive Eye Therapy) • Day + night use	6% N-acetylglucosamine, palmitoyl oligo- and tetrapeptides, apple stem cell extract, caffeine, sodium hyaluronate, vitamin E, optical blurring agents
<b>Vehicles (4)</b> • Same daily regimen use as Active product	No key benefit ingredients; base formulations were provided in identical packaging as active products; the vehicle day cream was formulated with identical UVA/UVB sunscreens

## Results

### Active products outperformed Vehicles

- The Active group began improving significantly more than the Vehicle group as early as week 2 and outperformed the Vehicle group on all aging parameters by week 12,  $P < 0.05$ . Differences in improvement were first observed at:
  - Week 2 for Fine Lines, Clarity, Laxity, Tactile Roughness, Eyelid Crepiness, and Overall Appearance
  - Week 4 for Dyschromia and Sallowness
  - Week 8 for Wrinkles and Visual Roughness
  - Week 12 for Pore Size and Eyelid Lifted Appearance

### Active products and Vehicles were equally well tolerated

- Mean tolerability scores were better than mild ( $< 0.5$  score on a 0-3 scale) for all graded parameters and adverse events were minimal (mild to moderate irritation N=4 (Active), N=2 (Vehicle))

### Anti-Aging effects of the Active products were apparent to subjects

- After 16 weeks, Active group participants agreed:
  - 95%: skin was more firm and radiant
  - 91%: skin looked younger and wrinkles were less noticeable
  - 98%: skin texture was smoother
  - 79%: brown spots were less apparent



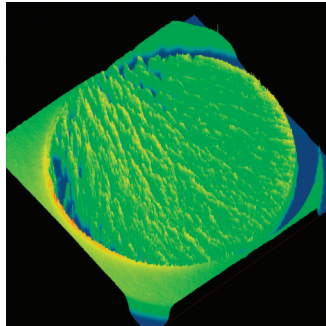
**Improvement in Crow's Feet and Eyelid Crepiness**



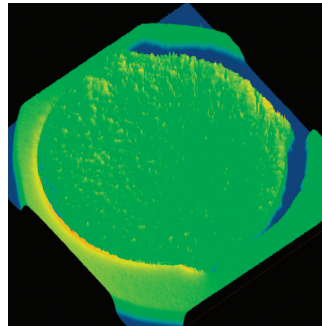
Week 0



Week 16



Week 0



Week 16

Improvements in periorcular fine lines and wrinkles and smoother skin texture can be observed in clinical photographs and corresponding silicone replicas.

**Improvement in Forehead Wrinkles**



Week 0



Week 8

**Reduced Pigmentation**



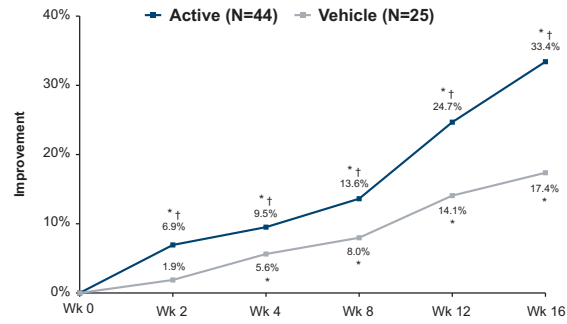
Week 0



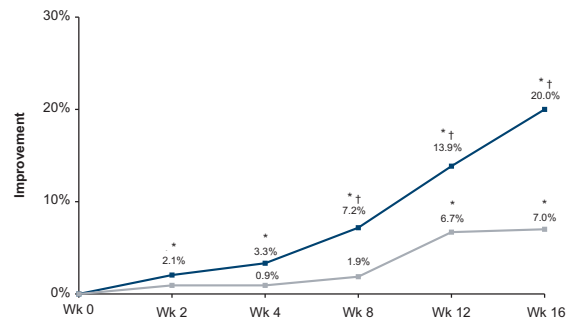
Week 16

## Clinical Grading Results

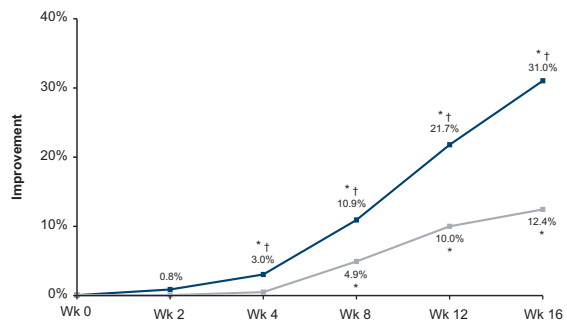
### Improvement in Fine Lines



### Improvement in Wrinkles



### Improvement in Dyschromia



\*Significantly better than baseline,  $P < 0.05$

†Significantly better than vehicle,  $P < 0.05$

## Conclusion

- The new high-potency, multi-mechanism skincare regimen delivers advanced comprehensive anti-aging benefits to photodamaged skin through the synergistic actions of multiple benefit ingredients and is well tolerated.
- These anti-aging effects are clinically measurable and statistically significant above and beyond the effect of the cosmetic vehicles and can be used to help restore the look and feel of youthful skin.