

New Multi-Modality, High-Potency, Physician-Dispensed Skincare Products for Intensive Anti-Aging Benefits

M. Elizabeth Briden MD¹, Irina Brouda MA², Brenda L. Edison BA², Barbara A. Green RPh MS²
¹Advanced Dermatology & Cosmetic Institute PA, Edina, MN USA and ²NeoStrata Company, Inc, Princeton, NJ USA

Introduction

The morphological and visible symptoms of skin aging are a combined result of natural age progression and cumulative exposure to damaging ultraviolet radiation with accompanying oxidation by free radicals. Effects are evident at all levels of the skin, including the stratum corneum, the epidermis, and the dermis. Each layer of skin is affected differently, with different cell types serving as targets, and different mechanisms of cellular and matrix deterioration prevailing. The myriad of events taking place at all levels of the skin during the processes of natural aging and photoaging cannot be addressed by any single cosmetic ingredient currently known.¹

We have tested a new line of multi-modality, high-potency, physician-dispensed skincare products developed to deliver anti-aging benefits targeting all skin layers via diverse yet complementary mechanisms of action. The new facial cleanser, day cream, night cream, and eye cream deliver more than 35% of proven benefit ingredients on a daily basis to provide antioxidant protection and to support moisturization, surface exfoliation, pigmentation evening, and dermal matrix building. Active benefit compounds include a proprietary blend of retinol (a cosmetic retinoid), N-acetyl glucosamine (an amino sugar), alpha-hydroxy, polyhydroxy, and bionic acids (AHA, PHA, BA), peptide signaling agents, apple stem cell extract, and broad spectrum antioxidants and sunscreens.

Test Products

Product	Key Benefit Ingredients	Proprietary Benefit Levels
Facial Cleanser (NeoStrata® Skin Active Exfoliating Wash)	Gluconolactone, maltobionic acid, botanical complex, and soap-free surfactants	PHA/BA: 8.5% Twice daily use
Day Cream (NeoStrata® Skin Active Matrix Support SPF 20)	N-acetyl glucosamine, retinol (0.1%), Vitamin E, peptides, pomegranate and coffee bush berry extracts, UVA/UVB sunscreens	Amino sugar: 8% Once daily use
Night Cream (NeoStrata® Skin Active Cellular Restoration)	Gluconolactone, glycolic acid, maltobionic acid, peptides, apple stem cell, grape seed, and fruit extracts	AHA/PHA/BA: 15% Once daily use
Eye Cream (NeoStrata® Skin Active Intensive Eye Therapy)	N-acetyl glucosamine, hyaluronic acid, Vitamin E, caffeine, peptides, and apple stem cell extract	Amino sugar: 6% Twice daily use

Test Methods

Test	Product	Patients	Study Procedures
Repeat Insult Patch Test (semi-occlusive patch)	-Facial Cleanser	104 adults per product	Induction Phase Challenge Phase
	-Day Cream		
	-Night Cream		
	-Eye Cream		
Ocular Irritation Potential Assessment	-Eye Cream	32 women 40-60 years old ½ wore contact lenses	Patients applied product to periocular areas twice daily for 4 weeks and evaluated skin benefits and aesthetics Ophthalmologist evaluated eye areas at weeks 0, 2, 4
	-Day Cream -Night Cream	33 women per product 18-45 years old	Patients applied one product to entire face twice daily for 4 weeks and evaluated skin benefits and aesthetics Dermatologist counted acne lesions / comedones at weeks 0, 2, 4
Four-Product Clinical Regimen Use Study	-Facial Cleanser	14 women 40-65 years old Moderate photodamage on the face	Patients used the 4 products in a skincare regimen for 6 months Patients evaluated skin benefits and aesthetics of the regimen and were photographed
	-Day Cream		
	-Night Cream		
	-Eye Cream		

Results

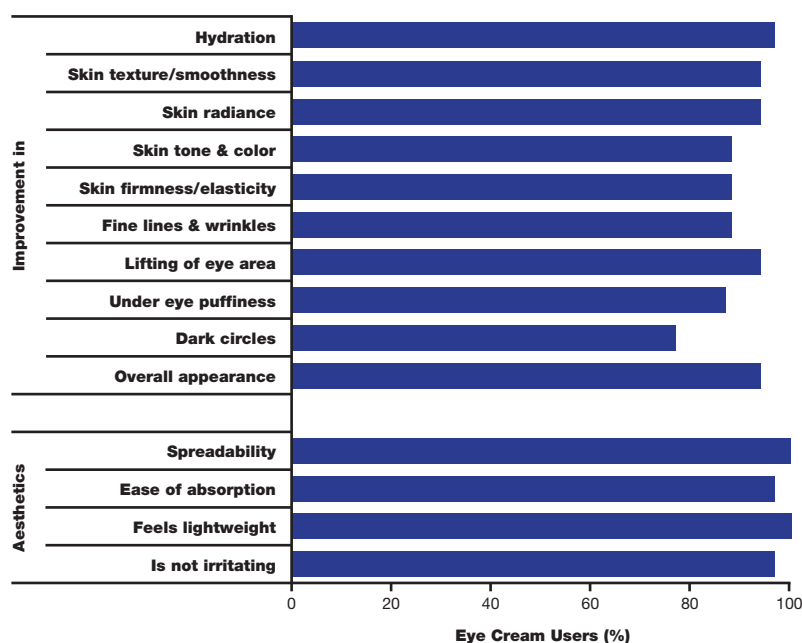
Repeat Insult Patch Test

- Facial Cleanser, Day Cream, Night Cream, and Eye Cream did not indicate a potential for skin irritation or allergic contact sensitization in adults.

Ocular Irritation Potential Assessment

- Eye Cream did not demonstrate a potential for eliciting ocular irritation in women, 40-60 years old.
- Eye Cream was well-tolerated regardless of contact lens use.
- Eye Cream showed significant benefits for reducing the signs of aging around the eye at 4 weeks (**Figure 1**).
- 81% of Eye Cream users saw younger looking skin around their eyes within 3 weeks.

Figure 1. Patient Ratings for Eye Cream at Week 4 (Excellent + Very Good + Good)



Acnegenicity / Comedogenicity Assessment

- Day Cream and Night Cream did not increase the number of acne lesions in adults, 18-45 years old.
- Day Cream and Night Cream are non-acnegenic and non-comedogenic.
- Day Cream and Night Cream users were pleased with the skin benefits and products' aesthetics (**Table 1**).

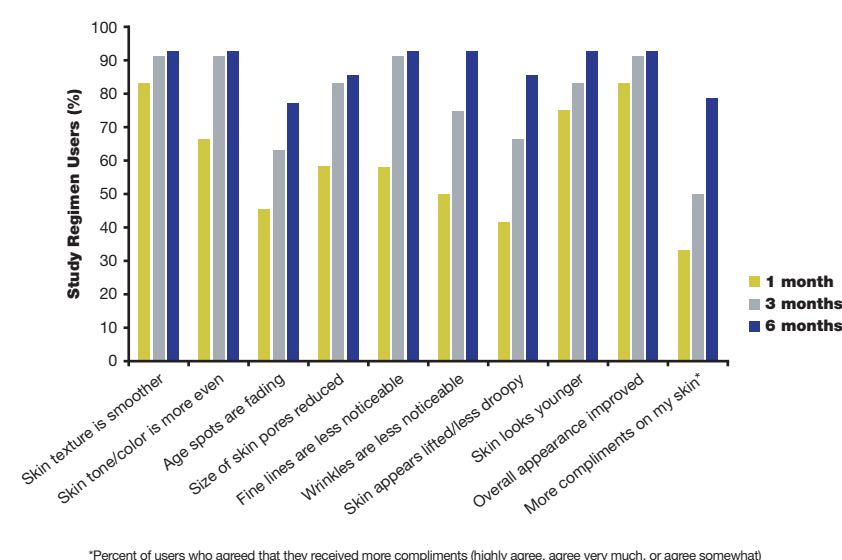
Table 1. Patient Ratings for Day Cream and Night Cream at Week 4 (Excellent + Very Good + Good)

Product Characteristic	Day Cream	Night Cream
Skin feels hydrated all day	97%	88%
Skin texture is smoother	91%	97%
Overall appearance improved	94%	97%
Good spreadability	94%	100%
Is gentle / not irritating	97%	97%
Does not sting / burn	94%	97%

Four-Product Clinical Regimen Use Study

- The four-product clinical regimen was well tolerated over 6 months of use in women, 40-65 years old.
- Regimen users reported noticeable benefits beginning as early as 1 month and continuing through 3 and 6 months of use (**Figure 2**).
- Regimen users preferred the study products to their usual skincare regimen (**Figure 3**).

Figure 2. Patient Ratings for the 4-Product Regimen (Excellent + Very Good + Good)



This 51 year-old woman used the 4-product skincare regimen daily



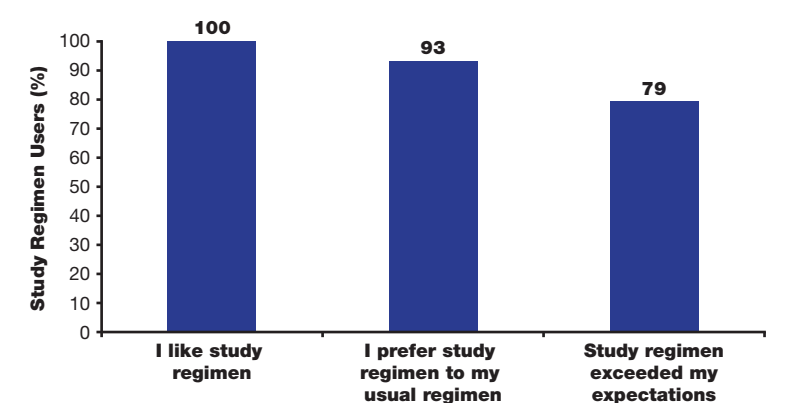
Week 0



Week 8

Note the diminished periocular lines and wrinkles, fewer dark spots, smoother texture, and more radiant, youthful skin after 8 weeks of treatment

Figure 3. Patients' Overall Opinions of the 4-Product Regimen After 6 Months of Use



Summary

The new multi-modality, high-potency, physician-dispensed Facial Cleanser, Day Cream, Night Cream, and Eye Cream were tested in the Repeated Insult Patch Test, an Ocular Irritation Potential Assessment, an Acnegenicity/Comedogenicity Assessment, and a 4-Product Clinical Regimen Use Study.

- Facial Cleanser, Day Cream, Night Cream, and Eye Cream were non-irritating and non-sensitizing.
- Eye Cream did not elicit ocular irritation and was well-tolerated regardless of contact lens use.
- Day and Night Cream were non-comedogenic and non-acnegenic.
- All four products were well-tolerated when used together in a 6-month skincare regimen.
- Users of products alone and in the skincare regimen reported multiple anti-aging skin benefits and were pleased with the products' tolerability and aesthetics.

Conclusions

- The new multi-modality, high-potency, physician-dispensed skincare products are non-irritating, non-sensitizing, non-comedogenic, well tolerated, and provide noticeable anti-aging effects when used individually or in combination.
 - 93% observed smoother skin texture, more even skin tone and less noticeable lines/wrinkles with regimen use
 - 86% reported smaller pore size and more lifted skin appearance with regimen use
 - 97% rated the day, night and eye cream as not irritating
- The Facial Cleanser, Day Cream, Night Cream, and Eye Cream product regimen delivers patient-perceived anti-aging benefits through synergistic actions of multiple benefit ingredients.
- The new high-strength skincare products can be used to restore the look and feel of more youthful skin and to reverse the visible signs of aging.

References

- Baumann L. Skin ageing and its treatment. *J Pathol.* 2007; 211: 241-251.