

A High-Strength Retinol Serum Enhanced with N-Acetyl Glucosamine Provides Significant Anti-Aging Effects in Combination with a Comprehensive Skincare Regimen

Joel Schlessinger, MD¹; Brenda L. Edison, BA²; Barbara A. Green, RPh, MS²; Heather Smith, BS²; Marisa D. Dufort, MS²

¹Skin Specialists P.C., Omaha, NE, USA; ²NeoStrata Company, Inc., a Johnson & Johnson Company, Princeton, NJ, USA

Introduction

Astute patients are increasingly seeking high-strength, physician-recommended anti-aging formulations that can be used at home to provide noticeable benefits to lines, sagging skin, texture and pigmentation. N-acetyl glucosamine (NAG) is a naturally occurring amino sugar compound that is a building block of hyaluronic acid (a glycosaminoglycan). Topical application increases hyaluronic acid in fibroblasts and keratinocytes, increases skin thickness, and helps to even skin tone.¹ Benefits from NAG include exfoliation, reduced appearance of lines and wrinkles, reduced tyrosinase activity and an overall pigment evening effect. Among physicians, retinol continues to be a proven ingredient for the management of photodamage² due to its ability to enhance exfoliation, decrease melanin, increase epidermal thickness and reduce matrix metalloproteinase (MMP) activity (collagenase) while increasing collagen.³

For this clinical study, a light serum was formulated with 4% NAG and 0.5% retinol in a time-released microencapsulate to maximize stability and enhance tolerability. Together, these well-known anti-aging ingredients work synergistically to increase hyaluronic acid, helping to build the skin's matrix, lifting and firming, and smoothing lines and wrinkles. The benefit actives were formulated in an elegant, photostabilized vehicle containing antioxidants, glycerin and calming bisabolol. This poster presents a summary of a 12-week clinical study evaluating the safety and effectiveness of this high-strength formula.

Study Methodology

Design	• A 12 week, Institutional Review Board approved, single center study
Population/Inclusion	• Women, ages 35-65 years with Fitzpatrick skin types I-IV with the presence of moderate photodamage (4-6 on a modified Griffiths' scale (0=none to 9=severe)) determined by the dermatologist and defined by fine lines, wrinkles and/or pigmentation of the face
Exclusion	• Known sensitivities or allergies to skincare products; history of disease or use of medication that could interfere with evaluations; routine use of antiaging topical products, including Rx retinoids within 3 months; hydroxyacids, retinol and other antiaging cosmetics within 1 month; cosmetic procedures (e.g. peels, laser, light treatments, microdermabrasion) within 9 months; and pregnancy/lactation
Duration/Evaluation Time Points	• 12 weeks with evaluations at Weeks 0, 6 and 12
Evaluation Tools	<ul style="list-style-type: none"> • Clinical Measures <ul style="list-style-type: none"> – Visual grading was conducted by the Board certified dermatologist for fine lines, wrinkles, mottled pigmentation, pore size, clarity/radiance, skin laxity and overall global photodamage using a 0-9 scale • Irritation/tolerability parameters such as dryness, erythema, itching, stinging/burning were graded using a 0-3 scale • Subjective Measures <ul style="list-style-type: none"> – Self-assessment questionnaires were completed by subjects • Photography <ul style="list-style-type: none"> – Standardized photographs of faces were taken using the VISIA-Complexion Analysis digital camera system
Statistics	• Dermatologist visual grading and self-assessment questionnaires were compared to baseline at each visit using the Wilcoxon signed-rank test ($p \leq 0.05$)
Safety	• Adverse events were recorded and tabulated

Test Products

The Treatment Serum was used in conjunction with a high-strength, but gentle NAG/polyhydroxy acid (PHA)/Bionic Acid containing regimen, and introduced gradually to allow the skin time to acclimate, and to minimize any irritation that can sometimes be associated with use of retinol.

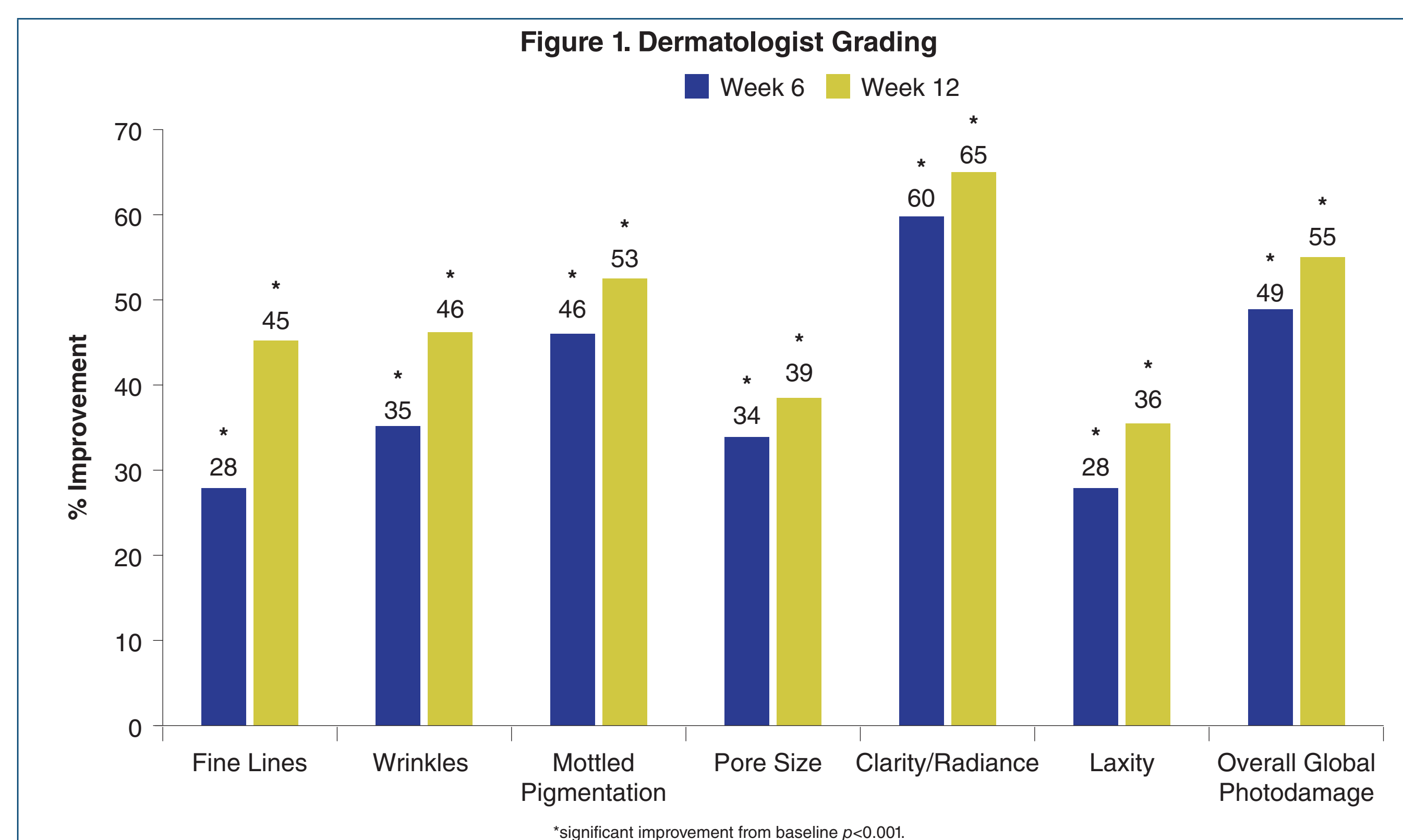
Product and Usage	Key Benefit Ingredients
Treatment Serum (NeoStrata [®] Skin Active Retinol + NAG Complex) > Week 1: 2x/week, at least 3 days apart > Weeks 2-3: every other night, as tolerated > Week 4: every night, as tolerated	0.5% Retinol 4% N-acetyl glucosamine (NAG)
REGIMEN Cleanser (NeoStrata [®] Facial Cleanser) > Twice daily; morning and night	4% PHA
Day Cream SPF 23 (NeoStrata [®] Daytime Protection Cream SPF 23) > Once daily in the morning	10% PHA/Bionic Acid
Night Cream (NeoStrata [®] Skin Active Dermal Replenishment) > Once daily at night; after application of Treatment Serum	8.5% NAG/Bionic Acid/N-acetyl tyrosinamide, plus peptides, ProdeW [®] amino acid blend, saccharide isomerate and chardonnay grape seed extract

Results

Thirty five women completed the study.

Dermatologist Clinical Grading

> All dermatologist graded anti-aging parameters were significantly improved from baseline at each time point ($p < 0.001$)

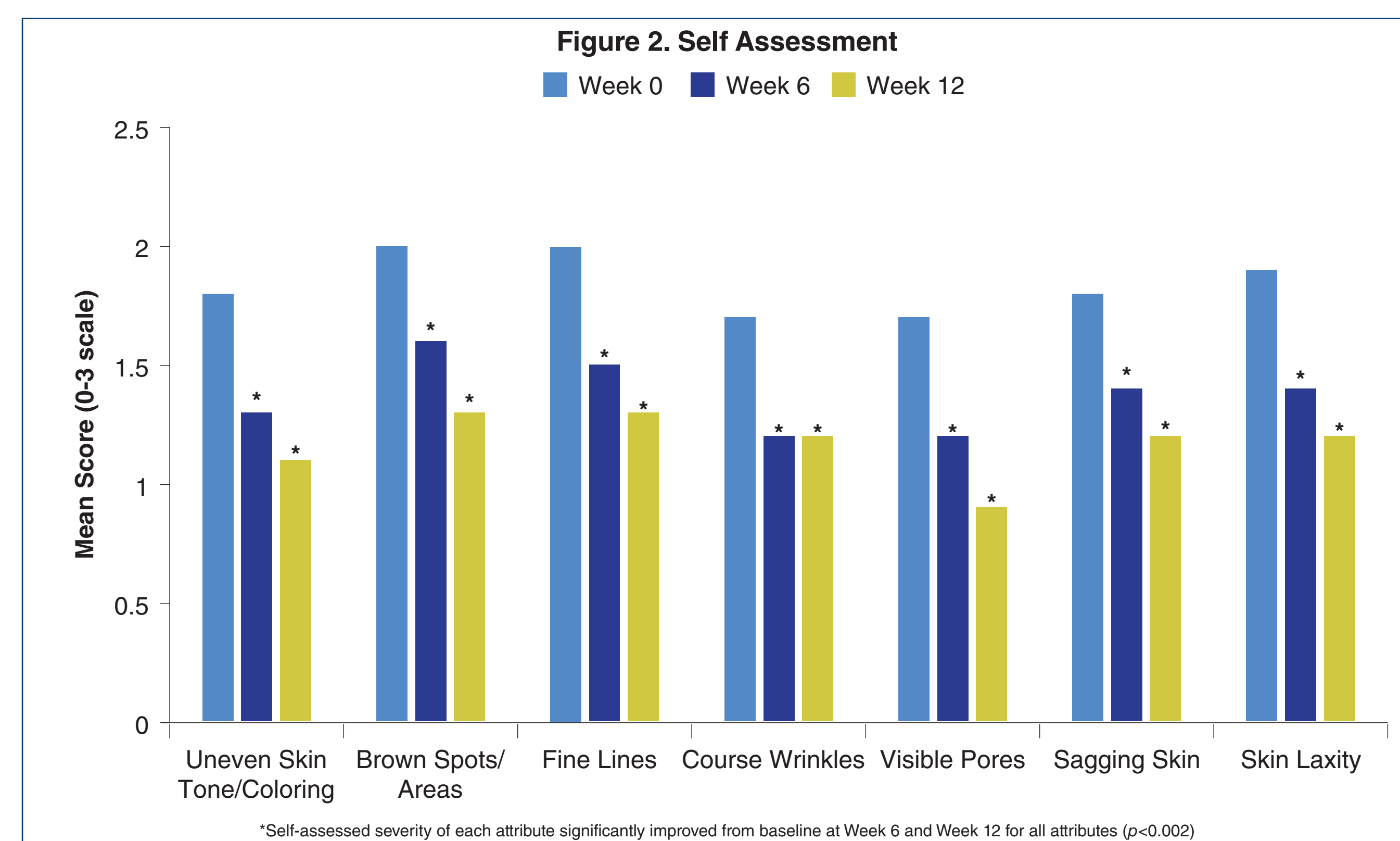


Tolerability

- > Subjects were able to acclimate to the high-strength regimen; mean irritation/tolerability scores were less than mild
- > Self-assessed skin sensitivity was rated higher at Week 6 but decreased again at Week 12; not unexpected for this regimen containing a high-strength retinol serum
- > 83% or greater of subjects rated the serum to be gentle and non irritating
- > There were 8 subjects who experienced 13 adverse events (AEs); 7 were unrelated to product use; 1 was deemed possibly related with mild itching on the forehead; the remainder were subject reports which included dryness, peeling, redness and irritation

Self Assessment

> Self-assessment supported the clinical findings with a perceived improvement in severity for each anti-aging parameter at 6 weeks and 12 weeks ($p < 0.002$)



- > The earliest time subjects thought the regimen made their skin look younger was 3 weeks on average (mean= 2.6 using a 0-3 scale)
- > The Treatment Serum was rated well for aesthetics: 97% absorbs well, 100% feels lightweight, 100% layers easily under night cream; 97% positive overall opinion

Clinical Photography

Figure 3. Improvement to Pigmentation



Figure 4. Improvements to Under Eye Lines, Forehead Texture and Overall Pigment



Figure 5. Improvement to Glabellar Lines



Conclusions

- > This high-strength retinol serum enhanced with N-acetyl glucosamine was well-tolerated and delivered clinically and consumer perceivable anti-aging benefits when tested as part of a comprehensive skincare regimen
 - Subjects were able to gradually acclimate to increased usage of the high-strength retinol serum under a physician's supervision
 - All dermatologist-graded parameters significantly improved
 - Self-assessment supports perceived anti-aging benefits
- > Clinical photography demonstrated obvious improvements in fine lines and wrinkles, uneven pigmentation, clarity and texture

References

- Small R, Green BA. Skin Care Products. In: Usatine RP, Pfenninger JL, Stulber DL, Small R, eds. *Dermatologic and Cosmetic Procedures in Office Practice*. Philadelphia, PA: Elsevier Saunders; 2012:286-297.
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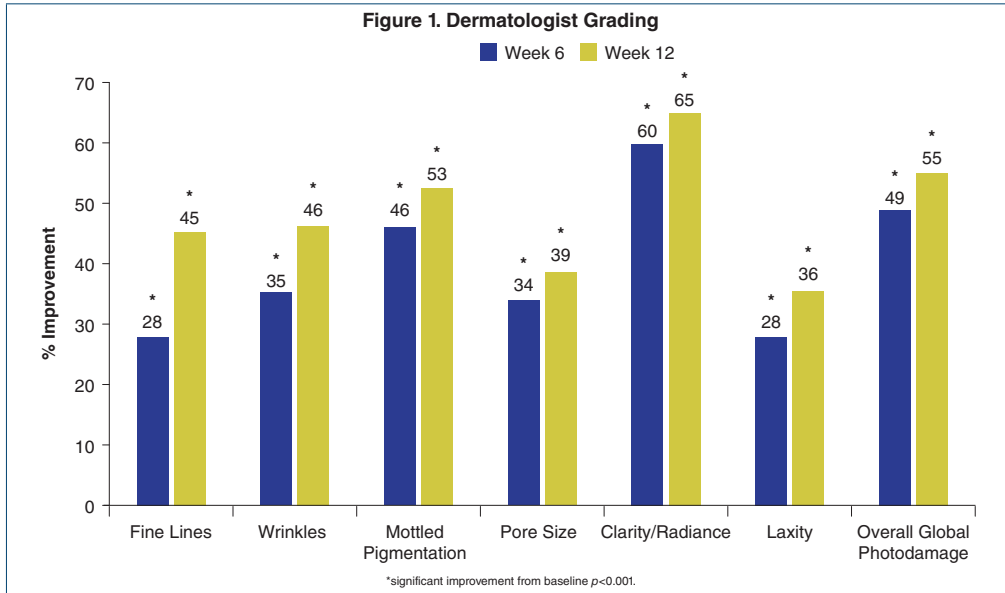
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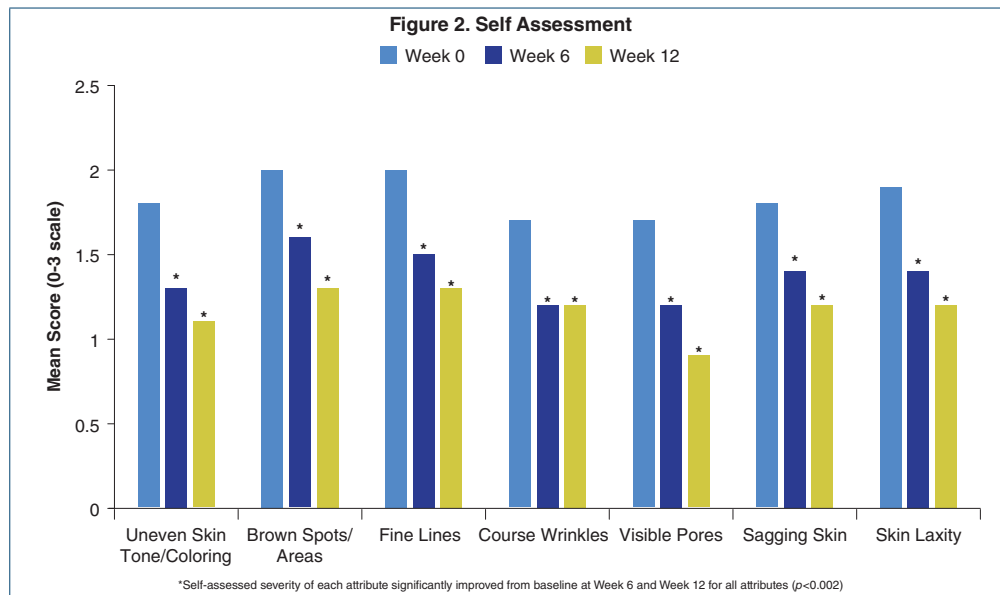


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