A High-Strength AHA/Bionic Acid Skincare Regimen in Combination With a Daily AHA Home Peel Containing N-Acetyl Tyrosinamide (Aminofil®) Significantly Improves Signs of Aging on the Face

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Introduction

An effective skincare regimen provides patients with enhanced antiaging and skin quality benefits between visits to the dermatologist. Increasingly, home peels have emerged as a desired consumer product for their ease of use and immediate results noted through skin radiance and smoothness, as well as long term antiaging effects that can be observed with consistent use. A daily home peel was formulated with 0.5% N-acetyl tyrosinamide (Aminofil®), a novel amino acid derivative shown to increase collagen in aged skin cells¹; increase hyaluronic acid in skin and cartilage cells *in vitro*; and increase pro-collagen and GAGs *in vivo* via histological assessment of human skin biopsies.² The daily home peel also contains 10% glycolic acid, an alpha-hydroxy acid (AHA) with clinically proven antiaging benefits for photodamaged skin.³-4

This poster presents a summary of a 12-week clinical study evaluating the tolerability and cosmetic effects of the daily home peel in conjunction with a high-strength AHA/Bionic Acid containing regimen.

Study Methodology

Safety

Study Methodology	
Design	A 12 week, Institutional Review Board approved, single center, prospective study with direct comparison to baseline condition
Population/Inclusion	Caucasian, non-sensitive skinned women, aged 40-60 years, with mild/moderate to marked facial photodamage (including fine lines, wrinkles and/or pigmentation; score of 1.5-3 on 0-4 scale)
Exclusion	Known allergies to skincare products; history of disease or use of medication that could interfere with evaluations; routine use of antiaging topical products, including prescription retinoids within 3 months; hydroxyacids, retinol and other antiaging cosmetics within 2 months; cosmetic procedures (e.g. peels, laser, light treatments, microdermabrasion) within 6 months; and pregnancy/lactation
Duration/Evaluation Time Points	12 weeks with evaluations at weeks 0, 6 and 12
Evaluation Tools	• Fine lines, wrinkles, mottled pigmentation, skin
 Clinical Measures 	laxity, large pore size and visual and tactile roughness were graded using a 0-4 scale with
Visual grading was conducted by the Board certified dermatologist	half point increments; predefined descriptors were anchored for each parameter at whole point values. Irritation/tolerability parameters such as dryness, erythema, itching, stinging/burning were graded using a 0-3 scale (none, mild, moderate, severe)
 Subjective Measures 	Self-assessment questionnaires were
Photography	 completed by subjects Standardized digital photographs of faces were taken using the Canfield Omnia camera system
Statistics	Clinical improvements were compared to baseline at each visit using the Student's t-test (<i>P</i> <0.05)

Adverse events were recorded and tabulated

Test Products

The daily home peel was used in conjunction with a high-strength AHA/Bionic Acid containing regimen. A gradual introduction of the daily home peel was initiated to allow the skin time to acclimate and to minimize any stinging/burning that can sometimes be associated with use of high-strength AHAs. In addition, the study site was provided with a mild alternate PHA-containing night cream for subjects that needed further time to acclimate to the regimen.

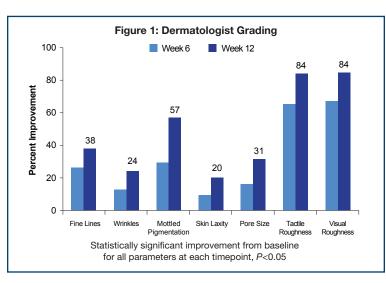
Product and Usage	Key Benefit Ingredients	
Daily Home Peel		
(NeoStrata® Smooth Surface Daily Peel)	0.5% N-acetyl tyrosinamide	
 Every other night for the first 2 weeks to allow the skin to acclimate to the high-strength AHA regimen 	(Aminofil [®]) 10% Glycolic acid	
Once daily at night thereafter		
Regimen		
Cleanser (NeoStrata® Foaming Glycolic Wash) • Twice daily; morning and night	20% AHA/Bionic Acid	
Day Cream SPF 20 (NeoStrata® Ultra Daytime Smoothing Cream SPF 20)	11% AHA/Bionic Acid	
Once daily in the morning		
Night Cream (NeoStrata® Ultra Smoothing Cream) Once daily at night; after application of Daily Home Peel	10% AHA/Bionic Acid	

Results

Thirty-four women completed the study.

Clinical Grading

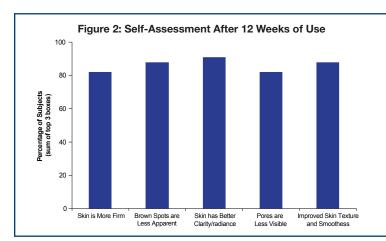
➤ All dermatologist-graded aging parameters including fine lines, wrinkles, mottled pigmentation, skin laxity, large pore size and visual and tactile roughness were significantly improved at each time point, *P*<0.05.



Results

Self-Assessment

- Self assessment supports clinical grading:
- Study participants agreed skin is more firm (82%), brown spots are less apparent (88%), skin has better clarity/radiance (91%), pores are less visible (82%) and skin texture and smoothness improved (88%). (Figure 2)
- On average, subjects thought the regimen made their skin look younger as early as 3 weeks after baseline.



Tolerability

- The high-strength regimen was well tolerated although some users reported stinging and dryness
 - The mild alternate night cream was used by only one subject prior to the week 6 visit
 - All subjects used the AHA regimen from weeks 6-12
- Physician graded irritation was low with mean scores of less than mild for erythema and stinging during the course of the study
- One subject experienced an adverse event described by the subject as small blister-like lesions to face over a 2 week period. The reaction was considered mild, no action was taken and it resolved on its own. There were no other adverse events reported.

Conclusions

- The regimen of AHA/Bionic acid products including the daily home peel containing N-acetyl tyrosinamide (Aminofil®) and glycolic acid showed significant firming, skin smoothing and pigmentation-evening benefits.
- Dermatologist grading demonstrated statistically significant improvements in the visual signs of aging; this was further supported by clinical photography as well as selfassessment for firmness, pigment, clarity and texture.
- The high-strength AHA regimen was tolerated under direction of a physician. An acclimation period is suggested when recommending this regimen.
- Addition of a daily home peel to a homecare product regimen is an effective antiaging option to complement the benefits between visits to the dermatologist.

Clinical Photography

Digital photography demonstrated obvious antiaging effects including fewer lines and wrinkles, more even pigmentation and increased firmness. (Figures 3-5)

Figure 3: Reduced appearance of forehead creases and improved texture after 12 weeks of treatment

Before After

Figure 4: Reduced appearance of pigmentation and smoother texture after 6 weeks of treatment



Figure 5: Reduced pigmentation, smoother texture after 12 weeks of treatment



References

- Khusial R, Conte J, Santhanam U. A novel mode of action to stimulate collagen production in aged skin cells. Glycobiology. 2012; 22: 1645.
 Farris PK, Edison BL, Weinkauf RL, Green BA. A nove
- Farris PK, Edison BL, Weinkauf RL, Green BA. A novel, volumizing cosmetic formulation significantly improves the appearance of target glabellar lines, nasolabial folds and crow's fet in a double-blind, vehicle-controlled clinical trial. J Drugs Dermatol. 2014;13(1):41-46.
- Ditre C.M., Griffin T.D., Murphy G.F., Sueki H., Telegar B., Johnson W.C., Yu R.J., Van Scott E.J. Effects of alpha hydroxyacids on photoaged skin: a pilot clinica histologic and ultrastructural study.
- J Am Ácad Dermatol. 1996; 34:187-95.
 Okano Y, Abe Y, Masaki H, Santhanam U, Ichihashi M, Funasaka Y. Biological effects of glycolic acid on dermal matrix metabolism mediated by dermal fibroblasts and epidermal keratinocytes. Exo Dermatol 200312 (Suppl 2):57-63.

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