Anti-Aging Effects and Tolerability of High Strength Hydroxy Acids in Males with Moderate to Severe Photoaging

Zoe Diana Draelos, MD Dermatology Consulting Services, High Point, NC, USA

Introduction

Male skin care is a rapidly expanding and poorly understood hygiene market. Where once cleansers and moisturizers were formulated for females, males are now expressing interest in products that are suitable for a bearded face to provide anti-aging effects. The challenge of facial shaving accompanied by different sebum, apocrine, and eccrine sweat production has created unique formulation considerations. The alpha-hydroxyacids (AHAs) provide cosmetic and therapeutic benefits to skin as a result of their ability to modulate the epidermal process of keratinization and improve the quality of the dermis in photoaged skin.¹ The polyhydroxy acids (PHAs), such as gluconolactone and lactobionic acid, provide anti-aging effects similar to AHAs with additional benefits including increased gentleness and skin tolerability, along with antioxidant effects and enhancement of stratum corneum barrier function.2-4

Objective

This poster will present clinical study results demonstrating the anti-aging benefits of high strength AHAs combined with PHAs in an exclusively male population.

Study Conduct

Design	prospective, direct-comparison to baseline scores; protocol received IRB approval and informed consent was executed
Subjects	30 men, 37-71 years of age, Fitzpatrick type I-III, presence of moderate to severe overall photodamage on the face
Product Application	subjects shaved their beard as they normally would in the morning after cleansing and before application of the day cream. All subjects received the following products:
• foaming cleanser	for use twice daily (20% total AHA/PHA: 18% glycolic acid and 2% lactobionic acid, pH 4.5)
• day cream SPF 15	for use in the morning (10% PHA: 8% gluconolactone and 2% lactobionic acid, pH 3.8)
night lotion	for use in the evening (15% AHA: 15% glycolic acid, pH 3.7)

Clinical Evaluations

• Clinical Grading (weeks 0, 2, 4, 8, 12)	scores were collected visually by a board certified dermatologist using a 5 point ordinal scale for the following parameters: fine lines, pore size, skin texture, mottled pigmentation, skin laxity/firmness and skin smoothness
• Tolerability/ Irritation Grading (weeks 0, 2, 4, 8, 12)	global evaluation of objective irritation and tolerability was conducted for erythema and desquamation and subjective irritation scores were collected for stinging using a 5 point ordinal scale
• Digital Photography (weeks 0, 4, 12)	collected using standardized lighting and positioning
• Self-Assessment (weeks 0, 2, 4, 8, 12)	collected via questionnaires
Statistics	
 Clinical grading and tolerability/irritation grading 	baseline scores were compared with subsequent timepoints using a two-tailed unpaired Mann-Whitney test, $p \le 0.05$
Self-Assessment	questionnaires were tabulated and a top box analysis was performed

Results

29 of 30 subjects completed the study; 1 subject discontinued at week 2 with isolated stinging and peri-orbital irritation which resolved within 24 hours upon discontinuation of the products.



> Clinical grading revealed significant improvements in the graded parameters at 12 weeks compared to baseline, p≤0.05.

Figure 2. Anti-Aging Effects



Clinical grading of skin texture and smoothness were statistically improved beginning at week 2 with continuing improvement through week 12, p≤0.05.

Tolerability

- > Irritation was noted after 2 weeks of use of these high strength products and subsided as the study continued.
- > A statistically significant increase compared to baseline for all irritation parameters was seen at week 2, p≤0.05. Desquamation and then erythema subsided as the study progressed and although stinging diminished with time, it was still significantly greater than baseline at the end of the study.
- > Although irritation was noted with clinical grading, 86% of subjects rated the products compatible with continued use at 12 weeks.





- > At 2 weeks 74% of subjects rated the product regimen to have good or better compatibility with their skin
- > At 12 weeks 86% of subjects rated the product regimen to have good or better compatibility with their skin



>Significant self-assessed skin improvements were noted within one month. >85% of the male subjects reported liking the regimen.

Figure 4b. Self-Assessment Time Until Skin Looked and Felt Younger



>92% of the male subjects reported their skin looked and felt younger after 4 weeks

Conclusion

Results of the clinical study indicate that an AHA and PHA anti-aging skin care regimen is well tolerated and efficacious in males with moderate to severe photoaged skin.

The anti-aging regimen significantly (p≤0.05) improved skin texture and smoothness as early as 2 weeks. After 12 weeks of use, the regimen significantly improved fine lines, pore size, evenness of skin tone and firmness. Irritation was noted at 2 weeks, however, it reduced over time as the skin became acclimated to the high strength AHA formulations. This is further supported by self-assessment where 86% of subjects rated the regimen to be good or better in skin compatibility at 12 weeks. Subjects also reported improvements in smoother, healthier and less oily skin, as well as a better shaving outcome with regular use of the products. Additionally, 92% of the subjects perceived that their skin looked younger within 4 weeks.

This poster demonstrates that use of an AHA and PHA anti-aging skin care reaimen provides:

- > Anti-aging and skin smoothing benefits which are noticeable to male users.
- > Significant improvements in pigmentation, skin texture, fine lines, pore size and firmness.
- > Better/easier shaving.
- > Special consideration should be given to products used in conjunction with shaving. In this study, the gentle PHA product was used following shaving and the AHA product was applied in the evening.

Cosmetic Benefits



> Diminished periocular lines and nasolabial fold lines, and improved skin clarity after 12 weeks

References

- 1. Ditre C.M., Griffin T.D., Murphy G.F., Sueki H., Telegan B., Johnson W.C., Yu R.J., Van Scott E.J. Effects of alpha hydroxyacids on photoaged skin: a pilot clinical, histologic and ultrastructural study. J Am Acad Dermatol 1996:34:187-95.
- Edison B.L., Green B.A., Wildnauer R.H., Sigler M.L. A polyhydroxy acid skin care regimen provides antiaging effects comparable to an alpha-hydroxyacid regimen. *Cutis* February 2004;73 (suppl 2):14-17.
 Briden ME, Green BA. The Next Generation Hydroxyacids. In: Draelos Z, Dover J, Alam M, eds. *Procedures in Cosmetic*
- meceuticals. Philadelphia, PA: Elsevier Saunders 2005; 205-212
- Bernstein E.F., Green B.A., Edison B., Wildnauer R.H. Poly Hydroxy Acids (PHAs): Clinical Uses for the Next Generation of Hydroxy Acids. Skin & Aging September 2001;9(suppl):4-11.

Poster exhibit at the 67th Annual Meeting of the American Academy of Dermatology; San Francisco, CA; March 6-10, 2009.

Anti-Aging Effects and Tolerability of High Strength Hydroxy Acids in Males with Moderate to Severe Photoaging Zoe Diana Draelos, MD Dematology Consulting Services, High Point, NC, USA

Introduction

Male skin care is a rapidly expanding and poorly understood hygiene market. Where once cleansers and moisturizers were formulated for females, males are now expressing interest in products that are suitable for a bearded face to provide anti-aging effects. The challenge of facial shaving accompanied by different sebum, apocrine, and eccrine sweat production has created unique formulation considerations. The alpha-hydroxyacids (AHAs) provide cosmetic and therapeutic benefits to skin as a result of their ability to modulate the epidermal process of keratinization and improve the quality of the dermis in photoaged skin.¹ The polyhydroxy acids (PHAs), such as gluconolactone and lactobionic acid, provide anti-aging effects similar to AHAs with additional benefits including increased gentleness and skin tolerability, along with antioxidant effects and enhancement of stratum corneum barrier function.2-4

Objective

This poster will present clinical study results demonstrating the anti-aging benefits of high strength AHAs combined with PHAs in an exclusively male population.

Study Conduct

Design	prospective, direct-comparison to baseline scores; protocol received IRB approval and informed consent was executed
Subjects	30 men, 37-71 years of age, Fitzpatrick type I-III, presence of moderate to severe overall photodamage on the face
Product Application	subjects shaved their beard as they normally would in the morning after cleansing and before application of the day cream. All subjects received the following products:
• foaming cleanser	for use twice daily (20% total AHA/PHA: 18% glycolic acid and 2% lactobionic acid, pH 4.5)
• day cream SPF 15	for use in the morning (10% PHA: 8% gluconolactone and 2% lactobionic acid, pH 3.8)
• night lotion	for use in the evening (15% AHA: 15% glycolic acid, pH 3.7)

Clinical Evaluations

Statistics • Clinical grading and baseline scores were compared with subsequent		
•	Self-Assessment (weeks 0, 2, 4, 8, 12)	collected via questionnaires
•	Digital Photography (weeks 0, 4, 12)	collected using standardized lighting and positioning
•	Tolerability/ Irritation Grading (weeks 0, 2, 4, 8, 12)	global evaluation of objective irritation and tolerability was conducted for erythema and desquamation and subjective irritation scores were collected for stinging using a 5 point ordinal scale
•	Clinical Grading (weeks 0, 2, 4, 8, 12)	scores were collected visually by a board certified dermatologist using a 5 point ordinal scale for the following parameters: fine lines, pore size, skin texture, mottled pigmentation, skin laxity/firmness and skin smoothness

tolerability/irritation timepoints using a two-tailed unpaired Mann-Whitney test, p≤0.05 grading questionnaires were tabulated and a top box analysis was Self-Assessment performed

Results

29 of 30 subjects completed the study; 1 subject discontinued at week 2 with isolated stinging and peri-orbital irritation which resolved within 24 hours upon discontinuation of the products.



Clinical grading revealed significant improvements in the graded parameters at 12 weeks compared to baseline, p≤0.05.

Figure 2. Anti-Aging Effects



➤ Clinical grading of skin texture and smoothness were statistically improved beginning at week 2 with continuing improvement through week 12, p≤0.05.

Tolerability

- Irritation was noted after 2 weeks of use of these high strength products and subsided as the study continued.
- ➤ A statistically significant increase compared to baseline for all irritation parameters was seen at week 2, p≤0.05. Desquamation and then erythema subsided as the study progressed and although stinging diminished with time, it was still significantly greater than baseline at the end of the study.
- Although irritation was noted with clinical grading, 86% of subjects rated the products compatible with continued use at 12 weeks.

Figure 3. Self-Assessment Compatibility of Regimen with Skin



At 2 weeks 74% of subjects rated the product regimen to have good or better compatibility with their skin.

At 12 weeks 86% of subjects rated the product regimen to have good or better compatibility with their skin.



Significant self-assessed skin improvements were noted within one month.
 85% of the male subjects reported liking the regimen.



Figure 4b. Self-Assessment Time Until Skin Looked and Felt Younger

>92% of the male subjects reported their skin looked and felt younger after 4 weeks.

Conclusion

Results of the clinical study indicate that an AHA and PHA anti-aging skin care regimen is well tolerated and efficacious in males with moderate to severe photoaged skin.

The anti-aging regimen significantly ($p \le 0.05$) improved skin texture and smoothness as early as 2 weeks. After 12 weeks of use, the regimen significantly improved fine lines, pore size, evenness of skin tone and firmness. Irritation was noted at 2 weeks, however, it reduced over time as the skin became acclimated to the high strength AHA formulations. This is further supported by self-assessment where 86% of subjects rated the regimen to be good or better in skin compatibility at 12 weeks. Subjects also reported improvements in smoother, healthier and less oily skin, as well as a better shaving outcome with regular use of the products. Additionally, 92% of the subjects perceived that their skin looked younger within 4 weeks.

This poster demonstrates that use of an AHA and PHA anti-aging skin care regimen provides:

- > Anti-aging and skin smoothing benefits which are noticeable to male users.
- Significant improvements in pigmentation, skin texture, fine lines, pore size and firmness.
- > Better/easier shaving.
- Special consideration should be given to products used in conjunction with shaving. In this study, the gentle PHA product was used following shaving and the AHA product was applied in the evening.



References

- Ditre C.M., Griffin T.D., Murphy G.F., Sueki H., Telegan B., Johnson W.C., Yu R.J., Van Scott E.J. Effects of alpha hydroxyacids on photoaged skin: a pilot clinical, histologic and ultrastructural study. J Am Acad Dermatol 1996;34:187-95.

- Dermator 1990;34: 187-95.
 Edison B.L., Green B.A., Wildnauer R.H., Sigler M.L. A polyhydroxy acid skin care regimen provides antiaging effects comparable to an alpha-hydroxyacid regimen. *Cutis* February 2004;73 (suppl 2):14-17.
 Briden ME, Green BA. The Next Generation Hydroxyacids. In: Draelos Z, Dover J, Alam M, eds. *Procedures in Cosmetic Dermatology: Cosmecouticals*. Philadelphia, PA: Elsevier Saunders 2005; 205-212.
 Bernstein E.F., Green B.A., Edison B., Wildnauer R.H. Poly Hydroxy Acids (PHAs): Clinical Uses for the Next Generation of Hydroxy Acids. *Skin & Aging* September 2001;9(suppl):4-11.

Poster exhibit at the 67th Annual Meeting of the American Academy of Dermatology; San Francisco, CA; March 6-10, 2009. Study sponsored by NeoStrata Company, Inc., Princeton, NJ, USA