

# Double-Blind, Randomized, Bilateral Comparison of Topical 6% Salicylic Acid Cream and 20% Alpha/Poly Hydroxy Acid Cream to Reduce Scaling of Lesions Associated with Moderate, Chronic Plaque Psoriasis

Barbara A. Green, RPh, MS,<sup>1</sup> Brenda L. Edison, BA,<sup>1</sup> Adele R. Clark, PA-C,<sup>2</sup> Steven R. Feldman, MD, PhD<sup>2</sup>  
<sup>1</sup>NeoStrata Company, Inc., Princeton, NJ USA; <sup>2</sup>Wake Forest University, Department of Dermatology Clinical Studies Center, Winston-Salem, NC USA

## Introduction

Psoriasis treatment frequently involves combination therapy that may include the use of descaling agents. Guidelines discuss using topical salicylic acid as a keratolytic to reduce scaling and soften plaques, but use of salicylic acid is limited on larger body surfaces and in children due to potential toxicity and during phototherapy due to UV absorption.<sup>1</sup> Furthermore, the use of 5% salicylic acid causes skin thinning,<sup>2</sup> which is an undesirable side effect, especially when used in combination with atrophogenic topical corticosteroids.

Alpha-hydroxy acids (AHAs) and polyhydroxy acids (PHAs) normalize keratinization and stratum corneum thickness in scaling conditions such as ichthyosis,<sup>3</sup> and promote dermal thickening.<sup>4-6</sup> AHAs increase collagen synthesis<sup>4,5</sup> and prevent the dermal thinning effect of topical corticosteroids.<sup>7</sup> Due to these added benefits, AHAs/PHAs may be a preferable alternative to salicylic acid for descaling psoriasis plaques.

## Objective

To compare the effectiveness and tolerability of 20% alpha/poly hydroxy acid cream (a commercially available cosmetic formulation) to 6% salicylic acid cream (a commercially available Rx formulation) in reducing scaling of lesions associated with moderate chronic plaque psoriasis.

## Study Methodology

<b>Design</b>	Randomized, double-blind, active-controlled, bilateral (side-by-side), direct comparison
<b>Population/Inclusion</b>	Adults with moderate psoriasis having Investigator's Global Assessment (IGA) of at least 3 and comparable, bilateral lesions no smaller than the size of a silver dollar with a grade of 3 for scaling and plaque elevation (on a scale of 0 to 5)
<b>Exclusion</b>	Topical psoriasis treatment within previous 2 weeks; phototherapy within previous 4 weeks; systemic or biologic treatments that were initiated or unstable during the previous 12 weeks, or were planning to be discontinued during the study; current or previous skin cancer; pregnancy/lactation
<b>Duration</b>	2 weeks
<b>Treatment</b>	<ul style="list-style-type: none"> <li><b>Assignment</b> <ul style="list-style-type: none"> <li>Side 1 ("AHA/PHA"): 20% AHA/PHA Cream (Problem Dry Skin Cream, NeoStrata Company, Inc.), [15% AHA (lactic acid + mandelic acid + glycolic acid) plus 5% PHA (gluconolactone + maltobionic acid)] pH 3.7</li> <li>Side 2 ("Sal Acid"): 6% Salicylic Acid Cream (Salex® Cream, Coria Laboratories, Ltd.), pH 4.4</li> </ul> </li> <li><b>Dosing</b> Twice daily application to assigned half of body and target lesion excluding face and scalp</li> </ul>
<b>Evaluation Visits</b>	Baseline, Week 1, Week 2
<b>Evaluation Tools</b>	<ul style="list-style-type: none"> <li><b>Investigator</b> Investigator's Global Assessment (IGA) of each body half using a 0-5 scale (clear, minimal, mild, moderate, severe, very severe) Target lesion grading of erythema, scaling, and induration/elevation using a 0-5 scale</li> <li><b>Patient</b> Self-assessment questionnaires of efficacy parameters using a 0-6 scale (none (0), mild (2), moderate (4), severe (6) with scores in between) Irritation, tolerability and aesthetic parameters (scale: agree completely, agree somewhat, neither agree nor disagree, disagree somewhat, disagree completely)</li> <li><b>Photography</b> Digital photographs of bilateral target lesions at baseline and week 2</li> </ul>
<b>Safety</b>	Adverse events were recorded and evaluated

## Statistics

- > Mean change from baseline in IGA, Erythema, Scaling and Induration scores within and between treatments: Wilcoxon Signed-Rank Test
- > Number of patients achieving a 2-point improvement in IGA by week 2: McNemar's Test
- > Mean change in self-assessed scores within and between treatments: Wilcoxon Signed-Rank Test
- > Statistical significance determined at p<0.05

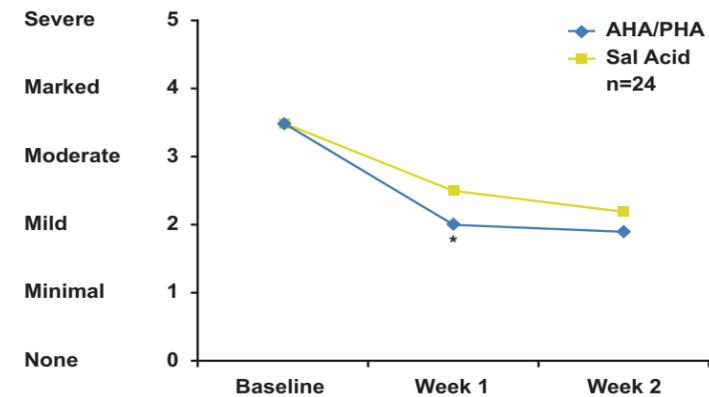
## Results

24 patients enrolled and completed the study. Patients tolerated both products equally well. There were 5 adverse events, none of which were considered related to the treatment creams.

### Investigator Graded Descaling Effects (Target Lesions)

- > AHA/PHA cream reduced scaling better than did Sal Acid cream at week 1 (p=0.005).
- > AHA/PHA cream and Sal Acid cream reduced induration after 1 and 2 weeks of treatment (p<0.05). Erythema was improved after 1 and 2 weeks with Sal Acid cream and after 2 weeks with AHA/PHA cream (p<0.05). There were no statistically significant differences between treatments for these parameters.

### Mean Clinically Assessed Scaling Scores

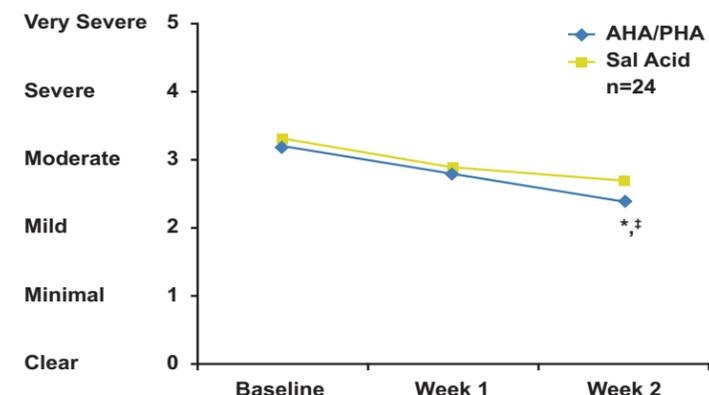


\*AHA/PHA cream was more effective than Sal Acid cream, p=0.005.

### Investigator Graded Descaling Effects (IGA)

- > AHA/PHA cream improved IGA better than Sal Acid cream at week 2 (p=0.016).
- > Psoriasis severity scores (IGA) improved by 2 grade points more often with AHA/PHA cream than Sal Acid cream at week 2 (p=0.046).

### Mean Investigator Global Assessment (IGA) Scores



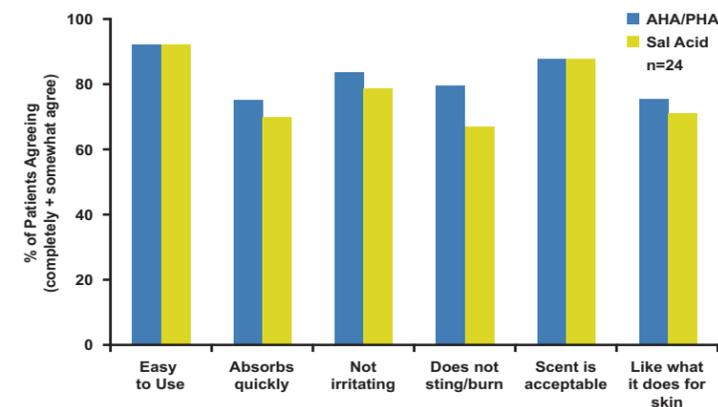
\*AHA/PHA cream was more effective than Sal Acid cream, p=0.016.

†More AHA/PHA cream treated sites improved by 2 grade points compared with Sal Acid cream treated sites, p=0.046.

## Self-Assessment

- > AHA/PHA cream and Sal Acid cream provided improvements in patient graded symptoms at week 1 and week 2 including: flaking, itching, raised appearance, roughness, discomfort and redness (p<0.05); differences between groups were not statistically significant.
- > Approximately 80% of AHA/PHA and Sal Acid users rated the products as "non-irritating" and an average of 76% of AHA/PHA users and 73% of Sal Acid users agreed the products were "non-stinging/non-burning" based on an average calculation of data across weeks 1 and 2. The AHA/PHA cream tended to be better tolerated at week 1 compared with week 2, while Sal Acid cream tended to be better tolerated at week 2 compared with week 1.
- > 38% of patients preferred AHA/PHA cream and 33% of patients preferred Sal Acid cream at week 2; 29% had no treatment preference.

### Self-Assessment Scores at Week 1



AHA/PHA cream and Sal Acid cream were rated equivalently by patients. There were no statistically significant differences between treatments at weeks 1 and 2.

## Conclusions

- > 20% AHA/PHA cream outperformed the prescription comparator cream containing 6% salicylic acid during this two-week descaling study by reducing scaling faster and improving overall psoriasis symptoms (IGA) more effectively.
- > AHA/PHA cream is a suitable nonprescription alternative to prescription salicylic acid cream for descaling. One week of treatment appears to be optimal to achieve a strong descaling effect and good skin tolerability with AHA/PHA cream.
- > AHA/PHA cream may be preferable to salicylic acid cream for psoriasis descaling because it contains AHAs, which have been shown to reduce steroid-induced atrophy<sup>7</sup> and provide a synergistic effect when used in combination with topical corticosteroids in the treatment of psoriasis.<sup>8</sup>

## References

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Poster exhibit at the 68th Annual Meeting of the American Academy of Dermatology, Miami, FL; March 5 - 9, 2010.  
 Study sponsored by NeoStrata Company, Inc., Princeton, NJ, USA

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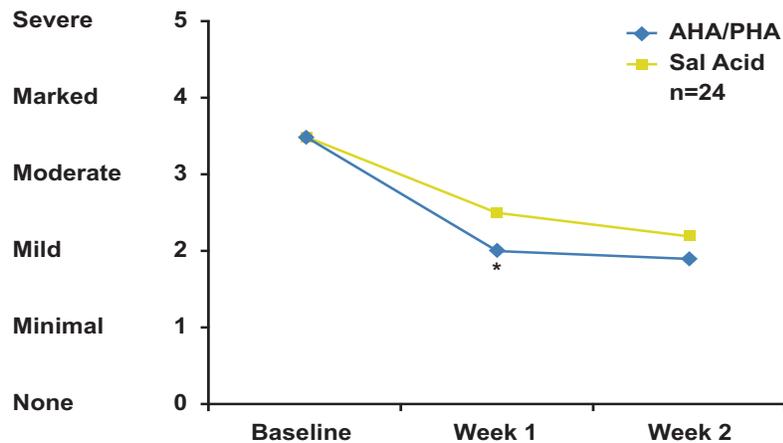
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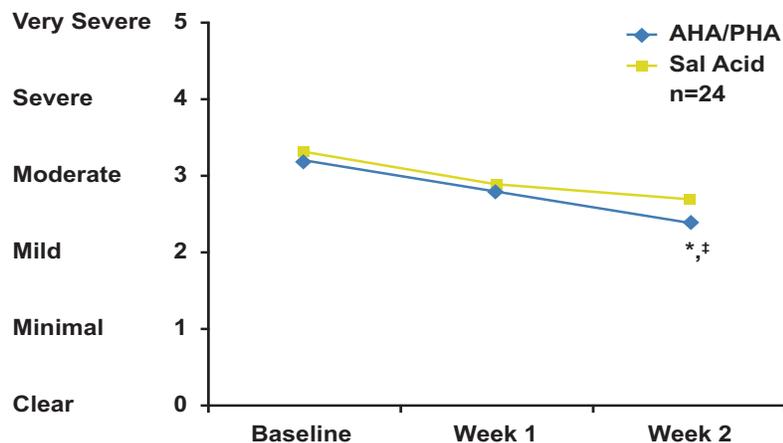


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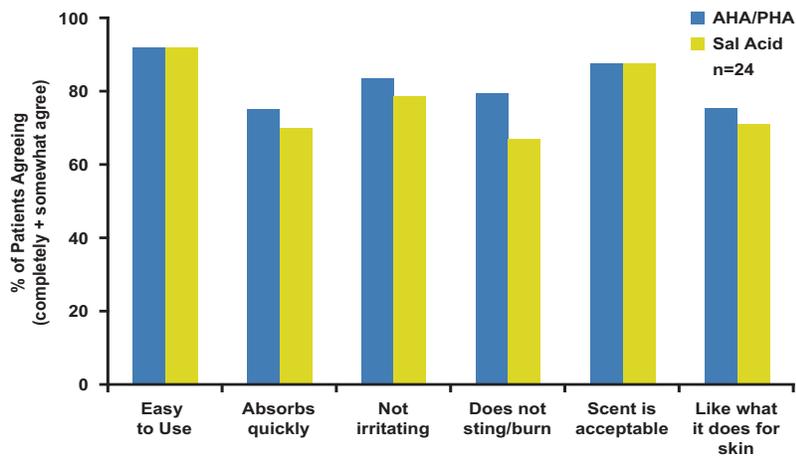
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**Left Elbow Before**



**After 2 weeks (AHA/PHA Cream)**



**Left Knee Before**



**After 2 weeks (AHA/PHA Cream)**



**Right Buttock Before**



**After 2 weeks (AHA/PHA Cream)**

