

# Evaluation of the Efficacy of an Exfoliating Cleanser and Urea-Containing Cream on Keratosis Pilaris using Clinical and 3D Image-Based Analysis

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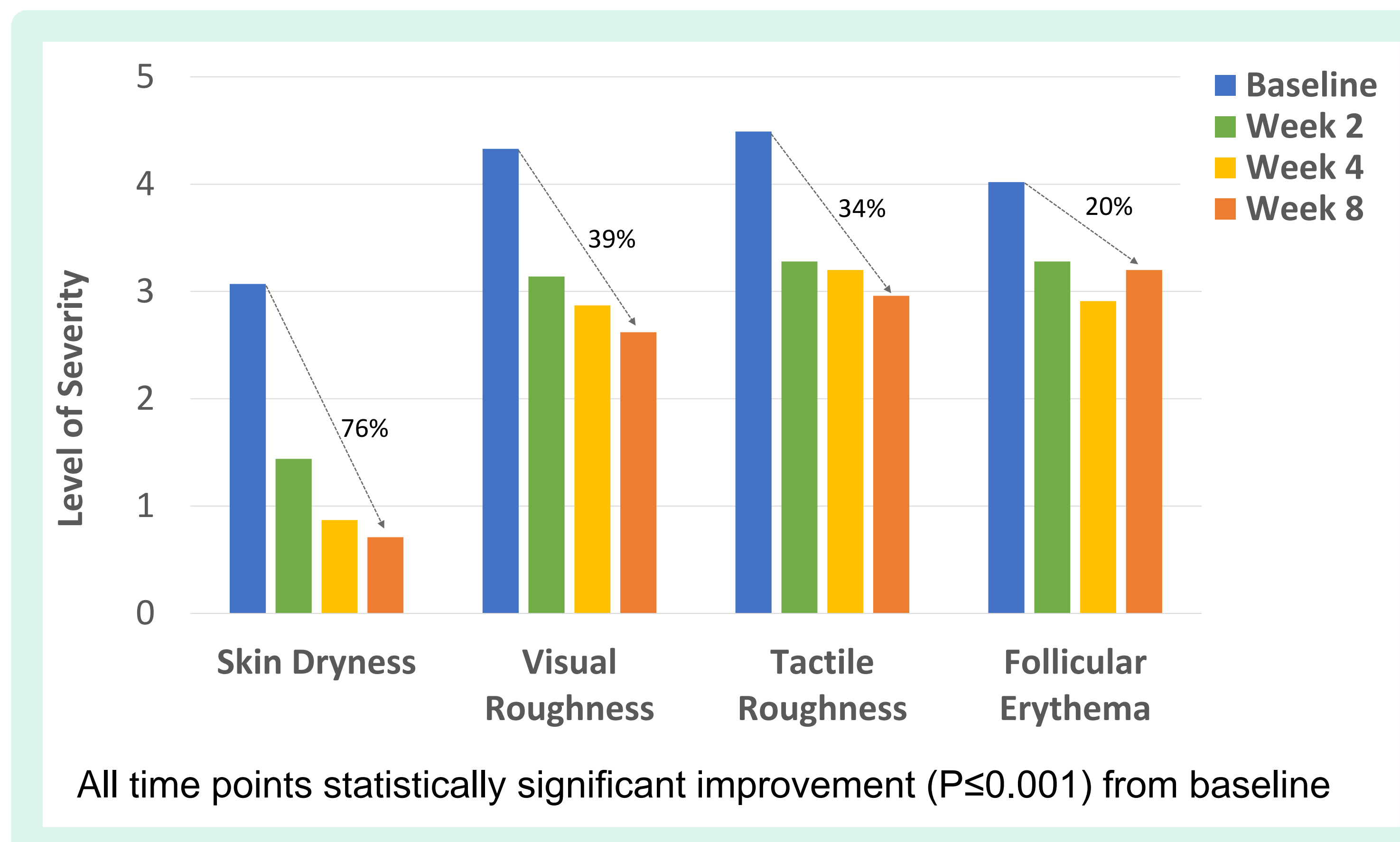
## INTRODUCTION

Keratosis pilaris (KP), a keratinization disorder, manifests as rough, bumpy skin on the proximal, lateral surface of the extremities, the face, and the buttocks. It is characterized by reduced skin barrier function, leaving the skin dry in many and with exacerbated symptoms in winter for most.<sup>1,2</sup> The KP phenotype is common, reported in up to 40% of the population globally, and is chronic. While it is asymptomatic, it is cosmetically undesirable and a source of psychological stress for many.<sup>1,3</sup> There are limited treatment options for keratosis pilaris that address both the spiny keratinous follicular plugs and follicular erythema and are also aesthetically suitable for long term application. Hyperkeratotic skin can benefit from topical formulations that hydrate to soften keratin, promote desquamation, and help to restore skin barrier function. Herein, we describe the efficacy evaluations for a daily ceramide-containing regimen including an exfoliating cleanser and cream with urea in women with KP on their upper arms or outer thighs. A 3D image-based analysis was employed to assess the texture of skin with KP for the first time.

## METHODS

This study included 45 women ages 18-50 years with moderate tactile and visual roughness additional mild to moderate follicular erythema on the upper arms or outer thighs diagnosed as KP by a dermatologist. Clinical efficacy was evaluated by expert dermatologist grading for skin texture, follicular erythema and dryness. Additionally, self-assessment questionnaires were completed at baseline, week 2, week 4 and week 8. Images were captured using a 2D Nomad Cam® and 3D imaging system Primos Lite®. Objective and subjective tolerance assessments were also performed at each study visit.

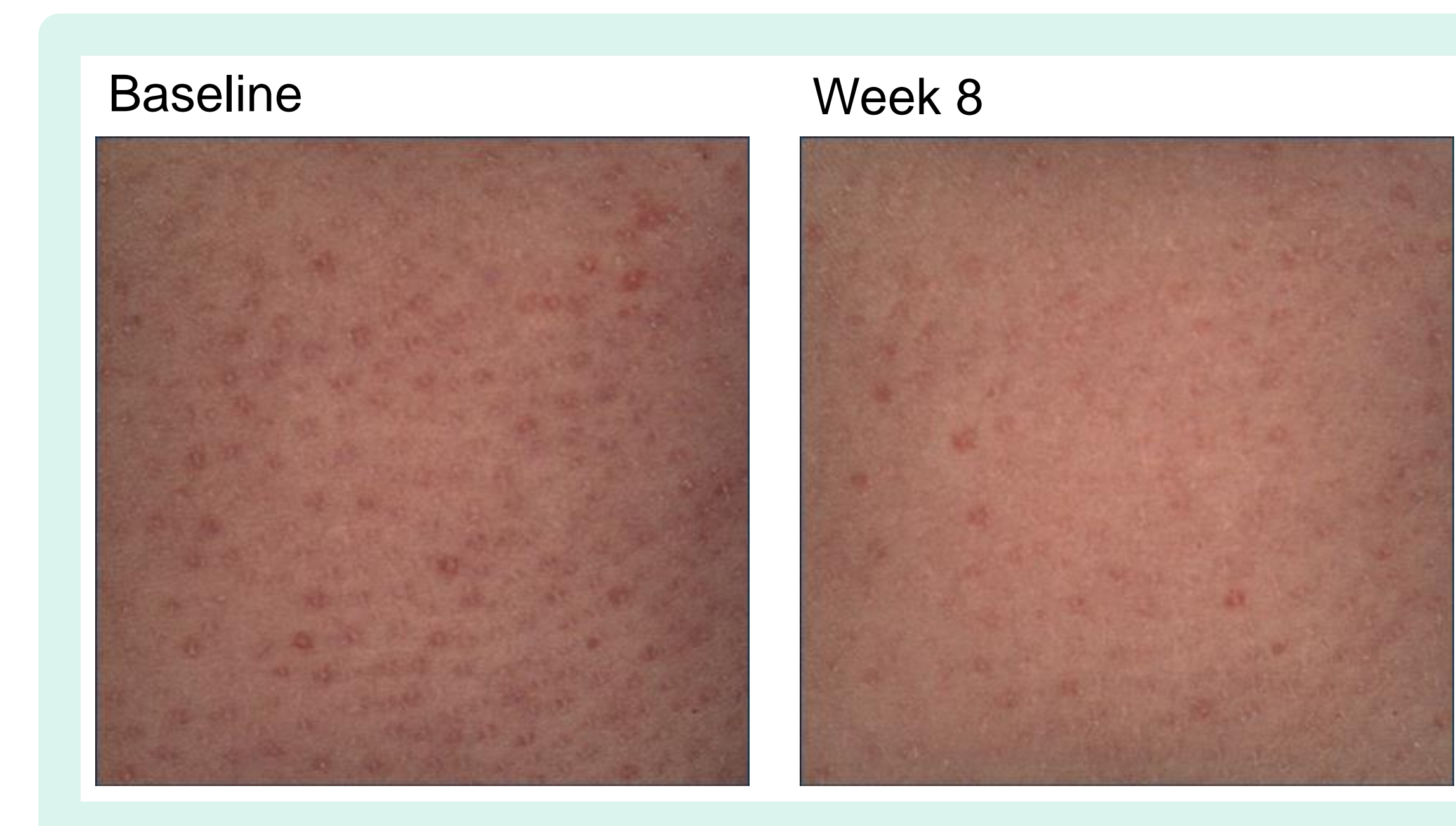
**Figure 1:** Severity of skin dryness, skin texture and follicular erythema evaluated by expert dermatologist grading.



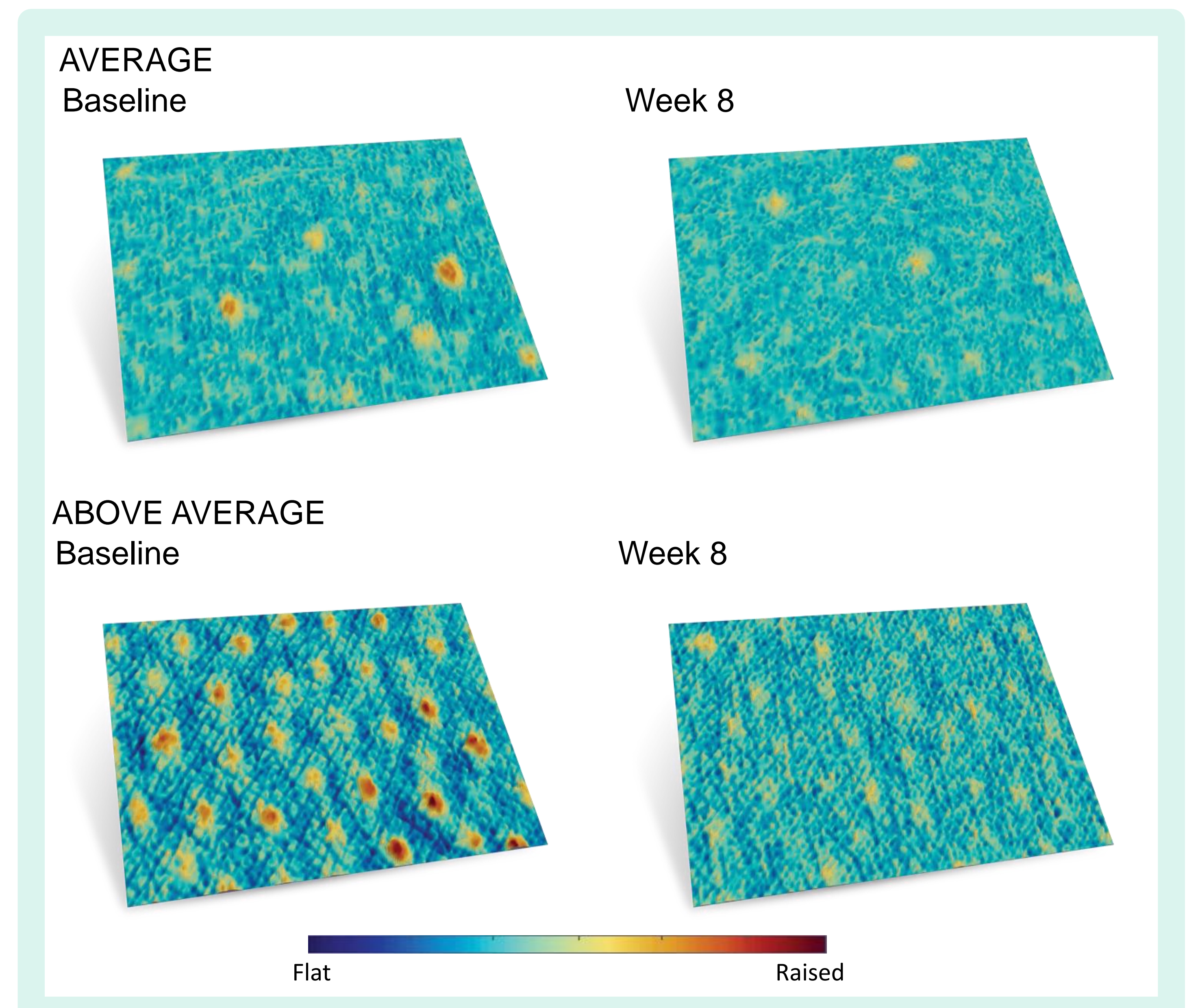
## RESULTS

- A statistically significant improvement ( $P < 0.0001$ ) was observed in dermatologists graded skin texture (tactile and visual), follicular erythema, skin dryness and the overall healthy appearance of the skin condition at all time points.
- Skin dryness was reduced by 76% and follicular erythema was reduced by 20% in 8 weeks. In the same time, skin texture visually improved by 39% and showed tactile improvement by 34%.
- The 3D image analysis also showed a statistically significant reduction in the roughness parameter.
- The formula was well tolerated and subjects were satisfied with the regimen and perceived an improvement in their skin quality.

**Figure 2:** Average improvement in visual roughness and follicular erythema from baseline to week 8.



**Figure 3:** 3D images of subjects with average and above average improvement in skin texture from baseline to week 8.



## CONCLUSIONS

3D image-based analysis is a novel approach to visualizing and evaluating the impact of an exfoliating cleanser and urea-containing cream on the uneven texture of keratosis pilaris. Dermatologist grading confirmed a reduction in both erythema and skin dryness. Global tolerance and self-assessment evaluations showed the regimen was well tolerated and well perceived.

<sup>1</sup>Wang, J. F., & Orlow, S. J. (2018). *American Journal of Clinical Dermatology*, 19(5), 733-757. <sup>2</sup>Gruber, R., et al. (2015). *The American Journal of Pathology*, 185(4), 1012-1021. <sup>3</sup>Poskitt, L., & Wilkinson, J. D. (1994). *British Journal of Dermatology*, 130(6), 711-713.