

Evaluation of a Gel Cleanser with PHA demonstrating Clinically Effective Sebum Reduction While Preserving Skin Barrier Integrity

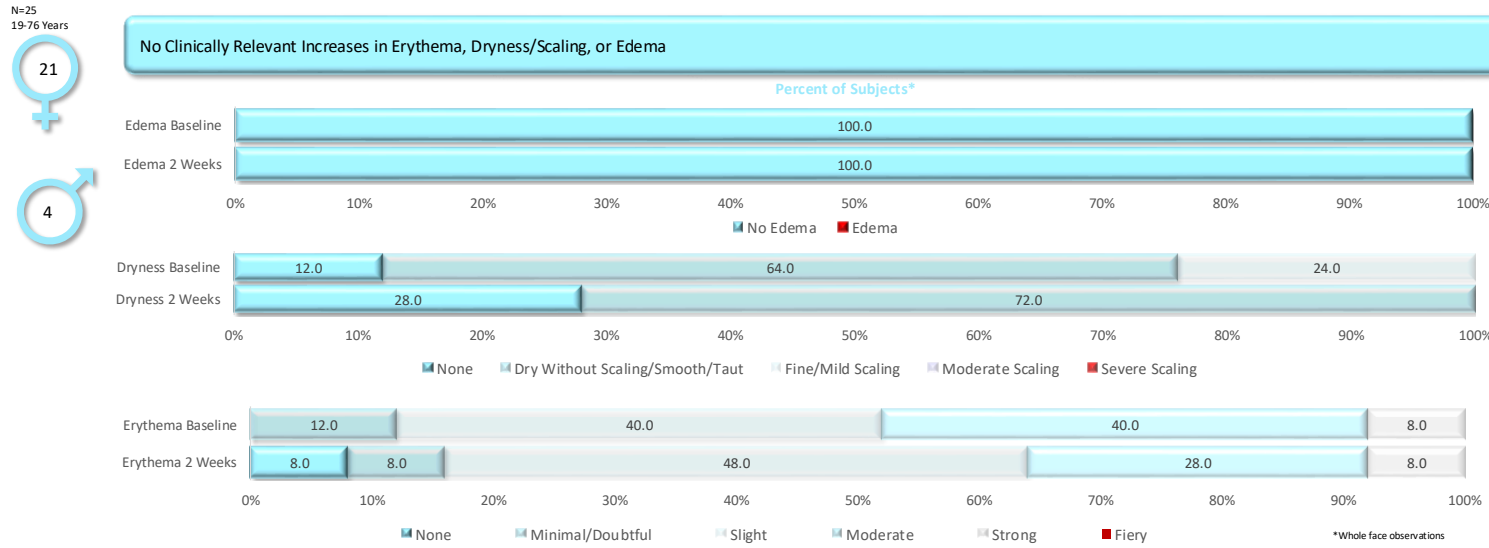
Cheri Frey, MD¹, Julie C. Harper, MD², Patricia K. Farris, MD³

1. Department of Dermatology, Howard University Hospital, Washington DC; 2. Dermatology and Skin Care Center of Birmingham in Birmingham, Alabama; 3. Tulane University School of Medicine, New Orleans, LA.

Key Findings: In clinical studies evaluating a gel cleanser formulated with coconut-based cleansing agents, glycerin, and gluconolactone, the product demonstrated strong cleansing efficacy while maintaining excellent skin tolerability. There was an 81.4% mean change in sebum levels (p<0.001) following a single use of gel cleanser. There was also statistically significant decreases in porphyrin counts and fractional area scores, indicating effective removal of impurities. Importantly, barrier function improved following a single application, with significant reductions in transepidermal water loss (TEWL). Repeated daily use was well tolerated in both adults with self-described sensitive skin and pediatric subjects aged 8–18 years, with no clinically meaningful increases in erythema, dryness, edema, or irritation observed during the study periods. These findings demonstrate that the cleanser effectively removes excess oil and impurities while preserving skin barrier integrity and maintaining excellent tolerability across age groups.

Safety in Use - Adult – Gel Cleanser

Objective: Determine the irritation potential of a cleanser after repeated application under real-life conditions to the skin in adults 18-79 years with self-described sensitive skin. This single-center, baseline-controlled, monadic clinical trial design of 14 days duration. Clinical skin assessments were performed by expert clinical graders prior to initial application/use of gel cleanser and again at 14 days following daily use. Evaluations included - Visual grading scales for erythema (6-point scale); dryness/scaling (5-point scale); and edema (2-point scale). **Instructions:** Massage 2-3 pumps onto wet skin. Rinse off and pat dry.



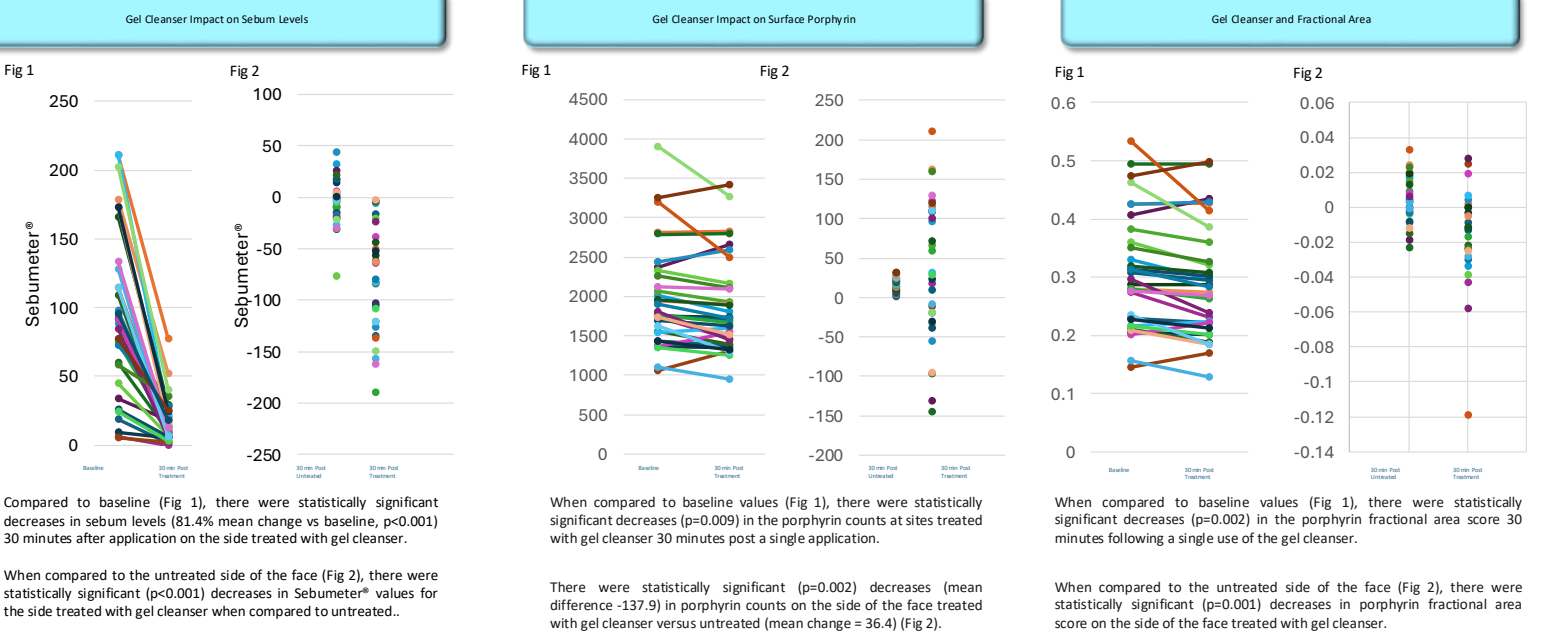
Well Tolerated in Those with Self-Described Sensitive Skin

Summary of Symptom Incidence and Severity	
Total Number of Subjects	25
Total Number of Responses	700
Total Number of Discomfort Reports	10
Overall Percentage of Discomfort Reports	1.43%
Average Score of Discomfort	1.00
Severe Discomfort Rate	0.00%

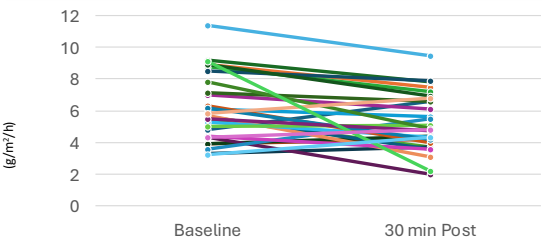
Discomfort Frequency, Severity, and Duration Analysis				
Symptom of Discomfort	Frequency	Frequency (% of Total)	Average Severity	Average Duration
Burning	0	0.00%	0.00	0.00
Itching	10	1.43%	1.00	342.00
Dryness	0	0.00%	0.00	0.00
Redness	0	0.00%	0.00	0.00
Other	0	0.00%	0.00	0.00
No Discomfort	98.75%			

Sebum and Porphyrin – Gel Cleanser

Objective: To evaluate the potential of a face cleanser, after a single application, to reduce casual sebum and impurities (porphyrins) on the surface of the skin, utilizing the Sebumeter® and the VISIA-CR® UV fluorescence imaging with image analysis. This single-center, randomized, single-blinded, baseline-controlled, split-face clinical trial of 8 days duration. Clinical skin assessments were performed by expert clinical graders prior to initial application/use of gel cleanser. VISIA-CR® image capture and Sebumeter® measurements were taken prior to and 30 minutes after gel cleanser use.



Barrier Function - TEWL



When compared to baseline values, there were statistically significant decreases (p=0.008*) in TEWL as measured by the VapoMeter® after a single usage of the gel cleanser.

This decrease in TEWL vs Untreated Control is indicative of a maintained skin barrier function

Safety in Use – Children and Teens – Gel Cleanser

Objective: Objective: To evaluate the potential for dermatological irritation and/or hypersensitivity of a cleanser in children 8-18 years of age after 4 weeks of use. This single-center, baseline-controlled, 4-week monadic investigations. Clinical skin assessments were performed by a board-certified dermatologist at baseline and Week 4. Erythema, edema, and dryness were evaluated using a 6-point ordinal grading scale defined as: 0=None; 0.5=Barely Perceptible; 1=Mild; 2=Moderate; 3=Marked; and 4=Severe.

