# Demonstrated Tolerability and Clinical Efficacy of Salicylic Acid Formulations as a First Line of Defense for Acne

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**Key Findings:** The routine use of salicylic acid (SA) containing products recommended for the management of acne significantly* reduced blemish appearance, the size of breakouts, blemish redness, and associated flakiness/dryness in acne prone and/or sensitive skin subjects. In addition, the impact of product use on the skin barrier was evaluated after 28 days. The use of a salicylic acid acne cleanser or salicylic acid serum was associated with a statistically significant average decrease* in TEWL, indicative of improved skin water barrier integrity. The use of a 2% salicylic acid cleanser, 2% salicylic acid serum, or 1.8% salicylic acid spot treatment was well tolerated in subjects 8-18 years of age and did not exhibit a potential for irritation or hypersensitivity during in-use conditions.

## Methods:

### Efficacy Studies Overview

**2% SA Cleanser**
- 28-day effectiveness
- Visual expert grading
- TEWL (Transepidermal water loss)
  - DermaLab Evaporimeter

20 ♀ 12 ♂ N=32

**2% SA Serum**
- 7-day effectiveness
- Visual expert grading
- TEWL (Transepidermal water loss)
  - DermaLab Evaporimeter

21 ♀ 10 ♂ N=31

**1.8% SA Spot Treatment**
- 24-hour effectiveness
- Visual expert grading

23 ♀ 7 ♂ N=30

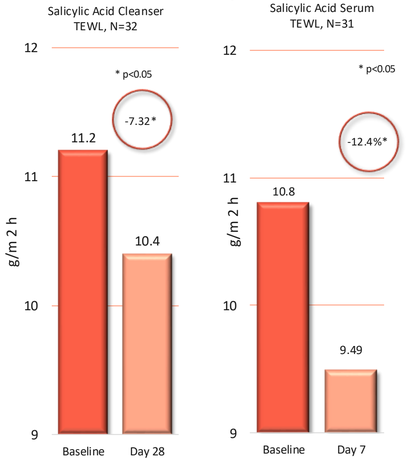
| | 2% SA Cleanser | 2% SA Serum | 1.8% SA Spot Treatment |
|---|---|---|---|
| Age | 18-43 | 18-43 | 18-45 |
| White | 15 | 15 | 11 |
| Hispanic | 14 | 13 | 16 |
| African American | 1 | 2 | 2 |
| Mixed/Other | 2 | 1 | 1 |

### Every Study Followed a Standardized Approach

1. 7-day washout with a daily wash procedure which was standardized with the use of a lab-issued gentle facial cleanser.
   - Only subjects who abstained from using any anti-acne, exfoliating, anti-aging, sun-protecting or moisturizing products throughout the entire study period including the washout phase were recruited for participation.
2. Limitation of sun exposure and wearing of sun protective clothing whenever possible.
3. Key inclusion criteria were individuals with self-assessed oily, combination or acne-prone skin and confirmed by the Investigator. Also, individuals with presence of mild to moderate acne, including visible blemishes, blackheads, or clogged pores, as confirmed by a skin assessment.
4. Participants were also instructed to keep a log noting the date and time of each application together with any subjective comments relating to product use.

## Findings:

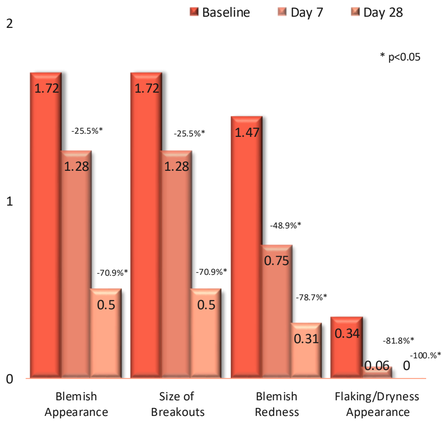
### A Significant Average Decrease In Transepidermal Water Loss (TEWL)




**Design:** 4-week (SA Cleanser), 7-day (SA Serum), computerized Evaporimeter using Dermalab System (cyberDERM, Inc.) Baseline and 28 days (SA Cleanser), Baseline and 7-day (SA Serum).
**Application:** Twice daily, 2% SA cleanser use (left) or once daily, 2% SA serum application (right)

2% Salicylic Acid Acne Cleanser with glycerin, super humectant Aquaxyl™, niacinamide, coconut-based cleansing agents

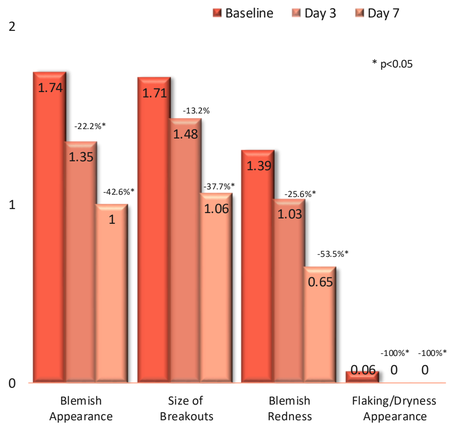
### Significant Mean Reductions of Common Acne Related Skin Complaints Were Seen as Early as 7 Days (N=32)




**Design:** 4-week visual expert grading (5-point scale) at 7 and 28 days.
**Application:** Twice daily.

2% Salicylic Acid Acne Serum with squalane, exfoliating willow bark, colloidal oatmeal

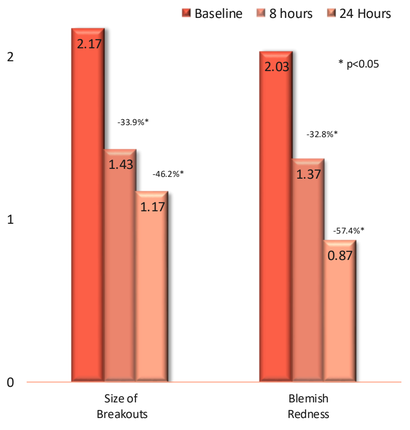
### Significant Mean Reductions of Common Acne Related Skin Complaints Were Seen by Day 3 (N=31)




**Design:** Efficacy of a facial serum when tested over a 7-day period using visual expert grading (5-point scale) at 3 and 7 days. Skin barrier integrity was determined instrumentally using TEWL measurements via DermaLab Evaporimeter®. **Application:** Once daily.

1.8% Salicylic Acid Spot Treatment

### Significant Mean Reductions of Common Acne Related Skin Complaints (N=30)




**Design:** Evaluate the efficacy of a topically applied acne spot treatment when tested over a 24-hour period. Effectiveness of the test product was evaluated objectively via visual expert grading. **Application**: Small amount of spot treatment directly to the blemish, surrounding skin, and pore area. Let it dry for 2 minutes. (8 hours based on 1 application, 24 hour based on 3 applications)

## Methods:

### Safety in Use Studies – Children and Teens

Designed to evaluate the potential for dermatological irritation and/or hypersensitivity after daily use. All SIU studies were conducted as single-center, baseline-controlled, 4-week monadic investigations. Participants included subjects with normal skin (cleanser group) and with self-perceived or parent-perceived acne-prone skin (serum and spot treatment groups). Recruitment also targeted 50% of the cohort reporting acne-prone skin to also have self-perceived or parent-perceived sensitive skin. 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.

**2% Salicylic Acid Cleanser**
20 ♀ 14 ♂ N=34

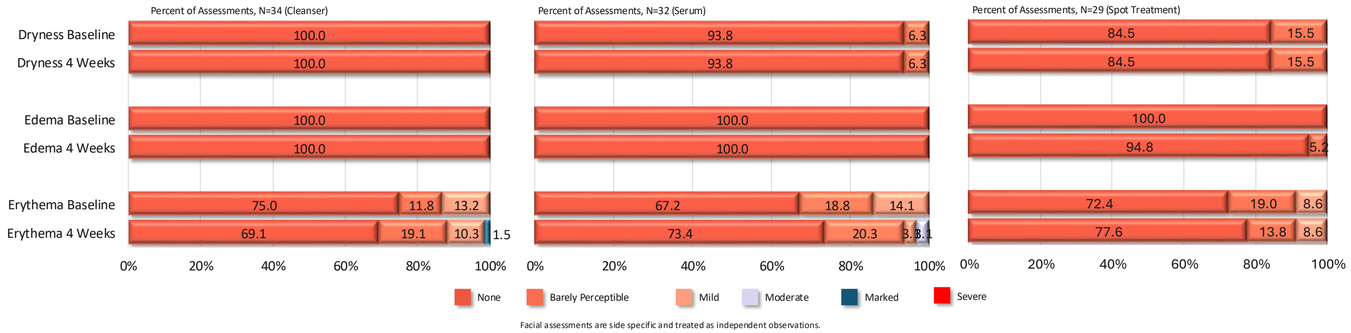
**2% Salicylic Acid Serum**
19 ♀ 13 ♂ N=32

**1.8% Salicylic Acid Spot Treatment**
19 ♀ 10 ♂ N=29

| | 2% Salicylic Acid Cleanser | 2% Salicylic Acid Serum | 1.8% Salicylic Acid Spot Treatment |
|---|---|---|---|
| Age | 12 to 18 | 12 to 18 | 12 to 18 |
| White | 19 | 20 | 7 |
| Hispanic | 7 | 6 | 12 |
| African American | 4 | 4 | 3 |
| Mixed/Other | 4 | 2 | 7 |

## Findings:

### Routine Use of a 2% Salicylic Acid Cleanser, 2% Salicylic Acid Serum, or 1.8% Salicylic Acid Acne Spot Treatment Was Well Tolerated in Pediatric Subjects 12-18 Years of Age With no Clinically Meaningful Changes in Erythema, Occurrence of Edema, or Dryness.




Facial assessments are side specific and treated as independent observations.