

# Comparison of Cutaneous Irritation With Repeated Application of Tazarotene 0.045% Lotion, Adapalene 0.3% Gel, and Trifarotene 0.005% Cream

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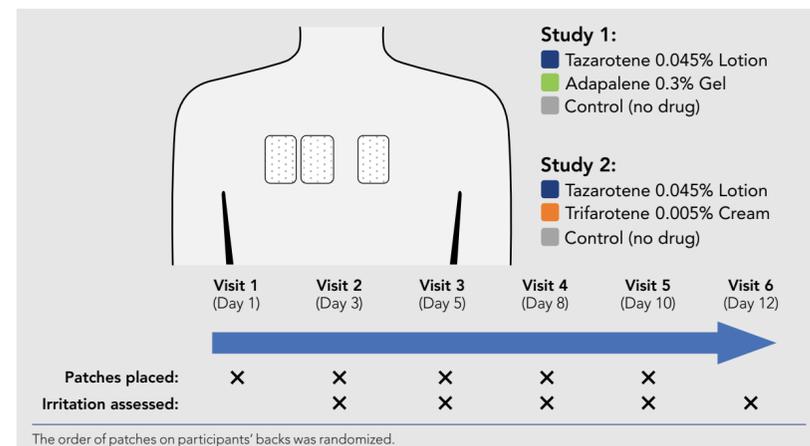
## SYNOPSIS

- Topical retinoids are a mainstay in the treatment of acne, but cutaneous irritation may limit their use and patient adherence
- Tolerability of topical retinoids can be impacted by the retinoid itself, the concentration used, and the vehicle used for its delivery,<sup>1</sup> as well as skin hydration
- Newer, third- and fourth-generation topical retinoid formulations have been developed using lower concentrations, enhanced vehicles, and/or novel retinoids to be efficacious while providing a more patient-friendly tolerability profile<sup>2</sup>
- Low-dose tazarotene 0.045% lotion was developed using polymeric emulsion technology to provide uniform and rapid distribution of tazarotene and hydrating ingredients on the skin in a highly spreadable formulation<sup>3</sup>

## OBJECTIVES

- To compare the tolerability of tazarotene 0.045% lotion with adapalene 0.3% gel and trifarotene 0.005% cream

FIGURE 1. Study Design



## METHODS

- Healthy adults (≥18 years) with Fitzpatrick skin types I–II and normal upper back skin were enrolled in two identical 12-day modified cumulative irritation patch studies
- In each study, two patches loaded with active ingredients and one control patch (no study product) were placed on participants' upper back in a randomized, double-blind fashion
- In Study 1, active patches were loaded with 0.1 cc of adapalene 0.3% gel or tazarotene 0.045% lotion; in Study 2, active patches were loaded with 0.1 cc of trifarotene 0.005% cream or tazarotene 0.045% lotion (Figure 1)
  - Patches were replaced every 2–3 days, for a total of 5 applications
- At each patch removal, Dermal Effects were assessed using an 8-point scale (0=no evidence of irritation; 7=strong reaction spreading beyond application site) and Other Effects were assessed using a 7-point scale (0=no other effects; 6=small petechial erosions and/or scabs)
  - Assessments were analyzed using a Wilcoxon signed-rank test; group differences were considered significant at a P-value of ≤0.05

## RESULTS

### Study 1: Adapalene 0.3% Gel vs Tazarotene 0.045% Lotion

- 20 White adults (22–69 years; 95% female) were enrolled and completed this study
- Tazarotene 0.045% lotion and adapalene 0.3% gel were both assessed as mildly irritating, with Dermal Effects mean scores <1 (Figure 2)
  - Differences in Dermal Effects mean scores between drugs were not statistically significant at any assessment, though there was slightly less irritation overall with tazarotene lotion than adapalene gel (highest mean scores: 0.50 and 0.80, respectively)
- Other Effects mean scores were negligible (≤0.05) with both drugs
- No irritation was observed at the control patch site at any study visit

FIGURE 2. Study 1: Irritation Potential of Adapalene 0.3% Gel vs Tazarotene 0.045% Lotion

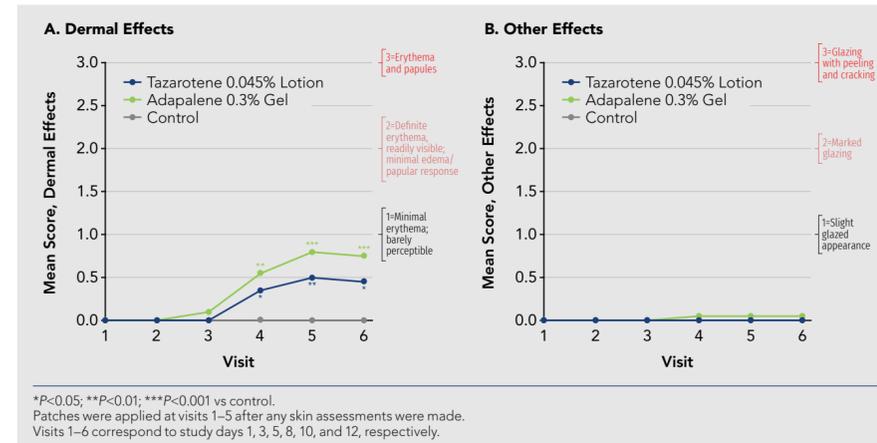
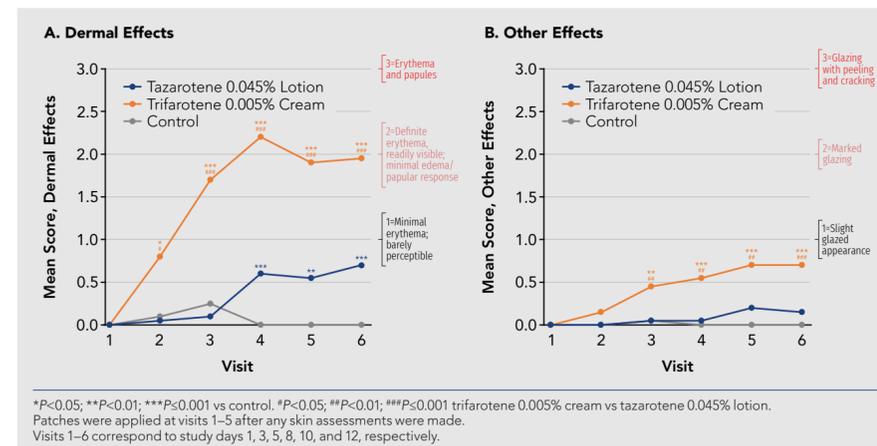


FIGURE 3. Study 2: Irritation Potential of Trifarotene 0.005% Cream vs Tazarotene 0.045% Lotion



### Study 2: Trifarotene 0.005% Cream vs Tazarotene 0.045% Lotion

- 20 adults (22–74 years; 90% female; 90% White, 10% African American) were enrolled and completed this study
- Dermal Effects mean scores with trifarotene cream were significantly greater than with tazarotene lotion at the first assessment (2 days after first patch application; P<0.05) and increased over the remaining visits (highest mean scores: 2.20 vs 0.70, respectively; P<0.001, all; Figure 3)
- Other Effects mean scores were significantly greater with trifarotene cream than with tazarotene lotion, beginning at the second assessment (4 days after first patch application) and continuing through remaining visits (highest mean scores: 0.70 vs 0.20, respectively; P<0.01, all)
- No irritation was observed at the control patch site at any study visit
- Images of representative participants are shown in Figure 4

FIGURE 4. Study 2: Participant Photographs at Visit 6 (Day 12; Final Assessment)

**42-year-old male**

Effects Score	Dermal	Other
Trifarotene	3	1
Tazarotene	0	0
Control	0	0

**30-year-old female**

Effects Score	Dermal	Other
Trifarotene	2	1
Tazarotene	1	0
Control	0	0

Individual results may vary.

## CONCLUSIONS

- In a modified cumulative irritation study, tazarotene 0.045% lotion was significantly less irritating than trifarotene 0.005% cream
- Tazarotene 0.045% lotion was numerically less irritating than adapalene 0.3% gel, one of the best-tolerated topical retinoids<sup>2,4</sup>
- Tazarotene 0.045% lotion allows for simultaneous, uniform, and rapid delivery of hydrating ingredients along with less than half the concentration of tazarotene versus other commercially available 0.1% formulations<sup>3</sup>
- The lower retinoid concentration combined with moisturizing/hydrating ingredients (sorbitol, light mineral oil, diethyl sebacate, water<sup>3</sup>) in a proprietary polymeric mesh vehicle may help minimize instances of retinoid-induced irritation

## REFERENCES

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## AUTHOR DISCLOSURES

Zoe Draelos received funding from Ortho Dermatologics to conduct the research presented in this poster. Patricia Farris serves as an advisor, speaker or consultant to Beauty, La Roche Posay, NeoStrata, Neutrogena, Nutraceutical Wellness, and USK. Hilary Baldwin has served as advisor, investigator, and on speakers' bureaus for Almirall, Cassiopea, Foamix, Galderma, Ortho Dermatologics, Sol Gel, and Sun Pharma. Emil Tanghetti has served as speaker for Novartis, Ortho Dermatologics, Sun Pharma, Lilly, Galderma, AbbVie, and Dermira; served as a consultant/clinical studies for Hologic, Ortho Dermatologics, and Galderma; and is a stockholder for Accure.