Tazarotene 0.045% Lotion for Truncal Acne: Efficacy, Tolerability, and Spreadability

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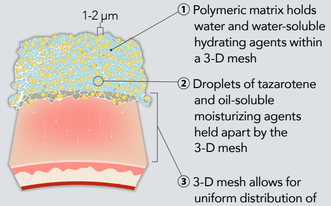
SYNOPSIS

- Truncal acne (occurring on the chest and back) is common among patients with facial acne,[1-3] though its pathophysiology may be somewhat different[4,5]
- As there are no specific guidelines for the treatment of truncal acne, facial acne treatment guidelines are often the basis for its management[3]
- Successful treatment of truncal acne is complicated by the involvement of a large body surface area that is typically covered in clothing[3]
- Topical vehicles that provide ease of spreadability, rapid cutaneous penetration/effective drug delivery, and lack of residue are highly desirable for truncal acne treatment[1]
- A lower-dose tazarotene 0.045% lotion formulation (Arazlo®; Ortho Dermatologics) was developed utilizing polymeric emulsion technology (**Figure 1**)[6]
  - This highly spreadable lotion formulation was developed to allow for more efficient delivery of tazarotene into dermal layers
  - In phase 1 studies, this lotion demonstrated low irritation/contact dermatitis potential and no allergic sensitization[7]

OBJECTIVES

- To evaluate tazarotene 0.045% lotion on the trunk using three studies with distinct objectives:
  - **Study 1:** summarize the efficacy, safety, and tolerability of tazarotene 0.045% lotion in the treatment of truncal acne
  - **Study 2:** compare the irritation potential with repeated application of tazarotene 0.045% lotion and trifarotene 0.005% cream on the trunk
  - **Study 3:** evaluate the spreadability of tazarotene 0.045% lotion and trifarotene 0.005% cream on the trunk

FIGURE 1. **Polymeric Emulsion Technology for Tazarotene 0.045% Lotion**



STUDY 1: EFFICACY, SAFETY, AND TOLERABILITY IN TRUNCAL ACNE

Tazarotene 0.045% Lotion[8]

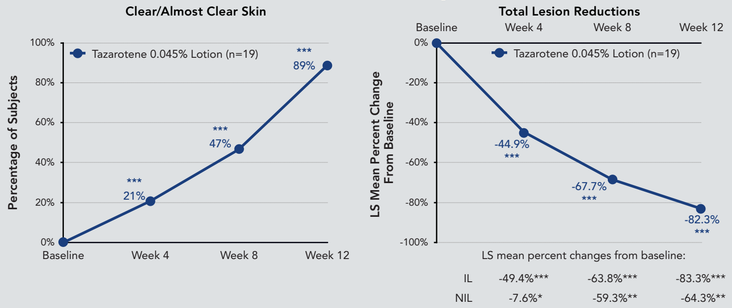
Study 1 Design

- Subjects aged ≥12 years
- Moderate truncal acne (Investigator's Global Assessment score = 3)
- Once-daily treatment with tazarotene 0.045% lotion for 12 weeks

Demographics

- Age (mean): 24.1 years
- Sex: 52.6% female
- Race: 52.6% White, 36.8% Black, 10.5% Biracial

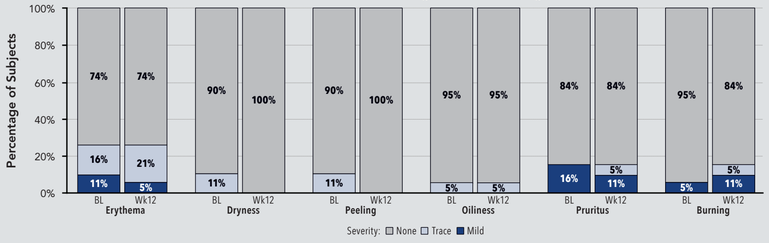
Truncal Efficacy



At Week 12:
- ~90% achieved clear or almost clear skin
- >80% reductions from baseline in total lesion counts

*$P<0.05$; **$P<0.01$; ***$P<0.001$ vs baseline. IL, inflammatory lesions; LS, least squares; NIL, noninflammatory lesions.

Cutaneous Tolerability and Safety



- Most subjects had no tolerability issues
- There were no significant changes from baseline to week 12 in any tolerability assessment

There were no adverse events related to tazarotene treatment in this study.
BL, baseline.

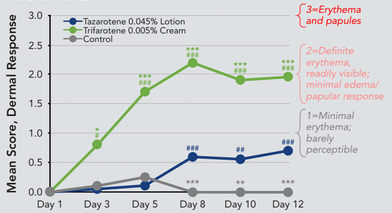
STUDY 2: IRRITATION POTENTIAL

Tazarotene 0.045% Lotion vs Trifarotene 0.005% Cream

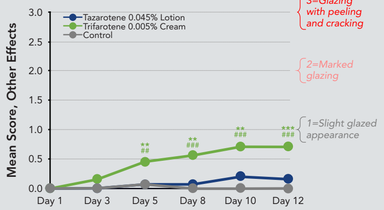
Study 2 Design

- Modified cumulative irritancy patch test in 20 healthy adults (22–74 years; Fitzpatrick skin types I-II)
- Patches loaded with tazarotene 0.045% lotion, trifarotene 0.005% cream, or control (no product) were applied to the upper back; patches replaced every 2–3 d for 12 d
- After each patch removal, skin was assessed for dermal effects (eg, erythema, edema, papules) and other effects (eg, glazing, peeling, cracking) on a scale of 0 to 7

A. Dermal Effects



B. Other Effects



- Over 12 days of exposure, tazarotene 0.045% lotion was associated with minimal irritation
- Tazarotene 0.045% lotion was significantly less irritating than trifarotene 0.005% cream 2 days after first patch application and continuing through day 12

*$P<0.05$; **$P<0.01$; ***$P\leq0.001$ vs tazarotene 0.045% lotion. #$P<0.05$; ##$P<0.01$; ###$P<0.001$ active drug vs control.

STUDY 3: SPREADABILITY

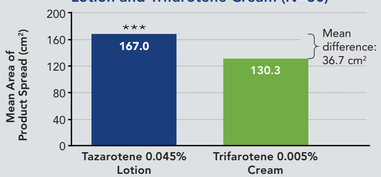
Tazarotene 0.045% Lotion vs Trifarotene 0.005% Cream[9]

Study 3 Design

- Double-blind split-body study of 30 healthy adults (18–59 years)
- Each product (0.1 mL) was applied to a 10 cm wide area on one side of subjects' backs and moved down the back until it would no longer spread; area of spread was then determined

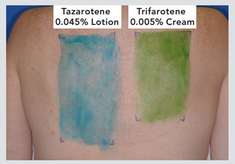
- On average, skin coverage with tazarotene 0.045% lotion was ~30% greater than with trifarotene 0.005% cream

Mean Spreadability of Tazarotene Lotion and Trifarotene Cream (N=30)



***$P<0.001$ vs trifarotene 0.005% cream.

Subject example



CONCLUSIONS

- Tazarotene 0.045% lotion utilizes polymeric emulsion technology to enhance hydration, moisturization, and skin barrier function
- Tazarotene 0.045% lotion led to statistically significant reductions in truncal acne severity and lesion counts; ~90% of subjects achieved clear or almost clear skin with 12 weeks of once-daily use and most subjects had no tolerability issues
- This easy-to-apply tazarotene lotion was associated with less irritation and ~30% greater skin coverage compared with trifarotene cream
  - Less product needed to cover the same skin area equals more applications per unit volume

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AUTHOR DISCLOSURES

Leon H Kircik has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. Zoe D Draelos received funding from Ortho Dermatologics to conduct the research presented here. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company.

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