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

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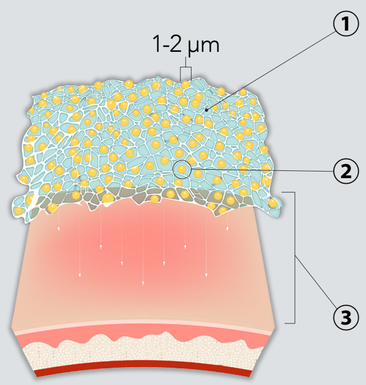
SYNOPSIS

- 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

- Study 1: to summarize the efficacy, safety, and tolerability of tazarotene 0.045% lotion in the treatment of truncal acne
- Study 2: to 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**



① Polymeric matrix holds water and water-soluble hydrating agents within a 3-D mesh

② Droplets of tazarotene and oil-soluble moisturizing agents held apart by the 3-D mesh

③ 3-D mesh allows for uniform distribution of tazarotene and moisturizing agents

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

Tazarotene 0.045% Lotion

Study 1 Design

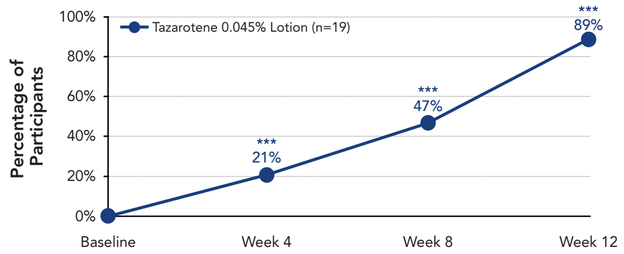
- Participants aged ≥12 years
- Moderate truncal acne (Investigator's Global Assessment score = 3)
- Once-daily treatment with tazarotene 0.045% lotion for 12 weeks

Demographics

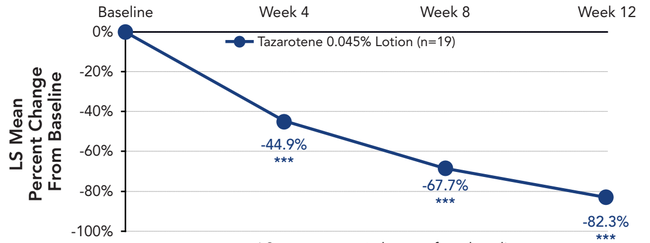
- Age (mean): 24.1 years
- Sex: 52.6% female
- Race: 52.6% White, 36.8% Black, 10.5% Biracial

Truncal Efficacy

Clear/Almost Clear Skin



Total Lesion Reductions



LS mean percent changes from baseline:

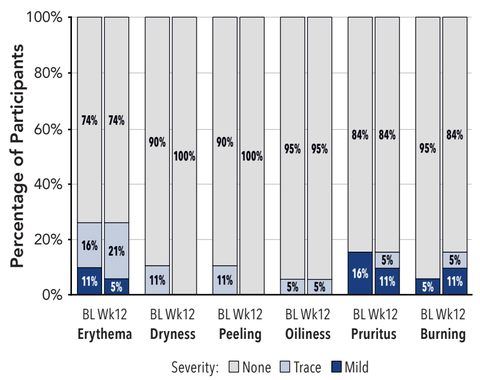
	Week 4	Week 8	Week 12
IL	-49.4%***	-63.8%***	-83.3%***
NIL	-7.6%*	-59.3%**	-64.3%**

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

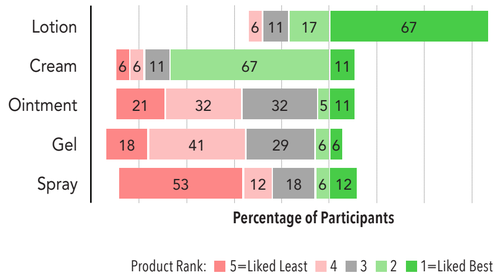


- **Most participants had no tolerability issues**
- **There were no significant changes from baseline to week 12 in any tolerability assessment**

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

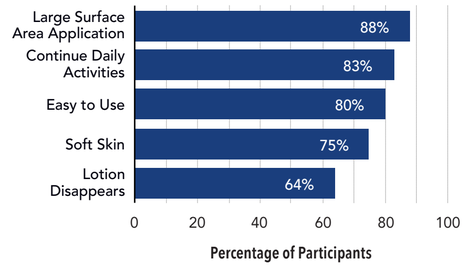
Patient Preference Questionnaire

Ranked Preference for Past Skin Medicines



Ratings of Tazarotene 0.045% Lotion

Percentage of participants rating the lotion as "good" or "excellent" compared to other medicines



- **Overall, participants preferred lotions over other types of topical treatments**
- **Most participants (64–88%) rated attributes of tazarotene 0.045% lotion as "good" or "excellent" in comparison to other medications**

Not all participants responded to all items on the questionnaire; percentages for each item are based upon the number of participants who responded to that item.

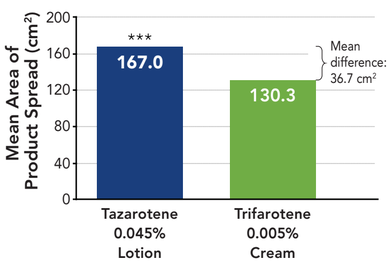
STUDY 2: SPREADABILITY

Tazarotene 0.045% Lotion vs Trifarotene 0.005% Cream[8]

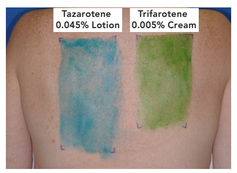
Study 2 Design

- 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 participants' backs and moved down the back until it would no longer spread; area of spread was then determined

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



Participant example



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

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

CONCLUSIONS

- Tazarotene 0.045% lotion utilizes polymeric emulsion technology to enhance hydration, moisturization, and skin barrier function
- Tazarotene 0.045% lotion led to significant reductions in truncal acne severity and lesion counts; ~90% of participants achieved clear or almost clear skin with 12 weeks of once-daily use and most participants had no tolerability issues
- This easy-to-apply tazarotene lotion has sensory and aesthetic properties preferred by patients[6] and resulted in ~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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