A Comparative Clinical Demonstration of the Spreadability of Tazarotene Lotion 0.045% versus Trifarotene Cream 0.005%

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SYNOPSIS

- The ability of a topical medication to spread is an important parameter, since only the thinnest layer of medication contacting the skin is physiologically active
- A thinner film is just as effective as a thicker film from an efficacy standpoint, but a thinner film will spread farther—exhibiting superior spreadability and increasing the number of applications while decreasing the cost per application
- From a rheological perspective, products exhibiting low yield stress and lower intrinsic viscosity will have better spreadability and require less effort to spread at the surface of the skin[1,2]
  - Yield stress is the minimum force required to make a structured fluid flow
  - Viscosity describes a fluid's resistance to flow (eg, the "thickness" of a fluid)

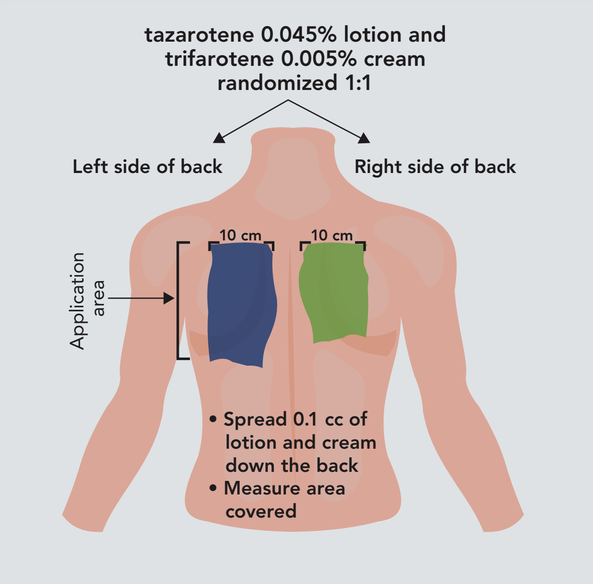
OBJECTIVE

- To compare the spreadability of two topical formulations: tazarotene 0.045% polymeric emulsion lotion versus trifarotene 0.005% cream
- To relate the rheological profile of topical products to their spreadability

METHODS

- This double-blind, split-body study enrolled male or female adults ≥18 years of age with normal back skin
  - Participants, who provided written informed consent, were assessed for limited back hair which would prevent application of the study products
- Tazarotene 0.045% lotion was applied to one randomized half of the back and trifarotene 0.005% cream was applied to the opposite randomized half of the back (**Figure 1**)
  - The back was divided at the vertebral column into right and left
  - Drugs were randomized for right or left application; however, the left back product was always pigmented blue and the right back product was always pigmented green. One toothpick tip of blue or green food-coloring gel was used to pigment the drugs
- The blinded dermatologist investigator was presented with 0.1 cc (0.1 mL) of each of the drugs for application by the unblinded coordinator
- Two 10 cm wide application areas were marked with a gentian violet marker, one on each side of the back; this mark defined the lateral bounds over which the lotion or cream were spread
- The investigator applied the products with a gloved hand to obtain an even film, moving study product down the back until it would no longer spread
- The lower extent of the study product application was marked with a gentian violet marker and measured in centimeters
- A two-tailed Student's t-test was used to assess the spreadability data

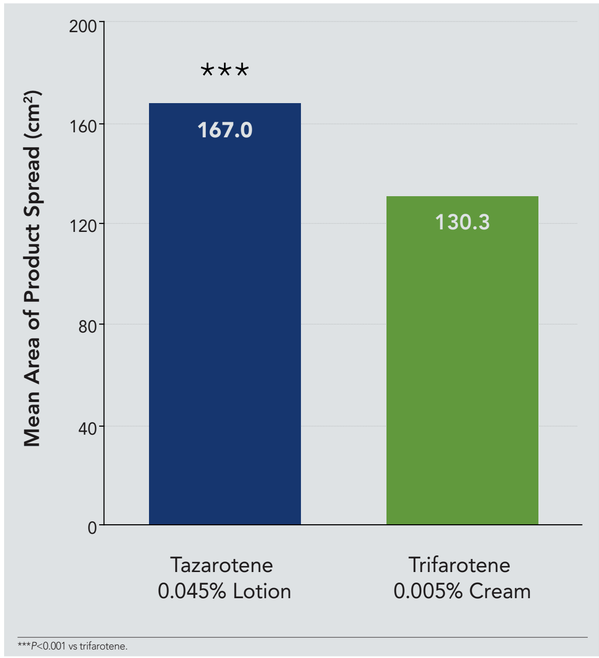
FIGURE 1. Study Schematic



RESULTS

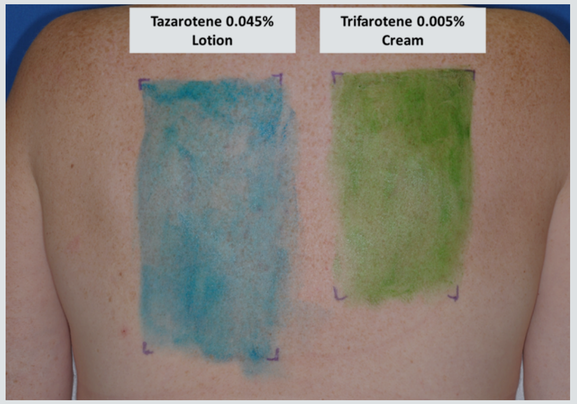
- A total of 30 participants were included in the study
- Participants ranged from 18 to 59 years of age; 26 (87%) were female
- Tazarotene 0.045% lotion spread over an average area measuring 10 cm x 16.70 cm (167.0 cm^2) while the trifarotene 0.005% cream spread over an average area measuring 10 cm x 13.03 cm (130.3 cm^2; $P<0.001$; **Figure 2**)
- No adverse reactions or adverse events occurred during the conduct of the study

FIGURE 2. Mean Spreadability of Tazarotene 0.045% Lotion and Trifarotene 0.005% Cream (N=30)



***$P<0.001$ vs trifarotene.

FIGURE 3. Spreadability of Tazarotene 0.045% Lotion and Trifarotene 0.005% Cream on a Participant



CONCLUSIONS

- The tazarotene 0.045% lotion spread on average 36.7 square centimeters farther than the trifarotene 0.005% cream
- These results are supported by the differences in the rheological profiles of the two products, in which tazarotene lotion exhibits lower yield stress and lower intrinsic viscosity versus trifarotene cream[3]

REFERENCES

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2. Kryscio DR, et al. *AAPS PharmSciTech*. 2008;9(1):84-86.
3. Data on File. Ortho Dermatologics.

AUTHOR DISCLOSURES

ZDD received funding from Ortho Dermatologics to conduct the research presented in this poster.
EAT has served as speaker for Novartis, Ortho Dermatologics, Sun Pharmaceuticals, Lilly, Galderma, AbbVie, and Dermira; served as a consultant/clinical studies for Hologic, Ortho Dermatologics, and Galderma; and is a stockholder for Accure.

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