

A Randomized, Observer-Blind, Split-Face Study to Assess Compatibility of Facial Foundation Makeup with Tretinoin 0.05% Lotion and Skin Texture After Application

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SYNOPSIS

- Tretinoin is a topical retinoid for the treatment of acne vulgaris, but current gel, foam, or cream formulations can cause irritation, limiting their use¹
- Tretinoin 0.05% lotion (Altreno[®] Ortho Dermatologics, Bridgewater, NJ) is a novel topical formulation—developed by utilizing polymeric emulsion technology²—that has demonstrated efficacy and safety for the treatment of moderate-to-severe acne^{3,4}

OBJECTIVE

- To assess the compatibility of tretinoin 0.05% lotion with foundation makeup immediately and 6 hours after application, as well as skin texture after makeup application

METHODS

- This was a single-center, evaluator-blinded, randomized, controlled study; eligible participants were females aged 18-50 years who used facial foundation makeup ≥5 days per week
- Participants were randomized to apply tretinoin 0.05% lotion to either the right or left side of the face before applying full-face foundation makeup
- Investigator-assessed foundation coverage and cutaneous tolerability were evaluated immediately after tretinoin application and foundation application and again at 6 hours post-foundation application
 - In this study, CeraVe[®] hydrating cleanser and CeraVe[®] moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin
- The participant-assessed makeup appearance questionnaire and facial images were obtained at the same timepoints for analysis of skin texture roughness using Antera 3D[®] imaging (Miravex Limited, Dublin, Ireland)

RESULTS

- A total of 30 participants were enrolled in the study (intent-to-treat [ITT] population) and 29 completed (per protocol population); 6 participants had Fitzpatrick skin type V or VI (Table 1)

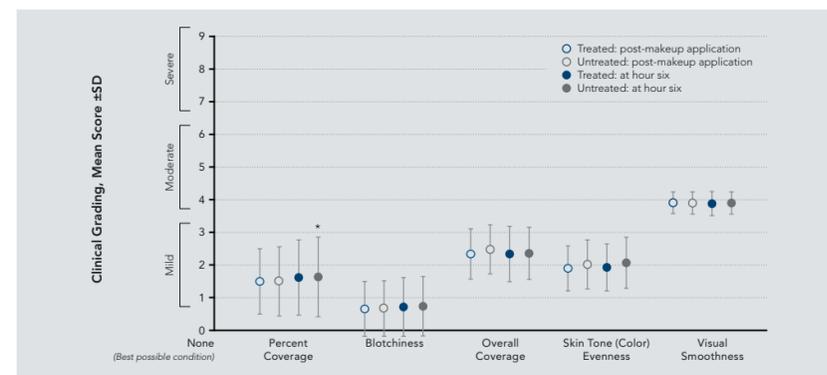
TABLE 1. Participant Demographics (ITT Population)

		Participants (N=30)
Age, mean (SD), y		35.2 (8.3)
Female, n (%)		30 (100)
Race, n (%)	White	23 (76.7)
	Black	6 (20.0)
	Multiracial	1 (3.3)
Ethnicity, n (%)	Not Hispanic or Latino	20 (66.7)
	Hispanic or Latino	10 (33.3)
Fitzpatrick skin type, n (%)	I	2 (6.7)
	II	7 (23.3)
	III	8 (26.7)
	IV	7 (23.3)
	V	5 (16.7)
	VI	1 (3.3)

ITT, intent-to-treat; SD, standard deviation.

- There were no significant differences between the tretinoin-treated and untreated sides for any outcome for clinical grading of foundation coverage (Figure 1)
 - On the untreated side, there was a small but statistically significant worsening in percent coverage

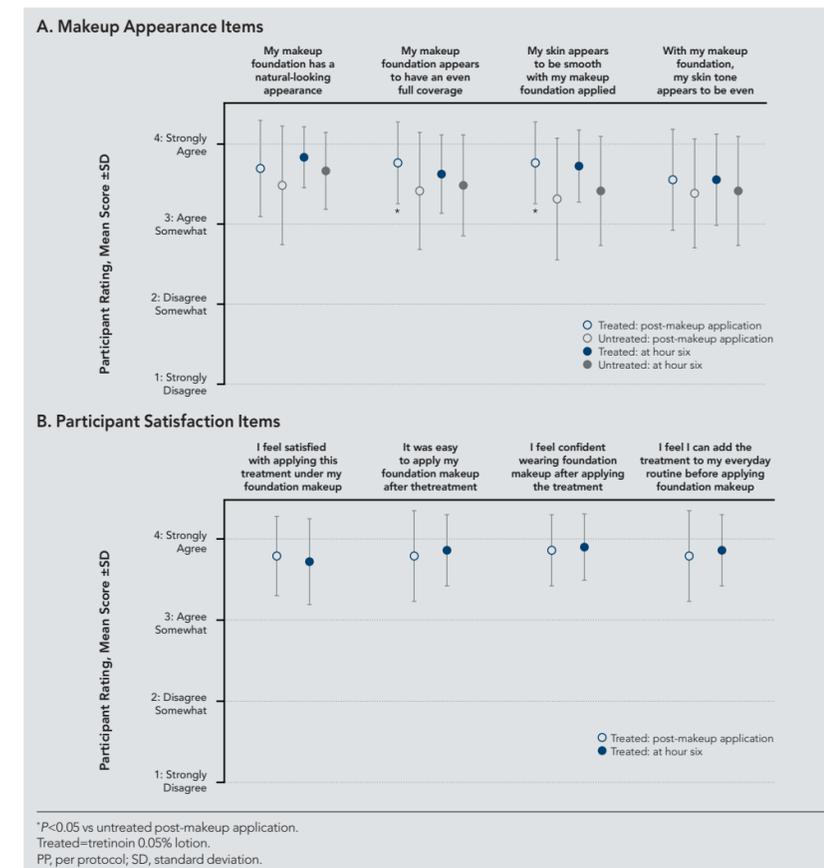
FIGURE 1. Investigator-Assessed Clinical Grading of Foundation Coverage Scores (PP Population)



*P<0.05 vs untreated post-make-up application. Treated=tretinoin 0.05% lotion. PP, per protocol; SD, standard deviation.

- Per participant ratings, even/full coverage and skin smoothness were significantly better on the treated side than on the untreated side immediately after foundation application (P=0.03 and P=0.01, respectively; Figure 2A)
 - No significant differences in makeup appearance were found at hour 6 (Figure 2A)
 - Participants indicated overall satisfaction with the tretinoin-treated side (Figure 2B)
- No significant differences in skin texture roughness were observed in the facial images between the tretinoin-treated and untreated sides after 6 hours compared with post-foundation application, or immediately after foundation application and at hour 6 compared with post-treatment application

FIGURE 2. Participant-Assessed Makeup Appearance Scores (PP Population)



- Consistent with phase 3 studies,³ most cutaneous tolerability outcomes had a rating of “none” from all 30 participants; no outcome was rated as “severe” by any participant
 - Some participants experienced mild erythema, dryness, and itching; 1 participant had moderate itching on the treated side at hour 6 (Table 2)

TABLE 2. Number of Participants with Mild or Moderate Ratings in Cutaneous Tolerability*

		Post-Foundation, n		At Hour 6, n	
		Mild	Moderate	Mild	Moderate
Erythema	Treated	4	0	4	0
	Untreated	4	0	4	0
Dryness	Treated	3	0	1	0
	Untreated	4	0	2	0
Burning	Treated	0	0	0	1
	Untreated	0	0	0	0
Itching	Treated	0	0	1	0
	Untreated	0	0	0	0

*All 30 intent-to-treat participants rated the following outcomes as “none” for both sides at both timepoints: edema, peeling, and stinging.

CONCLUSIONS

- Tretinoin 0.05% lotion was comparable to no treatment in most evaluations, but appeared beneficial with participant-assessed foundation coverage and skin smoothness immediately after foundation application
- Tretinoin lotion was also compatible for up to 6 hours post-foundation application and was well-tolerated

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AUTHOR DISCLOSURES

Dr. Bhatia has received honoraria from Ferndale Laboratories, Inc., Promius Pharma, LLC, Novartis, Allergan, Biofrontera AG, IntraDerm Pharmaceuticals, Almirall, Sun Pharmaceutical Industries, La Roche-Posay, Mayne Pharma Group, Ortho Dermatologics, Pierre Fabre Dermo-Cosmétique US, ISDIN, Galderma Laboratories, Skinfix, Inc., and grants/research funding from Aclaris Therapeutics, Inc., Asana Biosciences, LLC, Crown Laboratories, Inc., LEO Pharma US, DUSA Pharmaceuticals, Inc., Menlo Therapeutics, Par Pharmaceutical, Pfizer Inc., Perrigo Company, Realm Therapeutics, Sienna Biopharmaceuticals, Sol-Gel technologies, Soligenix, Inc., Strata Skin Sciences, Vidac Pharma, Brickell Biotech, Inc., Dermira, Glenmark Generics Inc., Sanofi/Regeneron, Actavis, BioPharmX, Foamix, Cutanea Life Sciences, MC2 Therapeutics, UCB, AbbVie, Atacama Therapeutics, Naked Biome Inc., Kiniksa Pharmaceuticals, Ltd., BMS, Dr. Reddy, and Vypome (Pending). Dr. Leon Kircik has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. Dr. Ava Shamban has received grants/research support and/or consulting from Galderma, Merz, Endo, Brickell, B10, Revance, Teoxane, and Allergan. Drs. Varsha Bhatt and Radhakrishnan Pillai are employees of Bausch Health Americas. Dr. Eric Guenin is an employee of Ortho Dermatologics.