

Tazarotene 0.1% Gel in the Treatment of Fingernail Psoriasis: A Double-Blind, Randomized, Vehicle-Controlled Study

Richard K. Scher, MD, FACP

Matthew Stiller, MD

Y. Isabel Zhu, MD, PhD

A double-blind, randomized, vehicle-controlled, parallel-group trial was performed to compare the efficacy and tolerability of tazarotene 0.1% gel and vehicle gel in 31 patients with fingernail psoriasis. Patients were randomized to receive tazarotene or vehicle gel, which they applied each evening for up to 24 weeks to 2 target fingernails, one under occlusion and one unoccluded. The tazarotene treatment resulted in a significantly greater reduction in onycholysis in occluded nails ($P \leq .05$ at weeks 4 and 12) and a significantly greater reduction in onycholysis in nonoccluded nails ($P \leq .05$ at week 24). Tazarotene also resulted in a significantly greater reduction in pitting in occluded nails ($P \leq .05$ at week 24). There were no other significant between-group differences in pitting, subungual hyperkeratosis, leukonychia, nail plate crumbling/loss, splinter hemorrhage, or nail growth rate. Tazarotene 0.1% gel was well tolerated with only 5 of the 21 tazarotene-treated patients reporting a treatment-related adverse event (all mild or moderate). In conclusion, tazarotene 0.1% gel can significantly reduce onycholysis (in occluded and nonoccluded nails)

and pitting (in occluded nails) and is well tolerated in the treatment of nail psoriasis.

Fingernail psoriasis results in significant socioeconomic problems, with most patients experiencing pain and/or restrictions in their daily activities.¹ Current treatment options are often poorly efficacious, associated with undesirable systemic effects, or time-consuming to administer.²

Tazarotene has been successfully used in the treatment of plaque psoriasis for several years, but there have been no reports of its specific use in nail psoriasis. To evaluate the clinical potential of this agent in nail psoriasis, a placebo-controlled clinical trial has been conducted to compare the efficacy and tolerability of once-daily tazarotene 0.1% gel with once-daily vehicle gel in both occluded and nonoccluded fingernails.

Methods

This was a double-blind, randomized, vehicle-controlled, parallel-group study conducted at Columbia University Presbyterian Medical Center, New York, New York.

Patients—Patients eligible for recruitment were adults with psoriasis affecting at least 2 fingernails with at least 3 of the following characteristics: pitting, onycholysis, subungual hyperkeratosis, leukonychia, nail plate crumbling/loss, splinter hemorrhages, or nail-bed discoloration.

Patients were excluded if they had had psoriasis for less than 6 months or if either of their 2 target fingernails (designated by the investigator)

Drs. Scher, Stiller, and Zhu are from the Department of Dermatology, Columbia University Presbyterian Medical Center, New York, New York.

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Reprints: Richard K. Scher, MD, FACP, Columbia Presbyterian Medical Associates, 16 E 60th St, New York, NY 10022 (e-mail: onychium@aol.com).

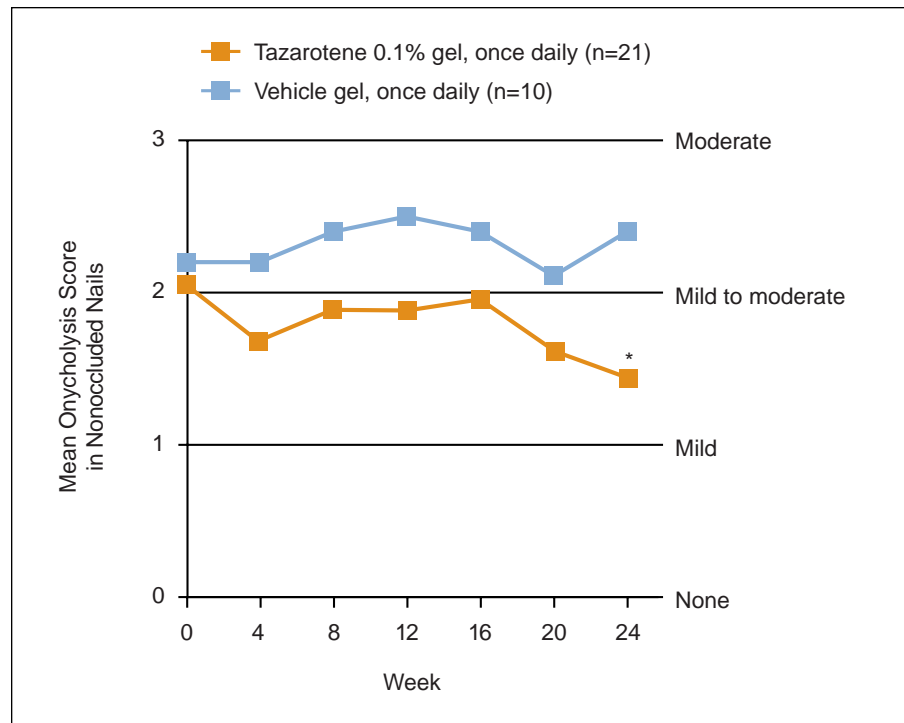


Figure 1. Mean onycholysis score in nonoccluded nails with once-daily applications of tazarotene 0.1% gel or vehicle gel. Asterisk indicates $P \leq .05$ vs vehicle.

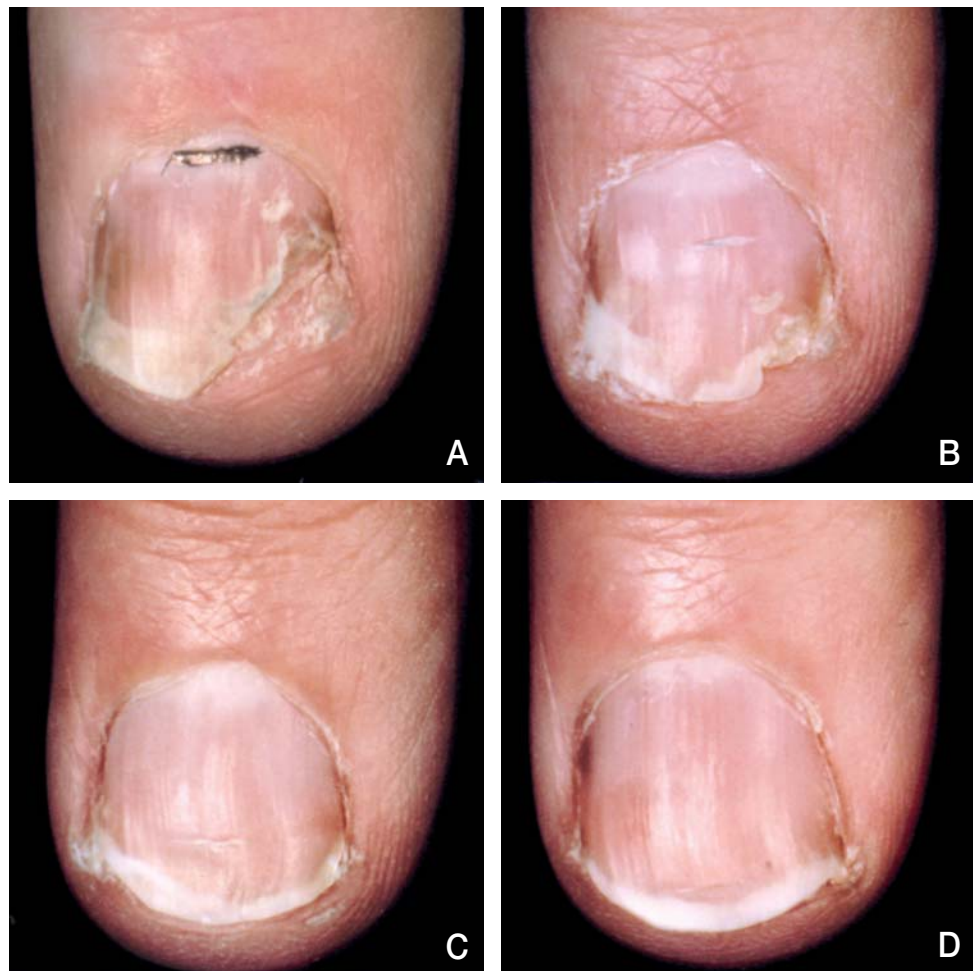


Figure 2. Improvement in onycholysis in nonoccluded nails after once-daily applications of tazarotene 0.1% gel or vehicle: (A) at baseline, (B) after 4 weeks of therapy, (C) after 8 weeks of therapy, and (D) after 12 weeks of therapy. An exacerbation in onycholysis occurred at week 16.

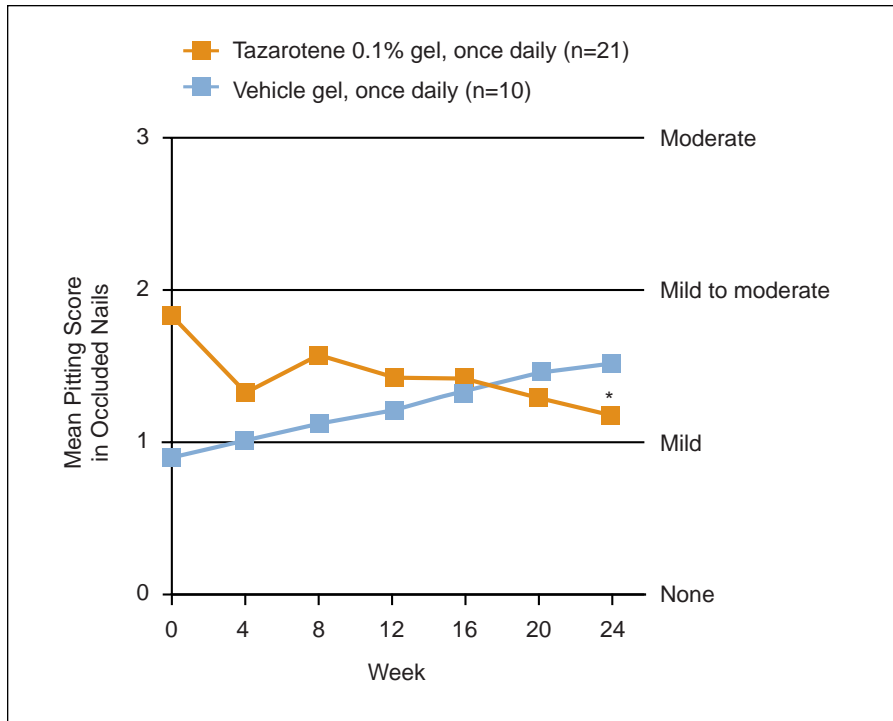


Figure 3. Mean pitting score in occluded nails with once-daily applications of tazarotene 0.1% gel or vehicle gel. Asterisk indicates $P \leq .05$ vs vehicle.

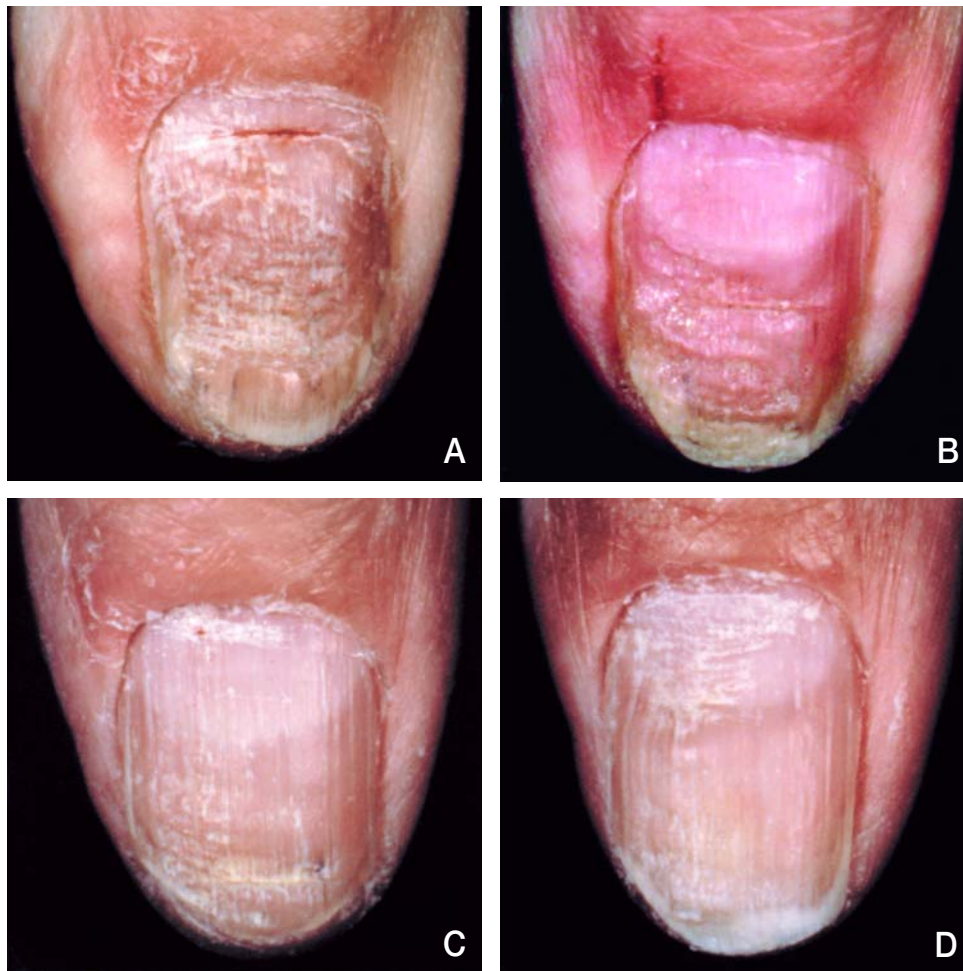


Figure 4. Improvement in pitting in occluded nails after once-daily applications of tazarotene 0.1% gel or vehicle: (A) at baseline, (B) after 8 weeks of therapy, (C) after 16 weeks of therapy, and (D) after 23 weeks of therapy.

had positive results with a potassium hydroxide stain or dermatophyte/fungal culture.

Approval was obtained from the internal review board of Columbia University Presbyterian Medical Center, and written informed consent was obtained from each patient or legal guardian.

Treatment Regimens—Patients were randomized to receive either tazarotene 0.1% gel or vehicle gel. Study medications were applied to the target fingernail and the surrounding nail folds once daily, in the evening, for up to 24 weeks. One target fingernail was occluded with polyethylene film/sheeting during the treatment period. The other target fingernail was not occluded. No other medications were allowed on the fingernails.

Washout periods were 4 weeks for topical fingernail medications and investigational drugs, 6 weeks for intralesional corticosteroids and UVB or psoralen plus UVA phototherapy, and 12 weeks for systemic antipsoriatic medications.

Outcome Measures—Pitting, onycholysis, subungual hyperkeratosis, leukonychia, nail plate crumbling/loss, splinter hemorrhages, and nail-bed discoloration were assessed on a 7-point scale (0=none, 1=mild, 2=mild to moderate, 3=moderate, 4=moderate to severe, 5=severe, 6=very severe). Nail growth was assessed by marking each target fingernail at each visit with a transverse groove parallel to the lunula. Nail growth was then measured from the notch at the proximal nail fold using an electronic caliper, with the growth rate being calculated from the distance advanced since the previous visit.

Results

Patient Demographics—A total of 31 patients (71% male, 29% female) with a mean age of 43 years were evaluated. Twenty-one patients received tazarotene, and 10 patients received vehicle. Most patients were Caucasian (25) and had had psoriasis for at least 10 years (19). One patient in the tazarotene group also had palmar psoriasis. The 2 treatment groups were well matched at baseline, with no significant between-group differences in demographic variables or target nail condition.

Efficacy—The tazarotene regimen was consistently more effective than vehicle in reducing onycholysis in occluded nails ($P \leq .05$ at weeks 4 and 12) and nonoccluded nails ($P \leq .05$ at week 24; Figures 1 and 2). The tazarotene regimen was also significantly more effective than vehicle in reducing pitting in occluded nails ($P \leq .05$ at week 24; Figures 3 and 4). There were no other significant between-group differences in pitting, subungual hyperkeratosis, leukonychia, nail plate crumbling/loss, splinter hemorrhage, or nail growth rate.

Tolerability—Five patients (all in the tazarotene group) reported treatment-related adverse events (peeling of proximal nail fold skin, irritation of skin on finger, periungual irritation, paronychia, and erythema of the proximal nail fold). All such adverse events were mild or moderate.

Comment

The literature contains few reports of vehicle-controlled trials in nail psoriasis, presumably due, at least in part, to the long duration of study required to evaluate the clinical potential of agents in nail conditions.

The results of the 6-month study reported here suggest that evening applications of tazarotene 0.1% gel to psoriatic fingernails and the surrounding nail folds can significantly reduce onycholysis (in occluded and nonoccluded nails) and pitting (in occluded nails) compared with vehicle. The tazarotene gel was also well tolerated.

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REFERENCES

1. de Jong EM, Seegers BA, Gulnick MK, et al. Psoriasis of the nails associated with disability in a large number of patients: results of a recent interview with 1,728 patients. *Dermatology*. 1996;193:300-303.
2. Scher RK. Psoriasis of the nails. *J Geriatr Dermatol*. 1995;3(suppl):56-57.