

# Treatment of Nail Psoriasis With Efalizumab: A Preliminary Study

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*Nail involvement is common in psoriasis, affecting 50% to 80% of all patients with the disorder. Pain may accompany nail involvement, restricting daily living activities, and therapy is limited by issues of efficacy and safety.*

*The cases of 4 participants who had been enrolled in a 3-year study of efalizumab for the treatment of chronic moderate to severe plaque psoriasis are presented in this preliminary study. In addition to the diagnosis of moderate to severe plaque psoriasis, each participant discussed in this report presented with nail involvement. These participants achieved clearance of their nail psoriasis within 19 to 33 weeks of efalizumab therapy. None of the participants demonstrated adverse effects during efalizumab therapy. Our experience with these participants suggests that efalizumab may help to improve psoriasis affecting the nails when used for the treatment of chronic moderate to severe plaque psoriasis.*

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**N**ail involvement is common in psoriasis, affecting 50% to 80% of all patients with the disorder.<sup>1,2</sup> Clinically, psoriasis affecting the nail involves both the matrix and the nail bed and may include pitting, oil spots (salmon patches), subungual hyperkeratosis, distal

onycholysis, leukonychia, thin nails, erythema of the lunulae, and splinter hemorrhages. In addition, pain occurs in approximately 50% of cases of psoriatic nails, with 15% of these cases being so severe that activities of daily living are restricted.<sup>3</sup>

Systemic therapy of nail psoriasis requires long treatment periods before complete resolution is achieved (fingernails, 6 months; toenails,  $\leq$ 12 months). Although a variety of modalities have been used to treat nail psoriasis, including topical and intralesional corticosteroids, systemic immunosuppressive therapies, and radiation, none of these treatments has proved to be consistently effective.<sup>1,2</sup> Adverse effects associated with these treatments and specifically related to the extremities or nails have been reported. Phalangeal atrophy has been observed with topical steroids applied under occlusion,<sup>4</sup> and nail thinning has been associated with prolonged retinoid therapy.<sup>5</sup> Studies with the biologic agent alefacept, a T-cell modulator, in the treatment of nail psoriasis have yielded varied results.<sup>6-8</sup> Clinical studies with infliximab, an anti-tumor necrosis factor agent, have demonstrated success<sup>9,10</sup>; however, anti-tumor necrosis factor agents also have been associated with the appearance of nail psoriasis.<sup>11</sup>

Efalizumab is a recombinant humanized monoclonal IgG1 antibody that interferes with many of the T-cell-targeted processes central to the pathogenesis of psoriasis; thus, it belongs to the class of T-cell-modulating biologic agents. The efficacy and safety of efalizumab have been examined in 4 phase 3 clinical studies, leading to its approval for the treatment of adults with chronic moderate to severe plaque psoriasis in more than 50 countries worldwide.<sup>12-16</sup> During our participation as investigators in a 3-year study of the efficacy of efalizumab, 4 participants entered the study at our center with

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psoriasis that also affected their nails. We present a retrospective review of the 4 participants with chronic moderate to severe plaque psoriasis who also had nail involvement and were treated with efalizumab. No other participants at our study center had nail involvement.

### Methods

The participants described in this report originally were enrolled in an open-label clinical study of the efficacy and safety of efalizumab. Participant selection and methods have been previously described for this 3-year institutional review board–approved study.<sup>14,16</sup> Participants were treated with or trained to self-administer weekly subcutaneous injections of efalizumab (1 mg/kg weekly). Additionally, participants at our study center were examined for nail involvement. A physician’s global psoriasis nail assessment (PGPNA) score (0=clear; 1=mild; 2=moderate; 3=severe) and nail photographs were obtained for each participant at baseline (before initiation of drug administration) and follow-up visits (subsequent to termination of drug). Although the more comprehensive Nail Psoriasis Severity Index<sup>17</sup> frequently is used to evaluate the extent of nail disease, the preliminary nature of this study supported the rationale to use the PGPNA to provide a gross evaluation of nail involvement.

### Results

Participant 1 was a 48-year-old man with a 23-year history of extensive severe plaque psoriasis that was progressively worsening. At baseline, his psoriasis area and severity index (PASI) score was 33.9 and his affected body surface area (BSA) was 46%. His disease included extensive fingernail involvement with pitting, oil spots, subungual hyperkeratosis, distal onycholysis, leukonychia, and splinter hemorrhages (Figure, A). His PGPNA score was 3 and his toenails were not affected. He initiated monotherapy with efalizumab 1 mg/kg weekly. After 33 weeks of efalizumab therapy, his PASI score had reduced to 1.7 and his affected BSA had reduced to 2.5%. He showed marked nail improvement and resolution of all initial clinical findings. He completed the study, and follow-up photographs were obtained 37 months after treatment initiation (Figure, B). He experienced no adverse effects during efalizumab therapy.

Participant 2, a 24-year-old woman, presented with a 3-year history of moderate plaque psoriasis, a PASI score of 25.6, and an affected BSA of 39%. At presentation, she had moderate fingernail and toenail involvement with pitting, oil spots, subungual hyperkeratosis, and mild distal onycholysis. Her PGPNA score was 2. Topical treatment had no effect on her disease. She initiated monotherapy



Fingernails before (A) and 37 months after efalizumab therapy (B) (participant 1).

with efalizumab 1 mg/kg weekly. After 23 weeks of efalizumab therapy, she had achieved complete clearance of disease. The fingernails and toenails also had cleared. She was continuously treated for 37 months and did not experience adverse effects while undergoing efalizumab therapy.

Participant 3, a 47-year-old woman, presented with a 36-year history of moderate plaque psoriasis, a PASI score of 19.1, and an affected BSA of 33%. Her disease included moderate fingernail involvement with pitting, oil spots, moderate subungual hyperkeratosis, mild distal onycholysis, and leukonychia. Her PGPNA score was 2, and her toenails were not affected. Treatment with the topical psoriasis medications tacrolimus, tazarotene, and calcipotriene was ineffective. After a 2-year treatment-free period, she initiated monotherapy with efalizumab 1 mg/kg weekly. After 19 weeks of continuous efalizumab therapy, she had achieved a PASI score of 2.7, her affected BSA had reduced to 10%, and her nails were free of disease. She was continuously treated for 38 months with no adverse effects observed during efalizumab therapy.

Participant 4 was a 56-year-old man who presented with a 25-year history of moderate plaque psoriasis,

a PASI score of 40.2, and an affected BSA of 80%. His psoriasis included moderate fingernail involvement with pitting, oil spots, mild subungual hyperkeratosis, mild distal onycholysis, and leukonychia. His toenails showed no signs of involvement. A PGPNA score of 2 was determined for his nail disease. His most recent treatment regimen with methotrexate was ineffective, and he was treatment free on initiation of efalizumab monotherapy. After 31 weeks of continuous therapy with efalizumab 1 mg/kg weekly, he had achieved a PASI score of 16.0, his affected BSA had reduced to 4%, and he had no evidence of nail psoriasis. At 8 months of treatment, his fingernails were still free of disease. The clearance of his disease positively impacted his lifestyle. He resumed his occupation in the automobile repair industry and began spending time outdoors. He was continuously treated for 8 months with no adverse effects while undergoing efalizumab therapy.

### Comment

Nail findings are summarized for each of the 4 participants before and after efalizumab therapy (Table). In addition to chronic plaque psoriasis affecting various sites on their bodies, each of these participants

## Summary of Nail Findings for Each Participant Before and After Efalizumab Therapy<sup>a</sup>

Nail Finding	Before Efalizumab Therapy				After Efalizumab Therapy			
	Participant No.							
	1	2	3	4	1	2	3	4
Pitting	+	+	+	+	-	-	-	-
Oil spots	+	+	+	+	-	-	-	-
Subungual hyperkeratosis	+	+	+	+	-	-	-	-
Distal onycholysis	+	+	+	+	-	-	-	-
Leukonychia	+	-	+	+	-	-	-	-
Splinter hemorrhages	+	-	-	-	-	-	-	-
PGPNA score <sup>b</sup>	3	2	2	2	0	0	0	0
Fingernail/Toenail involvement	Fingernail	Both	Fingernail	Fingernail	-	-	-	-

Abbreviation: PGPNA, physician's global psoriasis nail assessment.

<sup>a</sup>+ indicates nail finding is present; -, nail finding is absent.

<sup>b</sup>PGPNA score: 0=clear; 1=mild; 2=moderate; 3=severe.

presented with 4 to 6 clinical symptoms of nail psoriasis and moderate to severe PGPNA scores. Continuous treatment with efalizumab resulted in complete clearance of all nail findings and reduction of PGPNA scores to 0. None of these participants experienced adverse effects during efalizumab therapy.

This was a preliminary study, however, and was limited by several factors, including the small number of participants, use of a global scale, and lack of a control group. Despite these limitations, the results of this study suggest that efalizumab may help to improve psoriasis affecting the nails when used for the treatment of chronic moderate to severe plaque psoriasis.

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