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Treatment of Seborrheic Dermatitis and Post-Inflammatory Hypopigmentation With Roflumilast Foam in Skin of Color Patients

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INTRODUCTION

Seborrheic dermatitis (SD) is a common, chronic, and relapsing inflammatory skin disorder. It is characterized by pruritic, erythematous plaques with overlying greasy scale, typically distributed in areas rich in sebaceous glands, such as the scalp, face, ears, and upper torso.[1,2] Until recently, the pathogenesis of SD has been poorly understood.[3,4] A recent transcriptomic study examined the cutaneous molecular profile of patients with SD. It demonstrated that SD is an inflammatory skin disease driven by immune dysregulation and skin barrier dysfunction with *Malassezia* as a commensal contributor.[4] The immune and barrier dysregulation seen in patients with SD may make them susceptible to *Malassezia* colonization. This colonization can result in the characteristic erythema, pruritus, and barrier disruption seen in SD.[4] A comprehensive meta-analysis estimated the global pooled prevalence of SD at 4.38%, with South Africa (8.82%) and the United States (5.86%) reporting the highest rates.[5]

In darker skin tones (Fitzpatrick skin types IV-VI), persistent dyschromia can occur with variable post-inflammatory pigmentary changes (hyperpigmentation or hypopigmentation).[6,7] Post-inflammatory hypopigmentation (PIH) is a particularly common and prominently acquired pigmentary disorder in patients with skin of color (SOC).[8] It manifests as multiple, ill-defined, round or oval hypopigmented macules and patches with fine scale, often due to cutaneous inflammation, sequelae of inflammatory or infectious dermatoses, or dermatologic procedures. PIH can persist as long-term sequelae well after the active inflammatory disease has resolved.[8]

The pathophysiology of hypopigmentation involves decreased melanin production, impaired transfer of melanosomes to keratinocytes, and melanocyte destruction or dysfunction.[8] These dyschromias present a significant cosmetic concern, especially in SOC populations where the visual contrast against unaffected skin is stark. Disorders of pigmentation are the third most common reason for patients with SOC to seek dermatologic care.[9] Between 1993 and 2010, an estimated 24.7 million visits were related to dyschromia.[9,10] These conditions can profoundly negatively impact psychosocial functioning, quality of life, self-esteem, and workplace productivity.[8-11]

Despite its high prevalence, treating dyschromia remains challenging due to a lack of targeted therapies.[8] Management is highly individualized based on skin type and the specific pigmentary disorder. Hydroquinone remains the gold standard for hyperpigmentation, while sun protection and limitation of sun exposure are the most common strategies employed for both hyperpigmentation and hypopigmentation.[8] Other agents utilized for pigmentation disorders include topical corticosteroids, tretinoin, non-hydroquinone agents, chemical peels, and laser therapy.[9,10]

Historically, common therapies for SD included topical antifungal agents such as ketoconazole and anti-inflammatory agents, including topical steroids and off-label use of topical calcineurin inhibitors.[4,12] Topical steroids can cause local side effects like skin atrophy, telangiectasia, acne, and rosacea, and there is a known risk of severe systemic effects with prolonged use; they should only be used for a short duration to treat flares that are not controlled with other therapies.[3,12] Nonpharmacologic alternatives, including prescription nonsteroidal medical "device creams," can also be used to help alleviate symptoms associated with seborrheic dermatitis, particularly pruritus, erythema, scaling, and pain.[13] As an inflammatory condition, treating only the *Malassezia* does not address the core issue driving SD, which is dysregulation in the inflammatory pathways. Reliance on antifungal therapies can contribute to antifungal overuse and resistance.[4] To effectively manage SD and practice good antifungal stewardship, therapy must directly target the underlying inflammation. Furthermore, a significant unmet need exists in the SOC population for therapies that effectively treat the resulting dyspigmentation.

A particular mechanism of interest to both SD and dyschromia is phosphodiesterase-4 (PDE4) inhibition. PDE4 inhibitors act intracellularly to prevent the degradation of cyclic adenosine monophosphate (cAMP), thereby increasing its concentration. This elevated cAMP level downregulates pro-inflammatory mediators and promotes anti-inflammatory signaling.[14,15]

Topical roflumilast is a selective, highly potent PDE4 inhibitor that is indicated for the treatment of several inflammatory dermatoses, such as seborrheic dermatitis, plaque psoriasis,

including intertriginous areas, and atopic dermatitis.[16,17] A maximal use study researching the antifungal effects of roflumilast foam in SD reported that this treatment suggested a direct or indirect effect on *Malassezia*.[18] By effectively addressing the inflammatory pathways, treating SD with roflumilast foam leads to a reduction in *Malassezia* colonization and disease severity.[4,18] As observed in this case series, evaluation of roflumilast for SD revealed significant concomitant improvement in dyschromia and PIH in patients with SOC, a finding warranting further investigation. This effect is mechanistically plausible, as PDE4 inhibitors have demonstrated repigmentation in the autoimmune depigmenting disorder vitiligo.[19] Evidence suggests that cAMP signaling can regulate pigmentation, and a recent study reported that PDE4 inhibition stimulates melanin production, promoting melanocyte proliferation and melanization in vitro.[19] Similarly, a recent study out of China demonstrated that roflumilast enhances melanogenesis and protects melanocytes from oxidative stress-induced apoptosis.[20] This mechanism is further supported by the finding that lesional skin from active vitiligo patients exhibits higher PDE4 levels compared to healthy controls, and PDE4 inhibition was previously found effective in slowing the progression of vitiligo.[20]

We present a case series evaluating 15 patients with severe SD and associated PIH-related dyschromia treated with roflumilast foam 0.3% nightly as monotherapy. The treatment was well-tolerated, and no adverse events were reported. All 15 patients demonstrated a significant reduction in pruritus, flaking, and associated PIH. Furthermore, all patients reported a high degree of satisfaction with the treatment, noting ease of application and a marked reduction in pruritus within 1 week of initiating roflumilast foam. Consequently, all participants were amenable to continuing therapy for long-term symptom resolution and maintenance.

CASE SERIES

We performed a retrospective case series analysis of 15 patients treated in our clinic between June 2023 and July 2024, who were diagnosed with severe SD and associated PIH of scalp and/or face and neck, refractory to previous treatments. All patients had previously been treated unsuccessfully with topical corticosteroids and/or antifungals without symptom improvement. The case series included 8 males and 7 females, aged 10 to 57 years old. All patients were Fitzpatrick skin type V or VI, and none had any additional significant medical history. Prior to initiating roflumilast treatment, patients were screened for a history of liver impairment, informed consent was obtained, and patients were advised to avoid fire, flame, and smoking as the propellant in roflumilast foam is flammable. Patients were treated with roflumilast foam 0.3% qhs, and the initial follow-up assessment was 1 or 2 months after treatment initiation. Representative before-and-after clinical photographs of 2 patients from the series are included (Figures 1 and 2).

FIGURE 1. A 15-year-old female with seborrheic dermatitis and PIH of the scalp and face (Case #3 in Table 1). (A) Before photo: unsuccessfully managed with ketoconazole shampoo 2% biw, hydrocortisone ointment 2.5%, ketoconazole cream 2%, and fluocinonide solution 0.05% qhs for four weeks. (B) After photo: One month after monotherapy use of topical roflumilast foam 0.3% qhs.

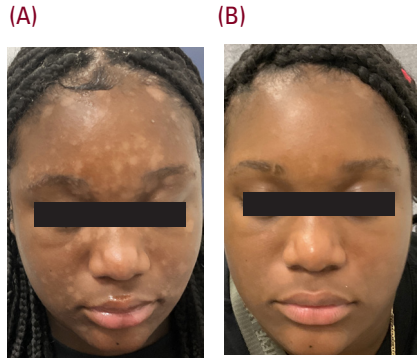
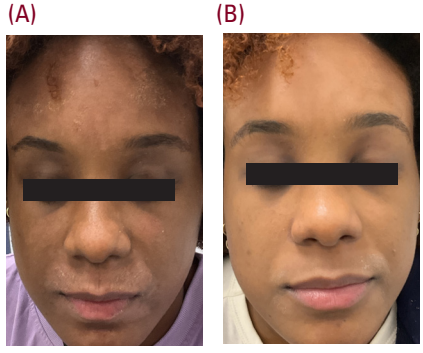


FIGURE 2. A 21-year-old female with seborrheic dermatitis and PIH of the scalp and face (Case #1 in Table 1). (A) Before photo: unsuccessfully managed with ketoconazole shampoo 2% biw and fluocinonide cream 0.05% qhs for four weeks. (B) After photo: One month after monotherapy use of topical roflumilast foam 0.3% qhs.



At baseline, all patients had severe SD and PIH and reported severe pruritus, ranging in score from 8 to 10 out of 10. As demonstrated in Table 1, 10 patients had their initial outcome assessment at 1 month, and all 10 patients reported improved itch with a pruritus score of 3/10 or less. All (100%) of the 5 patients who were assessed at 2 months reported complete resolution of itch and a 0/10 pruritus score. Notably, all patients self-reported a noticeable reduction in itch within 1 week of initiating roflumilast foam 0.3% qhs.

At 1-month follow-up, 8 patients had 90% reduction in PIH, and 2 patients had 80% reduction. The remaining 5 patients were assessed at 2 months, and all had 100% resolution of PIH, flaking, and pruritus (Table 1). There were no adverse events (AEs) reported, and only 1 out of 15 patients reported a tolerability complaint of application-site pain at week 2. This patient chose

TABLE 1.

Characteristics and Clinical Information of 15 Seborrheic Dermatitis Patients With Dyschromia

Case #	Biologic sex	Age	Fitzpatrick Type	Clinical Presentation	Prior Treatment	Current Treatment	Outcome	Long-Term Follow-Up
1	F	21	V	Severe SD & PIH of scalp & face	4 wks ketoconazole shampoo 2% biw, fluocinonide cream 0.05% qhs	ROF foam 0.3% qhs	90% reduction in PIH & flaking. Itch reduced from 9/10 to 2/10 at 1 mo w/ itch improvement w/in 1wk	Results maintained & itch completely resolved at 5-mo f/u
2	M	24	V	Severe SD & PIH of scalp	6 wks ketoconazole shampoo 2% biw, hydrocortisone oint 2.5%, ketoconazole cream 2% qhs	ROF foam 0.3% qhs	Reduction of 90% in PIH & 100% in flaking. Itch reduced from 10/10 to 3/10 at 1 mo w/ itch improvement w/in 1 wk	Results maintained & itch completely resolved at 8-mo f/u
3	F	15	V	Severe SD & PIH of scalp & face	4 wks ketoconazole shampoo 2% biw, hydrocortisone 2.5% oint, ketoconazole cream 2%, fluocinonide solution 0.05% qhs	ROF foam 0.3% qhs	80% reduction in PIH & flaking. Itch reduced from 9/10 to 3/10 at 1 mo w/ itch improvement w/in 1 wk	Results maintained & itch completely resolved at 6-mo f/u
4	M	13	V	Severe SD & PIH of scalp, face, & neck	18 wks ketoconazole shampoo 2% biw, hydrocortisone 2.5% oint, ketoconazole cream 2%, fluocinonide soln 0.05% qhs	ROF foam 0.3% qhs	Reduction of 90% in PIH & 100% in flaking. Itch reduced from 10/10 to 2/10 at 1mo w/ itch improvement w/in 1 wk	Results maintained & itch completely resolved at 5-mo f/u
5	M	10	V	Severe SD & PIH of scalp & face	16 wks ketoconazole shampoo 2% biw, hydrocortisone 1% cream, ketoconazole cream 2%	ROF foam 0.3% qhs	80% reduction in PIH & flaking. Itch reduced from 9/10 to 3/10 at 1 mo w/ itch improvement w/in 1 wk	Results maintained & itch completely resolved at 3-mo f/u
6	M	30	VI	Severe SD & PIH of scalp	40 wks ketoconazole shampoo 2% biw, hydrocortisone cream 1%, ketoconazole cream 2% qhs	ROF foam 0.3% qhs	Reduction of 90% in PIH & 100% in flaking. Itch reduced from 10/10 to 2/10 at 1 mo w/ itch improvement w/in 1 wk	Results maintained & itch completely resolved at 6-mo f/u
7	M	44	VI	Severe SD & PIH of scalp & face	4 wks ketoconazole shampoo 2% biw, qhs ketoconazole cream 2% qhs	ROF foam 0.3% qhs	Reduction of 90% in PIH & 100% in flaking. Itch reduced from 10/10 to 2/10 at 1 mo w/ itch improvement w/in 1 wk	Results maintained & itch completely resolved at 6-mo f/u
8	F	38	V	Severe SD & PIH of scalp	8 wks ketoconazole shampoo 2% biw, fluocinonide soln 0.05% qhs, ketoconazole cream 2% qhs	ROF foam 0.3% qhs	100% resolution of PIH, flaking, & itch (itch 10/10 before ROF) at 2 mos w/ itch improvement w/in 1 wk	Full resolution of symptoms & itch maintained at 12-mo f/u
9	F	11	V	Severe SD & PIH of scalp, face, & neck	12 wks ketoconazole shampoo 2% biw, hydrocortisone 1% cream, ketoconazole cream 2%	ROF foam 0.3% qhs	90% reduction in PIH & flaking. Itch reduced from 9/10 to 2/10 at 1 mo w/ itch improvement w/in 1 wk	Results maintained & itch completely resolved at 8-mo f/u
10	F	27	VI	Severe SD & PIH of scalp	2 wks ketoconazole shampoo 2% biw, hydrocortisone oint 2.5%, ketoconazole cream 2% qhs	ROF foam 0.3% qhs	100% resolution of PIH, flaking, & itch (itch 8/10 before ROF) at 2mos w/ itch improvement w/in 1 wk	Full resolution of symptoms & itch maintained at 12-mo f/u
11	F	29	V	Severe SD & PIH of scalp, face, & neck	16 wks ketoconazole shampoo 2% biw, hydrocortisone 1% cream, ketoconazole cream 2%, fluocinonide soln 0.05%	ROF foam 0.3% qhs	Reduction of 90% in PIH & 100% in flaking. Itch reduced from 10/ 10 to 2/10 at 1 mo w/ itch improvement w/in 1wk	Results maintained & itch completely resolved at 6-mo f/u
12	M	12	V	Severe SD & PIH of scalp & face	24 wks ketoconazole shampoo 2% biw, ketoconazole cream 2%	ROF foam 0.3% qhs	100% resolution of PIH, flaking, & itch (itch 10/10 before ROF) at 2 mos w/ itch improvement w/in 1 wk	Full resolution of symptoms & itch maintained at 12-mo f/u
13	M	57	V	Severe SD & PIH of scalp	8 wks ketoconazole shampoo 2% biw, hydrocortisone oint 2.5%, ketoconazole cream 2% qhs	ROF foam 0.3% qhs	90% reduction in PIH & flaking. Itch reduced from 9/10 to 2/10 at 1 mo w/ itch improvement w/in 1 wk	Results maintained & itch completely resolved at 8-mo f/u
14	F	35	V	Severe SD & PIH of scalp & face	4 wks ketoconazole shampoo 2% biw, hydrocortisone oint 2.5%, ketoconazole cream 2% qhs	ROF foam 0.3% qhs	100% resolution of PIH, flaking, & itch (itch 10/10 before ROF) at 2mos w/ itch improvement w/in 1 wk	Full resolution of symptoms & itch maintained at 12-mo f/u
15	F	28	VI	Severe SD & PIH of scalp & face	12 wks ketoconazole shampoo 2% biw, ketoconazole cream 2% qhs	ROF foam 0.3% qhs	100% resolution of PIH, flaking, & itch (itch 10/10 before ROF) at 2 mos w/ itch improvement w/in 1 wk	Full resolution of symptoms & itch maintained at 12-mo f/u

Abbreviations: F, female; M, male; SD, seborrheic dermatitis; PIH, postinflammatory hypopigmentation; biw, twice a week; soln, solution; oint, ointment; qhs, nightly; ROF, roflumilast; mo/mos, month/months; wk/wks, week/weeks

to continue treatment because he already noticed a reduction in flaking and itching. At 8 and 24 week follow-ups, the patient reported he no longer experienced application-site pain.

All patients reported a high degree of satisfaction with the treatment, citing ease of application and were amenable to continuing therapy for long-term symptom resolution and maintenance. The long-term follow-up period varied by patient and ranged from 3 to 12 months. Most (80%) patients had a long-term follow-up appointment between 6 and 12 months after treatment initiation. All 15 patients reported complete resolution of symptoms or results maintained at the long-term follow-up appointment.

DISCUSSION

While SD is a common condition, its impact on patients with SOC is often compounded by the development of dyschromia, which carries a significant and distressing psychosocial burden. Beyond the classic signs of erythema and scaling, this dyspigmentation is a primary concern for many patients with SOC and remains a substantial unmet therapeutic need, as current treatments primarily target inflammation but fail to address the associated pigmentary changes.

In this case series, topical roflumilast foam 0.3% used as monotherapy effectively resolved both the inflammatory signs and symptoms of SD and the associated dyschromia. The treatment was well-tolerated with no reported AEs.

The significant improvement in dyschromia observed in these cases is hypothesized to result from roflumilast's targeted anti-inflammatory mechanism. Inflammation is a primary driver of melanocyte dysfunction, and the potent inhibition of PDE4 by roflumilast leads to a broad reduction in key pro-inflammatory cytokines that are known to disrupt melanin production and function. The low molecular weight of roflumilast, combined with its optimized vehicle designed for enhanced delivery, achieves effective dermal penetration. It is hypothesized that this allows for direct modulation of the inflammatory response at the dermal-epidermal junction, targeting melanocytes and keratinocytes to restore normal pigmentary function. While promising, our observations are limited by the constraints of being a small, open-label case series. Further research would be beneficial to quantify the impact of roflumilast foam on dyschromia in SOC populations. Such research would clarify the role of PDE4 inhibition in melanocyte protection and explore the potential of topical roflumilast foam as a novel therapeutic option for inflammatory pigmentary disorders.

DISCLOSURES

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