SKIN

BRIEF ARTICLE

Successful Treatment of Refractory Seborrheic Dermatitis with Topical Roflumilast: A Case Series

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ABSTRACT

Background: Seborrheic dermatitis (SD) is a common skin disease that presents with pink scaly patches in areas with higher sebaceous gland density, such as the scalp, glabella, retroauricular folds, nasolabial folds, chest, and groin.
Case Reports: This is a case series of two patients with longstanding SD that did not respond adequately to topical corticosteroids or azoles and were successfully treated monotherapy with roflumilast cream 0.3%. Both patients responded within two months and continue to respond to treatment with topical roflumilast monotherapy.
Discussion: SD is commonly considered to be caused by Malassezia yeast proliferation and activity, however recent research has revealed that the inflammatory skin disease results from immune dysregulation and skin barrier disruption with Malassezia contributing as an exacerbating factor secondary to the primary pathogenesis. Thus, treatment with topical roflumilast, a highly potent phosphodiesterase-4 inhibitor, has been studied and demonstrated to be effective in treating the signs and symptoms of SD. Topical roflumilast 0.3% is formulated as a cream and a foam, with the foam approved for the treatment of SD. These cases demonstrate a successful treatment of patients with longstanding SD with roflumilast cream 0.3%.
Conclusion: These cases demonstrate that SD, treated with either roflumilast cream 0.3% or roflumilast foam 0.3% may provide improvement in signs and symptoms of SD.

INTRODUCTION

Seborrheic dermatitis (SD) is a common skin disease that presents with pink scaly patches in areas with higher sebaceous gland density, such as the scalp, glabella, retroauricular folds, nasolabial folds, chest, and groin. Most commonly reported symptoms are itching, redness, flaking and is estimated to affect nearly 5% of the world's population.[1,3] Literature on the pathogenesis of SD has been limited, however recent research in adults with SD suggests that the skin condition is unique from both atopic dermatitis and psoriasis including Th17/Th22 polarization, lipid metabolism abnormalities, and skin barrier disruption.[1-4] Inflammation caused by SD can be further exacerbated by the proliferation and activity of *Malassezia spp.*[2] Historical treatments for seborrheic target the underlying inflammation and *Malassezia spp* colonization and include topical antifungal agents such as

ketoconazole and topical corticosteroids. Roflumilast cream 0.3% is a highly selective, potent topical phosphodiesterase 4 (PDE4) inhibitor approved in 2022 by the FDA for the treatment of plaque psoriasis, including intertriginous disease, for ages 6 years and older. In 2023, Roflumilast foam 0.3% was approved for the treatment of SD for ages 9 years and older. While roflumilast foam 0.3% was adapted from roflumilast cream 0.3%, differences in excipients between cream and foam formulations have tended to result in treatment implications based on their cosmetic properties and ability to improve or worsen the underlying skin barrier dysfunction. For example, foams tend to be preferred for hair bearing surfaces but may contain alcohol and have a drying effect, whereas creams are generally more moisturizing and enhance skin barrier function. We present 2 cases of patients with longstanding SD that did not respond adequately to topical corticosteroids and azoles and were successfully treated with roflumilast cream 0.3%.

CASE REPORTS

Case Report One:

A 69-year-old white male who has suffered from SD since his teenage years presented to clinic with symptoms affecting his glabella, nasolabial fold, and mustache (**Figure 1a**). Upon examination, the SD was moderate in severity and significant pruritus was reported. The patient has previously tried hydrocortisone and ketoconazole shampoo with some improvement but also noted difficulty with adherence to treatment. The patient was provided roflumilast cream 0.3% and instructed to apply once daily to affected areas. At his 2 month follow up, the patient was completely clear and was therefore instructed to use twice weekly as maintenance (**Figure 1b**). Two months later, the patient returned to clinic with just a mild flare due to exhausting the quantity of product. Since roflumilast foam 0.3% was FDA approved for SD just before the patient visit, the patient was subsequently switched to the foam formulation and has continued to do well on treatment.

Case Report Two:

A 68-year-old white male who had a longstanding history of poorly controlled, pruritic SD on the seborrheic areas of the face presented to clinic seeking additional treatment options (**Figure 2a**). Previous treatments included desonide cream 0.05% and ketoconazole cream 2%, which led to partial resolution but never full clearance. At this time, the diagnosis was changed to sebopsoriasis, and the patient was started on roflumilast cream 0.3% once daily and directed to discontinue both the desonide 0.05% and ketoconazole 2% creams. One week later at follow up, the patient presented with limited improvement in his SD and instructed to continue to use roflumilast 0.3% once daily. At his four-week follow up, the patient reported using roflumilast 0.3% three times weekly as he was happy with the improvement in his SD. Upon examination, there was no evidence of SD on his face and the patient was instructed to continue roflumilast 0.3% as needed for maintenance therapy (**Figure 2b**).

DISCUSSION

SD is a chronic inflammatory condition that requires long term, continuous, treatment for which topical corticosteroids are not ideal, especially for patients with facial involvement. Additionally, formulations such as shampoos, topical foams and gels used to

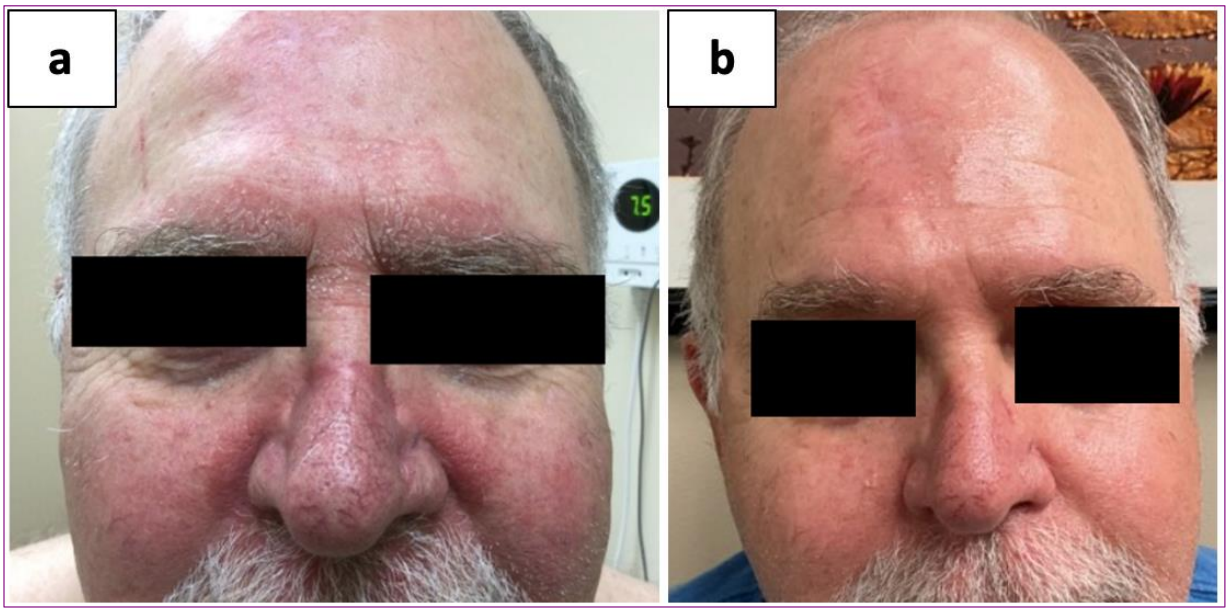

Figure 1. 69-year-old white male with SD before (**a**) and after (**b**) treatment with topical roflumilast 0.3%.

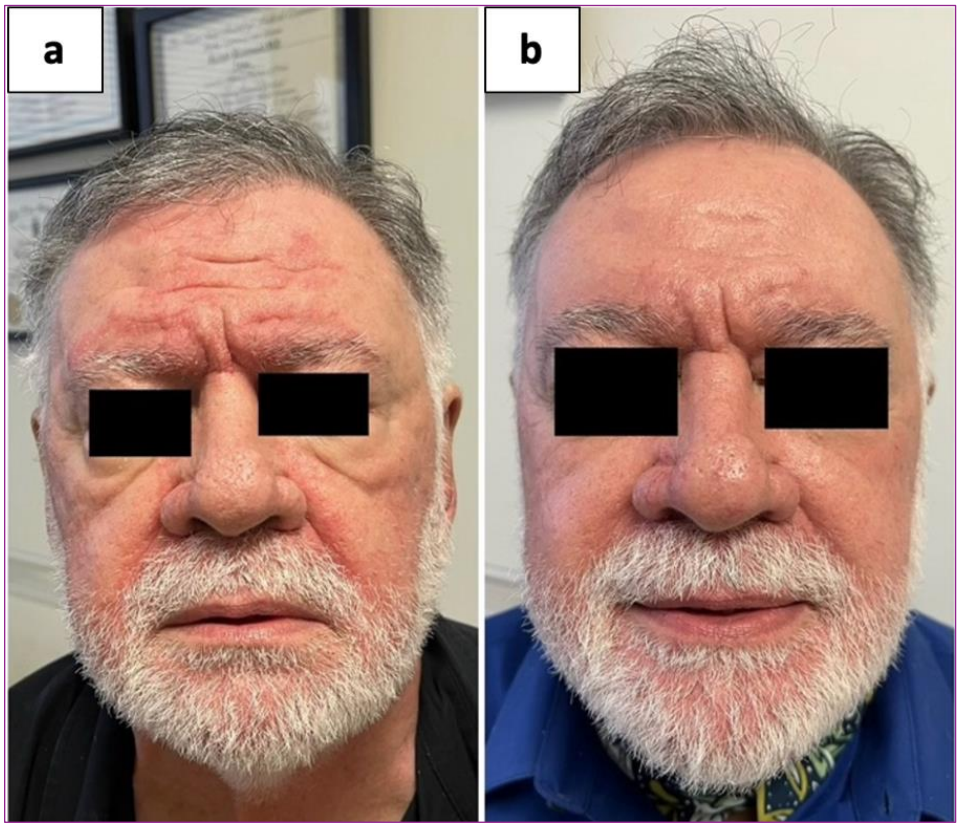

Figure 2. 68-year-old white male before (a) and after (b) treatment with roflumilast cream 0.3%.

treat SD contain short-chain alcohols that can damage skin and hair by dissolving natural oils. These cases of 68-, and 69-year-old white males with lifelong histories of poorly controlled SD were successfully treated with roflumilast cream 0.3% as roflumilast foam 0.3% had not yet been FDA approved. In a disease that is typically treated with topical corticosteroids and topical anti-fungals, this case highlights the utility of topical roflumilast 0.3% as an additional treatment option. Newly approved in December of 2023, roflumilast foam 0.3% was granted FDA approval for SD. While the clinical trials of patients with SD were conducted with roflumilast foam 0.3%, these cases demonstrate the consistent outcomes in patients with SD treated with roflumilast cream 0.3%.

CONCLUSION

These findings suggest that roflumilast cream, while not yet FDA-approved for SD or discussed in the literature, could be an effective treatment option, potentially favored by both physicians and patients for its differences in cosmetic properties.

Conflict of Interest Disclosures:
Smythe and Sohn have no conflicts to disclose.
Song has served as a consultant/speaker for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Janssen, Lilly, Galderma, Ortho-dermatologics, Novartis, Pfizer, Sanofi & Regeneron, LEO, UCB, Incyte, SUN, Dermavant, Arcutis, Alphyn, and Apogee. He is an investigator for Arcutis, SUN, Bristol Myers Squibb, Amgen, CorEvitas, DermBiont, Apogee, Incyte, Janssen, Pfizer, MoonLake, and TARGET-Derm.
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