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COMMENTARY

When Patient Diversity Informs Formulation: Reimagining Treatment for Seborrheic Dermatitis

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ABSTRACT

Seborrheic dermatitis (SD) impacts a diverse demographic, with treatment effectiveness and suitability varying across hair types and cultural practices. Available shampoo treatments contain surfactants that compromise hair moisture and integrity as well as requiring frequent use, which may not align with the routines of various hair types and cultural hair care practices. Most available topical foams and gels contain high concentrations of drying alcohols that damage hair color and moisture. Newly US Food and Drug Administration (FDA)-approved roflumilast 0.3% foam presents a significant advancement in the treatment of SD owing to its pH-balanced, residue-free formulation that is suited for all hair types, including patients with curly or coiled hair. It presents a culturally inclusive treatment option that offers effective management of SD while maintaining hair health and respecting diverse hair care needs and practices.

Keywords: Seborrheic dermatitis; Formulation; Foam

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Key Summary Points

Seborrheic dermatitis (SD) treatment effectiveness varies across different hair types and cultural practices, necessitating formulations that cater to diverse needs and respect cultural hair care practices.

Commonly used SD treatments, such as shampoos containing surfactants and topical foams with drying alcohols, may compromise hair integrity and color, highlighting the need for innovative formulations.

The recently FDA-approved roflumilast 0.3% foam presents a significant advancement in SD treatment, offering a pH-balanced, residue-free formulation suitable for all hair types and respecting diverse cultural hair care needs.

Embracing cultural inclusivity in SD treatment regimens is crucial for ensuring better patient outcomes, and further research is needed to explore the efficacy and safety of treatments across diverse patient populations, considering a wide range of hair types and cultural dimensions of hair care.

INTRODUCTION

Seborrheic dermatitis (SD) is a common dermatologic condition characterized by erythematous, scaly plaques associated with itch and often presenting with a characteristic distribution, including hair-bearing areas of the scalp, head, and neck. The condition's impact is broad, affecting individuals across a spectrum of hair types. Protective styles, oil treatments, chemical straightening, and personalized washing frequencies, among other diverse hair care practices, can have profound implications for scalp health and SD management [1]. The efficacy of SD treatments relies on their suitability for diverse hair types and histories. Commonly used topical treatments for SD, such as antifungal agents (e.g., ketoconazole, ciclopirox, miconazole), anti-inflammatory compounds (topical corticosteroids such as betamethasone valerate and clobetasol propionate), and keratolytic/humectant substances (e.g., propylene glycol) [2], may not adequately and uniformly serve the full spectrum of patient diversity, such as those belonging to certain racial or ethnic groups and those with curly or coily hair. This gap highlights the pressing need for treatments that are specifically formulated to cater to varied hair needs and respect the cultural context of hair care. This Commentary aims to share insights and perspectives on the current landscape of treatments for SD, encouraging discussion among peers and suggesting directions for future research, grounded in both professional, expert experience and the existing body of evidence.

FORMULATION CHALLENGES IN SD TREATMENTS

Formulating effective SD treatments requires a thoughtful approach to avoid excipients that could weaken hair or alter its color, which can reduce patient adherence and treatment efficacy (Fig. 1). Shampoo treatments require sufficient scalp contact time and are typically recommended for use several times weekly—a frequency incompatible with some hair care routines [3]. Furthermore, these treatments require an acidic pH to prevent hair fiber swelling or unwanted penetration of ingredients into the hair fiber. However, common surfactants like sodium laureth sulfate, found in ciclopirox 1% shampoo and clobetasol propionate 0.05% shampoo, have a pH of 7–9 in 10% solutions and can strip hair of its natural oils and color. This effect is further exacerbated when sodium chloride is added to increase shampoo viscosity [4]. Additionally, cocamide diethanolamine (DEA), a surfactant utilized in 2% ketoconazole shampoo, carries risk of contact dermatitis and is classified by the International Agency for Research on Cancer (IARC) as a Group 1B carcinogen, indicating possible

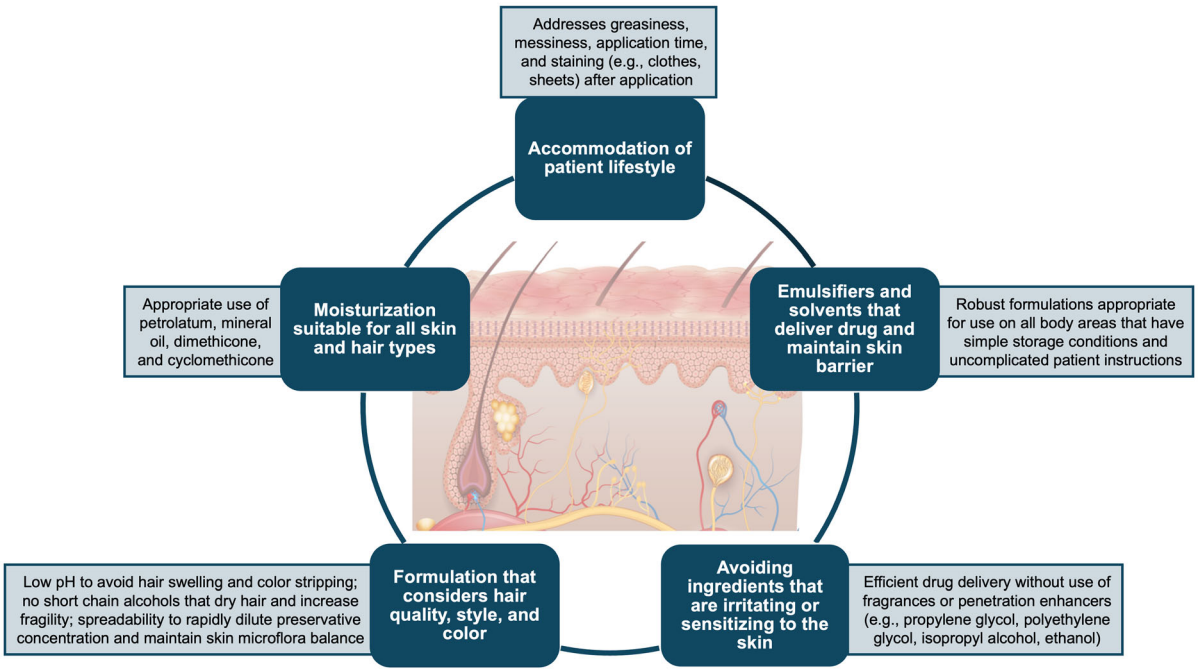

Fig. 1 Essential elements of topical therapy formulation to consider for seborrheic dermatitis and other inflammatory skin diseases

carcinogenicity to humans [5, 6]. Alternatives like cocamide monoethanolamine (MEA), used in 1% ketoconazole shampoo, are considered safer but may still promote hair dryness and fragility [7]. Furthermore, most topical foams and gels have high concentrations of short-chain alcohols like isopropyl alcohol and ethanol, causing significant drying and stripping of hair color. The presence of these alcohols, alongside the potential irritative and allergenic effects of propylene glycol [8], especially in higher concentrations, necessitates innovative treatments that preserve the integrity of diverse hair types while respecting cultural hair care practices are needed (Table 1).

ADVANCEMENTS WITH ROFLUMILAST FOAM

The recently US Food and Drug Adminstration (FDA)-approved roflumilast 0.3% foam offers a significant advancement in SD treatment, both in efficacy that has been proven highly effective and well tolerated, with substantial clearance of symptoms in almost 80% of patients and a low incidence of reactions at the site of application [9], and unique elements in formulation (Table 2). The formulation maintains the hair's natural pH and provides moisturization without leaving residue, a common issue with many topical treatments that is particularly problematic for those with textured hair. Central to its formulation is Crodafos CES, a blend of ceteth-10 phosphate, cetearyl phosphate, and cetostearyl alcohol. Crodafos CES is extensively used in the cosmetic industry, with applications ranging from sun protection and baby care products to a range of hair care items including permanent waves, hair colorants, conditioners, and styling aids, with many products tailored for curly and coily hair types [10]. In contrast to other topical treatments, roflumilast foam has a pH near 5.3, aligning with the natural pH of the stratum corneum. This pH optimization enhances drug delivery and bioavailability to inflamed skin by repelling the foam from the negatively charged hair fibers and ensuring the active ingredient is directed towards the scalp

Table 1 Key formulation concerns in topical shampoos, foams, gels, and solutions for seborrheic dermatitis treatment

Product	Application frequency	Key formulation concerns
Betamethasone valerate 0.12% foam	Twice daily	60% Ethanol; can cause significant drying and hair fragility
Ketoconazole 1–2% shampoo	Twice weekly	Cocamide diethanolamine (DEA) poses risk of contact dermatitis and is a potential carcinogen; alternatives like cocamide monoethanolamine (MEA) are safer but may dry hair
Ketoconazole 2% foam	Twice daily	58% Ethanol; can cause significant drying and hair fragility
Ketoconazole 2% gel	Once daily	34% Ethanol; less drying but still poses risk to hair integrity
Keratolytic/ humectant solution	Once daily	50% Ethanol; can cause significant drying and hair fragility
Ciclopirox 0.77% gel	Twice daily	Isopropyl alcohol predominant after water, specific concentration not disclosed; can strip hair of natural oils, pH not aligned with hair health
Ciclopirox 1–1.5% shampoo	Three times weekly	Contains sodium laureth sulfate which may compromise hair moisture and color, adding sodium chloride exacerbates this effect
Miconazole 2% solution	Once daily	Contains acetic acid and laureth-4 for pH adjustment and cleansing that can dry and irritate the scalp
Clobetasol propionate 0.05% shampoo	Twice weekly	Contains sodium laureth sulfate which, with a pH of 7–9, can strip hair of its natural oils and color, leading to dryness and potential damage
Propylene glycol 15% solution	Once daily	Can cause irritation and allergic reactions

rather than diffusing into or being adsorbed onto the hair [11].

Roflumilast foam's additional components further contribute to its suitability for all hair types. Diethylene glycol monoethyl ether (commercially known as ethoxydiglycol) provides longer-lasting and more uniform color and prevents split ends formation in hair care products [12]. Hexylene glycol, isopropyl palmitate, and white petrolatum provide moisturization to the hair, with white petrolatum being a preferred moisturizer in certain racial and ethnic groups as well as those with curly or coiled hair. Notably, roflumilast foam is free from high concentrations of alcohols or sulfates, reducing the risk of drying and frizzing.

Table 2 Unique formulation attributes of roflumilast 0.3% foam designed for application to hair-bearing areas of the scalp

Foam attribute	Benefit
Foam pH 5.3	Does not swell hair fiber—when the hair fiber is swollen by products having a pH value higher than 7, permanent hair color is stripped and unwanted penetration of ingredients into the hair fiber can occur
Foam emulsifier (Crodafos CES) desirable for use on all hair types	Common cosmetic emulsifier used in sun protection, baby care and hair care products tailored for curly and coily hair types
Low levels of the moisturizers hexylene glycol, isopropyl palmitate, and white petrolatum	Provides moisturization to the hair without leaving a residue that could decrease patient dosing compliance for some hair care routines
The foam excipient (DEGEE) that dissolves roflumilast is commonly used in hair care products	The cosmetic-grade solvent ethoxydiglycol provides longer-lasting and more uniform color and prevents split ends formation when used in hair care products
By excluding the use of short chain alcohols and sulfate surfactants, the foam product avoids drying the hair or making the hair more fragile and prone to breakage	

Furthermore, its once-daily application regimen ensures consistent delivery of the active ingredient independent of shampooing frequency, making it an ideal treatment for individuals who extend time between washes to preserve protective hairstyles or maintain hair integrity.

CONCLUSION

The treatment of SD necessitates a departure from the one-size-fits-all approach, which fails to accommodate a diversity of hair types and cultural hair care practices. The introduction of topical roflumilast 0.3% foam represents a significant advancement in dermatological care, reflecting a shift toward formulations that are inclusive of all hair types and considerate of various treatment histories such as perms, straightening, coloring, and bleaching. The foam's lightweight consistency ensures easy application and absorption, circumventing heavy buildup that can compromise hair health and styling practices. By embracing cultural inclusivity in treatment regimens, roflumilast foam fosters better adherence and patient–provider collaboration and fills a critical gap in culturally competent SD treatments. Acknowledging this progress, we call for rigorous future research to further explore the efficacy and safety of SD treatments across diverse patient populations, particularly highlighting the importance of considering the wide spectrum of hair types and the cultural dimensions of hair care. This focused inquiry is essential for advancing our understanding and management of seborrheic dermatitis, ensuring that treatment innovations continue to meet the nuanced needs of all patients.

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Declarations

Conflict of Interest. Meredith Tyree Polaskey has no conflicts to disclose. Heather Woolery-Lloyd has served as a consultant, speaker, and/or investigator for Ortho Dermatologics, L'Oréal, Eli Lillly and Company, Incyte, Pfizer Inc., Galderma, Allergan, Arcutis, Vyne, Eirion, and Regeneron Diane Hanna and Patrick Burnett are employees of Arcutis Biotherapeutics, Inc. Diane Hanna, Patrick Burnett, and David Osborne are shareholders of Arcutis Biotherapeutics, Inc and own stock. Raj Chovatiya has served as an advisor, consultant, speaker, and/or investigator for AbbVie, Amgen, Apogee Therapeutics, Arcutis, Argenx, ASLAN Pharmaceuticals, Beiersdorf, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Dermavant, Eli Lilly and Company, FIDE, Galderma, Genentech, GSK, Incyte, LEO Pharma, L'Oréal, Nektar Therapeutics, Novartis, Opsidio, Pfizer Inc., Regeneron, RAPT, Sanofi, Sitryx, and UCB.

Ethical Approval. This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

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