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Original Research Article

Clinical efficacy of a gentle anti-dandruff regimen

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ABSTRACT

Background: This study is aimed to evaluate the efficacy and safety gentle anti-dandruff regime in the management of dandruff in healthy, Indian participants suffering from dandruff.
Methods: A total of 55 subjects with clinically diagnosed moderate dandruff were selected based on inclusion and exclusion criteria. Study was conducted in 3 phases, wash-off phase for 2 weeks, treatment phase for 4 weeks, followed by a regression phase of 1 week (during which anti-dandruff regime was withdrawn. Participants applied anti-dandruff regime on their scalp as per the instructions provided during the treatment (thrice a week). This is a regime of anti-dandruff shampoo and anti-dandruff scalp treatment.
Results: Regime showed reduction in dandruff flakes from first treatment and show improvement till the end of treatment phase, and maintained the lower dandruff levels below the baseline levels even after 1 week of product withdrawal. There were no reported side effects like oiliness/redness/irritation etc., during treatment and regression phase.
Conclusions: Anti-dandruff regime is a safe and highly effective solution designed to combat dandruff, while simultaneously improving overall health of the scalp and hair.

Keywords: Gentle shampoo, Anti-antidandruff regimen, Scalp barrier, Sebum control

INTRODUCTION

Dandruff is a persistent scalp scaling condition that affects the scalps for both men and women, during puberty and can last till 60s (years) with a reported prevalence in 50% of population.[1] This condition compromises overall scalp and hair health characterized by scaling, itching, dryness, irritation and even hair fall.

Several research studies support the role of Malassezia species in the pathology of dandruff, confirming the role of microbiome dysbiosis on dandruff scalps.[2] Lypolytic Malassezia species which are in general considered commensals on scalp play a key role in development of dandruff.[3] Human scalps have high density of sebaceous glands, that secrete sebum secretions rich in triglycerides, squalene, sterols and waxes etc., that aid in homeostasis of epidermis to deliver biochemical machinery that supports scalp immunity.[4,5] Malassezia species with their lipolytic enzymes break the lipids into free fatty acids and are implicated in the development of dandruff pathology which includes hyperproliferation of keratinocytes, generation of microinflammation, incomplete differentiation of corneocytes leading to impaired barrier health.[6]

In a healthy scalp/skin, keratinocytes differentiate into corneocytes, become anucleated, releases lipid constituents and keratinocytes become cornified, building a strong lipid-protein barrier.[7] Parakeratosis (nucleus in the corneocytes) and presence of intracellular lipid droplets and loss of organized lipid layer was reported in the dandruff lesions [8] which are hall mark signs of barrier impairment in dandruff scalps that causes dryness. Human scalps inherently have low natural moisturizing

factors (NMF) compared to other regions of body.[9] NMF is essential to maintain the elastic nature and hydration of stratum corneum.[10] In Dandruff scalps NMF further drops making scalp stratum corneum dry, crack and develop scales culminating into loss of barrier integrity, itching, scaling and irritation.

Reducing the load of *Malassezia* on the dandruff scalps is one the common strategies to treat dandruff, which is generally achieved using shampoos made with anti-fungal ingredients like zinc pyrithione, climbazole, piroctone olamine etc., which works by inhibiting the *Malassezia* species growth. As impaired barrier makes the scalp sensitive, the present anti-dandruff regime is designed with mild sulfate free shampoo with plant-based cleansing agents followed by conditioning rinse off treatment with plant-based conditioners. The regimen contains optimum level of piroctone olamine to deliver anti-dandruff benefit along with barrier protection. The aim of the present clinical study is to evaluate the anti-dandruff efficacy of the above regimen in human volunteers (both male and female) suffering from dandruff.

METHODS

Ethics and informed consent

Present clinical study was carried out as per GLP and ICH guidelines in compliance with the local government regulations. The study was reviewed and approved by independent ethics committee in India and an informed consent was obtained from all study subjects. The study was registered on Clinical Trial Registry of India, under cosmetic study (CTRI/2025/02/080041) prospectively. Study was executed during February 2025 to May 2025 at Mascot Spincontrol India Pvt Ltd, Mumbai, India.

Study design

The study was a blinded, full head and monocentric, with regime of two test products (sulfate free shampoo + scalp rinse-off treatment). Subjects were recruited as per inclusion and exclusion criteria. Both male and female in the age group of 18-45 years suffering from dandruff were included in the study. Pregnant and lactating women were excluded from the study. Volunteers with severe hair fall or any scalp related problems or allergies that can potentially interfere in the study results were also excluded from the study as per the dermatologist's discretion. Subjects with moderate to severe dandruff were recruited and have undergone wash-out period of 2 weeks with a neutral shampoo. Post wash out, only those subjects meeting the inclusion and exclusion criteria and with total dandruff score ≥40 were proceeded into treatment phase. Total of 56 participants qualified for treatment phase and 55 completed the study.

On the baseline visit (day 0), subjects were acclimatized, followed by dermatologist visual assessment for adherent scalp flaking score (ASFS) and loose flakes, instrumental assessments to measure scalp sebum (using sebumeter), transepidermal water loss (using tewameter) and hair fall count (using combing test) while itch assessment done based on participant's feedback.

Test regime was used by volunteers at home (thrice a week) as per the instructions provided (shampoo was applied on wet scalp, massaged gently for 90 seconds and rinsed off, followed by scalp rinse-off treatment product, which was applied uniformly on scalp, massaged for 90 seconds rinsed-off). The subjects were instructed not to wash their hair 48 hours before assessment visit (only on day 1 subjects visit the venue for assessment after hair wash within 2 hours). The following were assessment visits: Baseline, on day 1(2 hours after first wash), week 1, week 2, week 4 and regression-week 1.

Test products were withdrawn on week 4 assessment, followed by 1 week of regression period during which subjects were given a neutral shampoo to use and final assessment was done on week 5 which is a regression assessment (regression-week 1). Consumer assessment on product efficacy and sensory was taken during assessment visits. The attributes included overall satisfaction on product efficacy and sensory like smell, texture, consistency etc.

Demographics of the study volunteers

The 55 subjects completed the study. Efficacy of the test products in reducing dandruff was assessed by dermatological visual assessment of both ASFS and loose flakes score. Additionally, improvement in barrier function and sebum were measured by instruments, whereas hair fall was assessed by combing test. Demographic characteristics of the subjects are depicted in Table 1.

Statistical analysis

All statistical tests were performed at two-sided 5% level of significance and 95% confidence interval and Statistical software PAST 4.03 and SigmaStat 3.5 were used for the analysis of the data. Paired t test was used to evaluate the efficacy of the product.

RESULTS

Efficacy in reducing adherent scalp flakes

Dandruff scales were assessed based on ASFS. The scalp area was divided into 8 parts and each partition was assessed individually on a 1-10 scale and added to get total ASFS. Anti-dandruff regime treatment showed significant reduction in ASFS from first wash onwards till 1-week regression (vs baseline). Anti-dandruff regime significantly reduced ASFS by 27.8 units by the end of 4 weeks (Figure 1) with sustained reduction till the 1-week regression (R-week 1).

Efficacy in reducing loose flakes

Scalps of study participants were evaluated for the presence of non-adherent/ loose dandruff flakes by partitioning scalp into 6 parts, using a scale from 0 to 10 for each partition. Anti-dandruff regime showed a significant reduction in the severity of loose flakes from first wash onwards till 1-week regression vs baseline (Figure 2). The present anti-dandruff regime significantly reduced loose flakes by 22.7 units by the end of 4 weeks treatment phase (vs baseline) with sustained reduction till 1-Week regression (R-week 1).

Efficacy in reducing scalp sebum levels

Scalp sebum levels were measured to quantify the amount of sebum on scalp to assess the effect of treatment. There was significant reduction in total scalp sebum levels (post wash at all assessment time points) from the first treatment onwards with sustained reduction till week 4 and 1-week regression assessment (R-Week 1). Anti-dandruff regime treatment demonstrated a significant sebum reduction by 47 units vs baseline (68% reduction) by the end of 4-week treatment phase (Figure 3) and sustained the sebum reduction till R-week 1.

Efficacy in improving scalp barrier properties

Dandruff scalps are often associated with impaired scalp barrier causing dryness and irritation. Hence to assess the improvement of barrier properties, trans-epidermal water loss (TEWL) was measured at all visits to assess the improvement of same. Anti-dandruff regime treatment showed significant reduction in the TEWL by 3 units compared to baseline by the end of treatment phase of 4 weeks (Figure 4) and have not returned to baseline line levels at 1 week regression (R-Week 1), indicating the long-lasting barrier recovering effects of the regime.

Efficacy in reducing hair fall from roots

Hair fall is also one of the problems associated with dandruff. Hair fall is assessed using combing test from baseline till regression week. Anti-dandruff regime treatment showed a significant reduction in hair fall (i.e., hair fall from root, with bulb throughout the treatment period till regression assessment points (R-Week1), with ~50% reduction in hair fall by end of 4-week treatment phase compared to baseline assessment (Figure 5).

Table 1: Demographics and volunteers characteristics at baseline.

Variables	Values
Age range (in years)	18-45 (inclusive of both the ages)
Gender category N (male: female)	Both male and female 55 (27: 28)
Total dandruff at baseline	Dermatological assessment ≥40 (ASFS + loose flakes score)

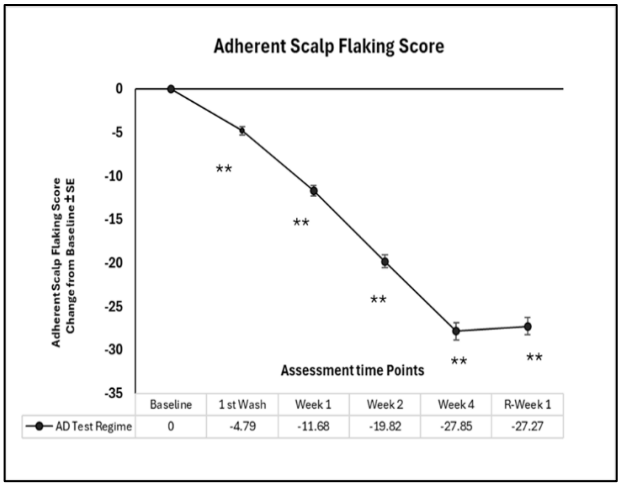

Figure 1: ASFS.
*Data expressed as change from baseline±SE, *p value<0.05 vs baseline.

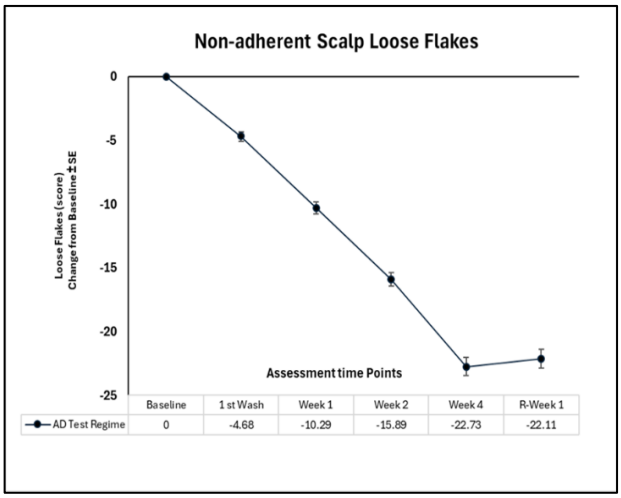

Figure 2: Non-adherent scalp loose flakes score.
*Data expressed as change from baseline±SE, **p value<0.05 vs baseline.

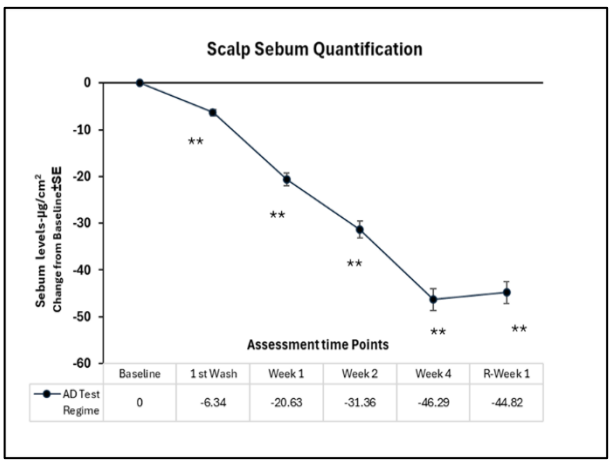

Figure 3: Scalp sebum quantification.
*Data expressed as change from baseline±SE, **p value<0.05 vs baseline.

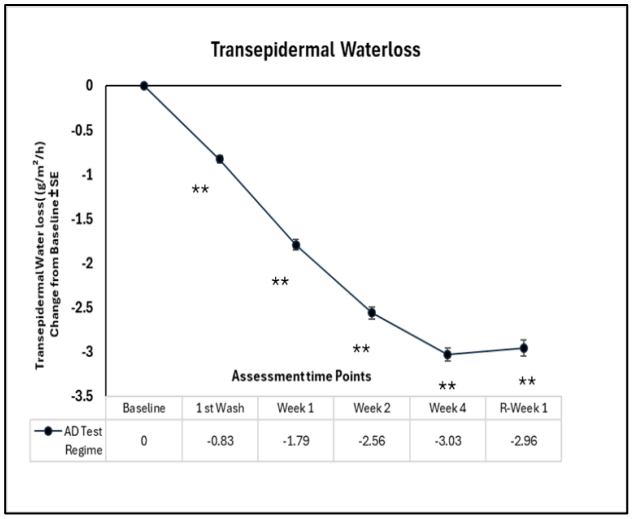

Figure 4: Transepidermal Waterloss.

*Data expressed as change from baseline±SE, **p value<0.05 vs baseline.

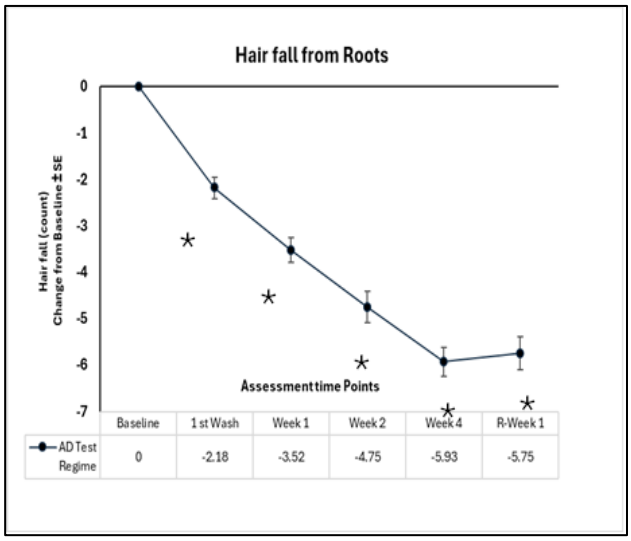

Figure 5: Hair fall from roots.

*Data expressed as change from baseline±SE, **p value<0.05 vs baseline.

DISCUSSION

Dandruff is an excessive scalp scaling condition with associated symptoms like dryness and itch, experienced by up to 50% of adult population, at some point of time which is equally prevalent in both men and women.[11] The onset of these conditions usually starts around adolescence and can remain chronic for up to 60 years.[12] Even though dandruff is not a life-threatening condition, chronic nature of this negatively impacts the lifestyle of sufferers due to it pruritic, excessive exfoliating symptoms. A cross-sectional study conducted with 2116 subjects revealed that dandruff suffers are more anxious about their social appearance than subjects without dandruff.[13] Owing to its chronic nature and demand to address these, market space is flooded with multiple dandruff treatment products with anti-fungal agents. However, it is prudent to take an approach to treat the condition, without further exacerbating the associated damaged barrier and itch.

Persistent and untreated dandruff causes poor scalp health leading to pruritus, dryness, erythema and hair fall.[14] Piroctone olamine is highly effective in reducing dandruff and works by inhibiting the growth of *M. furfur* species. Piroctone olamine penetrates the cell wall and interacts with iron and associated energy metabolism thus controlling growth of the organisms.[15] Decreased levels of *M. furfur* load were observed on dandruff scalps upon treatment with shampoos formulated with piroctone olamine.[16] The present study confirms that anti-dandruff regime developed with milder shampoos effectively delivered anti-dandruff efficacy by reducing the dandruff scales from first wash till the end of treatment phase, with sustained effect post withdrawing the product over one week (regression period).

Dandruff lesions show epidermal hyperplasia, accompanied by low levels of inflammation as estimated by high levels of IL-1α and IL-8 compared to non-dandruff lesions, which are hall mark inflammatory markers, along with decreased levels of barrier proteins, ceramides and fatty acids, which is a clear indication of altered epidermal homeostasis leading to impaired barrier integrity.[17] Hence shampoos and/or scalp regimes to treat dandruff need to be carefully crafted considering the existing damage on the scalp epidermis, which is highly susceptible to further inflammation/damage due to its damaged barrier. Controlling the growth of *Malassezia* helps resolve the imbalances associated with epidermal homeostasis and impaired barrier.[18] The present study confirms that anti-dandruff regime developed with sulfate free shampoo and scalp rinse off treatment indeed protected and improved the barrier integrity without exacerbating any associated conditions like itch throughout the treatment phase and sustained the protective benefit even after withdrawing the product (during 1 week regression).

Excesses of sebum on dandruff scalps have been implicated as one of the etiological factors in the progression of dandruff symptoms allowing the lipolytic *Malassezia* species grow luxuriantly by metabolizing the triglycerides, leaving the byproducts that irritate the scalp.[19,20] One of the functions of sebum is to deliver antioxidants like vitamin E on to the scalp and maintain the epidermal permeability barrier, however highly unsaturated squalene and fatty acids are susceptible to oxidation, triggering the chain of oxidative reactions leading to redox imbalance on dandruff scalps.[21,22] Reducing the sebum secretion can minimize the delivery of these susceptible oxidation moieties on the scalp and hence reduce the symptoms of dandruff. The present anti-dandruff treatment regime reduced the scalp sebum levels from first application till end of regression phase, supporting the resolution of dandruff flakes.

Accumulation of oxidative byproducts have been reported in dandruff scalps as measured by hydroxyoctadecadienoic acid and squalene peroxides and malondialdehyde as a consequence of oxidative stress on dandruff scalps.[23-25] Unresolved oxidative stress on scalp affects the hair follicles and pushes the hair to telogen phase prematurely leading hair fall.[26] High levels of proteases are known to expressed in resting hair follicles promoting the exit, leading to hair fall.[27] Kaur et al reported the efficacy of piroctone olamine as a potent protease inhibitor based on invitro studies, and piroctone olamine is a proven antioxidant with multiple clinical studies demonstrating that shampoos with piroctone olamine effectively improve scalp and hair health.[28-30] The present anti-dandruff regime made with optimized levels of piroctone olamine demonstrated 50% reduction in hair fall by the end of treatment phase and maintained the effect even during the regression phase (even after the product is withdrawn).

CONCLUSION

The present anti-dandruff regime is crafted with milder cleansing system with piroctone olamine delivered the end benefit of long-lasting anti-dandruff efficacy and improved scalp barrier integrity. The present treatment was effective in reducing dandruff flakes, improved scalp barrier, reduced sebum in 100 % of the study volunteers. 94% of the study participants felt, test regime provides anti-dandruff benefit from 1st treatment & 98% felt a reduction in scalp dryness. 100% of the users liked the sensory of the regime. There were no adverse events reported throughout the study till regression, indicating that the treatment is not only efficacious but also safe to use. The present clinical study concludes that anti-dandruff regime treatment crafted with milder cleansing system effectively provides anti-dandruff benefits and is safe to use in both men and women without any irritation/greasiness or oiliness.

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