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CHANGES IN SCALP MICROBIOTA, PRURITUS BIOMARKERS AND SEBUM LIPIDS IN SEBORRHEIC DERMATITIS: A CLINICAL STUDY COMPARING THE EFFICACY OF A PIROCTONE OLAMINE/ CICLOPIROX OLAMINE-BASED SHAMPOO WITH STANDARD MEDICAL CARE

M. Lévêque[1], M. Froliger[1], L. Darras[1], C. Huyghe[1], S Alvarez Georges[1], N. Chansard[1], C. Lauze[1], S. Baradat[1], V. Mengeaud[2]

1. R&D Department, Pierre-Fabre Dermo-Cosmetics & Personal Care, Toulouse, France

2. Medical Department, Laboratoires Dermatologiques DUCRAY, Pierre-Fabre Dermo-Cosmetics & Personal Care, Lavaur, France

INTRODUCTION & OBJECTIVES

- Seborrheic dermatitis (SD) is a chronic recurrent dermatosis characterized by flakes, pruritus and erythema, affecting sebum-rich areas such as the scalp. Pruritus undoubtedly negatively impacts the quality of life of patients affected by SD. A new shampoo (WS0060) containing an antifungal combination of Piroctone Olamine/Ciclopirox Olamine and an antipruritic complex was developed to treat scalp SD.
- Previous clinical studies have demonstrated its high tolerance and rapid effectiveness on dandruff, intense and recurring pruritus and erythema.
- The objective of this study is to compare the beneficial effects of WS0060 shampoo with those of a Standard Medical Care (SMC, 2% ketoconazole shampoo) after 4 weeks of use in subjects with mild to moderate SD, and to assess changes in scalp microbiota, pruritus biomarker expression and sebum lipid content underlying clinical efficacy.

MATERIALS & METHODS

This monocentric, blinded label randomized 4-week study was conducted in two parallel groups of subjects with mild to moderate scalp SD associated with erythema and pruritus (criteria) having a recent prescription of SMC (2% Ketoconazole shampoo) not yet initiated.

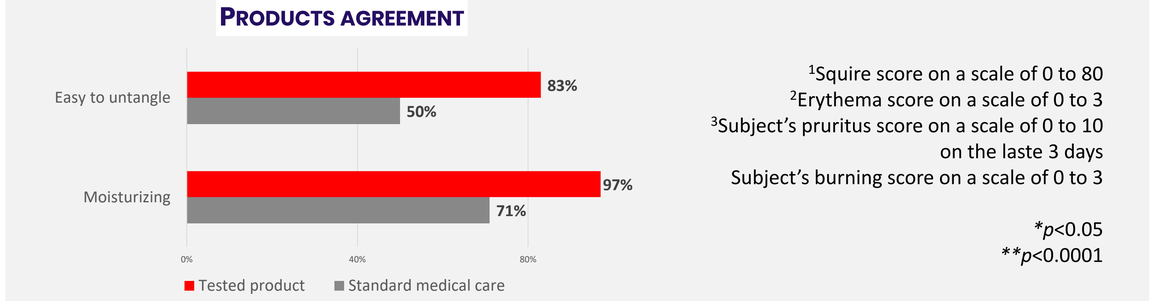
WS0060 shampoo was applied thrice a week when SMC was applied twice, completed with a third neutral shampoo. Efficacy was evaluated 3 days after the first application (D4), then weekly over a 4-week period (D7, D15, D22 and D29). The evaluation included clinical scoring of dandruff and erythema, and auto-assessment of the scalp discomfort sensations (pruritus and burning sensations). The perceived hair-care benefits of both products were also evaluated by subjects. Adverse events were assessed at each visit.

Swab samplings were performed in lesional areas at baseline and at the three following visits to investigate the evolution of six strains of scalp microbiota including three species of *Malassezia* known to be involved in scalp SD dysbiosis (digital droplet PCR analysis) and to quantify biomarkers of pruritus (S cathepsin, Histamine) through conventional protein assay analyses (ELISA, HTRF). Cigarette papers were used to collect sebum from the affected areas at baseline and during all subsequent visits, to analyze sebum lipid composition (SpiderMass technology).

RESULTS

58 subjects completed this study. From D4 to D29, both products provided a significant decrease in dandruff and erythema score, in pruritus and burning sensations. No significant difference was observed for all clinical evaluations between WS0060 shampoo and SMC. WS0060 shampoo showed better perceived hair-care benefits than SMC, especially for hair moisturizing and detangling efficacy at the end of the study. No subject reported adverse events linked to WS0060 shampoo.

CLINICAL EFFICACY

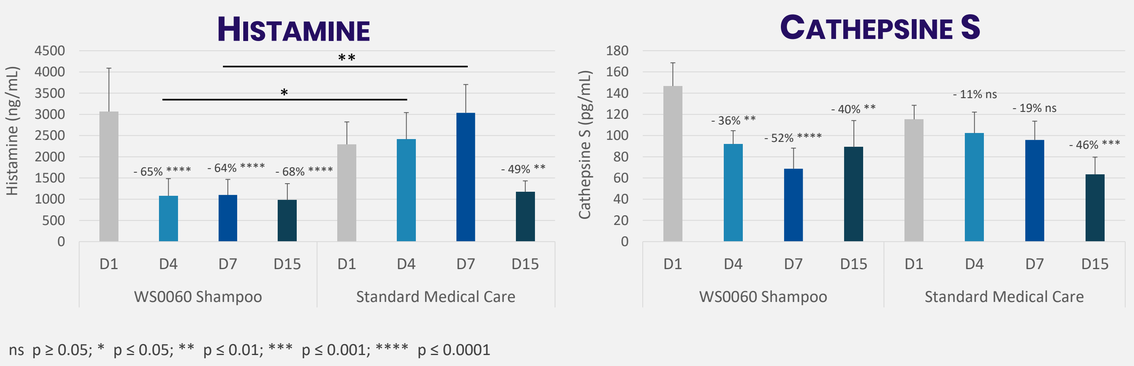


[1]Squire score on a scale of 0 to 80
[2]Erythema score on a scale of 0 to 3
[3]Subject's pruritus score on a scale of 0 to 10 on the laste 3 days
Subject's burning score on a scale of 0 to 3

*p<0.05
**p<0.0001

Cathepsin S and Histamine expressions were decreased in both groups, reaching significance after 2 weeks of treatment with SMC and from the first application with WS0060 shampoo. The overall inhibition of histamine expression in SD lesional areas was significantly stronger with WS0060 shampoo than with SMC (p=0.0104).

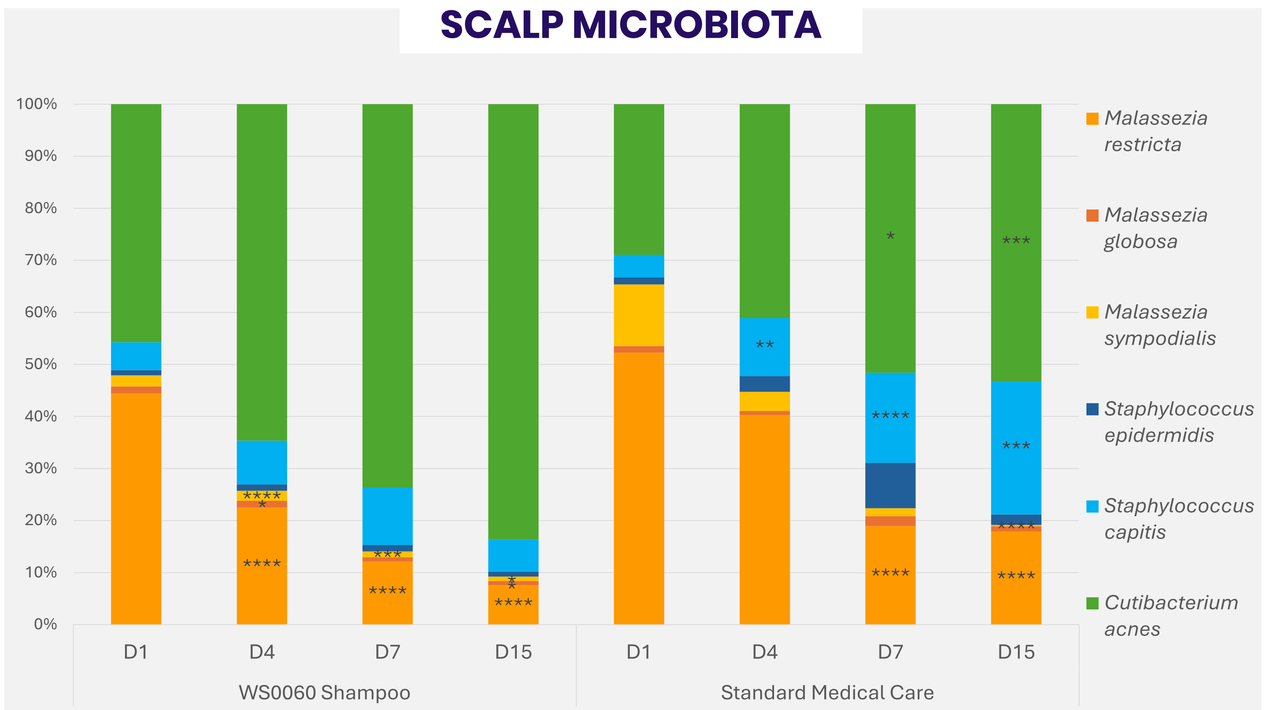
PRURITUS BIOMARKERS



ns p ≥ 0.05; * p ≤ 0.05; ** p ≤ 0.01; *** p ≤ 0.001; **** p ≤ 0.0001

Both products displayed a significant inhibition of *Malassezia restricta*, which occurred faster with WS0060 shampoo (from the first application). However, SMC resulted in an incomplete microbiota rebalancing effect, as it simultaneously increased *Staphylococcus capitis* abundance.

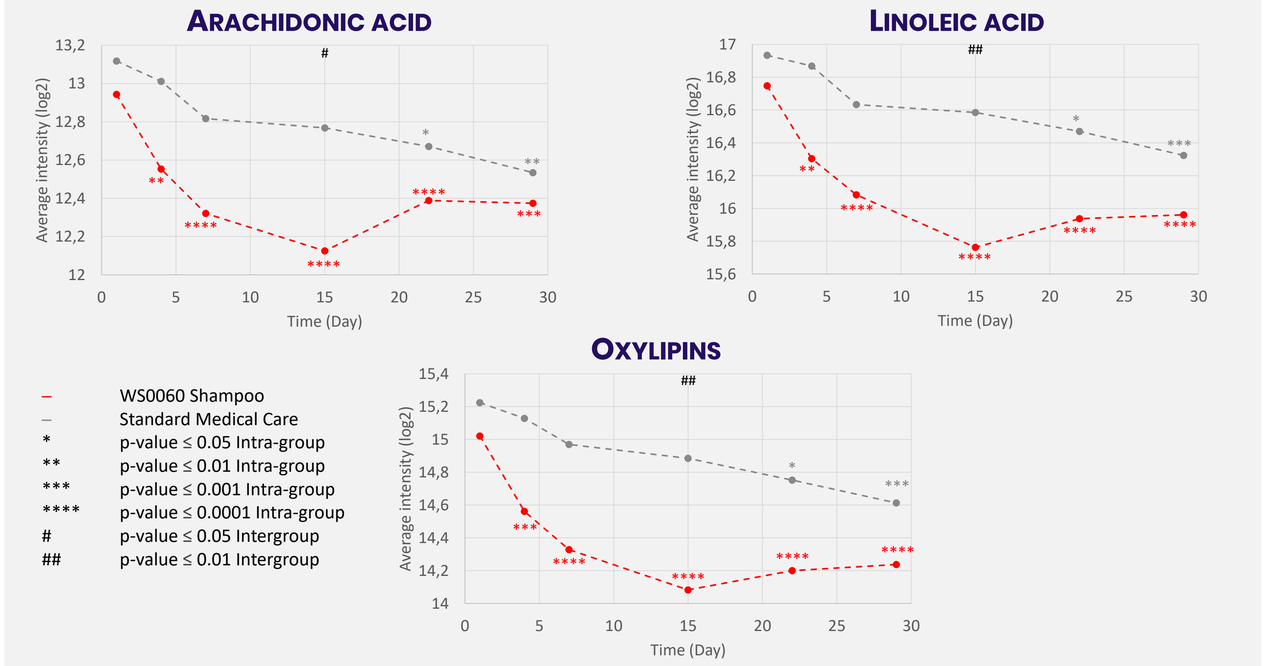
SCALP MICROBIOTA



ns p ≥ 0.05; * p ≤ 0.05; ** p ≤ 0.01; *** p ≤ 0.001; **** p ≤ 0.0001

Three pro-inflammatory lipids, oxylipins (9-HODE/13-HODE), arachidonic acid and linoleic acid, were significantly reduced from the first application with the WS0060 shampoo, whereas a significant reduction was observed with the SMC only on D22.

PRO-INFLAMMATORY LIPIDS



CONCLUSION

The study results show that WS0060 shampoo has clinical efficacy in scalp SD treatment that is statistically comparable to SMC, while providing better perceived hair-care benefits. It also induces significant biological modulation of three key pillars of SD physiopathology (microbiota balance, pruritus biomarker expression and pro-inflammatory lipid content in sebum) occurring from the first application.

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