

EFFICACY AND TOLERANCE OF A KERATOLYTIC AND HYDRATING SHAMPOO IN SUBJECTS WITH MILD-TO-MODERATE SCALP PSORIASIS: RESULTS FROM A DOUBLE-BLIND, RANDOMIZED, VEHICLE-CONTROLLED STUDY CONDUCTED UNDER REAL-LIFE CONDITIONS

Philippe Massiot¹, Pedro Contreiras Pinto², Virginie Rasmont³, Bianca Maria Piraccini⁴, Lidia Rudnicka⁵, Daniel Fernandes Melo⁶, Sergio Vano-Galvan⁷, Wen-Yu Wu⁸, Stephanie Leclerc-Mercier³, Delphine Kerob⁹

¹L'Oréal Research and Innovation, Clichy, France, ²PhDTrials, Lisboa, ³Vichy Laboratoires, Levallois-Perret, France, ⁴Division of Dermatology, Department of Specialized, Diagnostic, and Experimental Medicine, University of Bologna, Bologna, ⁵Department of Dermatology, Medical University of Warsaw, Poland, ⁶Dermatology Department, University of State of Rio de Janeiro (UERJ), Rio de Janeiro, Brazil, ⁷Ramon y Cajal University Hospital, TricoHRC, IRYCIS, University of Alcalá, Madrid, Spain, ⁸Department of Dermatology, Huashan Hospital Fudan University, Shanghai, China, ⁹Cosmetic Active International, Levallois-Perret, France

INTRODUCTION

Psoriasis is a chronic, inflammatory skin disease that affects 2% of the global population.¹

Scalp psoriasis is estimated to affect up to 80% of patients with psoriasis and can lead to a significant burden and impairment of quality of life (QoL).²⁻⁴

Due to its chronicity and the poor cosmeticity of topical treatments, compliance to local treatments is a frequent issue in psoriasis.

A keratolytic and hydrating shampoo containing 2% salicylic acid, 5% urea and 1% glycerin acting specifically on psoriasis symptoms has been developed for psoriasis prone scalp.

OBJECTIVE

To assess, under real-life conditions in subjects with mild-to-moderate scalp psoriasis, the efficacy and local tolerance of a keratolytic and hydrating shampoo after 30 days.

MATERIAL AND METHODS

- 67 adult subjects with mild to moderate psoriasis, applied the shampoo daily for 2 minutes from D1 to D15 and 3 times/week until D29.
- Assessments included the Psoriasis Scalp Severity Index, Investigator Global Assessment (IGA), as well as hair and scalp greasiness, irritation, SCALPDEX symptoms and product acceptability.

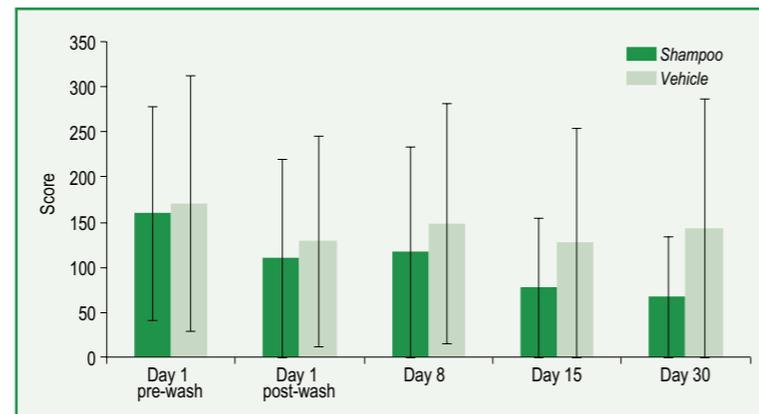
RESULTS

- 67 subjects were included, 65.7% females and 34.3% males, the mean age was 43.2 years and 86.6% had Phototype III.
- All subjects had sensitive scalp, 58.2% had mild and 41.8% moderate scalp psoriasis.
- After 4 weeks of product use:
 - The PSSI significantly ($p < 0.05$) had reduced by 39.0%, 37.2%, 63.0% and 69.0% immediately after washing at D1 and after 8, 15 and 30 days of use, respectively compared to a 22.8%, 5.5% and 19.6% decrease and 13.0% with the vehicle.
 - The symptom, emotion and functioning SCALPDEX items had significantly ($p < 0.05$) reduced as early as D1 sustaining until D30.
 - The IGA significantly ($p < 0.001$) decreased with the shampoo by 47.5% and by 6.9% with the vehicle.
 - Hair and scalp greasiness, and irritation significantly ($p < 0.05$) continuously improved with the shampoo until D30 while it worsened with the vehicle.
 - The evolution of symptom scores paralleled those of clinical signs.
 - The shampoo was well tolerated, subjects were highly satisfied and had an improved QoL.

CONCLUSION

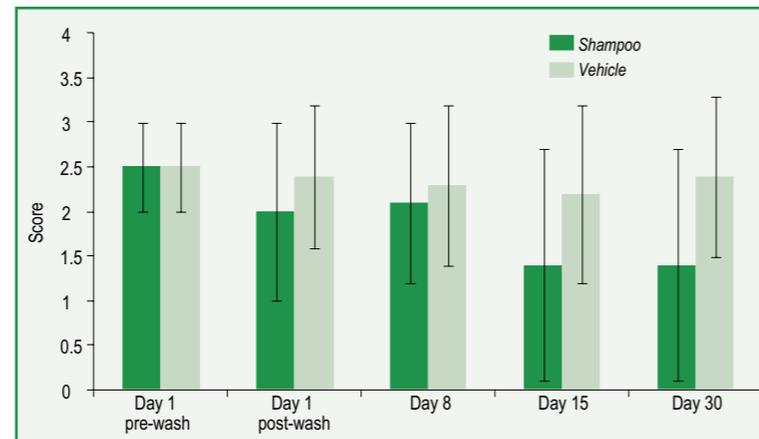
- The tested shampoo significantly improved clinical signs, symptoms and QoL of mild-to-moderate scalp psoriasis compared to vehicle, with efficacy observed as early as the first day of use, and up to 30 days.
- It was well tolerated and highly appreciated by the subjects.
- Compliance of use is expected to be good.

EVOLUTION OF THE PSORIASIS SCALP SEVERITY INDEX EVOLUTION OVER TIME



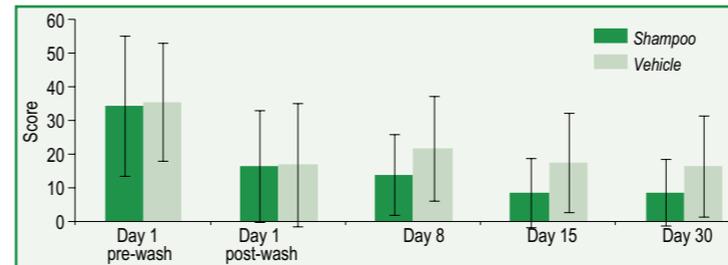
Differences of scores between the shampoo and the vehicle were statistically significant ($p < 0.05$) in favour of the shampoo at all post Day 1 pre-wash evaluations.

EVOLUTION OVER TIME OF THE INVESTIGATOR GLOBAL ASSESSMENT



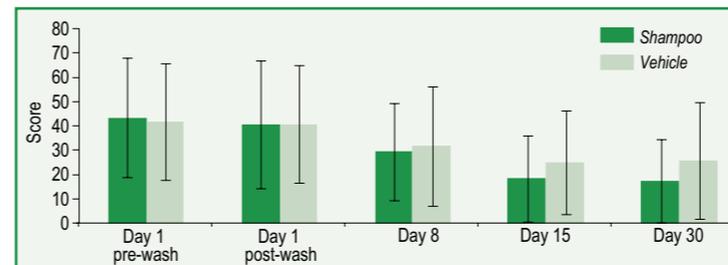
The investigators rated the shampoo significantly ($p < 0.05$) more beneficial than the vehicle at Day 1 post-wash, Day 15 and Day 30.

SYMPTOM SCALPDEX



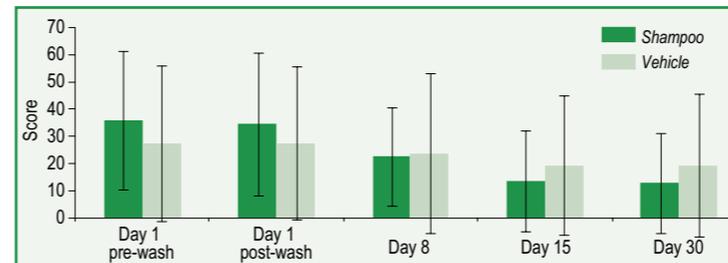
A statistically higher ($p < 0.05$) decrease of the symptom score in favour of the shampoo was observed at evaluation Day 15.

EMOTION SCALPDEX



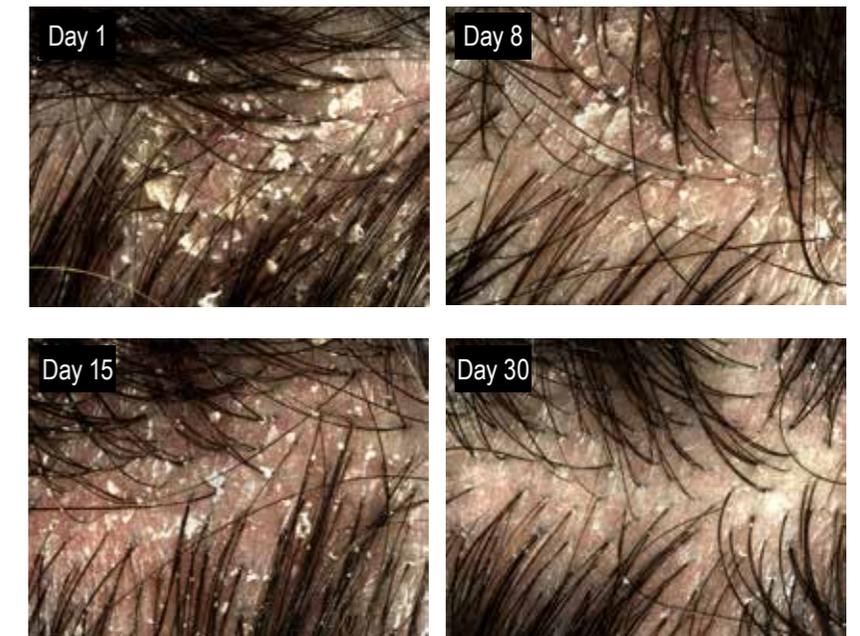
A statistically higher ($p < 0.05$) decrease of the emotion score in favour of the shampoo was observed at evaluation Day 15 and Day 30.

FUNCTIONING SCALPDEX



A statistically higher ($p < 0.05$) decrease of the functioning score in favour of the shampoo was observed at evaluation Day 15 and Day 30.

SUBJECT SCALP IMPROVING OVER TIME



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