

# Efficacy and tolerance of a selenium disulfide-based shampoo in Chinese subjects with mild-to-moderate scalp seborrheic dermatitis: results from a double-blind, randomized, vehicle-controlled study

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## 1 INTRODUCTION AND OBJECTIVES

Scalp seborrheic dermatitis (SD) is a chronic, relapsing inflammatory condition characterized by dandruff, erythema, and pruritus.<sup>1-3</sup> Studies indicate a global microbiota shift of scalp SD compared to healthy scalp, especially fungal colonization of *Malassezia spp.*<sup>1, 4, 5</sup>

Selenium disulfide (SeS<sub>2</sub>) is clinically beneficial in scalp SD.<sup>6-9</sup>

## 2 OBJECTIVES

The aim of this study was to assess the efficacy and tolerance of a 1% selenium disulfide-based shampoo (SeS<sub>2</sub>, also containing 0.9% Salicylic Acid, Vitamin E and Ceramide-R) in Chinese subjects with mild-to-moderate scalp SD.

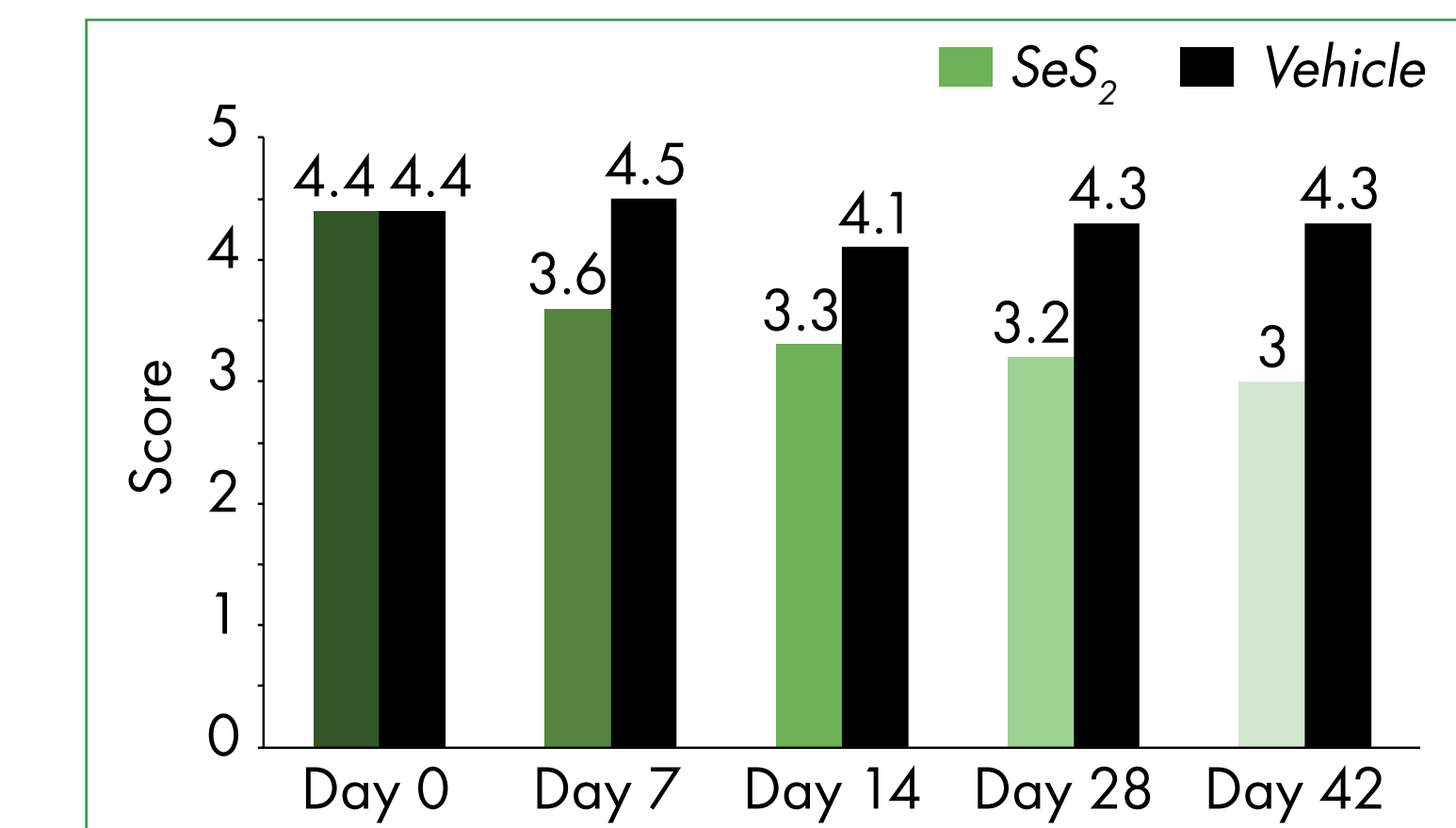
## 3 MATERIAL & METHODS

- Single-center, randomized, double-blind, vehicle-controlled study conducted in 58 subjects with mild-to-moderate scalp SD.
- After a 4-week washout period, subjects applied the tested shampoo (randomized into the SeS<sub>2</sub> or vehicle group) 3/week from Day 0 to Day 28 (treatment phase) and 1/week until Day 42 (maintenance phase).
- At Day 0, Day 7, Day 14, Day 28 and Day 42, SD severity score (mild (1–3), moderate (4–6), or severe (7–9)) including erythema, dandruff, lesion extent (% scalp area) and adherent scalp flaking score (ASFS) were assessed by dermatologists. Subject-assessed scores of scales, itching and greasiness were measured with visual analogue scale (VAS, ranging from 0 to 10).
- Instrumental measurements included sebum quantity and transepidermal water loss (TEWL) rate at all time points.
- Scalp fungal colonization was detected by fungal fluorescence staining at Day 0, Day 28 and Day 42.

## 4 RESULTS

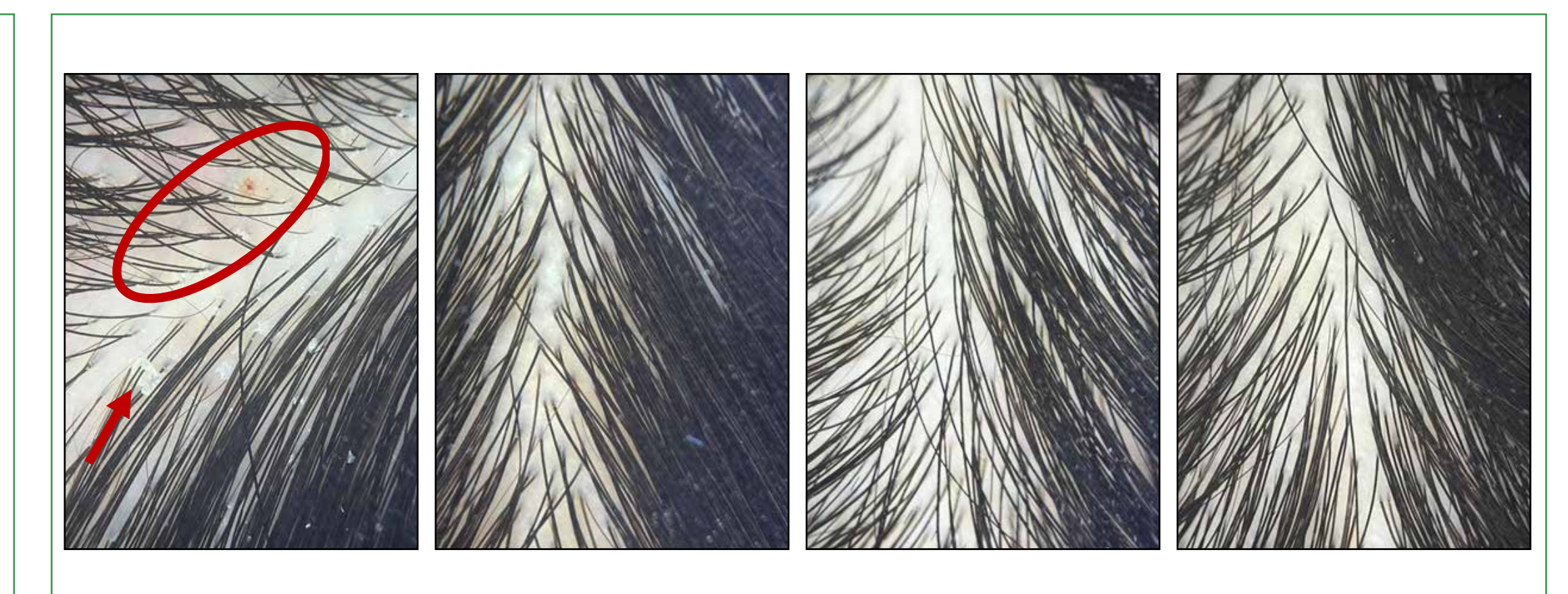
- 30 subjects in the SeS<sub>2</sub> group and 28 subjects in the vehicle group were included, with 63.8% females and 36.2% males, and a mean age of 29.9 years. The baseline SD score was 4.4.
- SeS<sub>2</sub> significantly ( $p < 0.05$ ) reduced the SD score by 18.2%, 25.8%, 27.3% and 31.2% after 7, 14, 28 and 42 days of use, with SD severity being downgraded, respectively compared to a 0%, 6.5%, 2.5% and 4.1% decrease with the vehicle (Figure 1a and 1b).
- The ASFS score was significantly ( $p < 0.05$ ) reduced with SeS<sub>2</sub> by 43.5%, 50.7%, 43.5% and 49.5% at Day 7, 14, 28 and 42 respectively (Figure 2).
- Scalp fungal colonization was greatly reduced to “negative or absence” in the SeS<sub>2</sub> group while no change (still in active multiplication) in the vehicle group at both Day 28 and Day 42 (Figure 3a and 3b).
- In terms of sebum production and TEWL, a mild decrease of sebum was observed after using SeS<sub>2</sub> shampoo for 7 days with a mild decrease of TEWL, while in the vehicle group a trend of increase was observed for both parameters during the study.
- According to the subjects, flaking and itching had significantly ( $p < 0.05$ ) reduced with SeS<sub>2</sub> at all visits. Greasiness also improved continuously with SeS<sub>2</sub> shampoo compared with the vehicle.
- Subjects were highly satisfied with SeS<sub>2</sub> shampoo.

**FIGURE 1a: Average SSD score at Day 0, Day 7, Day 14, Day 28 and Day 42**



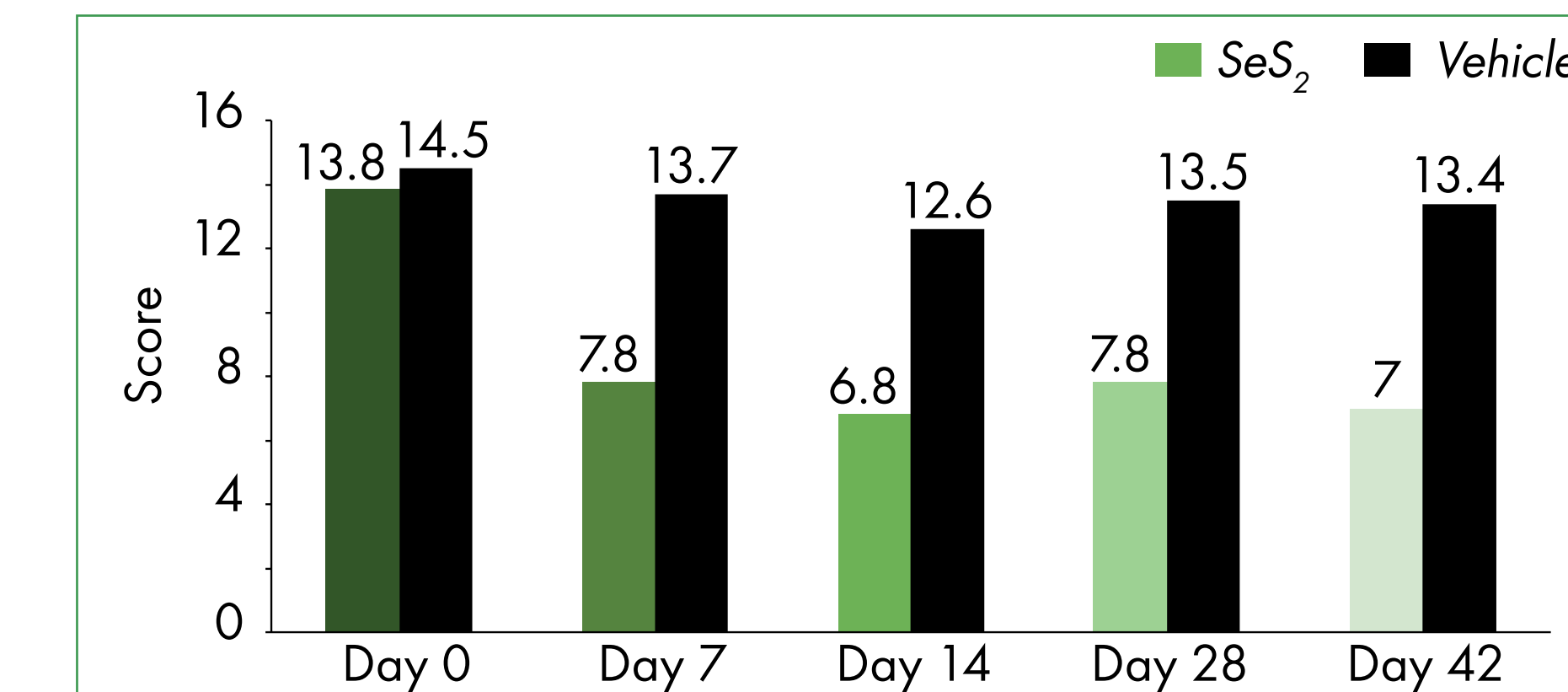
The SSD score was significantly ( $p < 0.05$ ) reduced at Day 7, 14, 28 and 42

**FIGURE 1b: A Female subject with moderate SSD (average case) at Day 0, Day 7, Day 14 and Day 28**



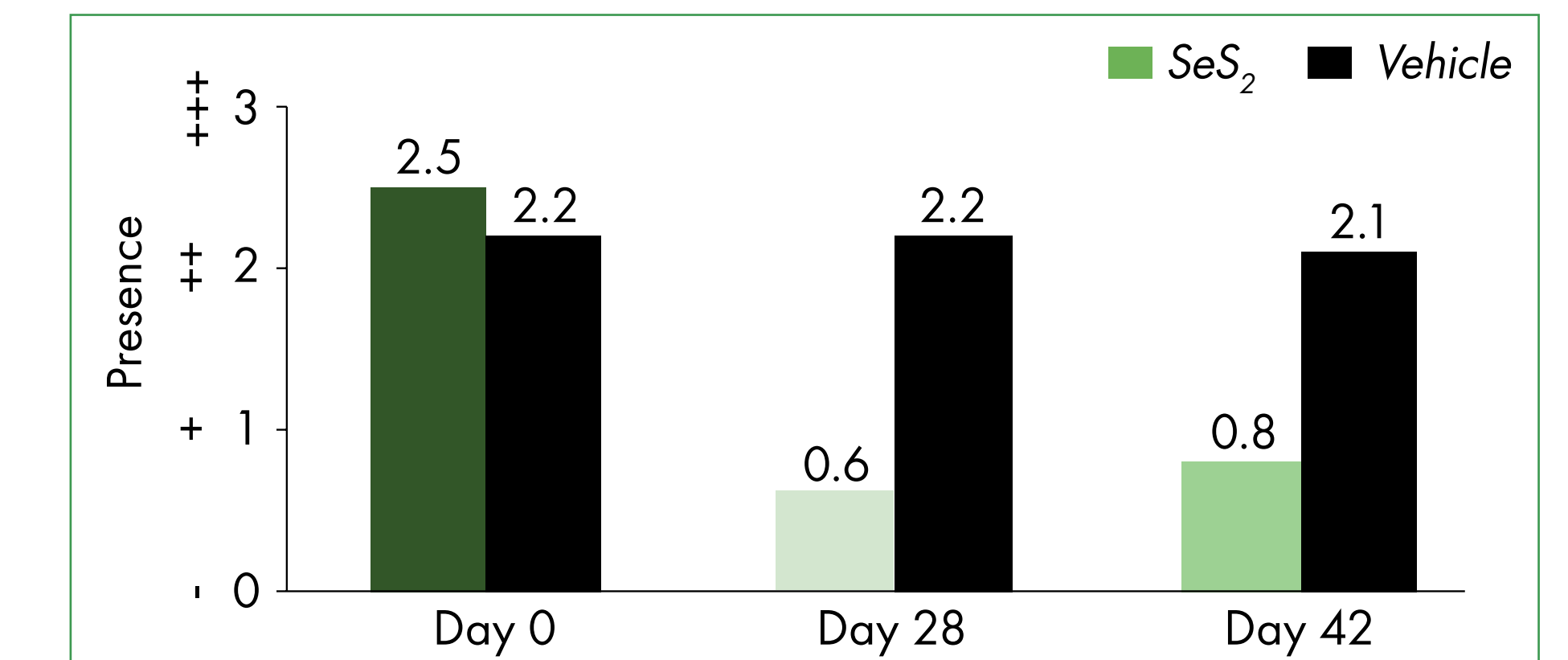
Circle: erythema Arrow: non-adherent flakes

**FIGURE 2: Average ASFS score at Day 0, Day 7, Day 14, Day 28 and Day 42**

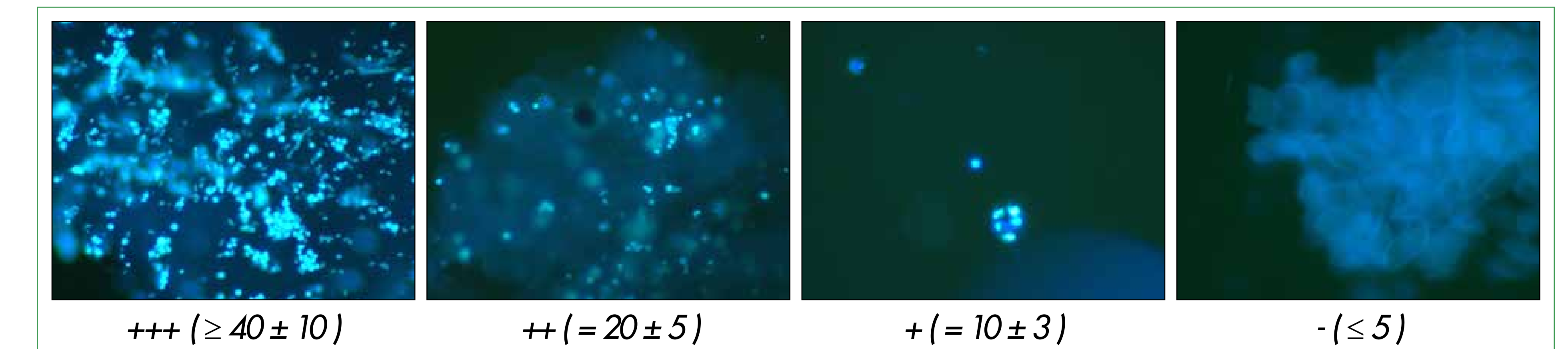


The ASFS score was significantly ( $p < 0.05$ ) reduced at Day 7, 14, 28 and 42

**FIGURE 3a: Average evolution of scalp fungal colonization over time**



**FIGURE 3b: Presence of fungal colonization using fluorescence staining at Day 0, Day 28 and Day 42**



## 5 CONCLUSION

The tested 1% SeS<sub>2</sub>-based shampoo formulation was beneficial and well tolerated in mild-to-moderate scalp SD of Chinese subjects and significantly reduced scalp fungal colonization compared with the vehicle, with a significant anti-dandruff, anti-erythema, anti-itchiness efficacy observed as early as the first week and up to 6 weeks of use.

**References:** 1. Borda LJ, Wikramanayake TC. Seborrheic Dermatitis and Dandruff: A Comprehensive Review. J Clin Invest Dermatol. 2015;3(2). 2. Naldi L. Seborrheic dermatitis. BMJ Clin Evid. 2010 Dec;1713. 3. Naldi L, Diphoom J. Seborrheic dermatitis of the scalp. BMJ Clin Evid. 2015 May;1713. 4. Bukvić Mokos Z, Kralj M, Basta-Juzbašić A, Lakoš Jukić I. Seborrheic dermatitis: an update. Acta Dermatol Venereol Croat. 2012;20(2):98-104. 5. Clavoud C, Jourdain R, Bar-Hen A, Tichit M, Bouchier C, Pouradier F, et al. Dandruff is associated with disequilibrium in the proportion of the major bacterial and fungal populations colonizing the scalp. PLoS One. 2013;8(3):e58203. 6. Clavoud C, Michelin C, Pourhamidi S, Ziane S, El Rawadi C, Muller B, et al. Selenium disulfide: a key ingredient to rebalance the scalp microbiome and sebum quality in the management of dandruff. Eur J Dermatol. 2023;33(S1):5-12. 7. Turcu G, Artenie C, Nowicka D, Arenbergerová M, Lazaridou E, Khabzei K, et al. Selenium Disulfide-based shampoo applied for 4 weeks significantly improves dandruff and seborrheic dermatitis. Eur J Dermatol. 2023;33(S1):19-23. 8. Massiot P, Clavoud C, Thomas M, Ott A, Guéniche A, Panhard S, et al. Continuous clinical improvement of mild-to-moderate seborrheic dermatitis and rebalancing of the scalp microbiome using a selenium disulfide-based shampoo after an initial treatment with ketoconazole. J Cosmet Dermatol. 2022 May;21(5):2215-2225. 9. Massiot P, Reygagne P, Chagnoleau C, Kanoun-Copy L, Pouradier F, Loussovain G, et al. Maintenance effect of a once-weekly regimen of a Selenium Disulfide-based shampoo in moderate-to-severe scalp seborrheic dermatitis after initial treatment with topical corticosteroid/salicylic acid. Eur J Dermatol. 2023;33(S1):13-8.

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