

A DOUBLE-BLIND, RANDOMIZED, PLACEBO CONTROLLED CLINICAL BILATERAL TRIAL EVALUATING THE EFFICACY AND SAFETY OF A NEW FORMULATION IN ACNEIC PATIENTS WITH RISKS OF POST-INFLAMMATORY HYPERPIGMENTED LESIONS

X. WANG^{1,2}, L. ZHAOXIA², Z. DAN², L. LI^{1,2}, S. SEITE¹

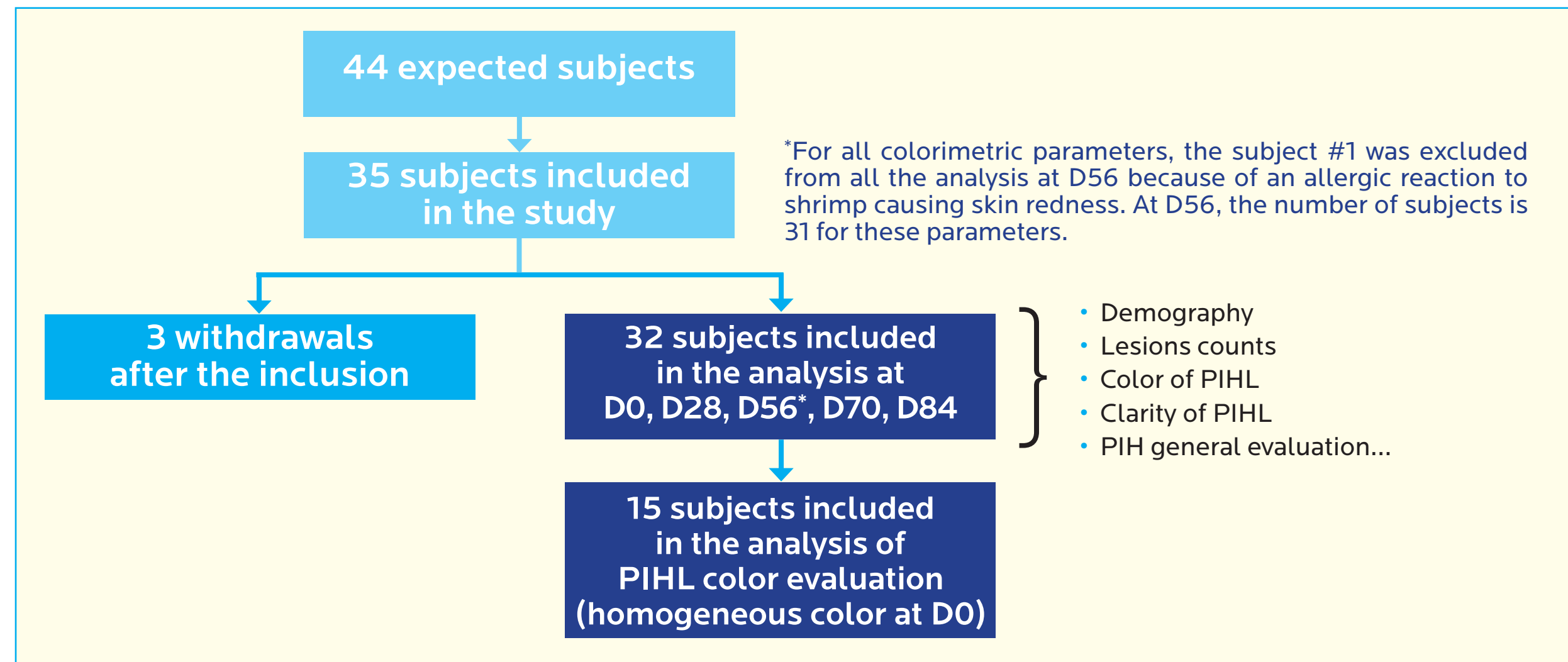
¹Department of Dermatology, West China Hospital, Sichuan University, Chengdu, China - ²Sichuan Province Cosmetics Engineering Technology Research Centre, Chengdu, China - ³La Roche-Posay Pharmaceutical Laboratories, Asnières, France

INTRODUCTION

Post-inflammatory hyperpigmentation (PIH) is an acquired, reactive hypermelanosis that is a sequelae of many cutaneous disorders with an inflammatory component including acne and particularly in high phototype and Asians. The objective of this study is to demonstrate the interest of a dermocosmetic formula containing anti-inflammatory ingredients in the prevention of the appearance of post-inflammatory hyperpigmented lesions in patients with mild to moderate acne.

METHODS

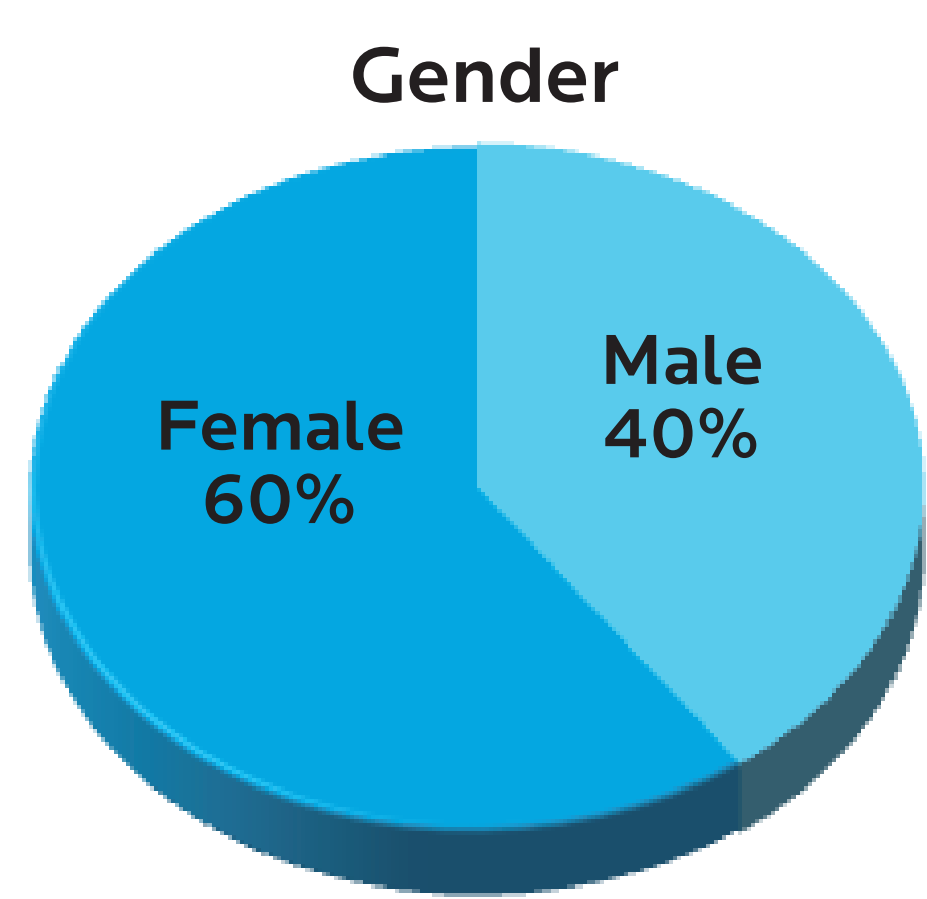
This single centre, double-blind, randomized, placebo controlled, bilateral (split-face) comparison was conducted during the winter season, on 35 Chinese acneic subjects with post-inflammatory hyperpigmented lesions of uniform color on both hemi-faces. The test formula was applied in the investigator center twice a day, for 56 days on one side of the face and a placebo formula on the other side of the face. Assessments included evaluation of the number and evolution of color of post-inflammatory hyperpigmented lesions (PIHL); acne grade (GEA) and lesion count both cross-polarized light and standard photography, together with clinical evaluations of global efficacy and safety.



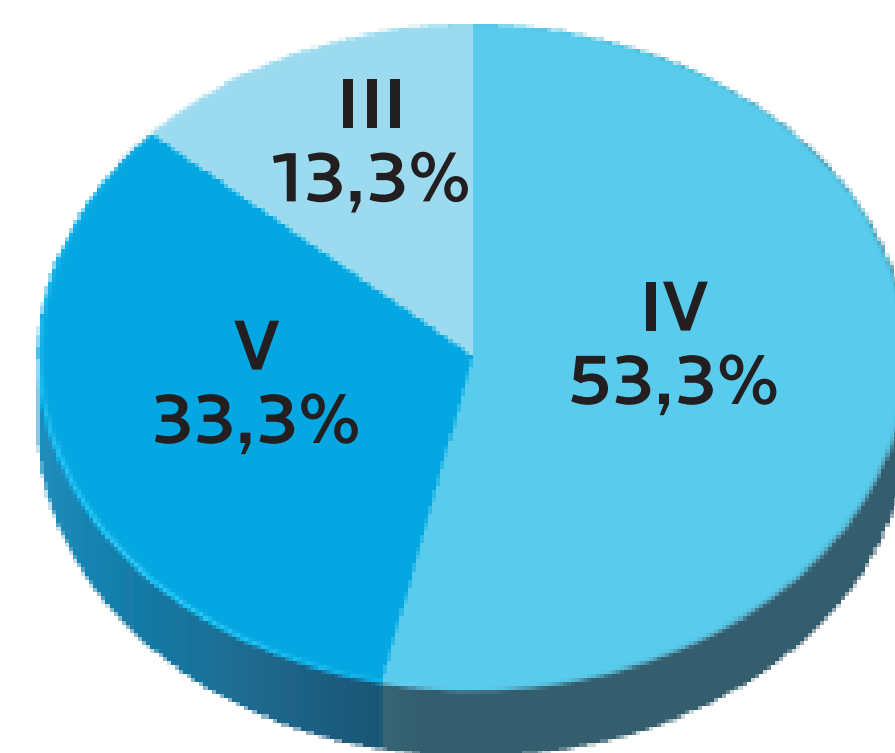
RESULTS

Patients characteristics:

Age: 23.7 ± 4.0 years old

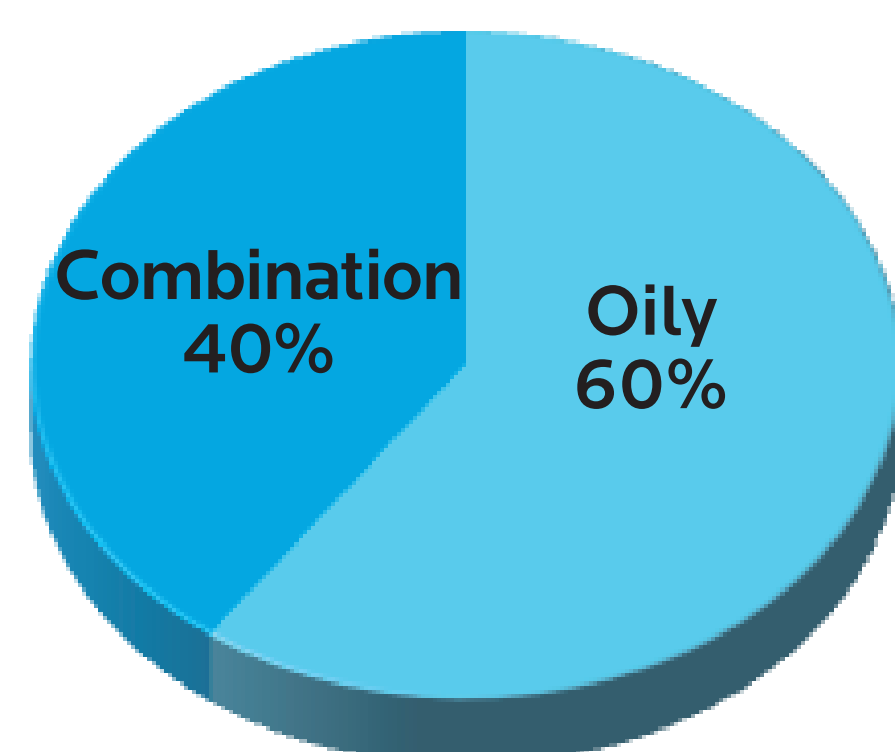


Phototype

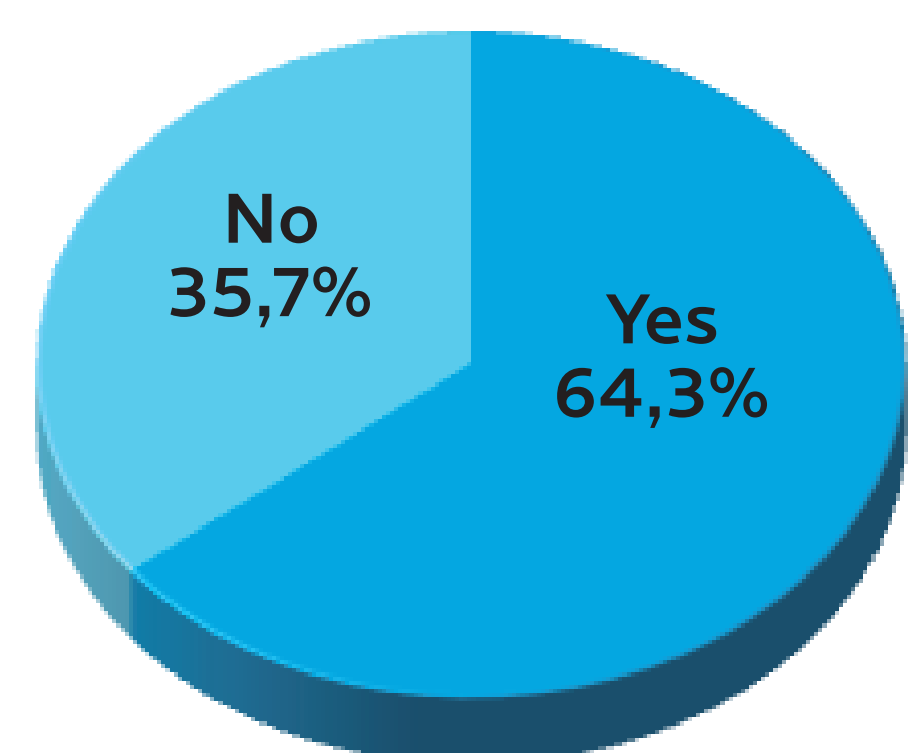


Duration of acne: 6.7 ± 4.1 years

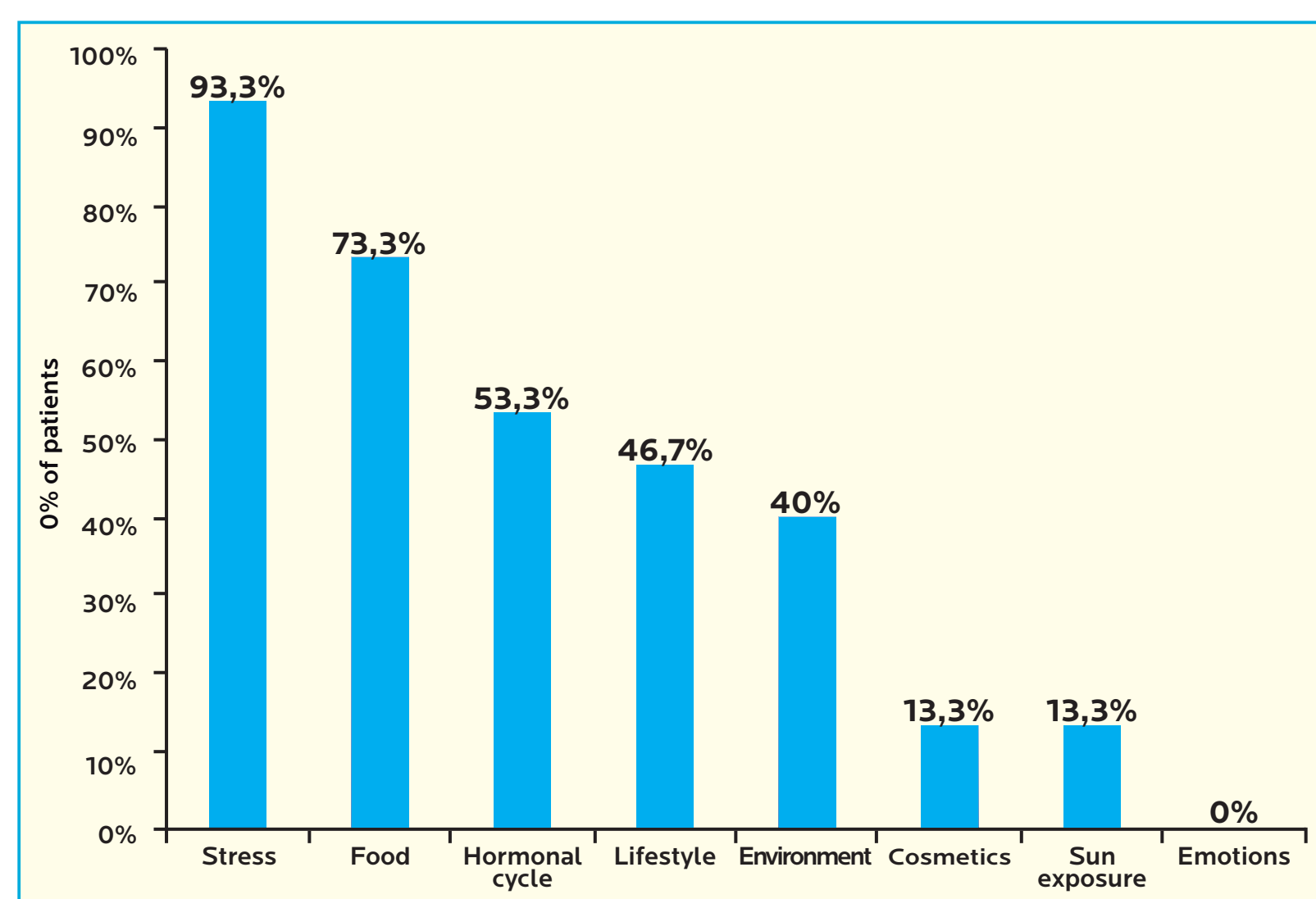
Skin type



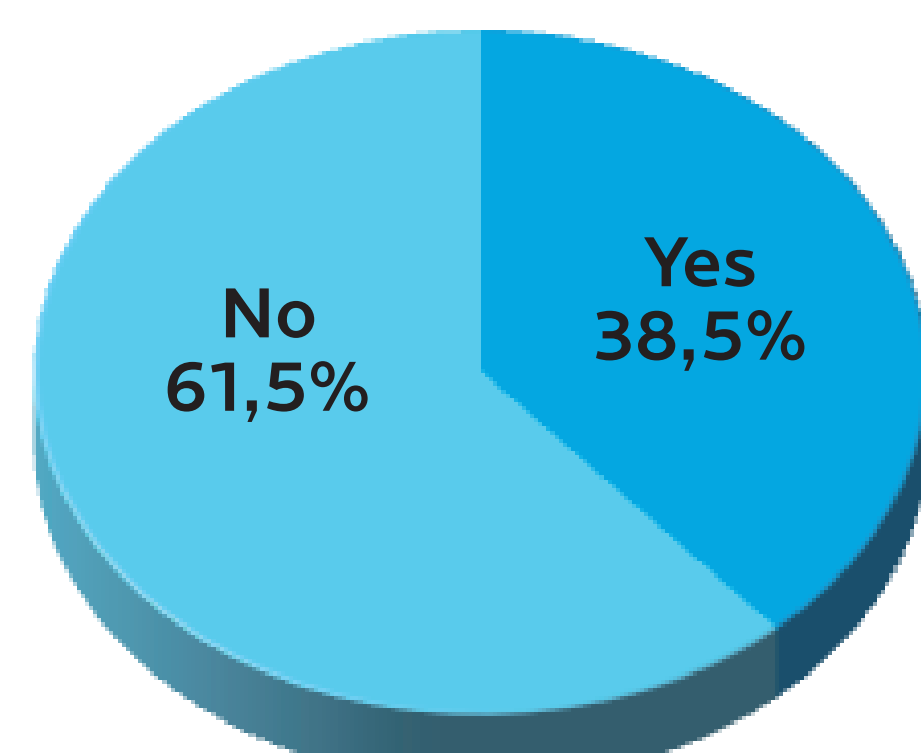
Previous family history of acne



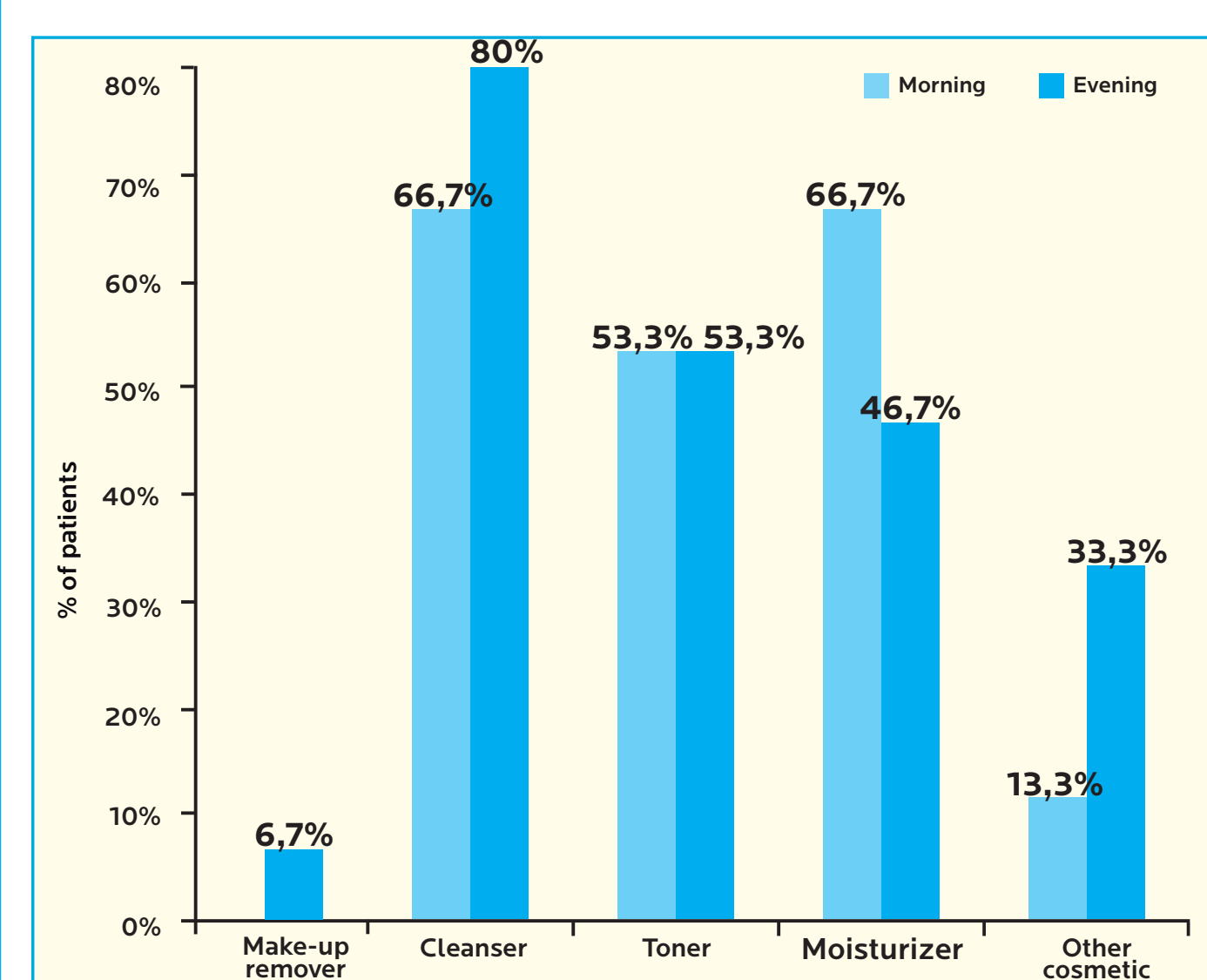
Factors which increase acne



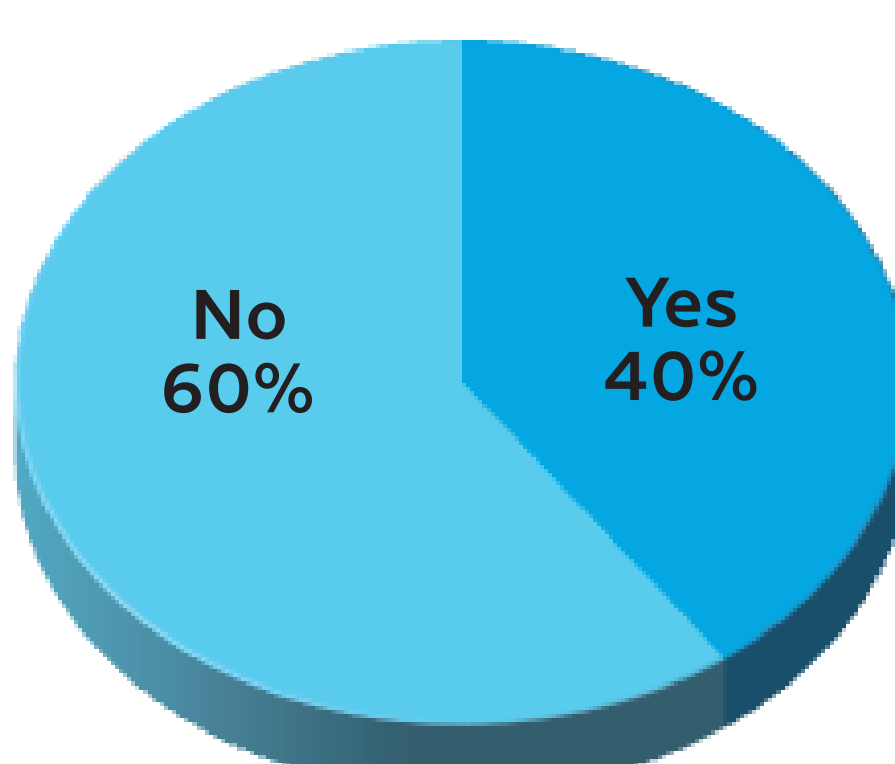
History of family on PIHL



Types of cosmetics used

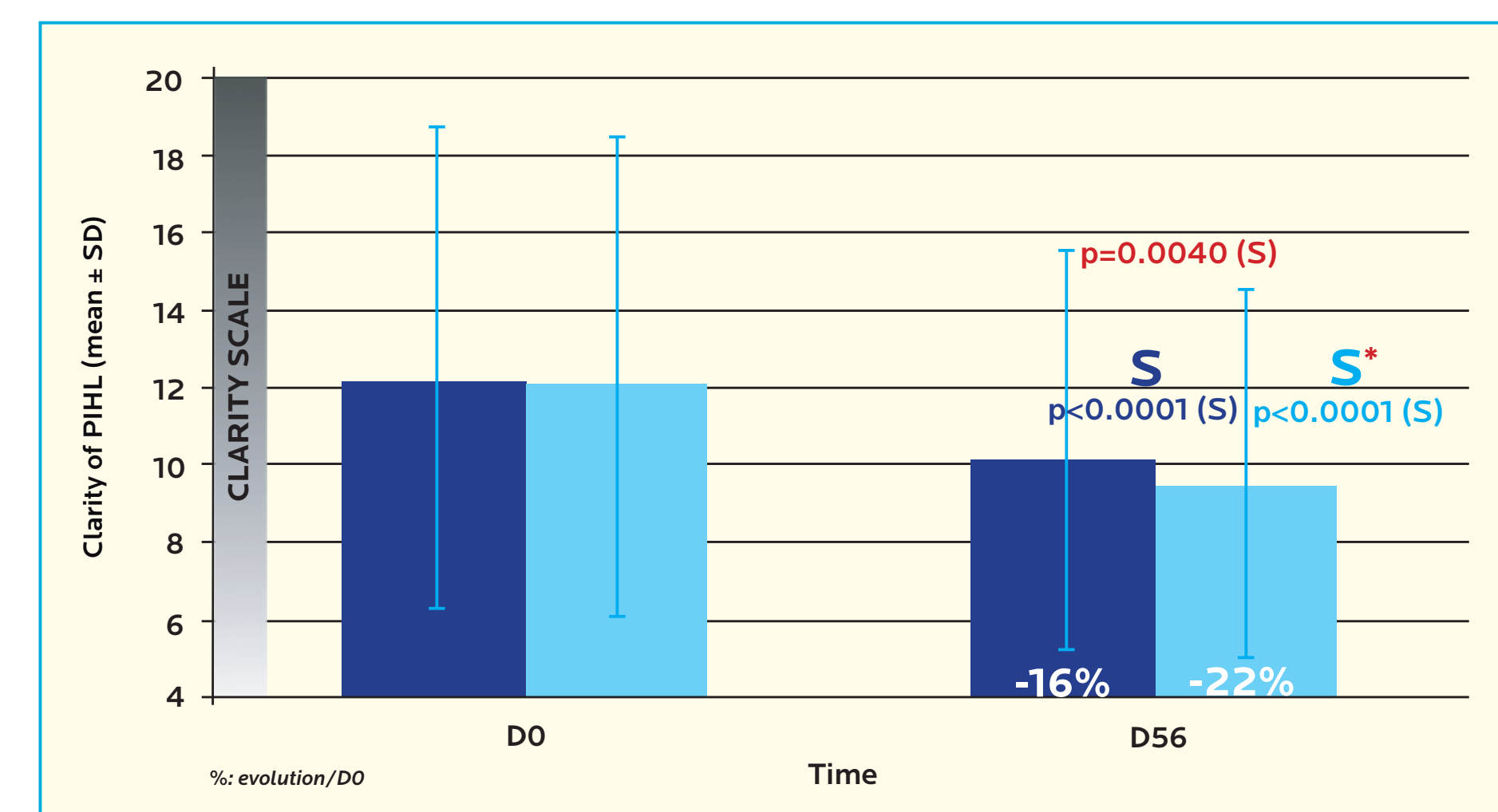
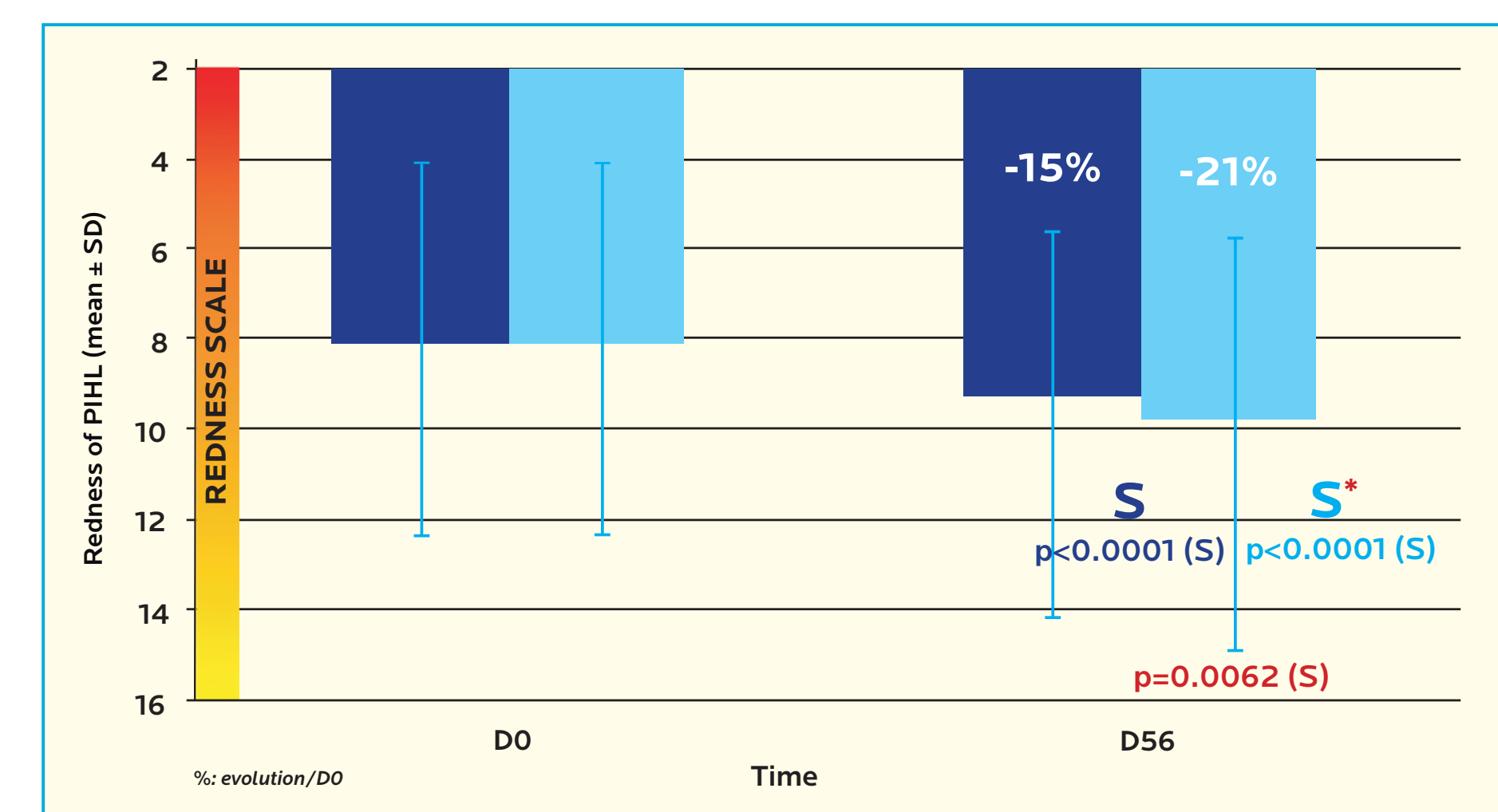
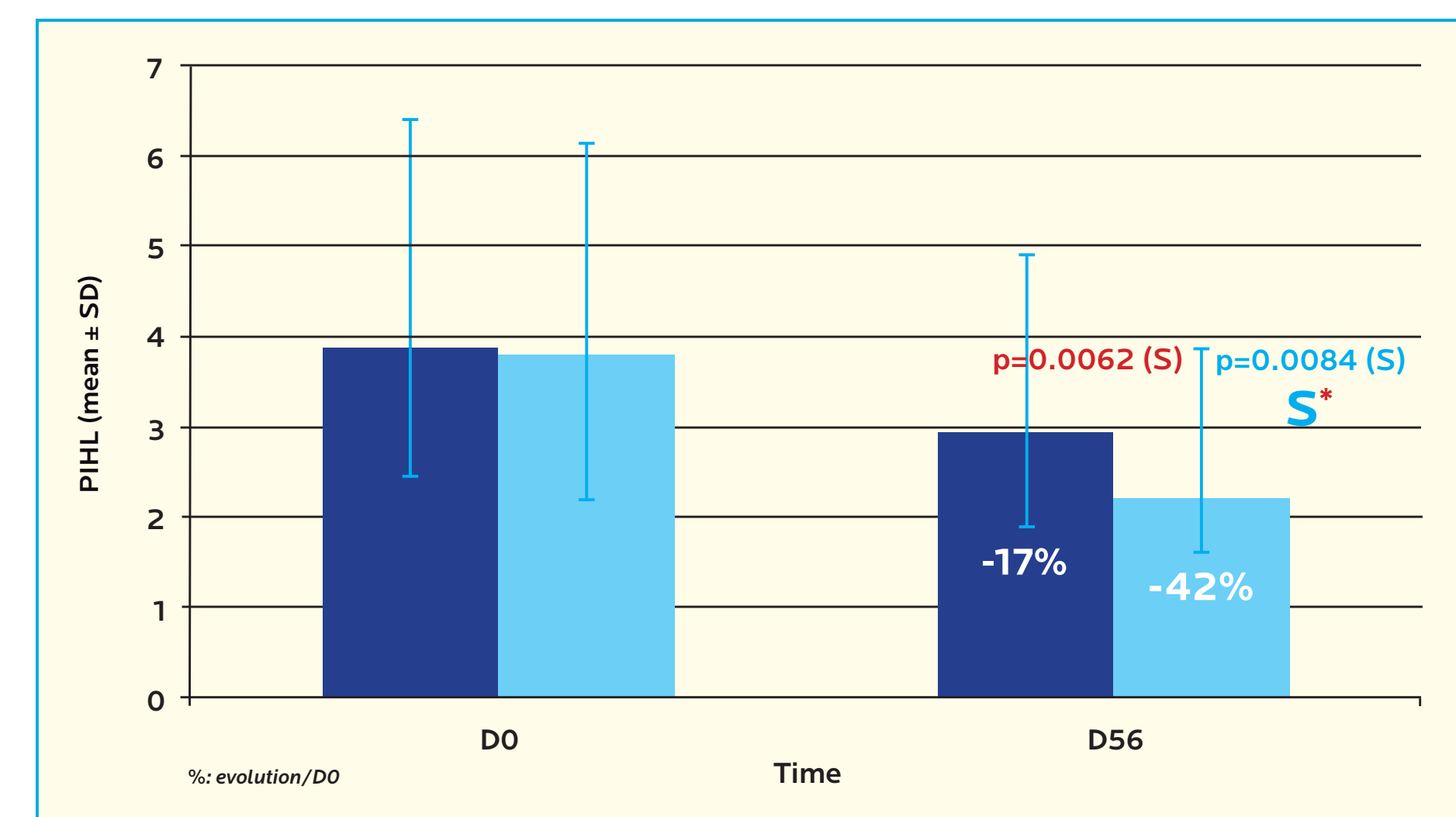
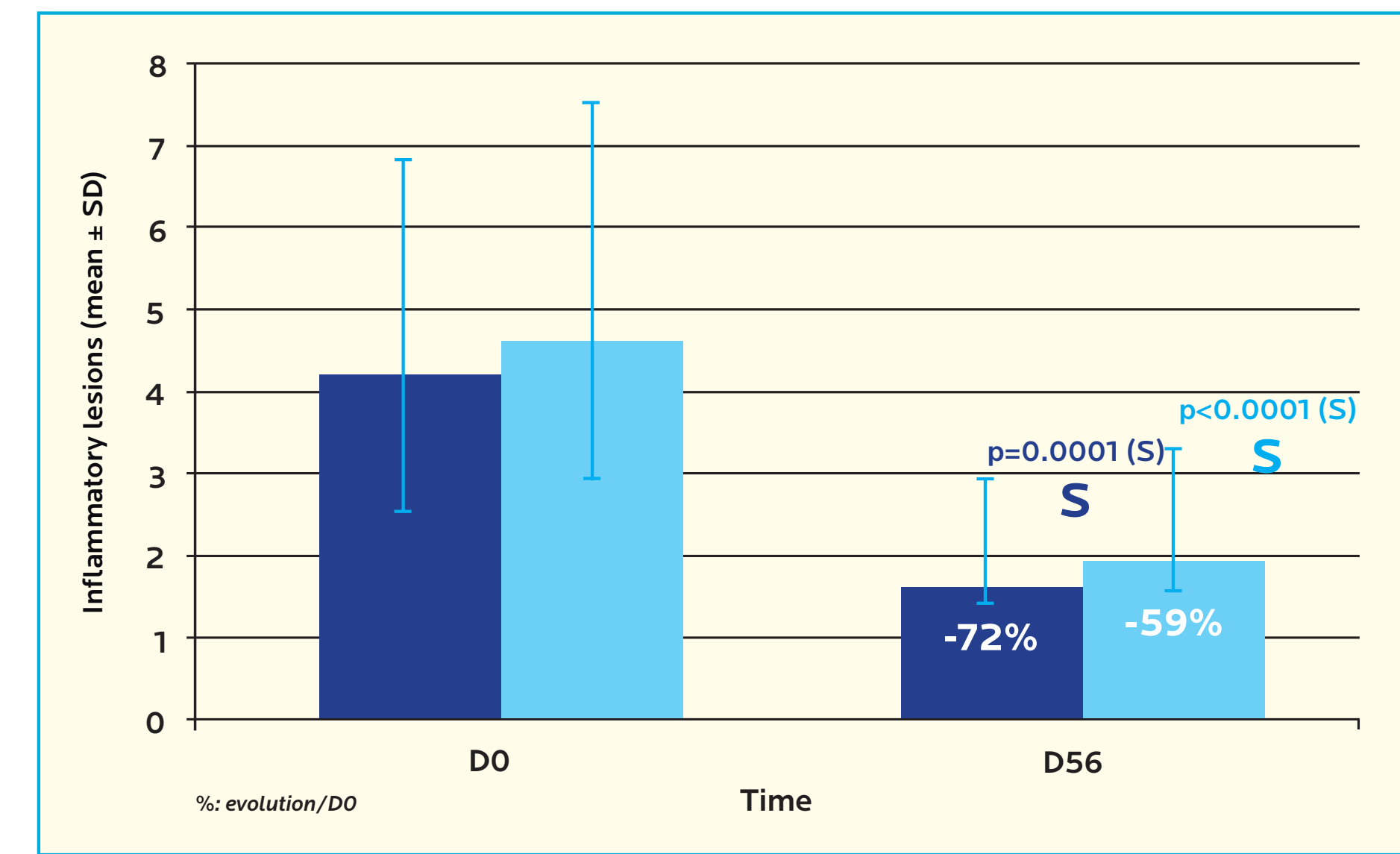
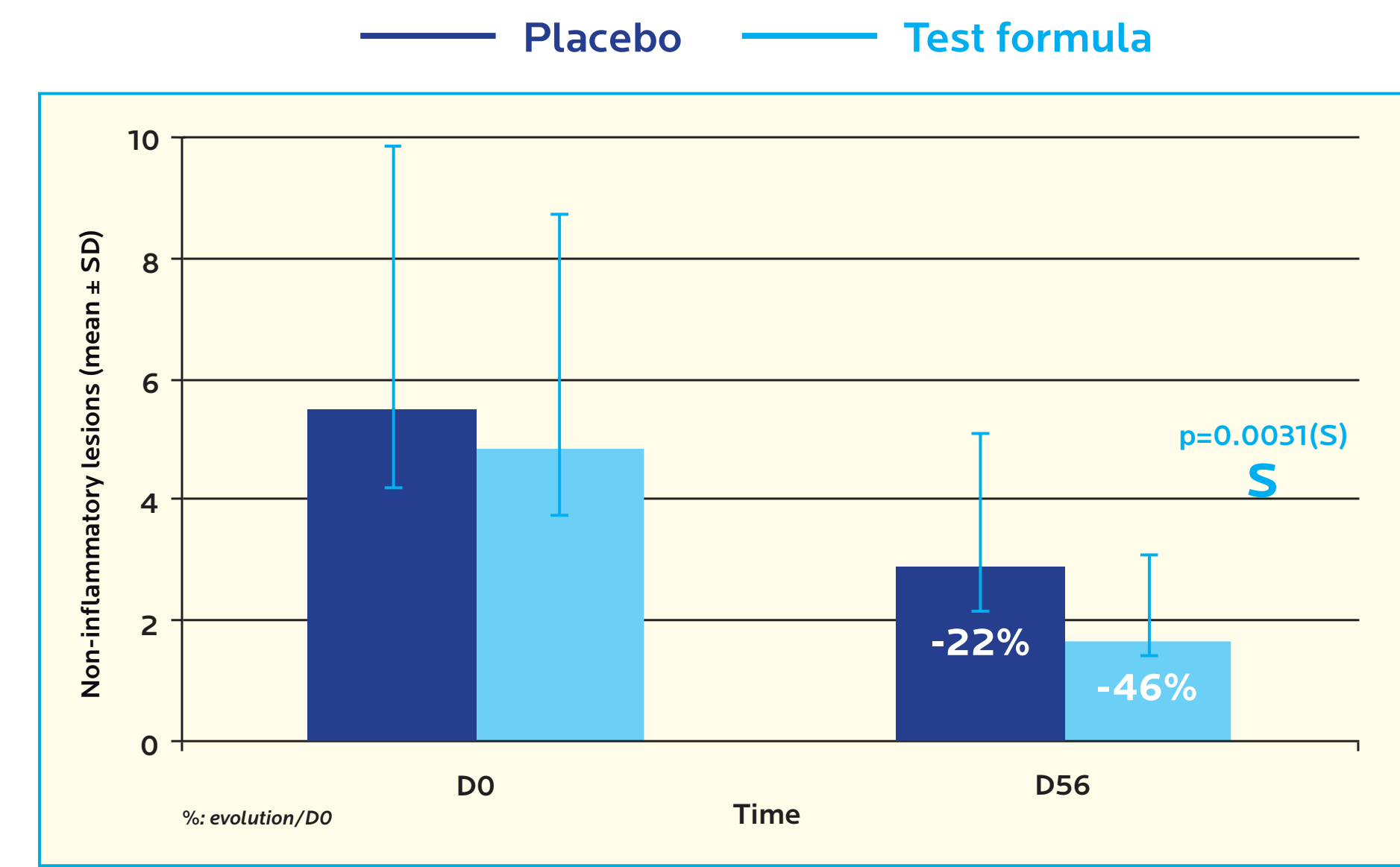


Sunscreen

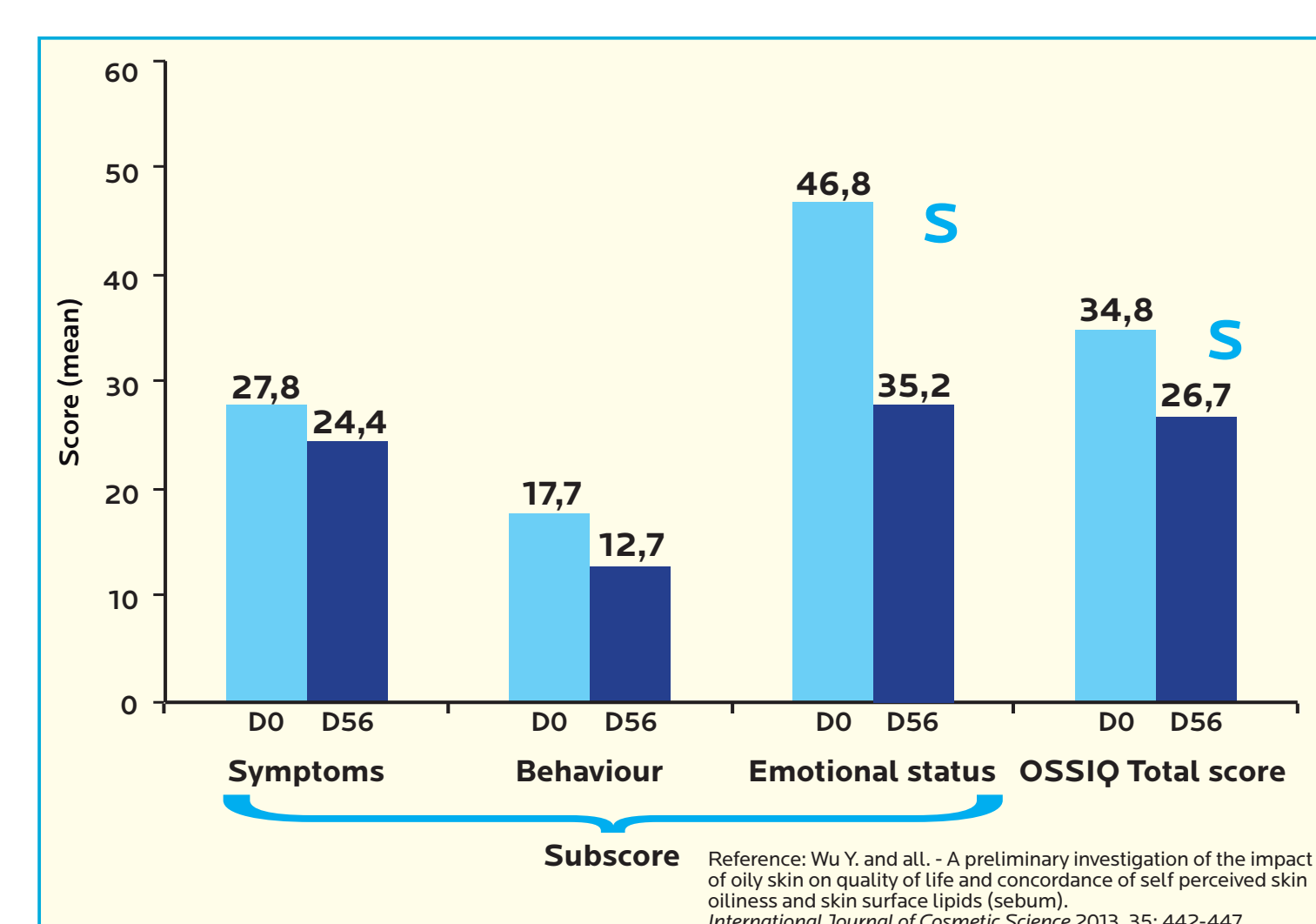


Neither ethnic skin products (whitening or bleaching creams) nor concomitant treatments were used.

At day 56, we noticed a significant reduction in inflammatory and non-inflammatory lesions associated with a significant difference between both treatments on the amelioration in the number and color (redness and clarity) of PIHL (clinical evaluation).



These results were supported by instrumental analysis (spectrophotometer evaluations of parameters L* (Lightness) and a* (Red/Green value)). Furthermore, at day 56 we noticed a significant improvement of the quality of life and self-image of patients using the OSSIQ (Oily Skin Self-Image) questionnaires (18 items).



CONCLUSION

This study demonstrated that the new formulation containing Lipohydroxy acid (LHA), Salicylic acid (SA), Linoleic acid, Niacinamide, Piroctone-olamine and Procerad (with an anti-inflammatory and anti-melanin synthesis action) allows to manage acneic patients with risks of post-inflammatory hyperpigmented lesions.