A SPLIT-FACE STUDY ASSESSING THE CLINICAL BENEFIT, TOLERABILITY AND SUBJECT SATISFACTION OF A DERMOCOSMETIC CREAM CONTAINING SPHINGOBIOMA AND NEUROSENSINE IN SUBJECTS WITH ROSACEA ASSOCIATED WITH ERYTHEMA AND SENSITIVE SKIN

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INTRODUCTION

Rosacea is a chronic inflammatory skin condition associated with an altered skin barrier and microbiome, inflammation and vasodilation.[1] Persistent erythema is a common primary feature, and can be associated with flushing, papules, as well as sensitive skin symptoms including tightness, stinging, burning and pain.[2,3] A specific dermocosmetic (DC) cream containing acetyl dipeptide-1 cetyl ester, a soothing compound (Neurosensine) that acts on skin sensitivity by decreasing erythema, irritation, and shea butter to moisturise the skin barrier has been developed for these patients.[4] Moreover, DC cream contains an extract of a flagellated bacterial strain of *Sphingomonas xenophaga* isolated from the endogenous flora component of La Roche Posay Thermal Spring Water. It restores the skin barrier, decreases inflammation and redness and inhibits the activity of pre-Kallikrein.

OBJECTIVES

This study assessed the benefit and local tolerance of DC cream in patients with rosacea associated with erythema and sensitive skin.

MATERIALS & METHODS

- Intra-individual single-blind study with a split-face design comparing DC cream applied twice daily with that of their usual skin care (USC) for 28 days in 22 female adult subjects >18 years of age, phototype I to IV with very mild to mild erythema, rosacea (IGA 1-2), and sensitive skin (positive skin stinging test with 15% lactic acid).
- Clinical evaluations at baseline, Day15 and Day 28 included erythema, skin tightness, burning sensation, stinging and pain on VAS scale (0=none to 10=very much), rosacea severity (0=none to 4=very severe; modified IGA Scale), stinging test and local tolerability.
- Instrumental evaluations included Chromameter (a* parameter; erythema), Corneometer and Tewameter. Digital images by ColorFace and Skincam were taken at all time points on both sides.
- Demodex density (SSSB method) was assessed at Baseline and Day 28.

RESULTS

- DC cream significantly reduced erythema after 15 ($p<0.001$) and 28 days ($p<0.01$). See Figure 1. The reduction was significantly higher with DC than with USC at both time points (D15: $p<0.05$; D28: $p<0.01$).
- Chromameter results for erythema showed a statistically significant difference in favour of DC cream compared to USC at both time points ($p<0.001$ at D15, and $p<0.01$ at D28) confirming clinically assessed results.
- Skin tightness significantly ($p<0.01$) decreased with DC cream by 22.2% and 30.6% at D15 and D28 respectively. Burning decreased by 72.7% at D15 and D28 (both $p<0.05$), as did stinging (-47.6% at D15 and -42.9% at D28; both $p<0.01$). Reductions were all significantly ($p\leq0.05$) higher with DC cream compared to USC at both post D0 time points.
- Corneometer measurements showed a statistically significant improvement in skin hydration with DC cream at D15 (+53.0%; $p<0.0001$) and D28 (+59.2%; $p<0.0001$). Improvements were significantly ($p<0.0001$) higher with DC than with USC, at both time points.
- TEWL significantly decreased with DC cream at D15 (-16.2%; $p<0.01$) and D28 (-14.5%; $p<0.05$). The decrease was significantly $p\leq0.05$) higher with DC cream than with USC at both time points.
- Skin sensitivity (Figure 2) had significantly decreased with DC cream at both time points (-53.5%; $p<0.0001$ at D15, and -62.8%; $p<0.001$ at D28). DC cream did significantly ($p<0.001$) better than USC as early as D15.
- At D28, a significant ($p<0.05$) reduction of the mean Demodex density was observed on the DC cream side (-56%) compared to the USC side. Figure 3 provides an example.
- Tolerance of DC cream was excellent in all subjects.
- Figure 4 provides comparative Colorface and Skincam images at D0, D15 and D28.

Figure 1
CLINICAL EVALUATION OF ERYTHEMA

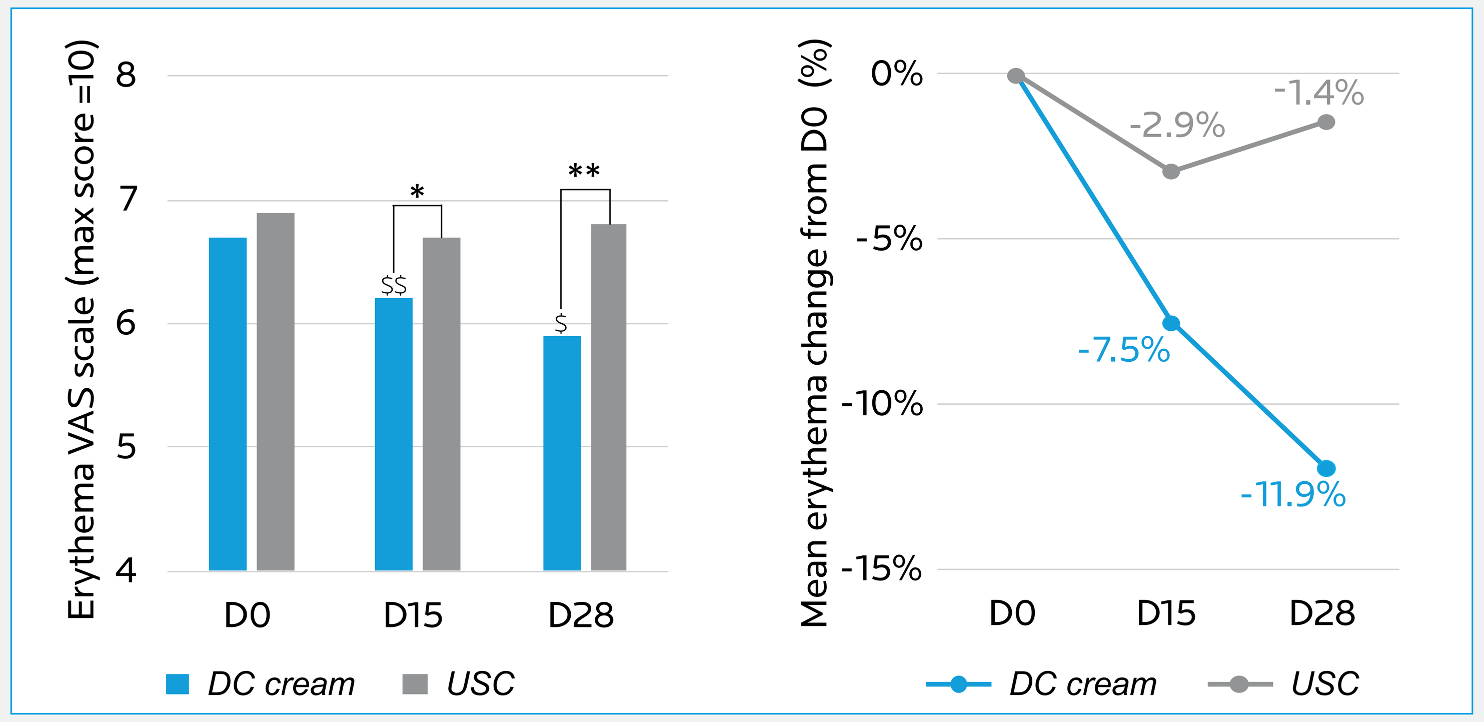
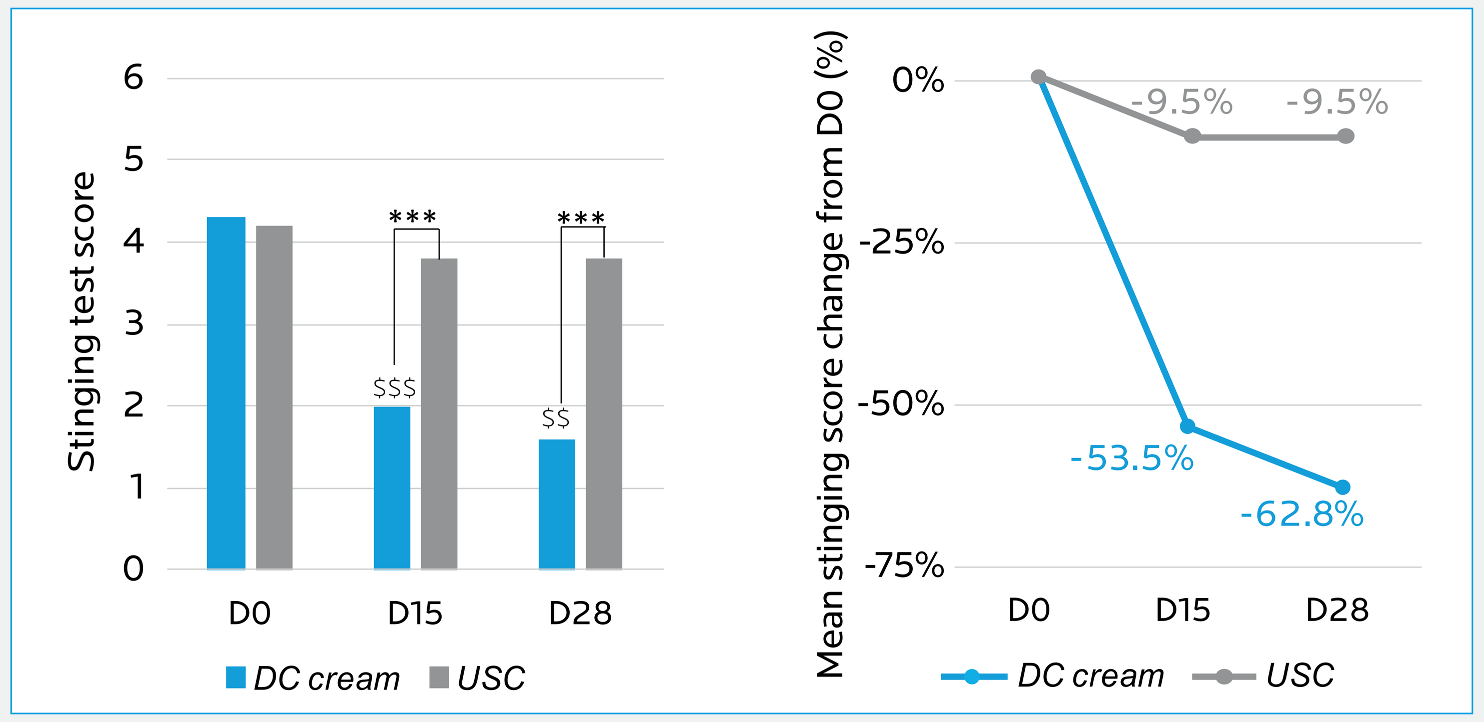


Figure 2
EVOLUTION OF SKIN SENSITIVITY USING STINGING TESTING OVER TIME



Significantly different from D0 : \$ (p<0.01) ; \$\$ (p<0.001), \$\$\$ (p<0.0001)
*Significantly different from USC : * (p<0.05) ; ** (p<0.01) ; *** (p<0.001)*

Figure 3
DEMODEX DENSITY WITH DC CREAM AT D0 AND AFTER 28 DAYS

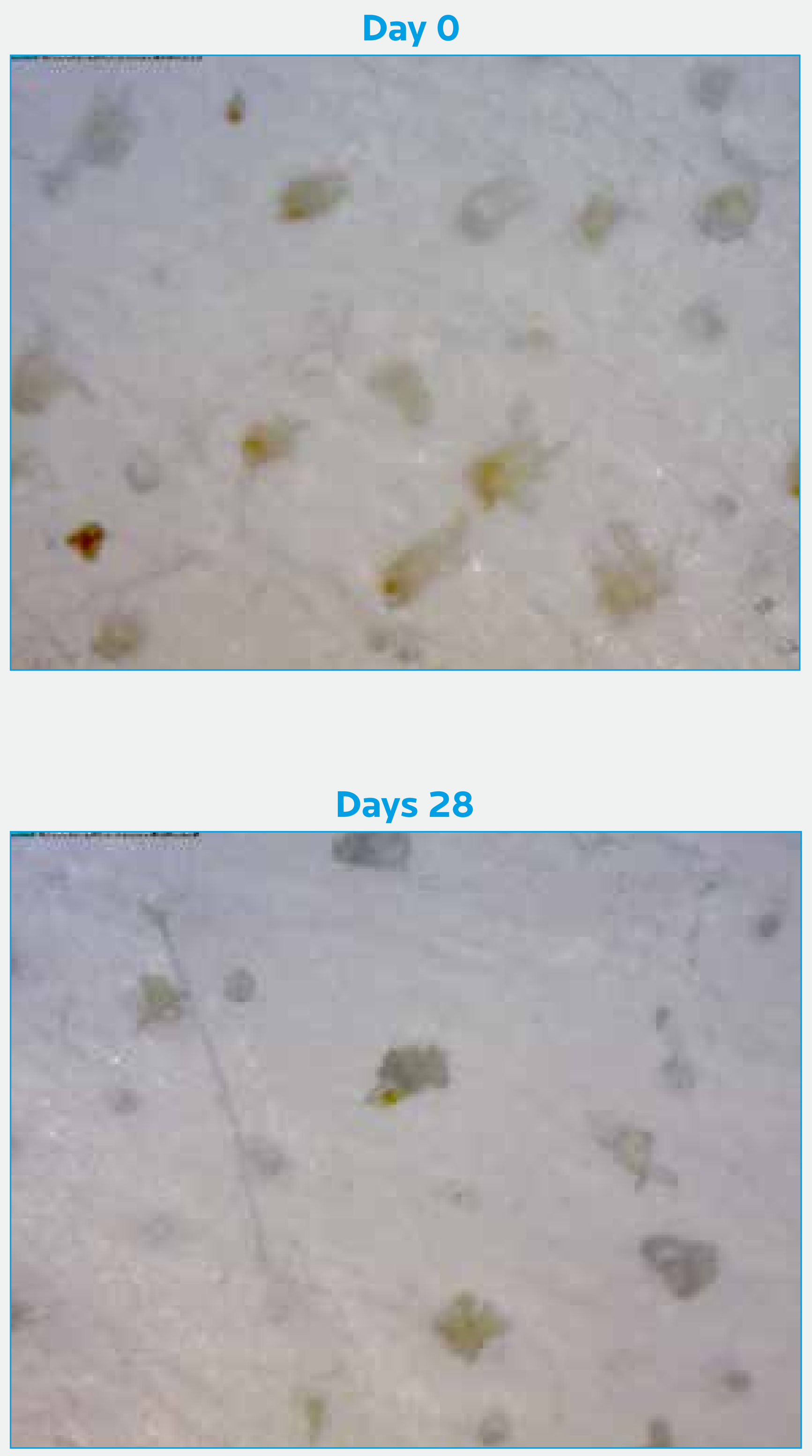
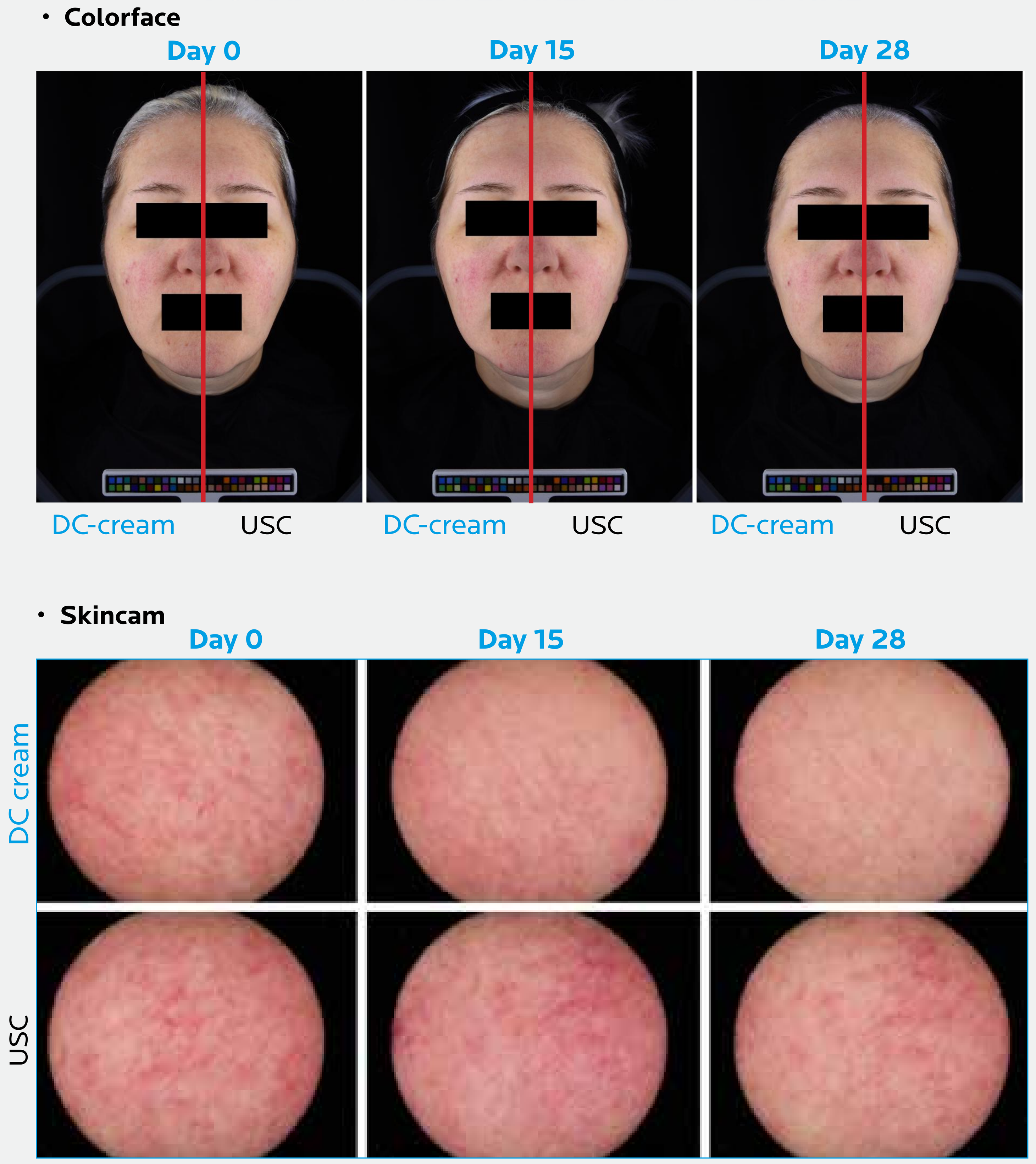


Figure 4
COLORFACE AND SKINCAM IMAGES OF DC- AND USC-TREATED HALF-FACES OVER TIME



CONCLUSION

A rosacea specific DC cream containing Sphingobioma and Neurosensine significantly improves skin redness, as well as skin sensitivity symptoms, skin hydration and TEWL in rosacea patients, by 15 days of twice-daily use, and significantly decreases Demodex count at D28, with a very good tolerance.

References

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