CHARACTERISTICS AND CONTROL OF THE PREMENSTRUAL ACNE FLARE UP WITH A DERMOCOSMETIC: DOUBLE BLIND RANDOMISED TRIAL

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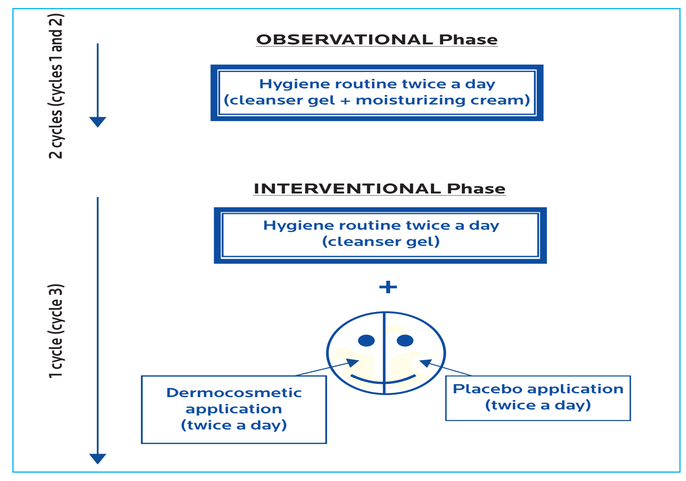
INTRODUCTION

Although several investigators have reported facial acne flare-ups during the luteal phase of the menstrual cycle (the premenstrual flare), this has been poorly investigated to date. We have performed a single-centre, controlled, randomised, double blinded, intra-individual (half-face) comparison with two objectives: the first was to clinically characterise the premenstrual acne flare-up in adult women in the absence of any acne treatment during 2 menstrual cycles using a standardised dermatological examination; the second objective was to demonstrate the benefit of a dermocosmetic product during one menstrual cycle.

METHODS

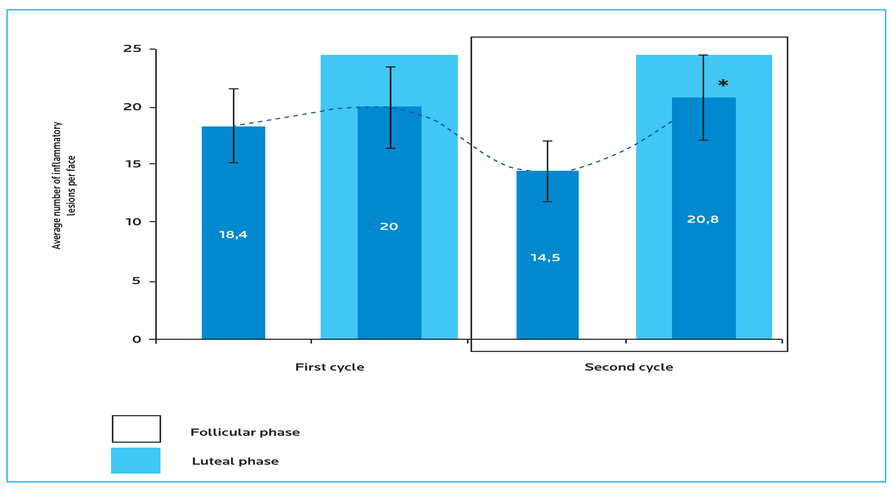
This comparative randomised study was performed on 32 women with premenstrual acne syndrome (GEA grade 2 and 3). Patients were first followed during 2 menstrual cycles (observational phase (cycles 1 and 2)) to quantify the number of lesions during (premenstrual) acne flare-ups. Secondly, the dermocosmetic formulation was applied twice daily on one half of their face and the placebo on the other half during one menstrual cycle (interventional phase (cycle 3)). All patients were observed at each luteal and follicular phase. The patients were instructed how to apply the products by a nurse in the study department. A total of seven study visits were performed: a screening visit followed by 2 visits during each menstrual cycle. The initial visit was planned during the follicular phase (between day 7 and day 12) and the second at the end of the luteal phase (between day 22 and day 28).

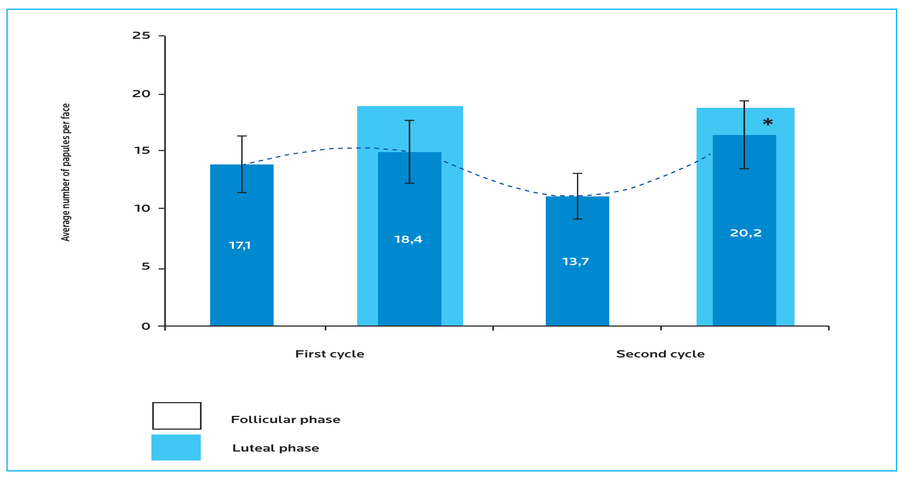


RESULTS

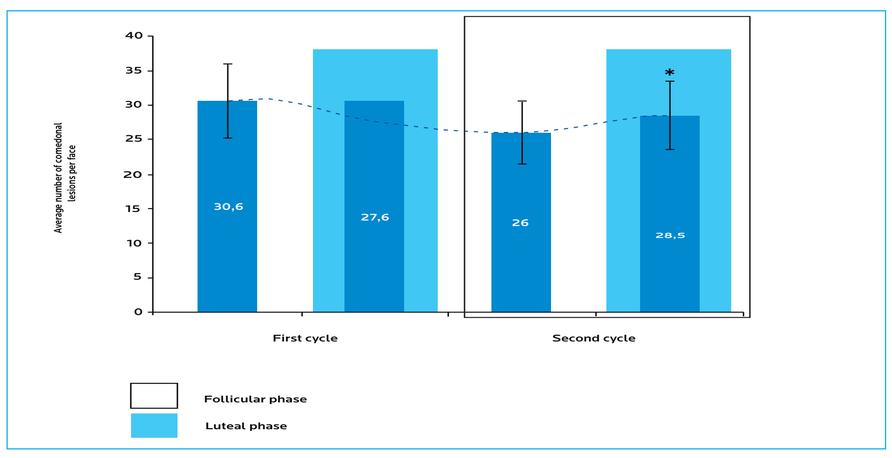
This study confirms the clinical «feeling» of women with premenstrual acne flares. These flares are characterized with a higher number of inflammatory acne lesions and to a lesser extent, non-inflammatory lesions in the luteal phase compared to the follicular phase of the menstrual cycle.

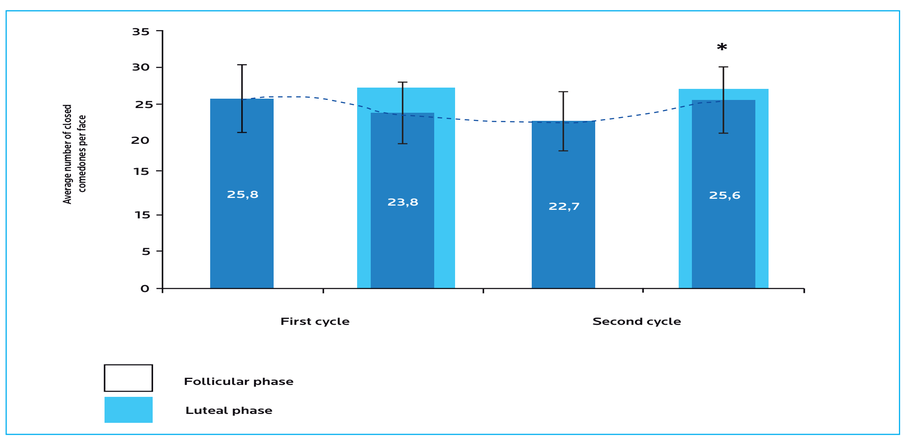
The mean number of superficial facial inflammatory lesions (papules and pustules) was significantly higher during the luteal phase than the follicular phase at the end of the second cycle (14.5 vs. 20.8, p=0.0005). Of these superficial inflammatory lesions, only the number of papules was significantly higher (13.7 vs. 20.2, p=0.0008). Papules increased in 74.2% of women.



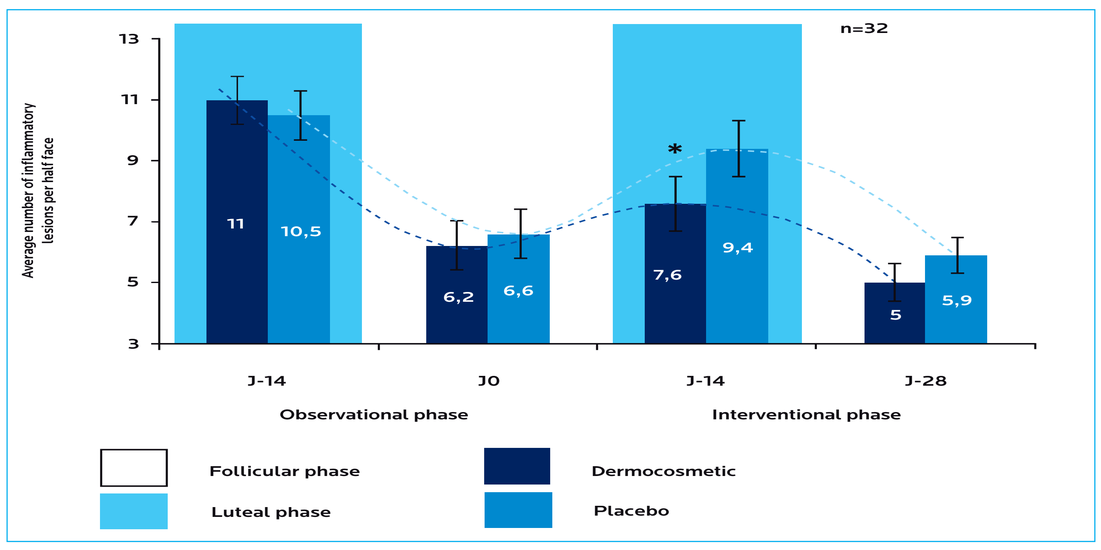


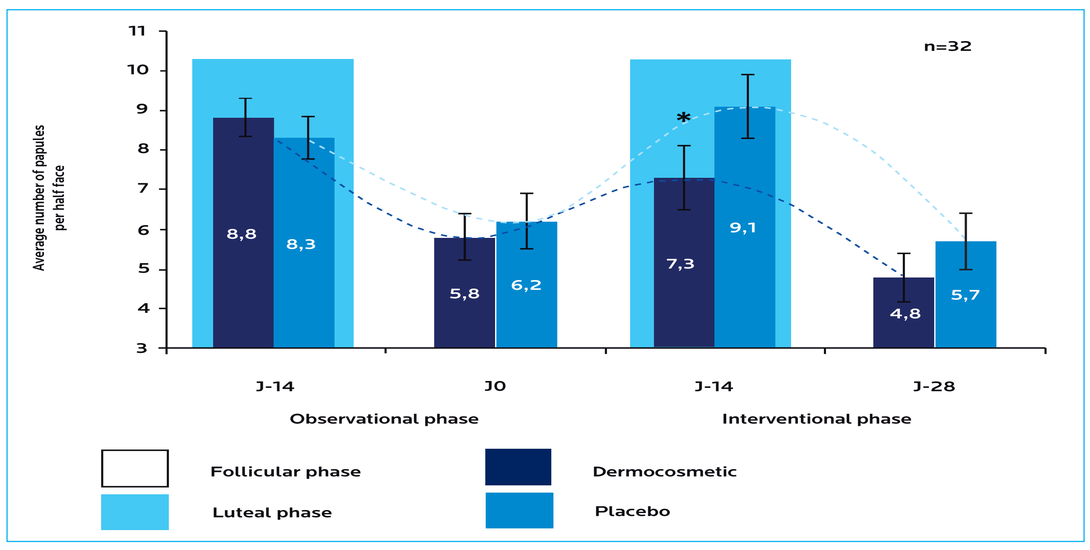
The mean number of facial of comedonal lesions (open and closed comedones) was also significantly higher during the luteal phase compared to the follicular phase at the end of the second cycle (28.5 vs. 26, p=0.04). Only the number of closed comedones was significantly higher (25.6 vs. 22.7, p=0.04). The increase of closed comedones was noted in 71% of women.





During the interventional phase, the half-face treated with the dermocosmetic formulation showed a significantly lower number of inflammatory lesions (p=0.01) and particularly of papules during the luteal phase compared to the half-face treated with the placebo.





Additionally, the increased number of inflammatory lesions and particularly of papules between the follicular phase and the luteal phase was significantly less (p=0.004) on the half-face treated with the dermocosmetic formulation. Tolerance of the dermocosmetic formulation was rated as good or excellent.

CONCLUSION

This study on the one hand enables premenstrual acne flare-up in adult women to be better characterised and in particular to prove that there is a significant increase in the number of papules and to a lesser extent of closed comedones. On the other hand, it reveals the benefit of a facial care regimen combined with a dermocosmetic, containing lipohydroxy acid, salicylic acid, linoleic acid, niacinamide and piroctone-olamine, appropriate for this premenstrual inflammatory flare-up.

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