A RANDOMIZED CONTROLLED CLINICAL STUDY ON THE EFFICACY AND QUALITY OF LIFE IMPROVEMENT OF SENSITIVE SKIN SUBJECTS USING A SPECIFIC DERMOCOSMETIC PRODUCT

Helena Polena[1], Sylwia Czainska[2], Ewa Chlebus[3], Monika Serafin[3], Benoit Cadars[1], Marlène Chavagnac[1], Christelle Graizeau[1,4], Michèle Sayag[1], Elodie Prestat-Marquis[1]

[1]NAOS Ecobiology Company (Bioderma), Research and Development Department, Aix-en-Provence, France; [2]NAOS Poland, Cracow, Poland; [3]Niepubliczny Zakład Opieki Zdrowotnej, NOVADERM, Warszawa, Poland; [4]NAOS Institute of Life Science, Aix-en-Provence, France

INTRODUCTION

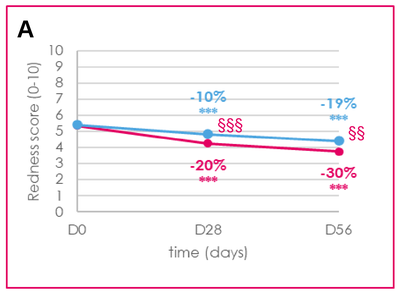
Sensitive skin syndrome (SSS) is a common skin condition defined by the occurrence of unpleasant sensory perceptions such as tightness, tingling, heat sensations, or itching in response to physical, thermal, chemical, hormonal, psychological, or other stimuli that normally do not provoke such sensations. Sensitive skin may have a normal appearance or be accompanied by clinical signs such as redness. It has an impact on patients' quality of life as symptoms occur immediately following exposure in response to different stimuli. In this context, we evaluate a dermocosmetic cream versus neutral cream (placebo) on the tolerance, efficacy and quality of life improvement of subjects with SSS in Poland.

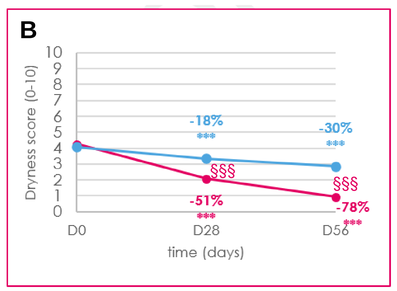
MATERIALS & METHODS

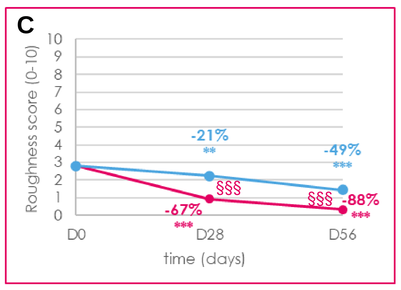
A double-blind randomized clinical study was performed on 100 subjects presenting common following features: self-reported facial sensitive skin, a Burden of Sensitive Skin (BoSS) total score equal or higher than 20 (out of 56) and responsiveness to the lactic acid stinging test (LAST) with redness (Mexameter). One group (n=50) applied the cream once to twice daily for 56 days (D56) and the other one (n=50) a placebo. The group using the cream was composed of 40 women and 10 men with mean age 43 years and phototypes II (54%) or III (46%). The assessment of the clinical signs (redness, dryness, roughness, squames) were performed by both the dermatologists and the subjects using a 11-point scale at D0, D28 and D56. With a similar scale, the functional signs (itching, pain, tightness, tingling, heat sensations) were self-evaluated. In addition, LAST-induced stinging sensations and redness, and the quality-of-life improvement (via the BoSS questionnaire) were evaluated at D0, D28 and D56. Adverse events were reported by the subjects during the study if noticed, and the global cutaneous acceptability was evaluated by the dermatologists at D56 using a 4-point rating scale.

RESULTS

Compared to D0, the cream significantly reduced all the clinical signs according to the dermatologists (**fig. 1**), and the subjects (at D28/D56: -28%/-41% skin redness, -53%/-76% skin dryness, -62%/-83% skin roughness and -69%/-87% squames). Moreover, the cream significantly decreased functional signs (**fig. 2**) except for pain. Compared to placebo, all previous clinical and functional signs were statistically improved (**fig. 1 & 2**).







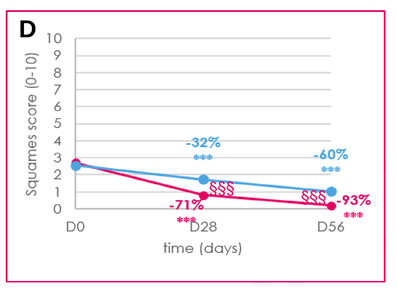
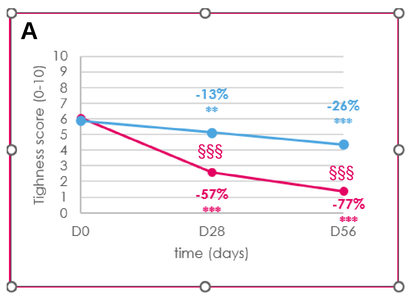
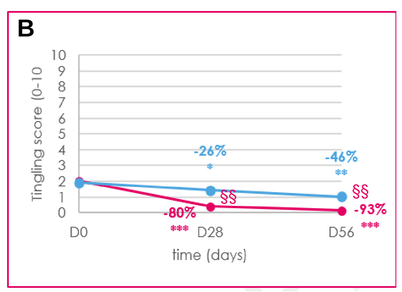
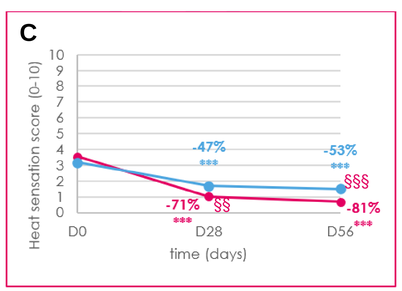


***Figure 1**: Skin redness (**A**), dryness (**B**), roughness (**C**) and squames (**D**) clinical evaluation by the dermatologists for **cream** and **placebo** groups.*







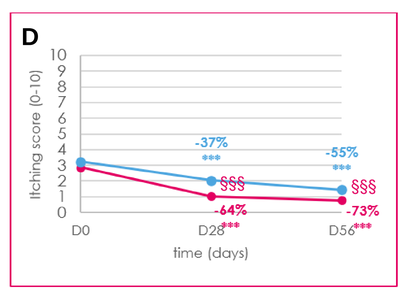


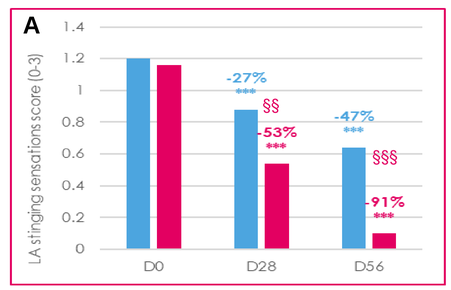
***Figure 2**: Feeling of tightness (**A**), tingling (**B**), heat sensations (**C**), and itching (**D**) assessed by the subjects in **cream** and **placebo** groups.*

Finally, all the subjects presented a **very good tolerance compared to 80% of the subjects who applied the placebo**, according to the investigators.

Redness induced by lactic acid significantly decreased by -9% at D28, and -15% at D56, like stinging sensations (**fig. 3A**) thanks to the cream and were significantly reduced vs the placebo. Similarly, the BoSS total score was significantly decreased (**fig. 3B**) and also significantly vs placebo, suggesting a quality-of-life improvement.

Wilcoxon's test:

- **p<0.05, **p<0.01, ***p<0.001 vs D0*
- *§§ p<0.005, §§§ p<0.001 vs placebo*



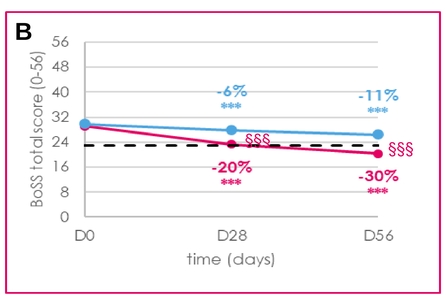


***Figure 3**: LAST (**A**) and BoSS total (**B**) scores in **cream** and **placebo** groups*

CONCLUSION

Showing very good tolerance and efficacy on SSS symptoms, associated with an improvement on the quality of life, this specific cream is well adapted for daily use application by patients suffering from SSS.

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