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LABORATOIRE A-DERMA

Efficacy of a balm with unique Vaseline-like texture on foot xerosis and superficial fissures in diabetics patients

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Introduction & Objectives

Skin xerosis, especially foot xerosis, is a common condition among **diabetics** which can lead to painful cracks and possibly neuropathic ulcers and infections. Regular use of moisturizers is recommended to help manage and prevent xerosis from developing. We assessed efficacy of a balm with unique Vaseline-like texture, who has demonstrated its effectiveness in hydrating the skin durably and intensely in previous clinical studies, on a new target population: diabetics patients suffering from foot xerosis and superficial fissures.

Materials & Methods

Population:

Adults suffering from controlled type 1 or 2 diabetes and presenting foot xerosis rated as 6 according to the Xerosis Assessment Scale (XAS) with superficial fissures, have been enrolled in a monocentric, open-labelled study. Patients with diabetes complications (arteriopathy, microangiopathy, neuropathy), presenting deep fissures on feet with damage to the dermis, with infection and vasculitis or suffering from foot ulcer or gangrene were not enrolled.

Study design:

Patients applied the balm containing 100% ingredients of natural origin to both feet, twice a day, for 27 days.

At every visit (D1, D5, D28), clinical evaluation of xerosis intensity, evaluation of skin hydration, photographs and pruritus assessment were performed. The repairing effect was assessed by investigator and patient after 4 and 27 days of application. The evolution of visible depth and length of superficial cracks was assessed through cracks detection analysis on photographs performed with SkinCamPro at D5 and D28, as well as the evolution of skin roughness and texture through roughness and texture image analysis. At D1 and D28, quality of life evaluation was performed, and cosmetic satisfaction and perceived effect evaluation questionnaire was completed by patients. The global soothing effect and the tolerance were also assessed at D28.

Results

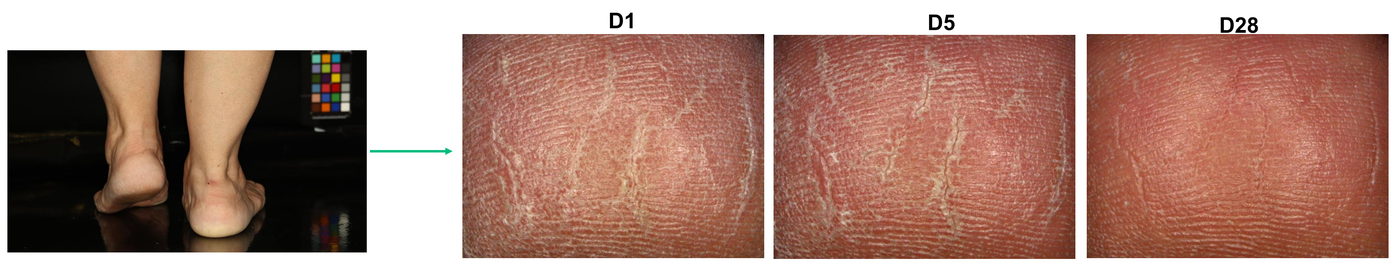
32 patients, aged 33 to 77 years old, with controlled type 1 or 2 diabetes and presenting foot xerosis and superficial fissures were enrolled.

CLINICAL EVIDENCE

Repairing efficacy

The repairing effect on superficial cracks was assessed by the investigator as significant on both feet as well as on a target crack at D28 ($p<0.001$).

Patients also perceived this significant global repairing efficacy ($p=0.004$).



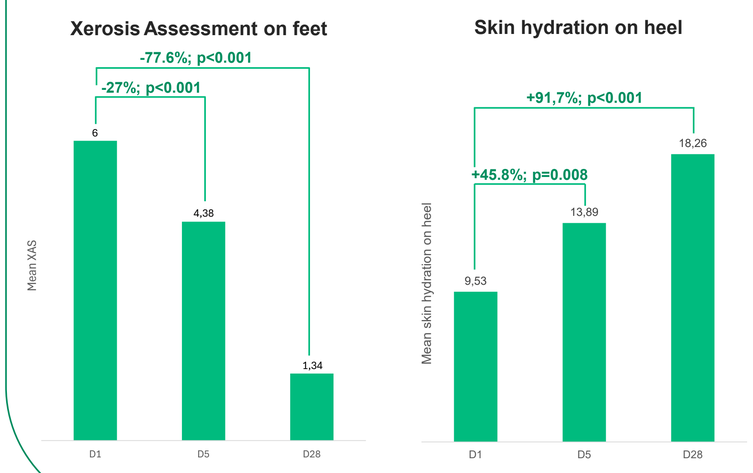
Conclusion

This study demonstrates the interest of using a balm with unique Vaseline-like texture to promote optimal repair of skin xerosis and superficial cracks while ensuring comfort and safety for diabetic patients.

Feet hydration

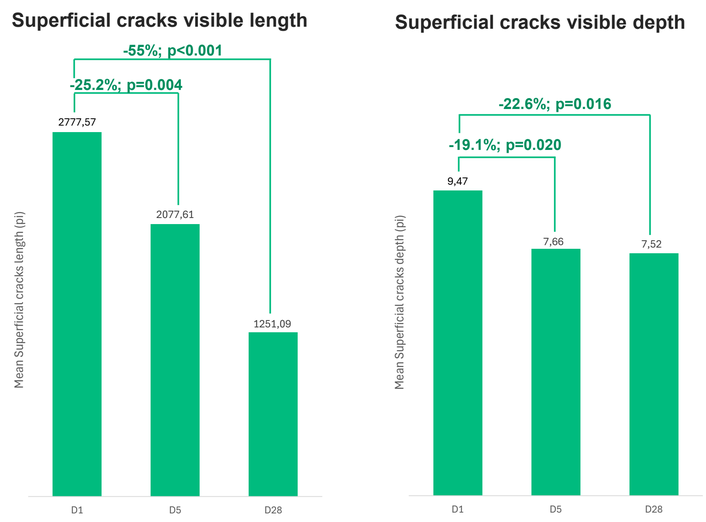
XAS significantly improved from 4 days of application and after 27 days of application.

This was confirmed by hydration index measurement on foot's heel from D5 and at D28.



Length and depth of superficial cracks

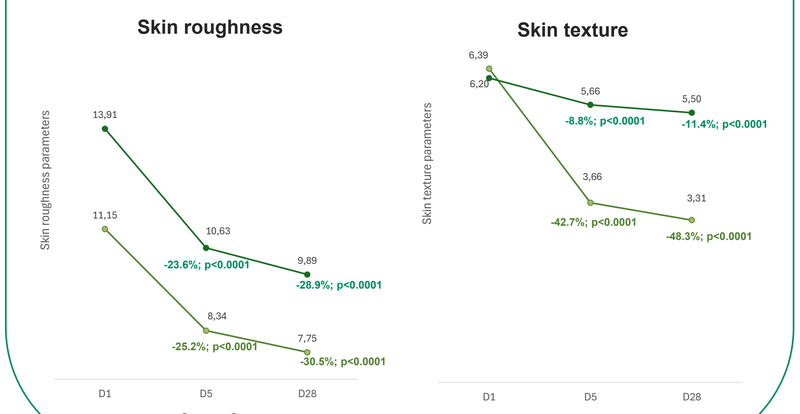
The length and the depth of superficial cracks decreased significantly at D5 and D28.



Improvement of skin texture

A more uniform and regular skin texture was observed with a significant decrease of :

- Skin roughness (Spa and Spq) at D5 and D28
- Skin texture (Contrast and entropy) at D5 and D28.

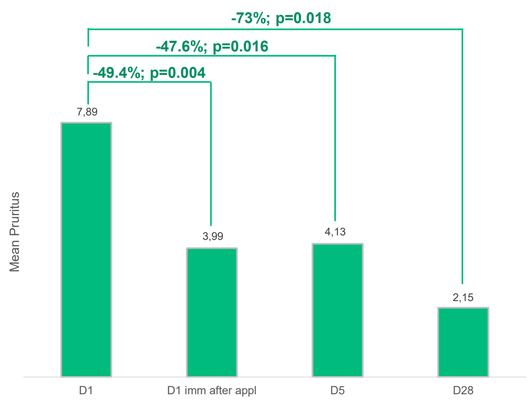


PATIENT-REPORTED PERCEPTIONS

Soothing effect was significantly appreciated by patients at D28 ($p=0.014$) and tolerance was judged excellent by the investigator.

Soothing of pruritus

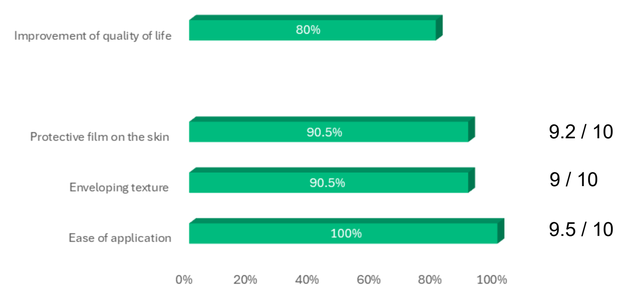
From the first application, the balm helped to immediately soothe the pruritus in the feet. These results were confirmed at D5 and D28.



Improvement of quality of life

80% of patients saw their quality of life improved after 27 days of application ($p=0.002$) including an improvement in feet comfort.

100% of patients found the product easy to apply with an enveloping texture and leaving a protective film on the skin.



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