

Efficacy of an Emollient Containing Urea in Adults Suffering from Mild to Moderate Keratosis Pilaris

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Dear Editor

Keratosis pilaris (KP) is a common but under-evaluated skin disorder, which causes keratinous plugs in the follicular orifice, mostly on the arms and legs, associated with dryness and roughness. Although KP is asymptomatic, the cosmetic appearance of KP can lead to psychosocial distress among patients [1]. The condition often improves over time, but several treatment options are available as emollients, exfoliants, anti-inflammatory medications, phototherapy, and various laser therapies [2]. Topical treatment is mainly based on emollients and keratolytics, but they have mainly a suspensive effect [1]. Safe, effective treatment with urea creams and lotions (from 10% concentration) had also been noticed. The aim of this study was to assess the efficacy of a dermocosmetic product containing urea to improve skin condition of patients with KP. This formula has been previously evaluated in comparison to a 10% urea lotion in patients suffering from atopic dermatitis and there was no difference between the two products in SCORAD reduction [5]. The present study complied with the ethical guidelines of the 1975 Declaration of Helsinki and was conducted in 2019 according to ICH guidelines for Good Clinical Practice. Patients (skin type I to IV) with a minimum age of 18 presenting mild (score 1, n=15) to moderate (score 2, n=9) keratosis pilaris (KP) (18 basic KP, 2 red KP and 4 pigmented KP) were included after having signed an informed consent. The emollient was applied once daily for 2 months to one arm or one leg (right or left) according to a randomization list. The dermatologist assessed the clinical grade of KP, the KP extent (cm²) and the KP lesion count. Dryness and roughness were evaluated using a Visual Analogue Scale (VAS). The patient quality of life was measured using the Dermatology Life Quality Index (DLQI), global assessment by VAS and product acceptability via questionnaires. To illustrate efficacy, C-cube[®] was used to measure erythema and roughness via 2D/3D acquisitions [3]. Evaluations were performed at baseline and 14, 28 and 56 days after the start of treatment.

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Twenty-four patients: 23 women (96%) and one man (4%) were included. At D56, the assessment by the dermatologist demonstrated that 42% of patient were improved in KP grading ($p=0.0209$), a 28.9% decrease in the extent of KP ($p=0.0122$), and a decrease in dryness (89.5%) ($p=0.0001$) and roughness (56.3%) ($p<0.0001$) at the treated site (FIG. 1). Image analysis of C-Cube pictures (FIG. 2) confirms the previous results of the dermatologist evaluation. The global assessment by the patient, including roughness and red or pigmented lesions severity also showed a significant decrease of at least 40% (roughness $p=0.0007$; red/pigmented lesions $p=0.001$) at D56.

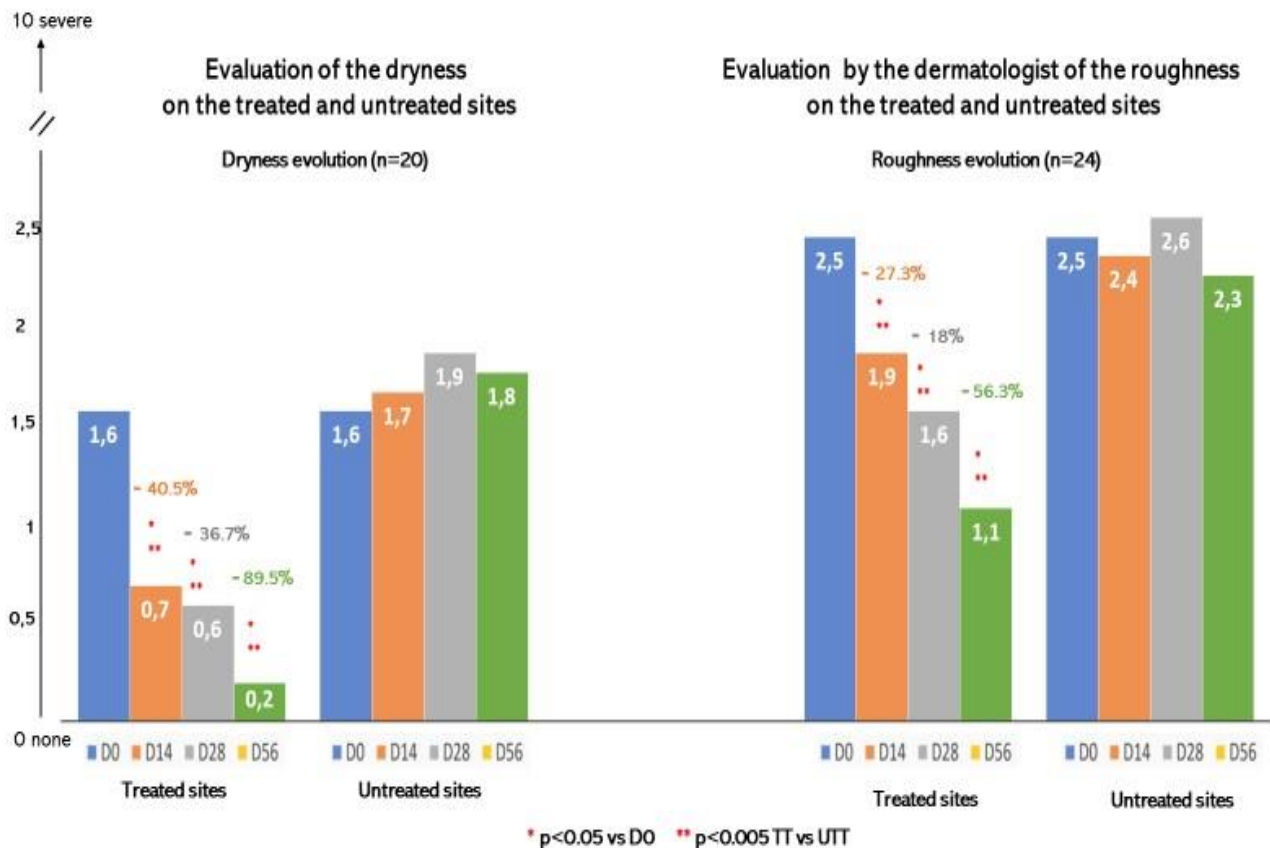


FIG. 1. Variation of the different evaluation criteria.

Compared to the untreated site, all the DLQI scores were significantly lower at D56. Compared to D0, the QOL (Quality of Life) had been improved significantly at D56 (-74.3% DLQI) with a marked impact on symptoms and feelings (-87.5%) and leisure activities (-78.8%). The quality of life of the patients was significantly improved even if KP has low impact on QoL according to patients enrolled in this study (low DLQI value at D0). This study shows the effectiveness of an emollient containing 5% urea associated with 0.2% APF [5], against the symptoms of KP and particularly an improvement of KP grade and a decrease of KP extent. From D14, dryness and roughness were strongly improved. A 3-point difference in DLQI indicates a clinically relevant improvement in patient quality of life [4].

C-CUBE analysis

The roughness observed with C-Cube® acquisitions
(by biometric measurement)

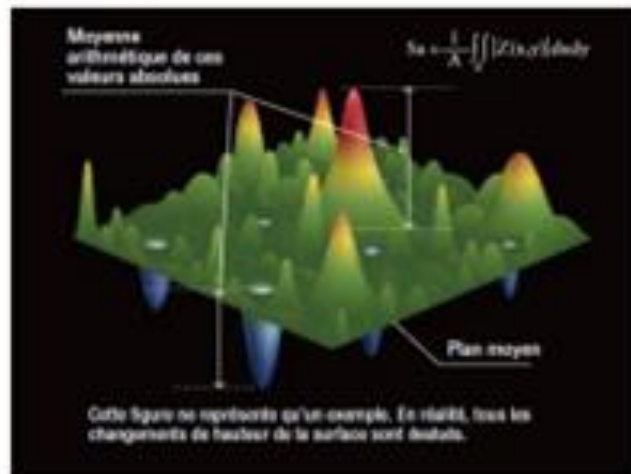


TABLE 1. Roughness evaluation from the C-Cube pictures.

Results of the roughness evolution with the C-Cube pictures

	Treated site			Untreated site		
C-Cube	D14-D0	D28-D0	D56-D0	D14	D28	D56
Roughness-Sa (µm)	-4.739%*	-4.318%*	-4.018%*	-2.199%*	-0.942%	-0.783%
Roughness-Sa (%)	-21.8%	-19.1%	-17.8%	-8.5%	-4%	-1.3%

*p<0.05 (versus D0)

Sa (µm) = the mean height of roughness compared to the mean plane of the surface, significantly decreased

1. Funding

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2. Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

3. Conflict of Interest

S. Seité, AL. Demessant-Flavigny, G Le Dantec are employees of La Roche-Posay, France.

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