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10% urea cream in senile xerosis: Clinical and instrumental evaluation

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Abstract

Background: Moisturizers represent the mainstay of treatment of xerosis and related pruritus in elderly patients.

Aim: In this study, we evaluated the efficacy and tolerability of a 10% urea cream in patients with senile xerosis.

Methods: Twenty patients affected by moderate-to-severe xerosis of the upper or lower extremities were enrolled and instructed to apply twice daily for 2 weeks a cream containing 10% urea. Evaluation was performed at baseline and after 7 and 14 days by: clinical examination, itch assessment using a Visual Analogue Scale (VAS), and dermoscopy.

Results: After 7 and 14 days of treatment, the tested urea-based cream resulted in a significant, progressive clinical improvement of xerosis and related pruritus in all patients. The clinical results were supported by dermoscopy that showed the reduction/disappearance of scales. The cream, that had a good cosmetological acceptability, was well tolerated with no report of stinging or burning and/or other side effects.

Conclusions: Urea confirms to represent a key molecule for the treatment of senile xerosis.

KEYWORDS
dermoscopy, topical treatment, urea cream, xerosis

1 | INTRODUCTION

Xerosis represents a common condition in elderly patients, affecting over 50% of individuals aged ≥65 years.[1,2] The exact etiology of xerosis is not entirely understood, likely depending on several genetic and environmental mechanisms, and changes in the keratinization process and lipid content in the stratum corneum probably represent the main factors in the elderly.[3,4] Xerosis is often associated with pruritus, mainly involving the extremities and more prominent at low temperature and humidity conditions.[2] The quality of life may be highly affected,[2] and scratching can lead to secondary infections or ulcerations and chronic wounds.[3] For these reasons, managing xerosis and maintaining moist skin are mandatory to prevent these complications.[3]

Moisturizers represent the mainstay of treatment of xerosis and related pruritus in elderly patients.[3] In this study, we evaluated the efficacy and tolerability of a 10% urea cream in patients with senile xerosis using clinical and dermoscopy evaluation.

2 | MATERIALS AND METHODS

Twenty patients (12 males and 8 females; aged 65–82 years), affected by moderate-to-severe xerosis of the upper or lower

TABLE 1 Assessment scores: clinical evaluation, itch measured by visual analogue scale (VAS), and dermoscopy evaluation

Score	Clinical evaluation	Itch (VAS)	Dermoscopy evaluation
0	Normal skin	Absent (VAS =0)	No scales
1	Mild xerosis	Mild (VAS =1–3.5)	Mild scales
2	Moderate xerosis	Moderate (VAS =3.6–6.5)	Moderate scales
3	Severe xerosis	Severe (VAS =6.6–10)	Severe scales

extremities, were enrolled and instructed to apply twice daily for 2 weeks a cream containing 10% urea (U-Life™-10). Exclusion criteria were positive history for diabetes and the use of topical moisturizers and/or other topical/systemic treatments for xerosis in the previous 30 days. A mild cleanser was allowed for the study duration. Evaluation was performed at baseline (T_0) and after 7 (T_1) and 14 days (T_2) by clinical examination, itch assessment using a Visual Analogue Scale (VAS), and dermoscopy.

Clinical evaluation was based on the estimation of skin dryness using a four-grade severity score (0 = normal skin; 1 = mild xerosis; 2 = moderate xerosis; 3 = severe xerosis). Itch was measured through VAS using a four-grade severity score (0 = no itch, corresponding to VAS equal to 0; 1 = mild itch, corresponding to VAS values up to 3.5; 2 = moderate itch, corresponding to VAS values between 3.6 and 6.5; 3 = severe itch, corresponding to VAS values between 6.6 and 10). Dermoscopy evaluation was based on the degree of surface scaling using a four-grade severity score (0 = absent scales; 1 = mild scales; 2 = moderate scales; 3 = severe scales). Scores obtained from each assessment were added up so to achieve, for each patient, a total score ranging from 0 to 12 (Table 1). Treatment response was rated as excellent when the total score was reduced by more than 70%, good when it was between 40 and 69%, average if <40%, and poor when <20%. Significance in

TABLE 2 Results: Baseline (T_0), 7 days (T_1) and end of treatment (T_2): mean scores for each item

	T_0	T_1	T_2
Clinical evaluation	2.5	1.05	0.25
Itch (VAS)	2.1	1.2	0.6
Dermoscopy evaluation	2.65	1.35	0.4
Total	7.2	3.6	1.25

difference between means after 7 (T1) and 14 days (T2) was tested by Student *t*-test. Pearson's test was performed to evaluate the correlation among the three scores.

At the end of treatment, patients were also asked to provide acceptability rating of the product based on spreadability, absorbency, odor, pleasantness, and ease of application using a four-grade score (0 = poor; 1 = discrete; 2 = good; 3 = excellent).

The study was conducted in accordance with the ethical principles outlined in the 2008 Helsinki Declaration and all subjects provided written informed consent.

3 | RESULTS

T_0, T_1, and T_2 scores are summarized in Table 2.

At baseline (T_0), the mean clinical score was 2.5 (range: 2–3), the mean VAS score was 2.1 (range: 1–3), and the mean dermoscopy score was 2.65. The mean total score was 7.2 (range: 5–8). After 7 days of treatment (T_1), the mean clinical score was 1.05 (range: 0–2), the mean VAS score was 1.2 (range: 0–3), and the mean dermoscopy score was 1.35 (range: 0–2). The mean total score was 3.6. (range: 0–6). All scores showed a significant statistical improvement ($p < 0.05$). After 14 days of treatment (T_2), the mean clinical score was 0.25 (range: 0–1), the mean VAS score was 0.6 (range: 0–2), and the mean dermoscopy score was 0.4 (range: 0–1). The mean total score was 1.25 (range: 0–3). All scores showed a significant statistical improvement ($p < 0.05$). Pearson's test demonstrated a correlation

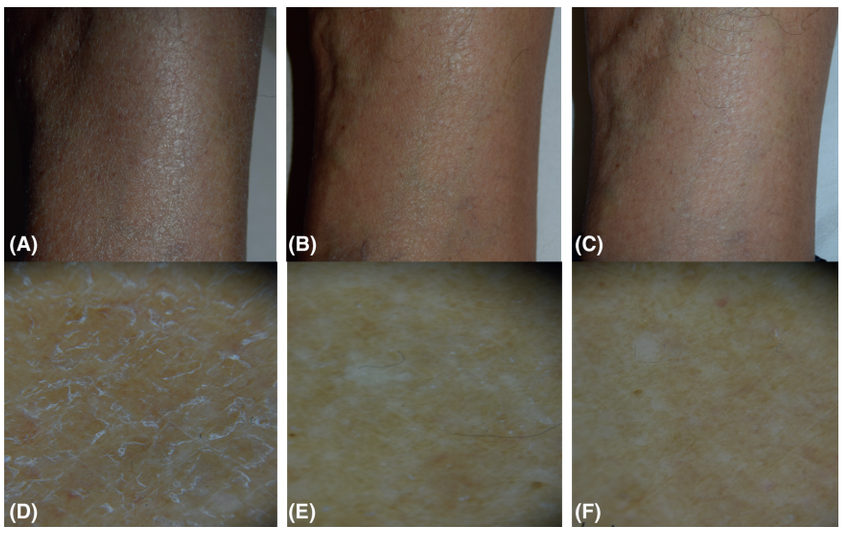

FIGURE 1 A 65-year-old man with severe xerosis of the lower legs. He had been using basic moisturizing with minimal results. Clinical (A–C) and dermoscopic (D–F) evaluation at baseline (A–D) and after 7 (B, E) and 14 days (C–F) treatment with 10% urea cream: excellent response

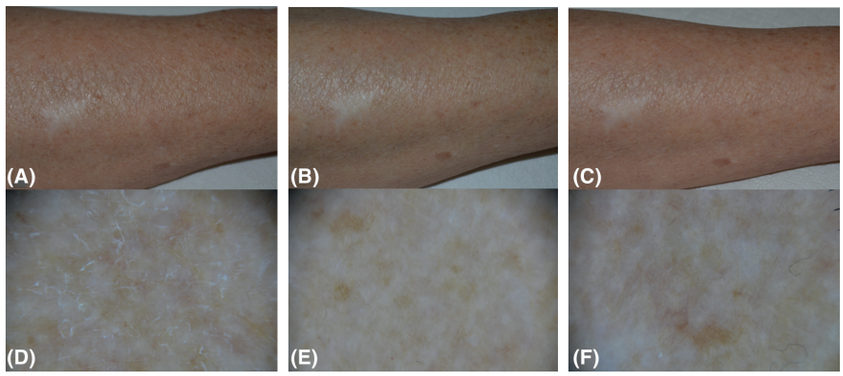

FIGURE 2 A 66-year-old woman with moderate xerosis of the upper arms. She reported limited achievement with moisturizing products and also complained of moderate itch. Clinical (A–C) and dermoscopic (D–F) evaluation at baseline (A–D) and after 7 (B, E) and 14 days (C–F) treatment with 10% urea cream: excellent response

between clinical and dermoscopy evaluation both at baseline, day 7 and 14 (r = 0.73, r = 0.76, r = 0.71, respectively). Overall, at the end of the study the response was excellent in 16 cases and good in the remaining 4 cases (Figures 1 and 2).

No side effects were recorded, and, at the end of the treatment, all patients gave a positive response regarding acceptability, with 14 patients judging the product as excellent, and 6 as good.

4 | DISCUSSION

Urea is a hygroscopic molecule physiologically present on the skin as a component of the complex mixture of the Natural Moisturizing Factor (NMF) that contributes to skin hydration.[5,6] It represents a very useful molecule in dermatology due to its unique moisturizing and keratolytic properties that are exerted in a dose-dependent manner.[6-8] In particular, at low concentrations (2–12%), urea acts as an emollient (filling the gaps between desquamating corneocytes thus contrasting dehydration) and a humectant (attracting water from dermis into epidermis and also from the external environment in humid conditions).[9,10] Moreover, some studies suggest that urea may regulate filaggrin gene expression necessary for proper barrier function maintenance.[10-12] Based on these properties, urea has been topically used for the treatment and prevention of senile xerosis or xerosis associated with skin diseases such as ichthyosis, atopic dermatitis and psoriasis, at concentrations ranging from 2 to 12% in different formulations.[6,13,14] Clinical studies have demonstrated that urea-based topical formulations regulate TEWL and restore the stratum corneum ability to attract and maintain hydration.[11]

In our study, after 7 and 14 days of treatment the tested urea-based cream resulted in a significant, progressive clinical improvement of xerosis and related pruritus in all patients. The clinical results were supported by dermoscopy that showed the reduction/disappearance of scales, thus confirming to represent a valid method for the objective evaluation of xerosis, as previously reported.[11,15] Interestingly, the Pearson's test showed a correlation between clinical and dermoscopy evaluation at all time points. In 16 out of 20 cases, the response was rated as excellent and in four cases good. The cream, that had a good cosmetological acceptability, was well tolerated with no report of stinging or burning and/or other side effects. This is important, as contact dermatitis is common in elderly patients who have used multiple treatments for xerosis.[3] In conclusion, urea confirms to represent a key molecule for the treatment of senile xerosis.

CONFLICT OF INTEREST

None to declare.

ETHICAL STATEMENT

This study received approval by the local ethical committee.

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