INTRODUCTION

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

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

MATERIALS AND 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

2 MATERIALS AND METHODS
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 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](image)

**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.
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.

**REFERENCES**

1. Berger TG, Shive M, Harper GM. Pruritus in the older patient: a clinical review. JAMA. 2013;310(22):2443-2450.
2. Izumi R, Negi O, Suzuki T, et al. Efficacy of an emollient containing diethylene glycol/dilinoleic acid copolymer for the treatment of dry skin and pruritus in patients with senile xerosis. J Cosmet Dermatol. 2017;16(4):e37-e41.
3. White-Chu EF, Reddy M. Dry skin in the elderly: complexities of a common problem. Clin Dermatol. 2011;29(1):37-42.
4. Horii I, Nakayama Y, Obata M, Tagami H. Stratum corneum hydration and amino acid content in xerotic skin. Br J Dermatol. 1989;121(5):587-592.
5. Verzì AE, Musumecc ML, Lacarrubba F, Micagi G. History of urea as a dermatological agent in clinical practice. Int J Clin Pract. 2020;74(Suppl 187):e13621.
6. Lacarrubba F, Nasca MR, Puglisi DF, Micagi G. Clinical evidences of urea at low concentration. Int J Clin Pract. 2020;74(Suppl 187):e13626.
7. Celleno L. Topical urea in skincare: a review. Dermatol Ther. 2018;31(6):e12690.
8. Dall’Oglio F, Tedeschi A, Verzì AE, Lacarrubba F, Micagi G. Clinical evidences of urea at medium concentration. Int J Clin Pract. 2020;74(Suppl 187):e13815.
9. Micagi G, Lacarrubba F. Optimising the use of urea in dermatology. Int J Clin Pract. 2020;74(Suppl 187):e13570.
10. Friedman AJ, von Grote EC, Meckfessel MH. Urea: a clinically oriented overview from bench to bedside. J Drugs Dermatol. 2016;15(5):633-639.
11. Benintende C, Boscaglia S, Dinotta F, Lacarrubba F, Micagi G. Treatment of ichthyosis vulgaris with a urea-based emulsion: videodermatoscopy and confocal microscopy evaluation. G Ital Dermatol Venereol. 2017;152(6):555-559.
12. Danby SG, Brown K, Higgs-Bayliss T, Chittock J, Albenali L, Cork MJ. The effect of an emollient containing Urea, Ceramide NP, and lactate on skin barrier structure and function in older people with dry skin. Skin Pharmacol Physiol. 2016;29(3):135-147.

13. Pan M, Heinecke G, Bernardo S, Tsui C, Levitt J. Urea: a comprehensive review of the clinical literature. Dermatol Online J. 2013;19(11):20392.

14. Micali G, Paternò V, Cannarella R, Dinotta F, Lacarrubba F. Evidence-based treatment of atopic dermatitis with topical moisturizers. G Ital Dermatol Venereol. 2018;153(3):396-402.

15. Hu SC, Lin CL, Yu HS. Dermoscopic assessment of xerosis severity, pigmentation pattern and vascular morphology in subjects with physiological aging and photoaging. Eur J Dermatol. 2019;29(3):274-280.

How to cite this article: Lacarrubba F, Verzì AE, Dinotta F, Micali G. 10% urea cream in senile xerosis: Clinical and instrumental evaluation. J Cosmet Dermatol. 2021;20(Suppl. 1):5-8. https://doi.org/10.1111/jocd.14093