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Feature Article

A daily skincare regimen with a unique ceramide and filaggrin formulation rapidly improves chronic xerosis, pruritus, and quality of life in older adults

Anne Lynn S. Chang, MD [a], Suephy C. Chen, MD, MS [b], Lars Osterberg, MD, MPH [c], Staci Brandt, PA-C, MBA, MS [d], Erika C. von Grote, PhD [e,*], Matthew H. Meckfessel, PhD [e]

[a] Stanford University School of Medicine, Department of Dermatology, USA
[b] Atlanta VA Medical Center, Division of Dermatology and Emory University Department of Dermatology, Division of Dermatology, USA
[c] Stanford University School of Medicine, Department of Medicine, USA
[d] Global Prairie, USA
[e] Galderma Laboratories, L.P, USA

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ABSTRACT

A skin care regimen which significantly improved atopic dermatitis and pruritus was evaluated for its efficacy and acceptability in senior subjects diagnosed with xerosis who also suffer from pruritus. This was an open-label, single-center study, designed to evaluate the daily use of a skin care regimen for 15 days. Assessments were made at baseline, day 8 and day 15 for visual skin dryness, transepidermal water loss (TEWL), hydration, desquamation, subject-perceived itch and quality of life (QoL). Twenty-five subjects, ages 60-73 years, had significantly improved skin visual dryness, hydration, desquamation, itch and QoL at days 8 and 15, relative to baseline ($P < .05$). TEWL was improved, though not significantly. Subjects expressed a high degree of satisfaction with the results. This regimen provides geriatric patients with an easily incorporated skin routine to help improve a common symptom of aging skin which negatively affects QoL.

Introduction

Aging skin is marked by a senescence-related decline in lipid and water content, which ultimately impairs epidermal barrier function. Xerosis and pruritus are consequences of this imbalance and can promote susceptibility to subsequent dermatological disorders.[1,2] Long-term and cross-sectional studies indicate that the prevalence of xerosis among senior adults is 30%–75%, and the severity of xerosis with pruritus progressively worsens with advancing age.[3–6] Xerosis is characterized by dry, scaly, cracked skin which typically affects the lower legs, but can also be present on much greater body surface areas such as the lower back, arms, and torso.[7,8] The symptoms of chronic xerosis and pruritus (itching) can disrupt sleep and cause emotional distress by interfering with daily activities and social interactions.[9,10]

In addition to xerosis, pruritus is also associated with certain systemic disease states and a variety of medications.[2,11,12] Systemic Pruritus is a frequent symptom associated with endocrine disorders, liver and kidney disease, and hematologic diseases.[13] The medications that can cause pruritus are numerous and polypharmacy is common among senior adults, increasing the risk of pruritus in this patient population. Common medications used to treat hypertension, hyperlipidemia, and hormonal disorders can all potentially cause pruritus.[13] Chronic itching can lead to skin damage, increasing the risk of secondary inflammatory dermatoses, infections, and contact dermatitis.[11] In community care settings such as nursing homes and hospitals, where heating and air conditioning are often forced-air systems, the skin's evaporative water loss can be accelerated and difficult to manage.[2] A recent multicenter, cross-sectional prevalence study revealed that 48.8% of nursing home residents and hospital patients ($N = 1710$) had dry skin, with areas such as the feet and legs most often affected.[14]

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* Corresponding author. 2746 Glory Ln Trophy Club, TX 76262, USA.
E-mail address: Erika.vongrote@gmail.com (E.C. von Grote).

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Ceramide content, in proper composition and ratio of cholesterol and free fatty acids, is a requisite for barrier function.[15] A decline in filaggrin, a corneocyte-housed protein and source of filaggrin breakdown products (FBPs), is also a consequence of skin senescence.[16] The FBPs which are mostly pyrrolidone carboxylic acid, urocanic acid, and free amino acids, contribute to the stratum corneum's (SC) acidic pH and are part of the natural moisturizing factors (NMFs) which provide humectant properties and facilitate water retention in the skin.[17–19] Skin senescence is also associated with an imbalance in the keratinization and desquamation process and disintegration of the intracellular tight junction system between corneocytes, increasing barrier permeability.[9]

The breakdown in cellular function that is associated with xerosis in senior adults shares a great degree of similarity to that of atopic dermatitis (AD), an inflammatory skin disease linked to genetic and immunological irregularities.[11,20] As in the case of AD, deficits or breakdowns in normal cellular activities within the SC collectively lead to a compromise in barrier integrity. In xerosis resulting from skin senescence, the progressive neutralization of the SC's protective acid mantle hinders the enzymatic activity necessary for lipid biosynthesis (ceramides mainly), and desquamation of corneocytes.[17,18,21,22]

An over-the-counter (OTC) skincare regimen consisting of a body wash and a moisturizer (available at an average cost of $15 each), which was specifically formulated for chronic xerosis, was shown to improve the skin hydration, skin barrier function, and quality of life in patients with AD-prone skin.[23–27] The similarity between atopic and senescent skin, with respect to clinical symptoms and cellular defects, prompted the present clinical pilot study, which evaluated the performance, tolerability, and safety of this skincare regimen in senior adult subjects diagnosed with xerosis and pruritus. The skincare regimen is formulated with sunflower seed oil (emollient), panthenol (humectant), and shea butter with stearic acid, linoleic acid and catechins (antioxidants). Many of these ingredients represent the mainstays in topical formulations, which are designed to reduce transepidermal water loss (TEWL) and soothe inflammatory dermatoses.[28] Uniquely, this skincare regimen also includes niacinamide (vitamin B_3), hydroxy palmitoyl sphinganine (ceramide), and a patented Filaggrin technology consisting of arginine and sodium pyrrolidone carboxylic acid (sodium-PCA).

The data present here show that this regimen significantly improved visual dryness, skin hydration, and pruritus in as little as one week in older adult subjects. The regimen also significantly improved quality of life (QoL) within one week and was well-liked by all study participants.

Methods

Participants

This clinical study was conducted in accordance with the International Conference on Harmonization (ICH) guidelines and the Declaration of Helsinki and was in compliance with the rules outlined in section 1.61 of the ICH Guidelines for Good Clinical Practice (GCP) regarding vulnerable subjects. Following Institutional Review Board approval and written informed consent, study participants were evaluated for eligibility which included participants 60 years of age or older with diagnoses of xerosis and pruritus made by a board-certified dermatologist. Other inclusion criteria included: no change in usual skincare routine for 30 days prior, daily routine washing of skin for 30 days prior, agreement to bathe/shower daily throughout the study duration, agreement to refrain from swimming and use of hot tubs throughout the study duration, agreement to comply with all study commitments and procedural requirements of the study protocol.

Exclusion criteria at screening included: active skin conditions (or body hair, tattoos, scars) interfering with collection or interpretation of study assessments, use of oral or topical OTC anti-itch treatment for 7 days prior, use of prescription topical anti-itch medication for 30 days prior, use of oral anti-itch medication for 6 months prior, use of oral or topical prescription or OTC retinoids 30 days prior; use of intramuscular (IM) steroids 90 days, administration of non-stable doses of statin lipid medications 30 days prior, a history of unstable hypertension, renal, or cardiac disease, participation in any other clinical trial of a drug, cosmetic or device within 30 days prior to baseline visit, any subjects employed by the study site or otherwise affiliated with the investigational research center.

Study design

This was a within-subject, repeated-measures, pilot study design, consisting of a single group of 25 subjects where subjects served as their own control. This study was performed at a single outpatient center over a 15-day period using open-label products (neither subjects nor investigator was blinded to the product's identity). There were 4 visits during the study: screening, baseline/day 1, day 8 and day 15. Adverse events assessments were conducted for all participants at every visit. All study-related procedures were performed by the contracted research organization, Reliance Clinical Testing Services, Inc.

The study's primary endpoint was the observed change in skin's visual dryness assessed by a board-certified dermatologist. Secondary endpoints were changes relative to baseline in corneometry values, TEWL values, desquamation index scores, and pruritus and QoL questionnaire scores. Safety endpoints were the incidence of adverse events. All statistical analyses were based on the study's safety population, which was defined as all enrolled subjects who received at least one dose of study product.

Data collection

At the screening visit, the Fitzpatrick Skin Type and visual dryness on the lower legs of each participant were assessed by the investigator, a board-certified dermatologist. At the baseline/day 1 visit, an evaluation of the lower legs was conducted for visual dryness. Corneometry was performed on the lower right leg, and TEWL was performed on the lower left leg. D-squame® tape assessments were performed on both lower legs at a site separate from corneometry and TEWL sites. Participants completed the ItchyQuant™ and ItchyQoL™ questionnaires. Participants were given Cetaphil® RestoraDerm® Body Wash and Cetaphil® RestoraDerm® Moisturizer (Galderma Laboratories, L.P., Fort Worth, TX) and instructed on how to use both products according to their specific application requirements, each at least once-daily for 14 days. At the day 8 visit, all assessments were made as described for day 1. Participants completed the ItchyQuant and ItchyQoL questionnaires. At the day 15 visit, all assessments were made as described for day 1 and 8. Participants completed the ItchyQuant and ItchyQoL questionnaires, and a cosmetic acceptability questionnaire upon study completion.

Visual dryness was evaluated by a board-certified dermatologist using a 5-point severity scale (0 = no dryness; 1 = light dryness, some small or wide squame cells; 2 = moderate dryness, a lot of small or wide scales; 3 = severe dryness, a lot of small scales; 4 = very severe dryness, a lot of big scales and/or irritation). Significance in mean change was determined by Wilcoxon Signed Rank test (Intra-Subject Change). Corneometry, a