

# Improvement in Skin Hydration Status Following 8% Ajwa Date (*Phoenix dactylifera L.*) Extract Lotion Application: A Clinical Trial on Xerosis Cutis Patients in an Elderly Population

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## Abstract

**Aim:** Xerosis cutis is expected in the elderly population, which tends to increase. Improving hydration is vital for treating xerosis cutis, including the use of *Phoenix dactylifera L.* or Ajwa dates. In a previous study, a significant increase in skin hydration was observed in participants who received the *Phoenix dactylifera L.* extract. This study aimed to analyze the efficacy of *Phoenix dactylifera L.* lotion 8% to repair the hydration status of patients with xerosis cutis in the elderly population.

**Materials and Methods:** A comprehensive true experimental study was conducted on eligible individuals with xerosis cutis at our hospital from January to February 2024. Participants received both types of lotion, namely 8% Ajwa dates and base lotion, on the right and left arms twice daily for four consecutive weeks. Before treatment and during the second and fourth weeks, skin hydration status was examined using a corneometer, tewameter, and overall dry skin (ODS) score.

**Results:** Among the 30 participants, both treatments had the same baseline skin hydration status. Both treatments showed their effect on hydration status through increased corneometer values (both had;  $P = 0.001$ ), decreased tewameter values (both had;  $P = 0.001$ ), and decreased ODS scores (both had;  $P = 0.001$ ). Moreover, a significant difference was observed between the two treatments at each observation time point for the assessed parameters.

**Conclusion:** Applying *Phoenix dactylifera L.* 8% extract lotion twice daily for 4 weeks can improve hydration in elderly individuals with xerosis cutis.

**Keywords:** Aged, antioxidant, ichthyosis, phoeniceae, skin diseases

## INTRODUCTION

Xerosis cutis is clinically characterized by a diminution or impairment in the moisture retention capacity of the stratum corneum, which is a critical component of skin barrier function. The stratum corneum serves as the first line of defense against external insults and is instrumental in minimizing transepidermal water loss (TEWL).<sup>1,2</sup> Epidemiological studies have established a global prevalence rate ranging from 29% to 85%, underscoring its widespread nature.<sup>3</sup> Clinically, xerosis cutis predominantly manifests in the upper extremities and trunk, with a higher frequency in the arms.<sup>4</sup> The foundational management of xerosis cutis involves enhancing cutaneous hydration, rectifying deficiencies in the lipid barrier, and

augmenting the overall barrier integrity of the skin. To this end, a regimen encompassing both hydrophilic and lipophilic components is advocated to effectively address the multifactorial pathophysiology of xerosis cutis.<sup>5</sup>

*Phoenix dactylifera L.*, commonly known as Ajwa dates, contains antioxidant compounds that attenuate oxidative stress by reducing free radicals.<sup>6</sup> The lipid content of Ajwa dates ranges from approximately 5-13%, encompassing both saturated and unsaturated fatty acids. Notably,

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lauric and oleic acids are the predominant fatty acids. Additionally, Ajwa dates exhibit a notable presence of tocopherols, tocotrienol, phytosterols, and an array of phenolic constituents, enhancing their nutritional profile.<sup>7</sup> The bioactive components within Ajwa dates, including flavonols, flavones, hydroxycyanidin, polysianidin, phenolates, and diverse phenolic acids, play a pivotal role in the inhibition of free radical production, thereby mitigating cellular damage within the skin matrix.<sup>8</sup> Despite the promising phytochemical profile of Ajwa dates, research exploring their potential therapeutic effects on xerosis cutis, particularly within the geriatric demographic, remains sparse. This investigation aimed to delineate the efficacy of a topical formulation derived from *Phoenix dactylifera L.* in ameliorating skin hydration and improving the clinical manifestations of xerosis cutis in elderly patients.

## MATERIALS AND METHODS

### Study Design

In this study, a true experimental with a pre-test and post-test control group was designed to determine the hydration status of the elderly xerosis cutis group who were routinely given 8% Ajwa date extract lotion, compared with those who were given base lotion as the control group. The research was conducted in Makassar City, South Sulawesi, on several elderly individuals from January 2024 to February 2024.

### Study Participants

A total of 30 subjects, comprising 19 female and 11 male participants aged 60-65 years with xerosis cutis, were included in the study. The exclusion criteria were patients with systemic diseases, those who had received topical, hormonal, and retinoids, and those with a history of hypersensitivity to Ajwa dates. Furthermore, patients with a documented history of hypersensitivity reactions to Ajwa dates were considered ineligible. Participants were considered to have withdrawn from the study if they failed to consistently apply a 4% formulation of Ajwa date extract lotion (or a base lotion as control) as prescribed or if adverse effects emerged at any point during the investigation.

### Ajwa Dates and Base-Lotion Preparation

Prepared 8 kg of round and blackish Ajwa dates and separated between the flesh and seeds. The date flesh is cut and then dried. Next, the date extract is made by maceration using a 96% ethanol solvent at a ratio of 1:2 (1 kg of Ajwa dates in 2 liters of solvent); the solution is left for 3x24 hours, then separated to obtain the filtrate and residue. The obtained ethanol filtrate

was evaporated using a rotary vacuum evaporator, thickening the extract in a water bath.

Preparing an Ajwa dates-infused lotion involves a meticulous process that adheres to stringent scientific principles to ensure the compound's stability and efficacy. Initially, precise quantification of the ingredients is essential. These components are segregated into two distinct phases based on their solubility properties and are subjected to controlled heating. The operation occurs in a beaker glass placed over a water bath to maintain a temperature range between 68 °C and 75 °C, facilitating melting. The composition comprises a water phase comprising TEA, glycerin, methylparaben, distilled water, and an oil phase comprising stearic acid, cetyl alcohol, liquid paraffin, and propylparaben. After melting, the oil is transferred to a mortar. Using a swift and consistent stirring technique, the mixture is mixed until homogeneity is achieved. Consequently, the aqueous phase is incrementally incorporated under vigorous stirring to achieve emulsification, which results in a uniform lotion base. The addition of the Ajwa date extract is the final step. This ingredient is meticulously blended into the emulsion to ensure continuous stirring and the formation of a homogenous and stable formulation.

The formulation of 8% Ajwa dates extract lotion is meticulously designed by combining a precise quantity of active and excipient ingredients to create a total batch size of 150 g. The active component, Ajwa date extract, was incorporated at a concentration of 8% w/w, resulting in 12 g of the extract. The excipient framework consisted of 2.5% w/w stearic acid (3.75 grams), serving as the primary emulsifying agent. Cetyl alcohol, included at 0.5% w/w (0.75 grams), functions as a co-emulsifier and stabilizing agent. Triethanolamine (TEA) at a 1% w/w concentration (1.5 grams), is used to adjust the pH and emulsify the lotion. Glycerin, a potent humectant, was added at a 5% w/w concentration (7.5 grams) to enhance skin hydration. Including Nipagin and Nipasol ensures preservation of the formulation, each at a 0.1% w/w concentration (0.15 grams), acting as antimicrobial preservatives. At a 7% w/w concentration (10.5 grams), liquid paraffin served as an occlusive agent, promoting skin barrier function. The vehicle of the lotion was completed with 121.7 grams of distilled water. For control purposes, a base lotion was formulated identically without Ajwa date extract, serving as a comparative standard for evaluating the therapeutic efficacy of the active ingredient. This meticulous formulation ensures a stable and efficacious product suitable for clinical evaluation.

### Intervention Procedure

The subjects in the research were interviewed directly using a prepared questionnaire to collect data on the identity, characteristics, and history of the subjects who signed the

informed consent form. Patients were assessed for epidermal moisture and TEWL using a Corneometer CM 825 (Courage + Khazaka, Cologne, Germany) and a Tewameter TM300 (Courage + Khazaka, Cologne, Germany) at a predetermined location. The examination room was initially prepared with a temperature of approximately 200 °C, relative humidity of 40-60%, and adequate lighting. After that, participants were asked to rest for 10-20 minutes before being examined by leaving the anterior side of the forearm to be examined open. Measurements were also performed on rinsed skin approximately 2 h after the application of Ajwa dates 8% cream. Measurements were taken three times in a row at 5 second intervals under the same pressure. These values were calculated as mean and were recorded as skin hydration and TEWL values. The hydration levels of the skin can be categorized based on their corneometer readings: Values less than 35 indicate a dehydrated skin condition; values ranging from 35 to 50 denote dry skin; and values greater than 50 suggest the skin falls within the normal hydration range. TEWL can be accurately measured using a tewameter. A value less than 8 g/h/m<sup>2</sup> indicates decreased TEWL, reflecting potentially impaired barrier function or underactive transepidermal water movement. Values maintained between 8 and 15 g/h/m<sup>2</sup> are considered normal, indicating a healthy equilibrium of water loss and an effective barrier function. Conversely, TEWL values greater than 15 g/h/m<sup>2</sup> denote increased TEWL, indicating excessive water loss likely due to compromised barrier integrity or heightened transepidermal water migration.

The degree of xerosis cutis was also assessed using the overall dry skin (ODS) score. The parameters that will be evaluated are 0 when there is no dry skin (xerosis), 1 when fine scales, minimal dry and dull skin, 2 when fine-medium scales, light rough skin, and whitish skin color appearance, 3 when fine-rough scales are uniformly distributed, rough skin is visible, mild redness, and some superficial cracks, 4 when dominated by rough scales, rough skin is visible, redness, eczematous changes, and cracks.

The patients were given two types of lotion; the right arm was treated with topical 8% Ajwa date extract lotion, and the left arm was treated with topical base lotion. The patients were instructed to apply the right arm and base lotion to the left arm twice daily for four consecutive weeks. Patients were re-examined at week two and week 4, using a Corneometer CM 825 and Tewameter TM300 at the predetermined location (using mica paper). In addition, the ODS was measured for comprehensive analysis.

### Ethical Consideration

Each respondent who met the inclusion criteria had their identity recorded and received information, as well as a

detailed explanation of what would be done during the study. Furthermore, the participants were asked for their willingness to be involved in the study by signing an informed consent letter. The Health Research Ethics Committee of Hasanuddin University Faculty of Medicine (approval number: 64/UN4.6.4.5.31/PP36/2024; protocol number: UH23120891, date: 25.01.2024) evaluated and approved the entire research protocol. No personal data were obtained, and confidentiality was ensured.

### Statistical analysis

The initial examination involved a comprehensive analysis of the frequency distribution, mean, standard deviation, and range. To substantiate the normality of the sample, the Kolmogorov-Smirnov test was applied meticulously, ensuring robust assessment of distribution characteristics. Given the deviation from the normal distribution observed within the data, our statistical methodology was carefully curated to address non-parametric conditions. The Friedman test was strategically employed to analyze more than two related samples, providing a powerful alternative to parametric equivalents by not assuming a normal distribution. Comparative analysis between two related samples necessitated the application of the Wilcoxon signed-rank test, which is recognized for its efficacy in handling non-parametric data. In scenarios necessitating the comparison of two independent samples, the selection of statistical tests was predicated on the data distribution characteristics. The independent samples t-test was deemed appropriate for datasets adhering to normality, providing precise metrics for evaluating mean differences between groups. Conversely, the Mann-Whitney U test was utilized for datasets that deviated from the normal distribution, facilitating a robust comparison that did not hinge on distributional assumptions. Statistical significance was determined using a threshold *P* value of  $\leq 0.05$ , underscoring the rigorous criteria for assessing the reliability of findings. All statistical procedures were executed within the SPSS version 23.0 (IBM Software, USA).

## RESULTS

The total number of subjects included in this study was 30 samples. No participants who experienced side effects or did not complete the entire lotion application schedule were excluded from the study. The baseline characteristics of the participants are presented in Table 1. The mean age of the subjects was 62.03±1.59 years, and the majority were female 63.33% of the sample.

Table 2 compares the chronometer values at all measurement times and intervention groups. At weeks 2 and 4, the arm

treated with 8% Ajwa date extract lotion had a significantly higher corneometer score than the arm treated with base lotion ( $P < 0.05$ ). The results of the Friedman test showed a significant difference in the average corneometer scores at weeks 0, 2, and 4 for arms treated with 8% Ajwa date extract lotion and base lotion ( $P < 0.05$ ).

Table 3 compares the tewameter values at all measurement times and intervention groups. In weeks 2 and 4, the results showed that the arm treated with 8% Ajwa date extract lotion had a significantly lower tewameter score than the arm treated with base lotion ( $P < 0.05$ ). The results of the Friedman test showed a significant difference in the average tewameter scores at weeks 0, 2, and 4 for arms treated with 8% Ajwa date extract lotion and base lotion ( $P < 0.05$ ).

**Table 1. Baseline characteristics of study participants**

Characteristics	Mean $\pm$ SD/n(%)
Age (years)	62.03 $\pm$ 1.59
<b>Gender</b>	
Male	11 (36.67%)
Female	19 (63.33%)

SD: Standard deviation

Table 4 compares the ODS scores at all measurement times and intervention groups. In weeks 2 and 4, the results showed that the arm treated with 8% Ajwa date extract lotion had significantly lower ODS scores than the arm treated with base lotion ( $P < 0.05$ ). The results of the Friedman test showed a significant difference in the average ODS scores at weeks 0, 2, and 4 for arms treated with 8% Ajwa date extract lotion and base lotion ( $P < 0.05$ ).

## DISCUSSION

Aging induces numerous physiological alterations in cutaneous structures that significantly impact the dermatological health of individuals aged  $> 60$  years. One of the most prevalent outcomes of aging is xerosis, which has profound implications for skin integrity and function. Central to this process is the role of the stratum corneum, predominantly composed of differentiated keratinocytes, which function as a critical barrier against environmental insults and water loss.<sup>9</sup> The deterioration in barrier function observed with advancing age can be attributed to several fundamental changes: a reduction in the lipid content on the skin surface, a decline in the rate of keratinocyte proliferation, and alterations in the composition

**Table 2. Comparison of corneometer results according to time and intervention**

Time of measurement	8% Ajwa date extract lotion	Base lotion	p <sup>b</sup>
	Mean $\pm$ SD	Mean $\pm$ SD	
Week-0	44.03 $\pm$ 6.44	43.39 $\pm$ 6.06	0.311
Week-2	71.61 $\pm$ 14.01	62.88 $\pm$ 6.65	0.007*
Week-4	104.84 $\pm$ 12.30	86.94 $\pm$ 7.19	0.001*
p <sup>a</sup>	0.001*	0.001*	

<sup>a</sup>Friedman test, <sup>b</sup>Mann Whitney test, \*significantly different at  $P < 0.05$ . SD: Standard deviation

**Table 3. Comparison of tewameter scores according to time and intervention**

Time of measurement	8% Ajwa date extract lotion	Base lotion	p <sup>b</sup>
	Mean $\pm$ SD	Mean $\pm$ SD	
Week-0	13.59 $\pm$ 1.11	14.14 $\pm$ 1.12	0.060
Week-2	10.93 $\pm$ 1.13	12.11 $\pm$ 1.11	0.001*
Week-4	8.59 $\pm$ 0.72	10.43 $\pm$ 0.93	0.001*
p <sup>a</sup>	0.001*	0.001*	

<sup>a</sup>Friedman test, <sup>b</sup>Mann Whitney test, \*significantly different at  $P < 0.05$ . SD: Standard deviation

**Table 4. Comparison of ODS results according to time and intervention**

Time of measurement	8% Ajwa date extract lotion	Base lotion	p <sup>b</sup>
	Mean $\pm$ SD	Mean $\pm$ SD	
Week-0	2.00 $\pm$ 0.79	2.03 $\pm$ 0.81	0.869
Week-2	1.10 $\pm$ 0.61	1.50 $\pm$ 0.68	0.027
Week-4	0.30 $\pm$ 0.47	1.00 $\pm$ 0.53	0.001*
p <sup>a</sup>	0.001*	0.001*	

<sup>a</sup>Friedman test, <sup>b</sup>Mann-Whitney U test, \*significantly different at  $P < 0.05$ . SD: Standard deviation, ODS: Overall dry skin

of the stratum corneum. These changes lead to enhanced TEWL and compromised skin moisture retention.<sup>3</sup>

Most patients with xerosis cutis in this study were female, accounting for 63.33%. These results are consistent with a previous study, which found that 15.49% of men and 84.51% of women had xerosis cutis. Similar findings were reported in another study, which showed that 99.1% of geriatric patients suffered from xerosis cutis, of whom 67.7% were women. This gender difference is attributed to higher and more stable sebum production in men than in women. Additionally, it has been reported that men's hand skin has a thicker dermis, whereas women's skin has a thinner hypodermis.<sup>3,10</sup> Ceramide decreases with age and vary based on sex and endocrine factors, such as hormones in women.<sup>5</sup> The number of estrogen receptors is higher in women than in men. Estrogen increases dermal hyaluronic acid levels, resulting in increased water content in the dermis. Estrogen deficiency accelerates xerosis. These changes are caused by structural alterations in the skin, such as decreased collagen content, dermal thickness, and elastin fibers.<sup>11</sup> Estrogen deficiency also contributes to skin dryness.<sup>12</sup>

Xerosis cutis is characterized by diminished hydration within the stratum corneum, leading to an inability of the stratum corneum to maintain an optimal water concentration gradient between the viable epidermal cells and the skin surface. This condition is characterized by a series of physiological changes, including reduced sebum and sweat production, inadequate cellular turnover, compromised functionality of the skin barrier, and escalation in TEWL.<sup>13</sup> The fundamental strategies for the topical management of xerosis cutis include enhancing skin hydration, addressing deficits in the lipid barrier, and fortifying the integrity of the skin barrier. Effective skin care regimens should focus on restoring the stratum corneum, leveraging natural moisturizing factors (NMF) present in corneocyte, and improving the functionality of the associated intercellular lipid matrix. The goal of optimal topical management for xerosis cutis is to closely replicate or rehabilitate the diverse constituents of the skin's protective barrier, thereby reinstating its protective function.<sup>5</sup>

Xerosis cutis, or dryness of the epidermal layer of the skin, caused by the stratum corneum, is characterized by a decrease in the quality and quantity of hydrophilic substances and lipids. Reduced hydration in the skin layers disrupts the normal regulation of skin homeostasis. Although normal in small amounts, water molecules lost from the stratum corneum can be dangerous if the amount exceeds the limit. This can result in NMF dysfunction in the stratum corneum, leading to skin moisture loss. NMF plays a crucial role in maintaining hydrated structures under conditions of disrupted hydration. The lipid matrix of the stratum corneum enclosing the corneocyte layer periodically desquamates to maintain

a healthy skin texture. Skin-barrier dysfunction causes the skin to experience dryness beyond normal limits and cannot prevent excessive moisture loss due to the stratum corneum.<sup>11</sup>

Effective management of xerosis, which is characterized by dry, rough, and scaly skin, focuses on enhancing barrier function and augmenting stratum corneum hydration. Within the stratum corneum, lipids-comprising ceramides, fatty acids, and cholesterol in roughly equal molar ratios-are vital in maintaining cutaneous barrier permeability and in various physiological and pathological states. These lipids form orderly, dense, flattened arrays within the stratum corneum, which contribute to its barrier properties.<sup>14</sup> The physiology of skin lipids and NMF undergo changes associated with aging, potentially leading to xerosis, even in the absence of overt dermatologic conditions among the elderly population. In this context, moisturizers that incorporate lipids and NMF are recognized for their efficacy in treating xerosis, thereby beneficial for aging and pathologically affected skin.<sup>15</sup> These formulations act by depositing a lipophilic layer over the skin surface and replenishing the intercellular lipid matrix, thus enhancing the skin barrier function.<sup>5</sup> In light of these findings, formulations such as lotions infused with Ajwa date extract, which is rich in beneficial lipids, are promising therapeutic approaches. By replenishing the intercellular lipid matrix, these lotions may facilitate the improvement of skin-barrier functionality, providing a novel intervention for effectively managing xerosis.

Ajwa dates are reported to contain bioactive compounds, including flavonoids, such as flavanols, flavonols, flavones, hydroxycinnamates, polysianidins, phenolates, and phenolic acids, that inhibit the production of free radicals that cause cell damage to the skin.<sup>5,16</sup> The types of polyphenols in Ajwa dates include phenolic acids, flavonoid glycosides, hydroxycinnamates, and proanthocyanidin oligomers. There was a strong relationship between the total phenol content and the antioxidant activity of Ajwa dates. Phenolic content can significantly reduce intracellular ROS content.<sup>17,18</sup>

The polyphenol content has a high level of polymerization, thus providing an antilipidemic effect, which is the basis for xerosis cutis due to reduced natural barrier function or a lack of moisturizing factors in the skin. Polyphenols, such as flavonoids, can also prevent skin fibroblasts from aging by targeting cellular pathways that are important for modulating cellular aging and the secretion of senescence-associated secretory phenotypes. The efficacy of polyphenols on dry and aging skin fibroblasts is primarily attributed to Ajwa dates, which can reduce ROS and inflammation. Topical administration of flavonoids has been shown to increase skin hydration by increasing aquaporin expression.<sup>16</sup>

Ajwa dates comprise a notable concentration of tocopherol, averaging 70.75 mg per 100 g, with a distribution of isomers where  $\alpha$ -tocotrienol predominates at 30.19%, followed by  $\gamma$ -tocopherol at 23.61%,  $\gamma$ -tocotrienol at 19.07%, and  $\alpha$ -tocopherol at 17.52%. These dates are also rich in phenolic compounds and tocopherols, and they are recognized for their potent antioxidant properties. These bioactive components are critical for modulating several physiological processes, including the maintenance of skin barrier homeostasis, modulation of inflammatory responses, and facilitation of wound repair mechanisms. Of particular interest is the role of  $\gamma$ -tocopherol, found in higher concentrations in Ajwa dates than in other sources. This isomer exhibits superior efficacy over  $\alpha$ -tocopherol in the human epidermis by inhibiting the synthesis of prostaglandin E2 and nitric oxide. Moreover, it provides protective measures against water loss, UVB-induced lipid peroxidation, and oxidative stress, thereby contributing to the epidermis's integrity and protective barrier function.<sup>7,18</sup>

### Study limitations

Prior research has not explored the impact of topical application of 8% Ajwa date extract lotion on xerosis cutis in elderly individuals, presenting a novel aspect of this investigation. However, the study is subject to certain limitations, including the exclusive use of a single vehicle and the concentration of the intervention. The study did not include a control group comprising healthy subjects for comparison. In addition, further analyses need to be conducted, including emulsion stability tests, antioxidant capacity tests, fatty acid analysis, toxicity testing, formulation development, and patch testing, to ensure the efficacy and safety of this lotion.

### CONCLUSION

Applying 8% Ajwa date extract lotion can improve hydration in elderly patients with xerosis cutis. Similar studies can be conducted using various Ajwa date vehicles and by varying the concentration of Ajwa date extract in the vehicle to optimize the hydration status effects.

### Footnote

**Ethics Committee Approval:** The Health Research Ethics Committee of Hasanuddin University Faculty of Medicine (approval number: 64/UN4.6.4.5.31/PP36/2024; protocol number: UH23120891, date: 25.01.2024) evaluated and approved the entire research protocol.

**Informed Consent:** The subjects in the research were interviewed directly using a prepared questionnaire to collect data on the identity, characteristics, and history of the subjects who signed the informed consent form.

### Authorship Contributions

Concept: F.D.L., N.N.W., A.R.N., F.T., W.W., A.A.Z., Design: F.D.L., N.N.W., A.R.N., F.T., W.W., A.A.Z., Data Collection or Processing: F.D.L., Analysis or Interpretation: F.D.L., N.N.W., A.R.N., F.T., W.W., A.A.Z., Literature Search: F.D.L., Writing: F.D.L., N.N.W., A.R.N., F.T., W.W., A.A.Z.

**Conflict of Interest:** The authors declared that they have no conflict of interest.

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