Original Article

Efficacy of 3% *Moringa Oleifera Lam* Leaf Extract Cream in Improving Xerosis Cutis in Patients with Type 2 Diabetes Mellitus

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Abstract

Background: *Moringa oleifera Lam* (*M. oleifera Lam*) leaves are plants that grow abundantly in Indonesia and are used as phytopharmaceutical. *Moringa oleifera Lam* leaves contain antioxidant, fatty acids, amino acids, vitamins, and minerals. These ingredients are involved in skin barrier, hydration, antioxidants, and anti-inflammatory, but the studies on the benefits of phytopharmaceutical plants on improving xerosis cutis in patients with type 2 diabetes mellitus (DM) are still limited.

Objectives: To assess the efficacy of 3% *M. oleifera Lam* leaf extract cream in reducing xerosis cutis in patients with type 2 DM.

Methods: Pilot study with pretest-posttest experimental design during April-August 2024. Parameters of Overall Dry Skin score (ODSS), tewameter, corneometer, sebumeter, and visual analogue score (VAS) were observed at baseline, 2 and 4 weeks. Dermatology Quality of Life Index (DLQI) was observed at pre- and post-treament.

Results: The total subjects were 66.7% females and 33.3% males, with a mean age of 64.53 ± 8.74 years. The grade 2 ODSS group of 43.4% at baseline had significant improvement at 4 weeks (p<0.001). The comparison of transepidermal water loss (TEWL) between baseline and 4 weeks showed a mean decrease of 16.94 ± 5.43 g/m^2/h (p<0.001) and hydration levels increase with a mean of -23.50 ± 10.09 AU (p<0.001). The improvement that resulted in normal sebum was 6.7% (p=0.500). The VAS of subject decreased and a significant difference in DLQI. Adverse effects of extract cream were not found in this study.

Conclusion: Treatment of xerosis cutis in patients with type 2 DM using 3% *M. oleifera Lam* leaf extract cream gives good results, but further study is required.

Keywords: *M. oleifera Lam* leaf extract, skin barrier, skin hydration, type 2 DM, xerosis cutis.

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Introduction

Moringa oleifera Lam leaves are phytopharmaceutical plants widely used as traditional medicine in tropical and subtropical countries. Currently, the leaves of *M. oleifera Lam* are widely distributed in Indonesia from Aceh to Merauke, with various names for each region, commonly known as *Moringa* leaves. *Moringa oleifera Lam* is also known as a miracle tree, mother's best friend, drumstick tree, or horse radish tree.[1] The leaves of *M. oleifera Lam*, which are extensively grown in Indonesia, are frequently utilized as medicine by the local population.[2] Most people use *M. oleifera Lam* leaves for DM, hyper-

tension, cholesterol, gout, cancer, and stomach diseases.[1]

Nowadays, the community makes extensive use of traditional medicine. The benefits of phytopharmacology include low side effects, affordability, community acceptance, and the ability to be employed in areas with limited access to medical services.[1,3] *Moringa oleifera Lam* leaves contain active compounds of antioxidants, essential acids, amino acids, vitamins, and minerals.[1,4] The bioactive content of *M. oleifera Lam* leaf extract cream have potential as a moisturizer, antioxidant, and anti-inflammatory.[1,4] In DM patients, topical moisturizers are frequently used to treat xerosis cutis.[5]

Xerosis cutis is a skin abnormality in the form of hydro-lipid deficiency, characterized by dull skin color, rough texture, redness, scales, fissures. It may also be accompanied by burning, tightness, pain, and pruritus.[6] Xerosis cutis is estimated to affect 42.7% of DM patients.[7] Legiawati *et al,* found 159 patients of type 2 DM with xerosis cutis.[8] Damayanti *et al,* reported DM was significantly associated with xerosis cutis in 47 of 299 elderly patients.[9] The cases of xerosis cutis at the Dermatology, Venereology, and Aesthetic Outpatient of Mohammad Hoesin General Hospital Palembang in 2021-2023 was 56 cases.[10]

Xerosis cutis is caused by impaired skin barrier function, decreased stratum corneum hydration,[11] imbalances of natural moisturizing factors (NMF), and intercellular lipids. Xerosis cutis in DM begins with chronic hyperglycemia causing the formation of advanced glycation end products (AGEs), proinflammatory cytokines, and oxidative stress.[8] Stingeni *et al,* using the ODSS reported the most grade 1 and 2 xerosis in type 2 DM patients. Diabetes mellitus patients' QOL may be impaired by xerosis cutis.[12]

Moringa oleifera Lam leaves contain chemicals that are advantageous. According to experimental studies, the essential fatty acids improve hydration, decrease inflammation and irritation, and produce an occlusive layer that retains moisture.[13] Skin moisture increased steadily for 12 weeks while TEWL significantly decreased in the *M. oleifera Lam* leaf extract cream group. Roman *et al,* supports the moisturizing effect of *M. oleifera Lam* leaf extract gel after 2 hours of application, there is an increase in stratum corneum hydration and sebum levels compared to the control.[13] The effects of *M. oleifera Lam* leaf on type 2 DM patients' xerosis cutis have not been studied. Therefore, the researcher is interested in investigating the effects of a 3% leaf extract cream from M. oleifera Lam on type 2 DM patients' xerosis cutis.

Methods

This study is a pilot study of one-group pretest-posttest clinical trial assessing the efficacy of 3% *M. oleifera Lam* extract cream to xerosis cutis in patients with type 2 DM from April – August 2024. The leaf samples have been tested for plant determination through organoleptic test. A 3% leaf extract cream of *M. oleifera Lam* was produced in partnership with the Pharmacy Department at Sriwijaya University in Palembang.

The pilot research method was used to determine the number of participants. Exclusion and inclusion criteria were applied to select the sample. Inclusion criteria were type 2 DM patients with xerosis cutis aged 45 years or older and signed informed consent. Individuals who did not follow the protocol, quit the study, or didn't maintain control for more than two weeks were excluded. The extract cream was applied 4.5 fingertip units (FTU) or 2.25 grams each on the right and left lower limbs every morning and night, approximately 3 minutes after bathing. Measurements of ODSS, TEWL (*Tewameter*® TM 300), skin hydration (*Corneometer*® CM 825), sebum (*Sebumeter*® SM 815), DLQI, VAS, and side effects of subjects were conducted every 2 weeks.

Data were analyzed using Statistical Package for the Social Sciences (SPSS, Inc, Chicago, Illinois; 2017) ver 26.0. Quantitative data were expressed as mean and standard deviation (SD). Qualitative data were presented as proportions or percentages. We conducted an outcome variable study on ODS score, TEWL, skin moisture, sebum levels, and QOL, using bivariate data analysis (paired T test, Wilcoxon, marginal homogeneity, Mc

Nemar) and multivariate data analysis (backward linear regression) before and after treatment.

Results

The demographic variables of study subjects are shown in Table 1. This study comprised of 10 male (33.3%), and 20 female (66.7%), with the male female ratio was 1:2. The largest age group was 55-64 years old as many as 12 subjects (40%). Most of the study subjects (n=13, 43.3%) with the education were diploma-bachelor. Housewives made up almost all of the subjects' occupations (40%). The majority of the cases had xerosis cutis over 6 weeks. Twenty subjects (66.7%) had type 2 DM disease for <5 years. Out of 16 subjects, 53.3% had HbA1c levels >6.5.

Table 2 presents the ODSS, TEWL, skin hydration, and sebum levels that were measured at baseline, 2 and 4 weeks. Thirteen subjects (43.4%) had grade 2 ODS at baseline, 15 subjects (50%) had grade 1 ODS at 2 weeks, and 19 subjects (63.4%) had no xerosis at 4 weeks. Up to 30 subjects (100%) had a mean TEWL of 25.66 ± 5.89 g/m²/h at baseline, and all subjects achieved normal TEWL at 4 weeks, with a mean of 8.72 ± 2.09 g/m²/h. Most subject' skin hydration levels were extremely dry at baseline; this comprised 60% subjects with a mean of 28.21 ± 7.59 AU, and it improved to 80% at 4 weeks with a mean of 51.71 ± 9.04 AU. All subjects had dry sebum levels at baseline (0.43 ± 0.57 µg/cm²). At 4 weeks, 2 subjects were able to achieve normal sebum (2.67 ± 2.12 µg/cm²).

Table 1: *The demographic variables of study subjects.*

Characteristics	Total n (%)	Mean (SD)
Gender		
• Male	10 (33.3)	
• Female	20 (66.7)	
Age, years		64.53 (8.74)
• 45-54	3 (10)	
• 55-64	12 (40)	
• 65-74	11 (36.7)	
• ≥75	4 (13.3)	
Education		
• Elementary school	3 (10)	
• Junior high school	2 (6.7)	
• Senior high school	12 (40)	
• Diploma-bachelor	13 (43.3)	
Work		
• Civil servant	10 (33.3)	
• housewives	12 (40)	
• Self-employed	4 (13.3)	
• Not work	4 (13.3)	
Xerosis cutis duration		1.97 (0.18)
• <6 weeks	1 (3.3)	
• >6 weeks	29 (96.7)	
DM Duration		1.33 (0.48)
• ≤5 years	20 (66.7)	
• >5 years	10 (33.3)	
DM medication		
• Sulfonylurea	3 (10)	
• Biguanide	10 (33.3)	
• Alpha Glucosidase inhibitors	1 (3.3)	
• DPP-IV inhibitors	1 (3.3)	
• Insulin	11 (36.7)	
• Combination	4 (13.3)	
HbA1c levels		
• ≤6.5 %	14 (46.7)	
• >6.5 %	16 (53.3)	
Comorbid disease		
• Hypertension	14 (46.7)	
• No comorbid	16 (53.3)	

TEWL Analysis

The average TEWL analysis at each measurement duration is shown in Figure 1A. There was a significant decrease in TEWL between baseline, 2 and 4 weeks after the administration of 3% *M. oleifera Lam* extract cream with a mean of 16.94 ± 5.43 g/m²/h (p<0.001). The results of the analysis showed a significant decrease in the TEWL of all 30 subjects (100%) at 4 weeks (p<0.001), indicating that 3% *M. oleifera Lam* extract cream can reduce TEWL.

Skin Hydration

A comparison of skin hydration level measurements between baseline and 4 weeks showed a significant mean increase of -23.50 ± 10.09 AU (p<0.001) (Figure. 1B). Improvement of subjects with very dry skin hydration at baseline 60% to dry 33.3% and moderately moist 66.7%, while dry

Table 2: *Xerosis cutis characteristics.*

Characteristics	Baseline		2 weeks		4 weeks	
	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)
ODSS						
• 0	0 (0)		6 (20)		19 (63.4)	
• 1	7 (23.3)		15 (50)		10 (33.3)	
• 2	13 (43.4)		9 (30)		1 (3.3)	
• 3	10 (33.3)		0 (0)		0 (0)	
TEWL (g/m²/h)	25.66 (5.89)		13.84 (4.91)		8.72 (2.09)	
• Increased	30 (100)		8 (26.7)		0 (0)	
• Normal	0 (0)		22 (73.3)		30 (100)	
Skin hydration (AU)	28.21 (7.59)		43.31 (10.39)		51.71 (9.04)	
• Very dry	18 (60)		2 (6.6)		0 (0)	
• Dry	12 (40)		17 (56.7)		6 (20)	
• Sufficiently moisturized	0 (0)		11 (36.7)		24 (80)	
Sebum (µg/cm²)	0.43 (0.57)		1.7 (0.87)		2.67 (2.12)	
• Dry	30 (100)		30 (100)		28 (93.3)	
• Normal	0 (0)		0 (0)		2 (6.7)	
VAS						
• No pruritus	0 (0)		14 (46.7)		27 (90)	
• Mild pruritus	0 (0)		11 (36.7)		3 (10)	
• Moderate pruritus	19 (63.3)		5 (16.6)		0 (0)	
• Severe pruritus	11 (36.7)		0 (0)		0 (0)	
• Very severe pruritus	0 (0)		0 (0)		0 (0)	

skin hydration became sufficiently moisturized 100% at 4 weeks (p<0.001).

Sebum Levels

Statistical analysis comparing baseline, 2 weeks, and 4 weeks showed that applying 3% *M. oleifera Lam* extract cream increased sebum levels (p<0.001) (Figure 1C). At 4 weeks, 27 subjects had increased sebum production, while 3 subjects had no change in sebum levels. A total of 2 subjects (6.7%) who experienced improvement reached normal sebum levels (>6 µg/cm²) and 28 subjects (93.3%) with dry sebum levels (0-6 µg/cm²) (p=0.500).

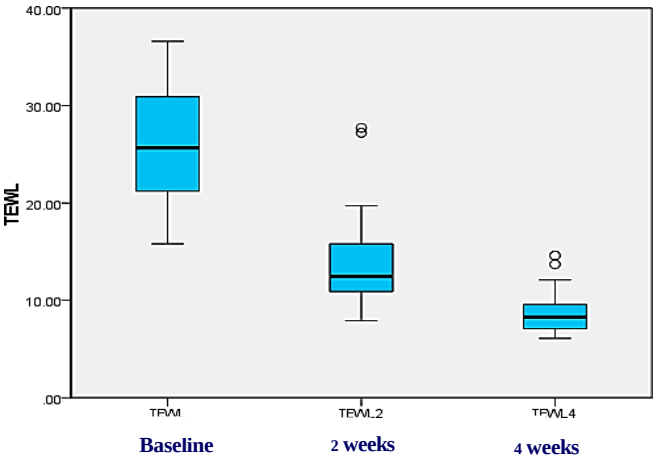
Pruritus and DLQI

Significant improvement in subjects with mild pruritus to no pruritus (10.5%), moderate pruritus to no pruritus (89.5%), and severe pruritus to no pruritus (90.9%) following therapy. According to this, 3% *M. oleifera Lam* extract can lessen pruritus for 4 weeks. The subject's DLQI decreased, as seen by the 4-week mean of 0.63 ± 0.81 compared to the baseline of 11.37±2.65.

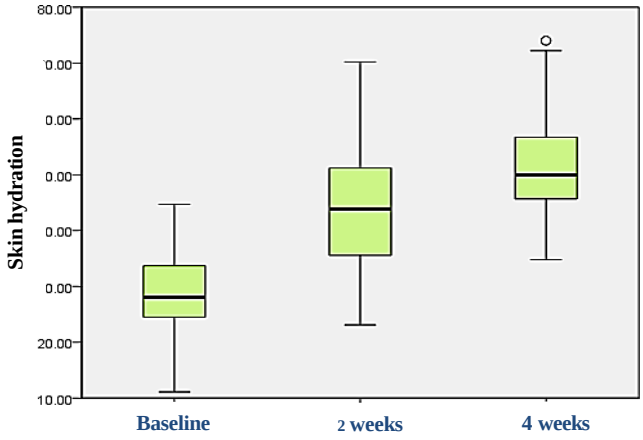
Multivariate analysis of several factor variables, age was found to influence sebum levels (p<0.05). The assessment of topical side effects was based on subjective complaints (pruritus, pain, burning) and objective (Draize score). After 4 weeks of observation, subjects showed no adverse effects.

Discussion

Skin alters continuously as a result of impaired corneocyte cohesiveness, peripheral vascular disease, peripheral neuropathy, microcirculation abnormalities, and alterations in skin barrier function are some of the multifactorial causes of xerosis cutis in patients with type 2 DM. Additionally, xerosis-induced pruritus might reduce a patient's quality of life.[12] In this study, 20 out of 30 subjects (66.7%) were female. At 40%, housewives were the most prevalent occupation. In a study with 159 subjects, Legiawati *et al,* also iden-



(A)



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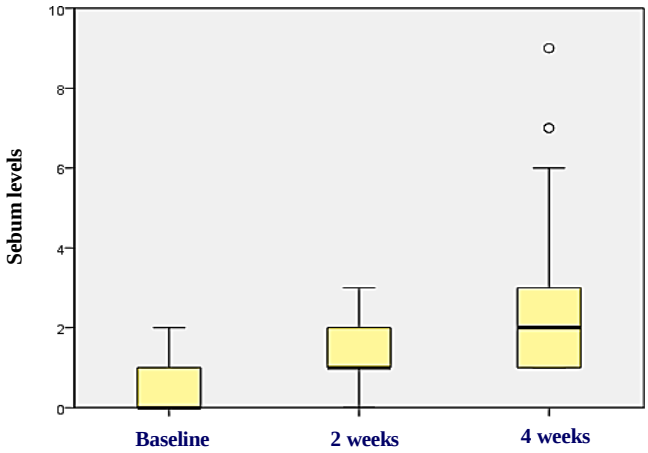

(C)

Figure 1: ***(A):*** *Comparison of mean TEWL depletion.* ***(B):*** *skin hydration,* ***(C):*** *and sebum levels improvement at each measurement time with 3% M. oleifera Lam extract cream.*

tified 75.4% were female who were mainly housewives (59.7%).[8] Due to a decline in the hormone estrogen, female sebum secretion significantly dec lines, whereas male sebum secretion is higher and lasts until age 70. Estrogen causes an increase in hyaluronic acid, which enhances the dermal water content. This may explain why women's skin is more at risk of xerosis.[14] Women's lifestyle and work habits such as sun exposure, wet work, or contact with irritants can increase the risk of xerosis in patients with DM.[12]

Elderly DM patients frequently get xerosis cutis between 26-44% of the time.[12] In this study, the majority of subjects were of age 55-64 years (40%). Fitriani *et al,* reported 72.5% of patients with type 2 DM aged 60-74 years.[15] Similar to Lai *et al*'s, study found a mean age of 58 years (10.9%) in 73 study subjects.[16] The hydration of the stratum corneum will decrease after the age of 40 years. Some of the underlying mechanisms include decreased stratum corneum lipid content, filaggrin and its metabolites, NMF, sebum and glycerol. The reduction of 17β-estradiol in postmenopausal women is linked to a decline in dermal cellular and homeostatic processes. Degradation of cells and extracellular components leads to xerosis, wrinkles, atrophy, a reduction in the function of the skin barrier, and antioxidant defense against oxidative stress. This is caused by a loss of collagen, elastin, fibroblast function, decreased vascularization, and increased MMP activity.[14]

Most subjects had diabetes for <5 years (66.7%), many took biguanides (33.3%) and insulin (36.7%), and HbA1c values were > 6.5% (53.3%). HbA1c levels were 7.46 ± 1.6%, and the average duration of type 2 DM using biguanides (73.6%) was 14.1 ± 10 years, which is different from the study by Stingeni *et al*. However, no significant relationship was found between xerosis with the length of DM and HbA1c levels.[11]

Thirteen subjects (43.4%) had grade 2 xerosis at baseline, according to this study's prevalence of subjects. These findings are comparable to those of 327 xerosis subjects with type 2 DM who stated that grade 1 and 2 xerosis affected 107 subjects

(35.7%).[11] Three subjects demonstrated a decrease in grade 2 xerosis to grade 1 (23.1%) and 10 subjects (76.9%) experienced no xerosis following 4 weeks of administration with *M. oleifera Lam* extract cream. The findings show that applying a 3% *M. oleifera Lam* extract cream significantly reduced the severity of xerosis.

Differences in DM skin are caused by continuous disruption of inter-corneocyte cohesion, disruption of moisture in the epidermis layer, and changes in skin barrier function.[11] When the skin barrier is damaged, TEWL rises, which can lower the stratum corneum's water content and result in aberrant corneocyte desquamation.[6] Sakai *et al,* found that whereas hyperglycemia did not impair skin barrier function, DM patients tended to have lower stratum corneum hydration conditions and lower sebaceous gland activity.[11]

All subjects in the TEWL group had an average of 25.66 ± 5.89 g/h/m^2 at baseline, but this decreased to 8.72 ± 2.09 g/h/m^2 over the course of 4 weeks after treatment ($p<0.001$). This demonstrated that TEWL significantly decreased from baseline to 4 weeks following the administration of 3% *M. oleifera Lam* extract. Ali *et al,* also observed a reduction in TEWL and an improvement in skin hydration up to 12 weeks following the application of a 3% *M. oleifera Lam* extract cream. *Moringa oleifera Lam* extract cream showed efficacy in improving skin moisture with antioxidant compounds and phenols that can reduce TEWL and prevent UV radiation.[17] *Moringa oleifera Lam* contains vitamin C, plays a role in the structure of the stratum corneum lipid barrier, regulates the composition of epidermal lipids, inhibits inflammation, increases collagen efficiency, and provides photoprotection.[1,17]

This study found that skin moisture levels at each measurement interval differed significantly before and after treatment. The subjects with most skin hydration levels at baseline had extremely dry skin, however after 4 weeks, their skin became moderately moist. Ali *et al*'s, comparison of 3% *M. oleifera Lam* extract cream and base cream on 11 subjects strengthens these conclusions by showing that the skin moisture levels of the 3% *M. oleifera Lam* extract cream group tended to increase until the 12-week. This is because the extract's significant amino acid content improves the stratum corneum's ability to retain water.[18]

The high concentration of vitamin E in *M. oleifera Lam* extract can improve skin hydration because it supports the skin's water bonding.[18] Vitamin B acts as a humectant by attracting water in the stratum corneum and increasing water content. Formulations for water-phase moisturizing creams also provide water straight to the skin, and the lipids in the cream form a layer on the skin's surface, reducing TEWL and improving skin hydration.[17] Gita *et al,* revealed that *M. oleifera Lam* ethanol extract lotion, at concentrations of 0.5%, 2%, and 5%, was effective in maintaining skin hydration, reducing wrinkles, and boosting collagen fiber density.[19] However, skin moisture parameters were not substantially changed by *M. oleifera Lam* extract cream at 3%, 6%, and 9% for 15 days. This conclusion is most likely the consequence of the short study time, which made it unable to observe the moisturizing effect.[18]

All subjects in this study had dry sebum levels. While 3 subjects had no change in sebum levels, 27 subjects had an increase in sebum after 4 weeks. Changes in the quantity, lipid composition and reduced activity of sebaceous glands in diabetic patients will aggravate xerosis cutis.[20] In xerosis, sebum production acts to provide an occlusive layer on the skin's surface to prevent TEWL, allowing sufficient or enhanced sebum production to conceal the skin barrier damage.[6] *M. oleifera Lam* leaf extract 3% cream contains essential fatty acids,[12] which act as an emollient with effects on skin barrier function.[16]

Patients with type 2 DM experience pruritus ranging from 18.4-27.5%.[21] Chronic pruritus has a negative impact on QOL. Repeated scratching can cause ulcers that develop into diabetic foot ulcers and disrupt sleep.[20] The use of emollients increases lipid levels, improves skin barrier function and moisture, reduces pruritus, and prevents infections caused by scratching.[21] Improvement in subjects with moderate pruritus was 63.3%, no pruritus was 89.5% and mild was 10.5%, while

severe pruritus was 36.7% compared to no pruritus 90.9% at 4 weeks after using 3% *M. oleifera Lam* extract cream. The DLQI had a moderate-to-large impact on the subjects' life at baseline, but by week 4, it decreased to no impact.

The 7.83% tannin components found in *Moringa oleifera La*m leaf extract have anti- inflammatory, antioxidant, and antipruritic properties.[22] At four weeks following therapy, there was a notable improvement in QOL and a significant decrease in VAS values in this study. These results are supported by Seok Jwa *et al*, which found that tannins can reduce pruritus by activating the inhibitory signals of Transient Receptor Potential Vanilloid Type 1 (TRPV1) and Transient Receptor Potential Ankyrin 1 (TRPA1).[23] TRPV1 sensitization causes the release of substance P from nerve terminals, which then activates mast cells and keratinocytes to release more cytokines.[20] Tannins suppress histamine release by blocking mast cell activation. In the meantime, type C nerve fibers, which have nerve terminals in the epidermis, mediate the TRPA1 signal pathway. Tannins have an antipruritic effect by inhibiting TRPA1 activity.[23]

This study demonstrated that age has an effect on sebum levels. In the aging process, the stratum corneum shows a decrease in total lipid content of more than 30% because epidermal lipid synthesis is reduced, especially in cholesterol synthesis. The number of sebaceous glands and subcutaneous fat decreases, especially in the feet, causing the skin to become dry and cracked, making it more susceptible to infection.[17]

In the present study, 30 subjects were treated with 3% *M. oleifera Lam* leaf extract cream for 4 weeks, and no adverse effects were reported. The safety 3% *M. oleifera Lam* leaf extract cream was conducted through a semi-occlusive patch test for 48 hours and no skin irritation was found.[24] According to Lukaszewska *et al*, adding *M. oleifera leaf* extract to a body wash gel that contains sodium coco sulfate surfactant can lessen the possibility of skin irritation and improve product safety. The proteins, polyphenols, and flavonoids make the solution molecules stable, which lowers the possibility of irritation.[25]

This study has limitations including the number of research participants are restricted to one treatment group with no control group; it is based on a single hospital; and the follow-up observation period is brief. In order to standardize the treatment of xerosis cutis in clinical practice, a bigger sample size and a longer period of follow-up observation are still required. This study mainly clarifies the advantages of *M. oleifera Lam* 3% extract cream as a natural treatment for xerosis cutis in patients with type 2 DM. The effect of *M. oleifera Lam leaf* 3% extract cream in xerosis through antioxidation, stratum corneum hydration, and skin barrier function.

Conclusion

The application of a 3% *M. oleifera Lam leaf* extract cream lowers the degree of xerosis cutis, increases skin moisture, reduces TEWL, raises sebum levels, and improves VAS value and the QOL for individuals with type 2 DM. To expand on the study's findings, a double-blind randomized clinical trial research design or a multicenter study design can be employed.

Ethical Approval: The Universitas Sriwijaya, approved this study vide No. No.DP.04.03/D.XVIII. 6.8/ETIK/091/2024.

Conflict of Interest: There was no conflict of interest to be declared by any author.

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Author's Contribution

F, IS, MIHP: Conception & design, acquisition of data, drafting of article, analysis & interpretation of data, critical revision of the article, final approval of the version to be published.

EB, SS, SK, YFY: Conception & design, acquisition of data, analysis & interpretation of data, critical revision of the article.

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