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ORIGINAL CONTRIBUTION

Efficacy of anti-inflammatory moisturizer vs hydrophilic cream in elderly patients with moderate to severe xerosis: A split site, triple-blinded, randomized, controlled trial

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Abstract

Background: Xerosis is a common problem among the elderly, characterized by dry-scaling erythema, fissuring, or pruritus, which could be treated by anti-inflammatory moisturizers without side effects of steroids.

Aims: We aimed to investigate the efficacy of anti-inflammatory moisturizer (MAS062D lotion) vs hydrophilic cream for the improvement of dry and barrier function skin in xerosis patients.

Methods: A split site, triple-blinded, randomized, controlled trial was conducted in the elderly with moderate to severe xerosis, who received the 28-day twice daily application of MAS062D lotion and hydrophilic cream on the assigned shins. The evaluations on day 0, 14, and 28 were performed using clinical assessment, skin hydration by corneometer, transepidermal water loss (TEWL), and biometric assessment.

Results: There were 24 Thai elderly patients, of whom 87.5% were female (mean age = 58.04 years and mean xerosis severity scale (XSS) = 4.83). Both treatments revealed similar statistically significant improvement in XSS ($P < .001$). Interestingly, MAS062D lotion–treated side remarkably showed improvement of skin hydration compared with hydrophilic-treated side for 26.86 ± 7.94 vs 25.84 ± 5.1, 41.24 ± 6.92 vs 20.96 ± 6.8, 50.49 ± 8.2 vs 21.75 ± 8.29 at baseline, day 14, and 28, respectively (P-value < .001). Moreover, MAS062D lotion significantly yielded greater decrease in TEWL measurement and more erythema improvement than hydrophilic cream (P-value < .001). No serious adverse effects were observed with either treatment.

Conclusion: The MAS062D lotion could potentially be an efficacious treatment for improvement of xerosis in the elderly, which is also safe and refrains from steroid side effects.

KEYWORDS

anti-inflammatory agents, dermatitis, eczema, emollients, nonsteroidal, skin aging, therapeutics

1 | INTRODUCTION

Xerosis is a common skin disease among the elderly, presented by dry, rough, fissured, and scaling skin with pruritus.[1] Following a dysfunction or a decrease of stratum corneum lipid,[1] the elderly are noticeably vulnerable to skin barrier impairment. Whilst, inflammation and pruritus are the signs of xerosis, resulting from an increased permeability due to the perturbing of the stratum corneum's defensive functions.[1,2]

Principally, treatment of xerosis consists of moisturizer application.[3] Nonetheless, it is unlikely to use moisturizers alone for pruritus and inflammation treatment in severe cases despite the potential to improve dry skin. Thus, topical corticosteroids and antihistamines are additionally applied for treatment of inflammation and prevention of pruritus.[4] However, steroids are medically known to cause many side effects in the elderly patients, especially those with skin atrophy, telangiectasia, purpura, and further perturbation of skin integrity.[5]

Following its moisturizing and anti-inflammatory efficacies, MAS062D lotion[6,7] could be used for the xerosis treatment of the elderly patients to restore skin barrier dysfunction and hydration, particularly to decelerate the inflammatory process and avoid the side effects of steroids. Hence, we aimed to investigate the efficacy of MAS062D lotion when compared to hydrophilic cream for better improvement of the moisturizing process and skin barrier function among the moderate to severe xerosis elderly patients.

2 | MATERIALS AND METHODS

2.1 | Subjects

Thai elderly patients aged 50-70 years and diagnosed with moderate to severe xerosis categorized by xerosis severity scale (XSS for 3-6)[8,9] and Fitzpatrick skin type III (54.1%) and IV (45.9%) were enrolled. Exclusion criteria were those sensitive to the test agents, current skin diseases requiring for treatment, conditions interfering to the study, use of oral/topical steroids or oral isotretinoin, diuretics or immunosuppressant or laser, and photo or light therapy during 4 weeks prior to the study. Patients were asked to sign the informed consent before their participation. Also, they had to refrain from using other topical treatments and moisturizers during the course of study.

2.2 | Study design

This split site, triple-blinded, randomized, controlled trial was performed between March and June 2017 in accordance with the Declaration of Helsinki, at Benchakitti Park Hospital, Bangkok, Thailand, and approved by the Human Research Ethics Committee of Thammasat University (MTU-EC-OO-2-087/59).

2.3 | MAS062D moisturizer lotion

The anti-inflammatory ingredients of MAS062D moisturizer lotion (Atopiclair lotion, Sinclair Pharma Srl) include vitis vinifera, vitamins C and E, telmesteine, hyaluronic acid (HA), glycyrrhetinic acid (GrA), and shea butter. While, other ingredients comprise aqua, ethylhexyl palmitate, pentylene glycol, arachidyl alcohol, behenyl alcohol, arachidyl glucoside, glyceryl stearate, PEG-100 stearate, butylene glycol, capryloyl glycine, bisabolol, carbomer, ethylhexylglycerin, piroctone olamine, sodium hydroxide, allantoin, DMDM hydantoin, disodium EDTA, and propyl gallate and ceteth 20. Also, the product (oil in water emulsion) contains emollient, humectants, and occlusive components.[8]

2.4 | Hydrophilic cream

Hydrophilic cream base (King Chulalongkorn Memorial Hospital) is the moisturizer with semi-liquid and oil in water formula, commonly used for treatment of many skin diseases, including xerosis. This moisturizer additionally contains both occlusive and humectant ingredients, such as cetyl alcohol, stearic acid, propylene glycol, and propyl paraben.

2.5 | Treatment and follow-up

Both MAS062D lotion and hydrophilic cream were prepared into the 50 mL bottles with label "A" and label "B." Patients were told to randomly apply 5-mL moisturizer of the bottle "A" on the left shin using the right hand and 5-mL moisturizer of the bottle "B" on the right shin using the left hand to avoid contamination, twice daily for 28 days, by the computer-generated table of random numbers. The follow-up was at baseline, day 14, and 28 to evaluate the results of clinical treatment, photography, skin biophysical measurement, and biometric assessment.

2.6 | Study assessment

The clinical assessment and noninvasive objective measurement were done at baseline, day 14, and 28 by a blinded dermatologist. Xerosis was measured and evaluated using the xerosis severity scale (XSS).

With the XSS scoring from grade 1 to 6 on the clinical features, the criteria set for each grade could be classified as: mild (0 = normal skin, 1 = dusty appearance, occasional minute skin flakes and 2 = generalized dusty appearance, many minute skin flakes), moderate (3 = scaling with flat borders and 4 = well-defined heavy scaling with raised borders, shallow fissures), and severe (5 = large scale plates, fissures and 6 = large scale plates, deep erythematous fissures).[9] The clinical evaluation and investigator global assessment (IGA) were scored on a 5-point scale (0 = no improvement, 1 = slight improvement, 2 = mild improvement, 3 = moderate improvement, 4 = excellent improvement).[9]

The subjective clinical adverse effect assessment was evaluated using a 4-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe).[9,10] Whilst, the objective assessment was evaluated by a blinded researcher after the subjects were acclimated to standard atmospheric conditions for at least 30 minutes with 40%-60% relative humidity.

The room temperature was maintained at 21-23°C. Three measurements were taken at the same spot on the shin with the report of mean results. Meanwhile, participants were advised to avoid using their lotions on the day of visit and instructed to regularly apply the studied moisturizers throughout the study.

The corneometer CM 825™ (Courage & Khazaka Electronic GmbH)[11] was used to evaluate skin hydration. Whereas, the measurement of transepidermal water loss (TEWL) was conducted using the Tewameter™ 210 (Courage & Khazaka Electronic GmbH) in accordance with the standard recommendation.[12] In addition, the biometric assessment using Antera 3D™ analysis camera (Miravex limited)[13] was done to evaluate the following parameters: hemoglobin (erythema),[14] wrinkles, melanin, and skin texture of the shin.

2.7 | Statistical analysis

The reference values from previously equivalent randomized trials[9] were applied to calculate a sample size (effect size = 0.25, alpha error = 0.05, power = 0.9, and 20% dropout rate), which yielded 24 subjects. The values were reported as mean ± SD and summarized by descriptive statistics. The paired t test and ANOVA test were used for the measurement of XXS changes, corneometer, TEWL, and biometric assessment among the subjects at baseline, day 14, and 28. Wilcoxon signed-rank test was also applied for differences in the IGA at week 2 and 4. The *P*-value < .05 was considered as statistical significance. The statistician was unaware and blinded to the study.

3 | RESULTS

3.1 | Demographic data

There were 24 Thai elderly subjects with moderate to severe xerosis and Fitzpatrick skin type III (54.1%) and IV (45.9%) who completed the study. The majority of them (87.5%) were female (mean age = 58.04 ± 6.93 years and mean XSS = 4.83 ± 0.7).

3.2 | Clinical assessment

The same significant improvement was precisely observed with mean XSS of MAS062D lotion and hydrophilic cream for 4.83 ± 0.7, 3.33 ± 0.82, 1.83 ± 0.82 (*P*-value < .001) at baseline, day 14, and 28, respectively (*P* = 1.000).

Moreover, the clinical evaluation showed a significant improvement (*P* < .001) on day 14 and 28 for dryness, smoothness, and moistness of skin on the MAS062D lotion–treated side when compared to the hydrophilic cream–treated side. (Figure 1).

3.3 | Biophysical evaluation

The TEWL measurement yielded a statistically significant decrease in the MAS062D lotion–treated side on day 14 and 28 for 5.4 ± 3.18 and 4.83 ± 1.84g/h/m^2 compared with the hydrophilic-treated side for 8.63 ± 3.92 and 8.54 ± 4.53g/h/m^2, respectively (*P*-value < .001; Table 1). Additionally, the MAS062D lotion–treated side showed a significantly better improvement of TEWL measurement than the hydrophilic cream–treated side for 45.55% vs 7.68%, (*P* < .001) at day 28. However, no statistically

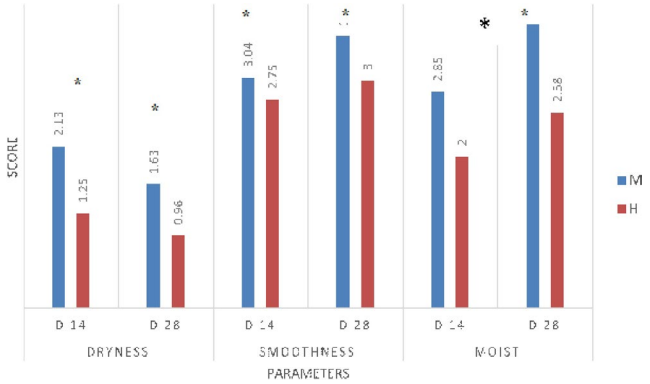

FIGURE 1 The clinical evaluation score of dryness, smoothness, and moistness of MAS062D lotion–treated sides and hydrophilic-treated sides at day 14 and 28, respectively (D, days; H, hydrophilic cream; M, MAS062D lotion, **P*-value < 0.001)

significant decrease in the TEWL was noted for the MAS062D lotion–treated sides or the hydrophilic-treated sides alone on day 14 and 28. (Figure 2).

Whereas, the corneometer measurement demonstrated a dramatic increase of skin hydration on the MAS062D lotion–treated side, with statistical difference on day 14 and 28 for 41.24 ± 6.92 and 50.49 ± 8.20 compared with the hydrophilic cream–treated side for 20.96 ± 6.80 and 21.75 ± 8.29, respectively (*P*-value < .001). Besides, a significantly worsened skin hydration was observed on the hydrophilic cream–treated side. While, the MAS062D lotion–treated side showed a greater significant improvement of skin hydration than the hydrophilic cream–treated side for 87.97% vs −15.83%, (*P* < .001) at day 28. (Figure 3).

3.4 | Biometric assessment

The hemoglobin index yielded a significant decrease of erythema from skin inflammation at day 14 and 28 on the MAS062D lotion–treated side compared with the hydrophilic-treated side for 1.19 ± 0.18, 1.15 ± 0.17 and 1.24 ± 0.17, 1.26 ± 0.17, respectively (*P*-value < .001). Meanwhile, the hydrophilic-treated side revealed a statistically significant increase of hemoglobin index on day 14 (*P* = .026) and 28 (*P* < .001), compared with the baseline for 1.19 ± 0.19, 1.24 ± 0.17, and 1.26 ± 0.17, respectively. In particular, the MAS062D lotion–treated side showed a significantly better improvement of redness than the hydrophilic cream–treated side for −4.17% vs 5.88%, (*P* < .001) at day 28. (Figure 4).

Furthermore, there was a statistically significant decrease in melanin index on the MAS062D lotion–treated side compared with the hydrophilic-treated side on day 28 for 0.56 ± 0.07, 0.59 ± 0.07 (*P* = .005). Whereas, the MAS062D lotion–treated side significantly demonstrated a better improvement of melanin index than the hydrophilic cream–treated side for −1.75% vs 1.72%, (*P* = .005) at day 28. Meanwhile, the roughness texture on day 28 on the MAS062D lotion–treated side (5.84 ± 1.47) also showed a significant improvement compared with the hydrophilic-treated side

TABLE 1 The biophysical evaluation of TEWL and corneometer and biometric evaluation of hemoglobin (erythema), melanin, texture, and wrinkles between the MAS062D lotion–treated sides and the hydrophilic-treated sides on day 14 and 28, respectively

	MAS062D lotion	Hydrophilic	*P*-value
Biophysical parameters			
TEWL			
Baseline	8.87 ± 10.11	9.25 ± 10.14	.793
Day 14	5.4 ± 3.18	8.63 ± 3.92	<.001[a]
Day 28	4.83 ± 1.84	8.54 ± 4.53	<.001[a]
P-value, baseline vs day 14	.111	.754	
P-value, baseline vs day 28	.056	.748	
Corneometer			
Baseline	26.86 ± 7.94	25.84 ± 5.1	.480
Day 14	41.24 ± 6.92	20.96 ± 6.80	<.001[a]
Day 28	50.49 ± 8.20	21.75 ± 8.29	<.001[a]
P-value, baseline vs day 14	<.001[a]	.002[a]	
P-value, baseline vs day 28	<.001[a]	.050	
Biometric parameter			
Hemoglobin index			
Baseline	1.2 ± 0.16	1.19 ± 0.19	.646
Day 14	1.19 ± 0.18	1.24 ± 0.17	.011[a]
Day 28	1.15 ± 0.17	1.26 ± 0.17	<.001[a]
P-value, baseline vs day 14	.492	.026[a]	
P-value, baseline vs day 28	.039[a]	<.001[a]	
Melanin index			
Baseline	0.57 ± 0.07	0.58 ± 0.07	.313
Day 14	0.58 ± 0.07	0.59 ± 0.07	.435
Day 28	0.56 ± 0.07	0.59 ± 0.07	.005[a]
P-value, baseline vs day 14	.158	.445	
P-value, baseline vs day 28	.079	.452	
Texture (roughness)			
Baseline	7.67 ± 1.70	7.93 ± 2.61	.429
Day 14	7.54 ± 2.40	8.52 ± 2.86	.062
Day 28	5.84 ± 1.47	8.5 ± 1.98	<.001[a]
P-value, baseline vs day 14	.718	.014[a]	
P-value, baseline vs day 28	<.001[a]	.051	
Wrinkles			
Baseline	7.88 ± 1.52	8.2 ± 2.31	.263
Day 14	7.8 ± 2.11	8.57 ± 2.34	.059
Day 28	6.37 ± 1.32	8.62 ± 1.68	<.001[a]
P-value, baseline vs day 14	.816	.081	
P-value, baseline vs day 28	<.001[a]	.136	

Note: Values presented as mean ± SD, *P*-value corresponding to paired *t* test.
[*]*P*-value < .05.

(8.5 ± 1.98; −23.86% vs 7.19%; $P < .001$), with a statistically significant improvement in wrinkles on the MAS062D lotion–treated side compared with the hydrophilic cream–treated side on day 28 for 6.37 ± 1.32 and 8.62 ± 1.68, respectively (−19.16% vs 5.12%; $P < .001$).

3.5 | Adverse effects

No subject was observed with greater dryness, burning, pain, edema, sensitive skin, oozing, and hyperpigmentation. Adverse reactions on the MAS062D lotion–treated side included mild itch (1 subject), mild

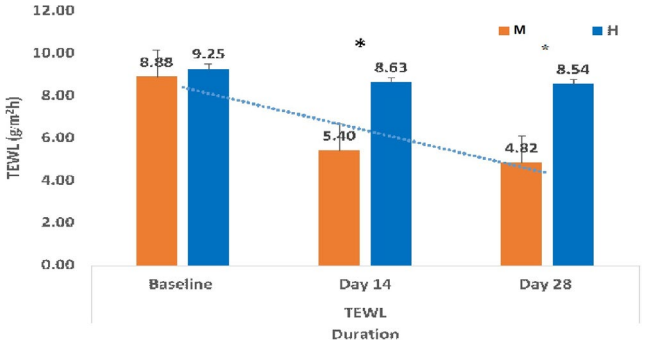

FIGURE 2 The TEWL measurement of the MAS062D lotion–treated sides and the hydrophilic-treated sides at baseline, day 14, and 28, respectively (H, hydrophilic cream; M, MAS062D lotion; *P-value < 0.001)

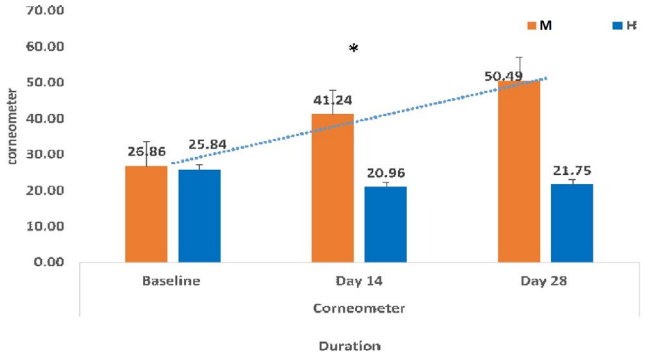

FIGURE 3 The values of skin hydration measured by corneometer on the MAS062D lotion–treated sides and the hydrophilic-treated sides at baseline, day 14, and day 28, respectively (H, hydrophilic cream; M, MAS062D lotion; *P-value < 0.001)

erythema (1 subject), and mild sensitive skin (1 subject), with similar incidence to the hydrophilic-treated side. In addition, there was no statistical significance (P-value > .005) of adverse reactions on the MAS062D lotion–treated sides and the hydrophilic cream–treated sides. Both treatments were well tolerated without serious adverse effects over the study course.

4 | DISCUSSION

Xerosis in the elderly is the intrinsic multifactorial changes in keratinization and lipid contents, as well as the extrinsic factors such as use of diuretic drugs and overuse of heaters or air conditioners. Normally, pruritus is caused by xerosis, leading to inflammation, excoriations, and risk of skin infections.[1,15]

Despite the efficacy of topical steroids for treatment of pruritus and inflammation in xerosis patients, the cautious use is recommended among the elderly due to their sensitive skin, particularly to agents causing skin atrophy and further perturbing of skin integrity.[15] Whilst, corticosteroids can decrease stratum corneum thickness, reduce corneo-desmosome density in lower stratum corneum, and disrupt lipid lamellae, resulting in the impairment of skin integrity detected by the increasing of transepidermal water loss.[4] Hence, moisturizers should have a crucial role to prevent and treat xerosis conditions.[16] Importantly, nonsteroid moisturizers with anti-inflammatory ingredients can be efficacious to prevent and treat inflammation that further causes xerosis eczema and secondary infection. In particular, these treatment agents are safe from the topical steroid adverse effects.[6,7,17]

In this study, the MAS062D lotion yielded comparable efficacies to the hydrophilic cream for the improvement of clinical xerosis symptoms as measured by XSS. Noticeably, the results were evaluated by biophysical parameters, including TEWL measurement, as well as corneometer and biometric assessment. Meanwhile, the MAS062D lotion demonstrated a significant improvement of xerosis conditions (hemoglobin, texture, and wrinkle), with better skin hydration and lower TEWL from baseline compared with the hydrophilic cream. Thus, the efficacies of the MAS062D lotion could be well explained by the moisturizer components such as humectants, emollients, and occlusive ingredients for a significant improvement of skin hydration, skin texture, and wrinkle by corneometer and biometric assessment. While, the TEWL evaluated by Tewameter tended to improve at day 14 and 28. Moreover, its active anti-inflammatory agents including vitis vinisfera, telmesteine, HA, and GrA without steroids ameliorated the inflammation in xerosis, following the improvement of biometric assessment of hemoglobin index.[8,18,19] In the meantime, the spectacular improvement of xerosis and inflammation after the MAS062D lotion treatment could be from the active ingredients, including the standardized vitis vinifera (grapevine) extract in the MAS062D with the activity of antioxidants and antiprotease for protection against the breakdown of epidermis.[18] Whilst, telmesteine contained antiprotease action and inhibits elastase, collagenase, and matrix metalloproteinase, with high levels of expression in the inflammatory skin diseases such as atopic dermatitis.[6] In particular, GrA was the active metabolite in licorice root extract, with anti-inflammatory and antipruritic activity to block endogenous cortisol degradation through the inhibition of 11-beta-hydroxysteroid dehydrogenase. Moreover, GrA remarkably potentiated the cutaneous hydrocortisone activity.[20]

When comparing with the previous study, the MAS062D lotion and the moisturizer-containing ceramide combined with some filaggrin components revealed a significant improvement in visual dryness, corneometer, and tewameter measurements.[21] However, our study provided further biometric information on the redness, which demonstrated the improvement of inflammation.

Surprisingly, the epidermal growth factor (EGF) is a popular component in moisturizers for xerosis treatment, with a significant improvement in skin hydration and TEWL.[9] Nonetheless, the long-term use of EGF would trigger the dysregulation of EGF receptor (EGFR)/ligand system and abnormal activation of EGFR signaling that might be contributed to chronic inflammatory disorders and skin cancer.[22,23] As a result, the MAS062D lotion could be an effective optional treatment for xerosis to obtain the profound skin

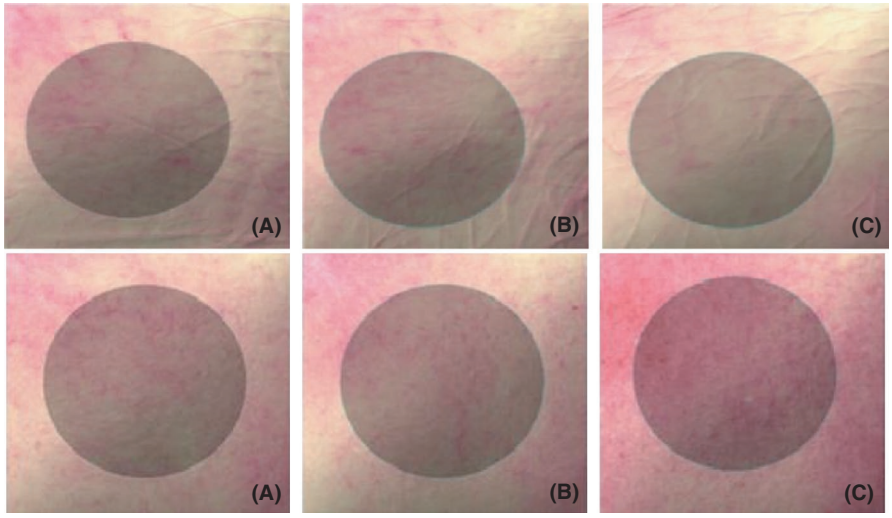

FIGURE 4 The biometric erythema assessment of the MAS062D lotion (upper row)–treated sides and the hydrophilic cream (lower row)–treated sides at baseline (A), day 14 (B), and 28 (C), respectively

features, such as increasing skin hydration, decreasing TEWL, filling skin surface, reducing skin coloration, and especially reducing redness from inflammation without side effects when compared to the EGF.

Besides the effective results to ameliorate xerosis, the MAS062D lotion could also benefit other inflammatory skin diseases, especially in children and adults with atopic dermatitis (AD) and contact dermatitis.[7,17] Likewise, our study ratified that the MAS062D lotion beneficially yielded additional potentiality for effective treatment of different skin diseases, such as atopic dermatitis, contact dermatitis, and xerosis.[23] Nevertheless, the efficacious treatment of xerosis in the elderly required the consistent application of moisturizers and also the avoidance of behavioral and environmental factors contributing to xerosis, such as hot water bathing, harsh soap or cleanser, rubbing sponge or cloth, and exfoliative gel.[15]

This study was, however, limited by the small sample size and the short period of study. In a bid to ratify the efficacies of this MAS062D lotion, larger sample size, longer duration, and better comparison with other moisturizers or steroids should be highly suggested.

5 | CONCLUSION

The MAS062D moisturizer lotion could be an efficacious treatment with anti-inflammatory ingredients for xerosis treatment in the elderly, which is safe from steroid side effects.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

ETHICAL APPROVAL

This study was approved by the Human Research Ethics Committee of Thammasat University (MTU-EC-OO-2-087/59).

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