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Pre-Clinical and Clinical Efficacy of an Oat-containing Lotion Demonstrated Increased Protein, Ceramide, Skin Resiliency and Speed of Healing of the Skin Barrier

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Oat Treatment Significantly Increased and Protected Filaggrin and Loricrin, *In Vitro* and *Ex Vivo* Models

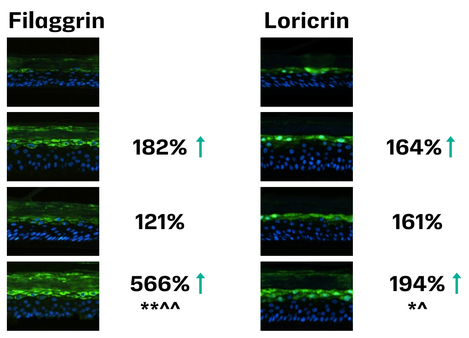
Introduction

Oat and concentrated components of oat *(Avena sativa)* have long been ingredients of choice for soothing and repairing skin[1]. Filaggrin and loricrin are essential structural proteins involved in barrier integrity. A topical lotion containing three oat components was clinically tested to determine skin resiliency and speed of healing through tape stripping (TS) insult, along with analysis of tape strips for effect on ceramides *in vivo*.

Method

An Oat formulation (OF) was compared to untreated, vehicle and positive control on reconstructed human epidermis (RHE) for filaggrin and loricrin via immunohistochemistry. Greater green staining represents an increase in the endpoints.

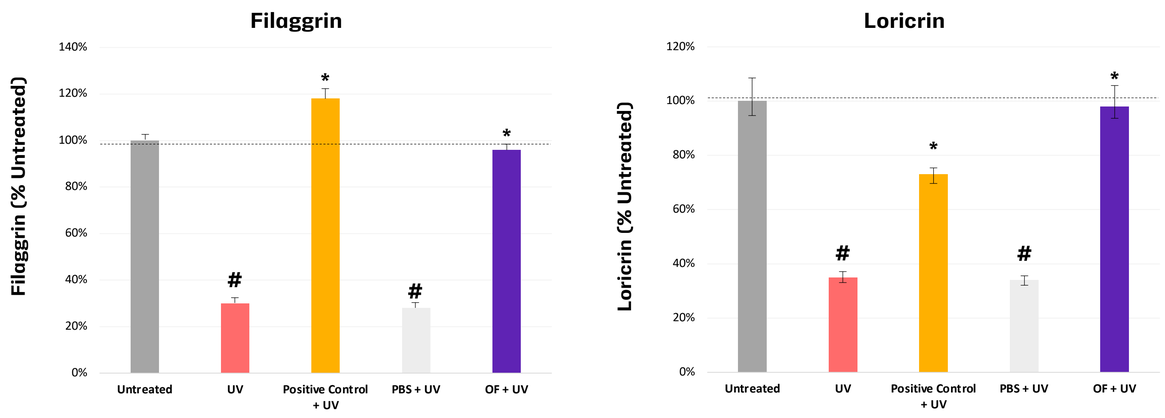
Figure 1. OF Benefit to Skin Proteins, RHE



vs Positive Control: * p<0.05, ** p<0.01
vs Vehicle: ^ p<0.05, ^^ p<0.01

OF significantly increased filaggrin (566%) and loricrin (194%) production vs. untreated and significantly is better than positive control (WY14643-pirinixic acid) and the moisturizing lotion vehicle, p<0.05.

Figure 2. OF Benefit to Skin Proteins, *Ex Vivo*



OF preserved filaggrin and loricrin, mitigating UV-induced reductions in human skin explants, comparable with the positive control (Vit C + Vit E).

* p<0.05 vs UV # p<0.05 vs Untreated PBS (phosphate buffered saline) acted as a negative control

A Triple Oat Containing Lotion Showed Greater Recovery and Resiliency of Skin in a 4-Week Clinical Study

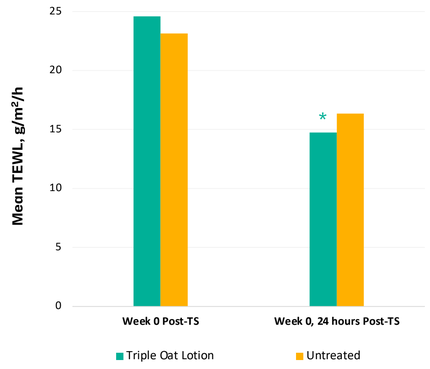
Study Design and Population

- A 4 week, randomized, controlled clinical study of females with mild to moderate visual dryness and transepidermal water loss (TEWL) on the lower lateral legs ≥6 g/m²/h were enrolled, including 47% Caucasian, 44% Black or African American, 6% Asian, and 3% multi-racial; 19% were Hispanic or Latino.
- A range of skin tones were included and 44% had self-perceived sensitive skin.
- Physical insult via TS (25 D-Squame tape strips [TS]) was conducted before initial application of the triple oat-containing lotion and after 4 weeks of twice daily application.
- Prior to product application, TEWL was measured before TS and after TS. One-time application occurred after TS, and TEWL was measured 24 hours post-TS. Product was then applied twice daily for 4 weeks with TEWL measurements conducted at week 4 before TS, after TS and 24 hours post-TS. After 4 weeks, redness via chromameter was conducted before TS, after TS and 1 hour post-TS.
- After 4 weeks of use, TS were analyzed for changes in skin barrier lipids by shotgun lipidomics.

Results

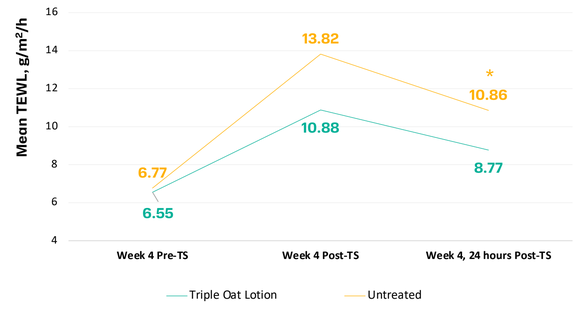
- 32 participants completed the study.

Figure 3. Greater Recovery After Insult (after 1 application)



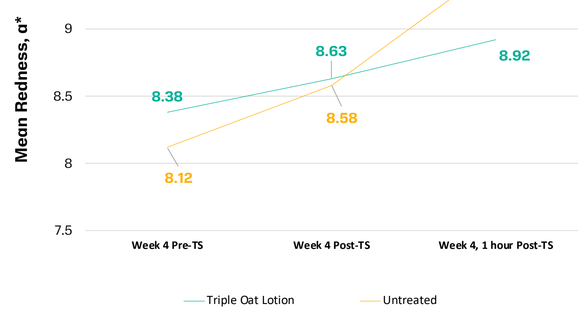
- TEWL was significantly improved 24 h after TS and 1 application of triple oat lotion vs untreated, * p=0.019.

Figure 4. Greater Resiliency After Insult, TEWL (after 4 weeks twice daily application)



- TEWL was not significantly different comparing Pre-TS and 24 h for triple oat lotion, p=0.193.
- Untreated had significantly higher TEWL at 24 h compared to Pre-TS, * p=0.003.
- Treated skin demonstrates greater resiliency to TS insult.

Figure 5. Greater Resiliency After Insult, Redness (after 4 weeks twice daily application)



- Redness values (a*), were not significantly different comparing Pre-TS to Post-TS or 1 h Post-TS for the triple oat lotion, p>0.05.
- Untreated skin was significantly more red (worsening) at 1 h post-TS compared with Pre-TS; * p<0.001.
- Treated skin had less redness showing its resiliency to insult.

Triple Oat Containing Lotion Increases Crucial Acyl-ceramides in Compromised Skin

Endogenous Ceramides – Introduction

Table 1. Compromised Skin Conditions Lead to a Decrease in Crucial Acyl (Very Long Chain) Ceramides [2]

Changes In Ceramide Levels In Different Skin Pathologies			
Ceramide class / feature	Dry skin (xerosis)	Atopic dermatitis (AD)	Inflammatory / barrier-impaired skin
Total ceramides	**Decrease**		
	Associated with reduced hydration and barrier strength	Evident through increased permeability and SC dysfunction	Characteristic feature of barrier-impaired skin
Short-chain ceramides (< C42)	**Increase**		
	Linked to less efficient lipid packing	Consistent with altered lamellar lipid organization	Indicative of impaired SC structure
Long-chain ceramides (> C42)	**Decrease**		
	Associated with compromised dense lipid packing	Contributing to barrier defects and higher TEWL	Characteristic of weakened barrier
Acyl-ceramides (Very Long Chain, >C63) (EOS, EOH, EOP, EOdS)	**Decrease**		
	Characteristic of impaired lamellar phase formation	Key structural deficit in AD-associated SC lipid organization	Consistent with weakened lipid organization

An ideal intervention would:

- Increase total ceramides
- Support production of long chain ceramides vs short chain
- Increase Acyl (very long chain) ceramides

Endogenous Ceramides – Results

Figure 6. Analysis of Acyl-Ceramides (Very Long Chain, >C63)



* -P < 0.05 vs Untreated

- Successive TS (25 TS) was used to generate the insult.
- After 4 weeks of treatment, TS (1-5) were collected for analysis of lipids. Results shown are from TS3.
- A significant (p<0.05) increase in the production of extra-long chain acyl ceramides (14%) was seen with the triple oat containing lotion group compared to the untreated group.
- This *in vivo* increase in acyl ceramides further corroborates the resiliency observed with TEWL and redness (a*) measurements.

Conclusion

Use of an oat-containing lotion showed a benefit in:

- **Production of skin barrier proteins**
  - Oat treatment significantly increased filaggrin (566%) and loricrin (194%) expression in RHE and protected against UV-induced degradation of filaggrin and loricrin in human skin explants.
- **Skin Resiliency with Faster Healing**
  - Significantly greater/faster recovery in TEWL after 1 use.
  - Resisted insult and recovered in 24 h in TEWL whereas Untreated had significant worsening.
  - Resisted insult in Redness whereas Untreated had significant worsening.
- **Production of essential long chain ceramides**
  - Significant (p<0.05) 14% improvement vs untreated group in very long chain acyl ceramides after 4 weeks of recovery.
  - Acyl ceramides are essential for skin barrier function; deficiencies correlate to significant water loss.[2,3,4]
  - Reduced levels of Acyl ceramides can disrupt the barrier and is common in those with atopic eczema, atopic dermatitis, psoriasis, and dry skin.[2-4]

References

1. Kierland R et al. Collected papers of the Mayo Clinic and the Mayo Foundation. W.B. Saunders Company, 1951. **2.** Carine J et al. Evaluation of a novel skin emollient cream on skin lipidome and lipid organization. Skin Pharmacol Physiol.2023;36:125-39. **3.** Janssens M et al. Increase in short-chain ceramides correlates with an altered lipid organization and decreased barrier function in atopic eczema patients. J Lipid Res 2012;53:2755-66. **4.** Ishikawa J et al. Changes in the ceramide profile of atopic dermatitis patients. J Invest Dermatol. 2010;130: 2511-14.

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