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An Oat-containing Glycerin Skin Protectant Ointment Shows Sustained Resiliency and Offers Benefits Over a Petrolatum Ointment

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Introduction

- Dry skin conditions are affected by deficiencies in hyaluronic acid (HA) and filaggrin degradation products pyrrolidone carboxylic acid (PCA) and urocanic acid (UCA), as major components of natural moisturizing factors (NMFs).
- Consumers who desire the benefits of typical ointments are often deterred by unpleasant aesthetic pain points, including slow absorption, heaviness, and a greasy feel.
- A novel non-greasy oat (Avena sativa) and glycerin ointment was tested on dry skin providing healing benefits within the skin when compared with a standard petrolatum ointment that offers occlusion as a primary benefit **(Figure 1).**[1,2]

Figure 1. Improved Visual Dryness and Moisturization, Sustained Throughout Regression

Black/African American, Fitzpatrick Type VI



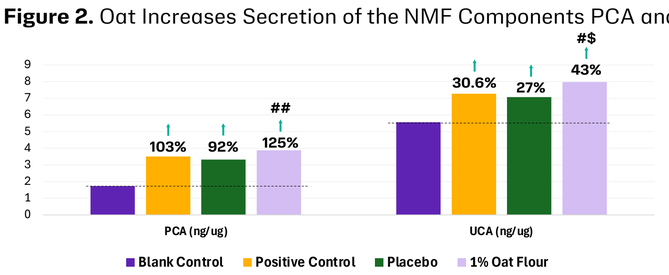
Oat Formulation (OF) Increased NMFs PCA and UCA Levels in RHE and Protected HA From UV-induced Reduction in Human Skin Explants

An *in vitro* study on an OF was completed to evaluate the effects of PCA, UCA, and HA in skin.

Study 1: Methods and Results

3D reconstructed human epidermis (RHE) model was used to evaluate the effect of oat flour on PCA and UCA production **(Figure 2).**

Figure 2. Oat Increases Secretion of the NMF Components PCA and UCA



Positive Control: WY14643 (pirinixic acid), a known selective PPARα agonist. Placebo: Formula minus 1% Oat Flour.

p<0.01 vs Placebo

# p<0.05 vs Placebo

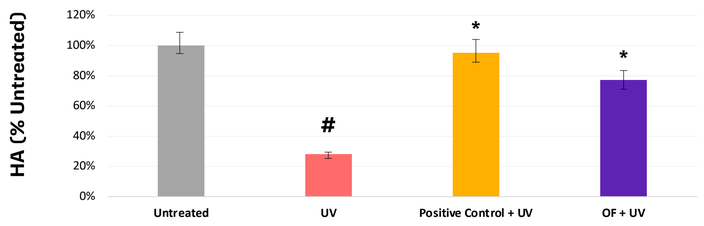
$ p<0.05 vs Positive Control.

PPARα, peroxisome proliferator-activated receptor alpha

Study 2: Methods and Results

Human skin explants were subjected to UV radiation to assess protective effects of OF against UV-induced HA degradations. **(Figure 3)**. HA was assessed via immunofluorescence and image analysis

Figure 3. OF Protects Against UV Induced Degradation of HA



Positive control: Vitamin C + Vitamin E.

# p<0.05 vs Untreated

* p<0.05 vs UV

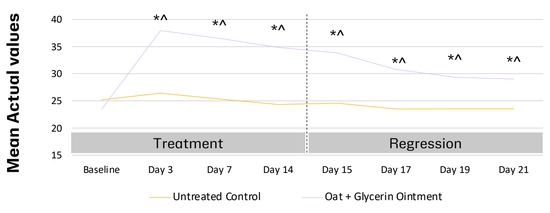
HA, hyaluronic acid

An Oat + Glycerin Ointment Provides Meaningful Clinical and Moisturization Benefits Sustained Throughout Regression

Study 3: Methods and Results

- A 3-week clinical regression study including a 2-week treatment period followed by a 1-week regression period, with direct comparison to baseline, untreated control, and petrolatum ointment, was conducted with 58 female subjects, aged 25-65 years and Fitzpatrick Skin Types I – VI, on lower legs.
- Inclusion criteria included mild to moderate dry skin defined as an average Corneometer® value of 15 – 50 a.u.
- The Oat + Glycerin Ointment and Petrolatum Ointment were applied to their respective test site twice daily for 2 weeks, with an untreated control.

Figure 4. Oat + Glycerin Ointment Increases Hydration (Corneometer)



*statistically significant vs Baseline (p<0.01)
^statistically significant vs Untreated Control (p<0.001)

Oat + Glycerin Ointment provides:

- Statistically significant moisturization compared with baseline and untreated during the 2-week treatment phase and through 7 days of regression **(Figure 4)**

Table 1. Oat + Glycerin Ointment Improves Visual Dryness (Mean Values)

	Treatment Phase				Regression Phase			
	Baseline	Day 3	Day 7	Day 14	Day 15	Day 17	Day 19	Day 21
Oat + Glycerin Ointment	1.48	0.17*^	0.15*^	0.15*^	0.17*^	0.44*^	0.62*^	0.68*^
Untreated	1.57	0.99*	0.92*	1.06*	0.96*	1.51	1.59	1.52

*statistically significant vs Baseline (p<0.001) ^statistically significant vs Untreated Control (p<0.001)

Table 2. Oat + Glycerin Ointment Improves Tactile Surface Roughness (Mean Values)

	Treatment Phase				Regression Phase			
	Baseline	Day 3	Day 7	Day 14	Day 15	Day 17	Day 19	Day 21
Oat + Glycerin Ointment	1.13	0.34*^	0.17*^	0.14*^	0.24*^	0.36*^	0.47*^	0.54*
Untreated	1.21	1.04	0.78*	0.7*	0.76*	0.88*	0.95*	1

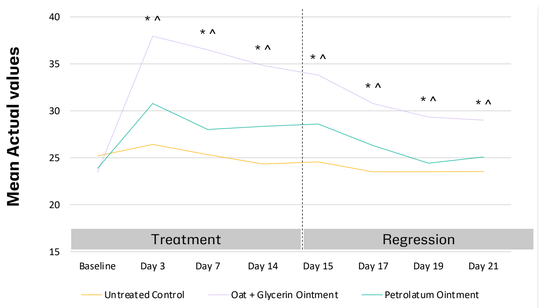
*statistically significant vs. Baseline (p<0.001) ^statistically significant vs Untreated Control (p<0.001 Day 3 – Day 17, p<0.05 Day 19)

Oat + Glycerin Ointment provides:

- Statistically significant improvement in dryness compared with baseline and untreated during the 2-week treatment phase and through 7 days of regression **(Table 1)**
- Statistically significant improvement in tactile surface roughness compared with baseline and untreated during the 2-week treatment phase and 5 days of regression **(Table 2)**

An Oat + Glycerin Ointment Provides Clinical Superiority in Moisturization Over a Leading Petrolatum Ointment

Figure 5. Oat + Glycerin Ointment Increases Hydration (Corneometer) over a Leading Petrolatum Ointment



*statistically significant vs Petrolatum Ointment (p<0.001)
^statistically significant vs Untreated Control (p<0.001)

Oat + Glycerin Ointment provides:

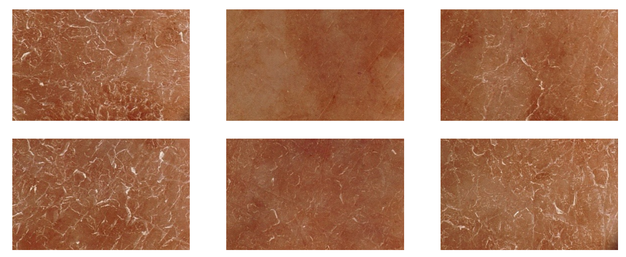
- Statistically significant increase in skin hydration (measured via Corneometer) vs a leading Petrolatum Ointment **(Figure 5)**
- Provides twice the hydration during treatment phase
- Provides 2x more lasting hydration during the regression phase (up to 1 week of not using after twice daily use for 2 weeks)

Clinical Photography

- Clinical photography supports visual and instrumental data
  - Oat + Glycerin Ointment demonstrates greater benefit after treatment and regression (1 week after discontinuing product usage) than a leading Petrolatum Ointment **(Figure 6)**

Figure 6. Improved in Visual Dryness & Moisturization

White, Fitzpatrick Skin Type II



Oat + Glycerin Ointment Achieves Preference Over a Leading Petrolatum Ointment

Study 4: Consumer Perception of Superiority

Methods

A blinded in-home consumer use test was conducted to determine aesthetic superiority to a leading petrolatum ointment.

- ASTM Standard Guidelines for superiority were followed (ASTM E1958-22).
- Population:
  - 419 female participants, ages 18-60 years.
  - Diverse mix of ethnicities/races to match US census across 4 regions in the US.
  - Self-perceived dry skin on face and body with approximately half of the subjects with self-perceived sensitive skin.
- Test product and usage: Oat + Glycerin Ointment was applied once to forearms.

Results

Oat + Glycerin Ointment Achieved Superiority Over a leading Petrolatum Ointment for:

- Has a more non-greasy feel.
- Absorbs faster.
- Leaves skin feeling more moisturized.

Overall Conclusions

- **The Oat + Glycerin Ointment demonstrated numerous preclinical benefits:**
  - Oat flour elevated NMFs PCA and UCA, with statistically significant improvements over placebo and positive control (p<0.01 and p<0.05, respectively).
  - Oat flour also protected against UV-induced degradation of HA in human skin explants.
  - These 2 mechanisms of action support the role of oat in enhancing hydration and maintaining skin suppleness.
- In a clinical study, an Oat + Glycerin Ointment outperformed a leading Petrolatum Ointment for moisturization, including a 1-week regression period.
- Oat + Glycerin Ointment demonstrated numerous clinical endpoints including visual dryness, tactile surface roughness, and moisturization.
- Oat + Glycerin Ointment showed superior aesthetics and achieved overall preference in a competitive consumer study against a leading Petrolatum Ointment.

References

1. Basu MN et al. Natural moisturizing factors in children with and without eczema: Associations with lifestyle and genetic factors. JEADV 2022;36,2:255-62.
2. Muhammad P et al. Effectiveness of topical hyaluronic acid of different molecular weights in xerosis cutis treatment in elderly: a double-blind, randomized controlled trial. Arch Dermatol Res 2024;316:329.

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