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Clinical Testing of Dermo-Protective Products against Environmental, Chemical and Climatic insults

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Introduction:

Skin barrier integrity assumes prime importance in the maintenance of healthy skin structure and function. Besides normal aging, other factors that cause the skin barrier to be compromised, include pollution, environmental and chemical insults. Disruption of the barrier can lead to increased permeability and thinning of the horny layer which if not checked can lead to inflammation and various skin diseases. Our objective was to assess the efficacy of dermo-protectants against environmental, chemical, and climatic insults using clinical grading, imaging, along with bioinstrumentation in three *in-vivo* models.

Materials & Methods:

N=35 healthy females (18-65y), who provided written signed informed consent and met the inclusion/exclusion criteria were enrolled in each of the three clinical trials.

Scoring scales: -A 5-point visual dryness scoring scale and a 4-point visual and tactile roughness scoring scale were used by expert graders.
-A 0-5 scoring scale for Visibility of coal dust PM on skin with 0 equivalent to 0% -no visible signs of PM to 5- equal to 100% particulate matter remains.
-Bioinstrumentation: Skin surface hydration was measured with the Corneometer® CM825 and Trans-epidermal water loss with the Tewameter® TM300 (Courage + Khazaka; Germany).

1. **Pollution Clinical Trial: TA**'s: 1) Lotion 2a) Cleansing Lotion, 2b) Gentle Cream Scrub
   An area of the qualified subject's inner volar forearm was marked and split into two sections. Coal dust particulate matter (PM) 2.5 was used to cause skin pollution and checked for adhesion and removal.

2. **Chemical Insult Clinical Trial: TA's:** Code B: (Dermo-protectant formulation) Code C: (Untreated).
   The objective of this study was to compare the TEWL and skin hydration pre and post use of specific moisturizer applied twice daily for 15 days and TEWL was measured pre- and post- application of SLS to compare moisturizer treated and untreated sites.

STUDY FLOW

	RUN IN	TREATMENT PHASE						
Study Time Point	Day -3	Day 1	Day 4	Day 7	Day 10	Day 13	Day 14	Day 15
Visit		1	2	3	4	5	6	7
Informed Consent	√							
Inclusion/Exclusion Criteria	√							
Medical History/Con meds	√							
Demographics	√							
Visual Assessment	√	√						√
Corneometer	√	√*	√**			√*	√** √**	√ 3
TEWL	√	√	√*	√*	√*	√*	√*	√ 3
TA application-twice daily 7-9 hours apart		√ √	√ √	√ √	√ √	√ √	√ √	
SLS 1% application							1 2	3
AE review	√	√	√	√	√	√	√ √	√

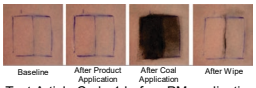
*pre application; **Post application; [1]site not patched with SLS; [2]site patched with SLS; [3]24hr post SLS.

0.1mL of the test article was applied by spreading the test article with a clean finger cot and allowed to dry. No treatment was made to the untreated control site. Subjects with dryness scores of 1.0 or greater continued to the treatment phase. The treatment phase was two weeks in duration. One 6X6cm site was assigned to each outer leg of subjects. Following the final application of the moisturizer on Day 14 AM and instrument readings, half of each test site received an application of SLS (1% w/v) via an occlusive patch. After 12 hours, patches were removed by study staff and the sites were rinsed and allowed to dry overnight.

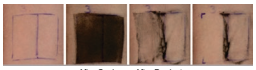
3. **Environment Induced Dry Skin Trial: TA:** Code A: (Lotion)- 2ul/cm² applied using a fresh finger cot.
   Subjects with at least moderate dry skin dryness (score of ≥2) at each test site following a washout period of five days with Ivory soap. One test site 5x5cm was marked on both the right and left lateral leg. Clinical assessments of visual dryness and tactile roughness and instrumental measurement of skin hydration (Corneometer®) and TEWL (Tewameter®) were taken at baseline prior to first application and then post application at 10 mins, 4 and 8 hours.

Results & Discussion:

1. ANTIPOLLUTION EFFICACY OF DERMOPROTECTIVE PRODUCT



Test Article Code 1 before PM application



PM application followed by TA's.

- 85% particulate removal was seen at the site with prior TA application followed by cleansing.
- 98% particulate removal was seen at the site with prior TA application followed by cleansing with a cleansing lotion and Gentle cream scrub.

2. EFFICACY OF DERMOPROTECTANT PRODUCT AGAINST CHEMICAL INSULT:

TEWL MEASUREMENTS:

Code	Visit	Mean Score	Mean Change from Baseline[1]	t-test p-value
B	Baseline	3.81		
	Day 4	3.46	-0.35	0.0994
	Day 7	3.40	-0.42	0.0394[3]
	Day 10	3.31	-0.50	0.0851
	Day 13	3.60	-0.28	0.3044
	Day 14	3.24	-0.45	0.0730
C	Baseline	3.69		
	Day 4	3.83	0.14	0.4974
	Day 7	4.53	0.83	0.0022[2]
	Day 10	4.02	0.32	0.1983
	Day 13	4.64	0.89	0.0220[2]
	Day 14	4.54	1.02	<0.0001[2]

	Day 7	Day 10
ANCOVA p-value:	<0.0001[4]	0.0640
Significant Comparisons:	C vs. B	Not Applicable

	Day 14
ANCOVA p-value:	0.0005[4]
Significant Comparisons:	C vs. B

TEWL MEASUREMENTS: Analysis of differences from Day 14 to Day 15 for SLS treated sites only.

Code	Visit	Mean Score	Mean Change from Baseline	t-test p-value[1]
B	Baseline (Day 14)	3.24		
	Day 15	9.38	6.14	<0.0001
C	Baseline (Day 14)	4.54		
	Day 15	14.02	9.49	<0.0001

[1]Mean changes from baseline were calculated such that negative values indicate reduction & positive values indicate an increase
[2]Significant increase in transepidermal water loss from baseline
[3]Significant decrease in transepidermal water loss from baseline
[4]Significant difference among treatments

CORNEOMETER MEASUREMENTS: (Moisturization Ability)

Code	Visit	Mean Score	Mean Change from Baseline[1]	t-test p-value
B	Baseline	23.56		
	Day 1 Post-trt.	28.89	5.32	<0.0001[2]
	Day 13	16.14	-7.47	<0.0001[3]
C	Baseline	23.86		
	Day 1 Post-trt.	23.14	-0.72	0.2198
	Day 13	14.80	-8.77	<0.0001[3]

Between Treatment Analysis using changes from baseline

	Day 1 Post Treatment	Day 13
ANCOVA p- value:	<0.0001[4]	0.0671
Significant Comparisons:	C vs. B	Not applicable

[1]Mean changes from baseline were calculated such that negative values indicate a reduction and positive values indicate an increase.
[2] Significant increase in skin surface hydration from baseline
[3] Significant decrease in skin surface hydration from baseline
[4] Significant differences among treatments

CORNEOMETER MEASUREMENTS: (Results pertaining to Long Lasting)

Code	Visit	Mean Score	Mean Change from Baseline	t-test p-value
B	Baseline (Day 14 Time 0)	26.17		
	Day 14 (Time 12 Hrs.)	18.95	-7.22	<0.0001[2]
	Day 15 (Time 24 Hrs.)	19.65	-6.52	<0.0001[3]
C	Baseline (Day 14 Time 0)	22.74		
	Day 14 (Time 12 Hrs.)	19.24	-3.50	0.0001[3]
	Day 15 (Time 24 Hrs.)	20.38	-2.35	0.0117[3]

	Day 15 (Time 24 Hrs.)
ANCOVA p-value:	0.0014[4]
Significant Comparisons	C vs. B

[1] Mean changes from baseline were calculated such that negative values indicate a reduction and positive values indicate an increase.
[2] Significant decrease in skin surface hydration from baseline
[3] Significant differences among treatments

VISUAL SCORES

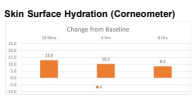
VISUAL SCORES - Within-treatment Analysis

Code	Visit	Mean Score	Mean Change from Baseline[1]	Signed Rank p-value[2]
B	Day 15 Non-SLS site	2.09		
	Day 15 SLS Site	2.01	-0.07	>0.5000
C	Day 15 Non-SLS site	2.19		
	Day 15 SLS Site	2.07	-0.12	0.2592

Rank Sum p-value: >0.5000 (Significant Comparisons: Not Applicable)

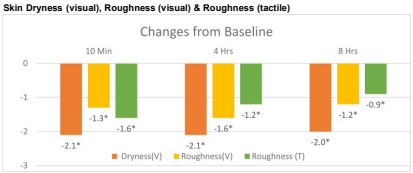
3. EFFICACY OF DERMOPROTECTANT PRODUCT AGAINST SKIN DRYNESS

Skin Surface Hydration (Corneometer)



Trans Epidermal Water Loss (Tewameter)

Skin Dryness (visual), Roughness (visual) & Roughness (tactile)



Conclusions:

Environmental pollutants impact our skin health and life quality and protection from these negative impacts is very important. Use of a lotion can help protect the skin before exposure to pollution while after exposure to pollution a Gentle cream scrub providing moisture and exfoliation benefits along with a moisturizer routinely limits skin damage associated with pollution exposure and with irritants.
Low outdoor temperatures and low relative humidity in the winter lead to decreased ability of SC to retain water and contribute to dry skin conditions which, if ignored, can lead to a variety of issues like pruritus, ichthyosis, eczema and psoriasis. Moisturizers are helpful in maintaining the skin barrier and help prevent dry skin. Being in direct contact with the skin, dermo-protectants help protect and modulate skin characteristics and functioning, thus making them unique and versatile, outstepping the original boundaries of a product for providing beauty alone.
Clinical trials testing dermo-protectants for proving product efficacy and its extent, with proper study designs and techniques, is important in not only adding value for the consumer but also important for maintaining a competitive edge.

References:

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5. Alexander H, Brown S, Danby S, Fluhr C. (2018) Research Techniques made simple: Trans epidermal water loss measurements as a research tool. J. Invest. Dermatol. 138:2295-2300.