CUPRON PILLOWCASE STUDY

Summer 2009

Objective: **Test the improvement of facial skin appearance characteristics using Cupron pillowcases containing copper oxide.**

Results: **Cupron has again demonstrated the cosmetic efficacy of its non-sensitizing, non-irritating, natural copper oxide technology via an independently monitored, double blind, placebo controlled, parallel, randomized study.**

For the two 28-day periods between June 4, 2009 and July 2, 2009 (first group) and June 11, 2009 and July 9, 2009 (second group), Essex Laboratories, an independent cosmetic clinical testing laboratory located in Verona, New Jersey, USA, conducted a test to determine if sleeping on a pillowcase containing Cupron copper oxide technology results in the improvement of the appearance of facial characteristics such as wrinkles and fine lines.

During the testing period an independent principal investigator, Toni F. Miller, PhD, DABT, BCFE was responsible for monitoring and reviewing all aspects of the study. The study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and Essex Testing Clinic (ETC) Standard Operating Procedures (SOPs). Informed Consent was obtained from each of the 63 enrolled volunteer panelists. The study was conducted in a double-blind fashion with the code broken only at the final report writing after all evaluations and analyses were completed. The 63 panelists that were empanelled for the study were randomly assigned to the control pillowcase or the test pillowcase test group. No participant knew which pillowcase was the active or placebo product. None of the expert graders or clinical technical staff involved in the study knew the identity of the pillowcase.

Synopsis

We hypothesized that sleeping on fabrics containing copper-impregnated fibers would have a positive cosmetic effect on the skin. The aim of this study was to confirm our hypothesis.

A four week, double blind, parallel, randomized study was carried out, in which 63 volunteers, aged 35-65, were enrolled. Each panelist was randomly given either a pillowcase containing Cupron patented copper oxide yarn (0.4% weight/weight) or a control pillowcase not containing copper oxide at all. All panelists were required to sleep only on the pillowcase they obtained and to report back after 4 weeks. At Day 0 and at Day 28, a trained technician evaluated crow's feet, fine lines and wrinkles on the face of each panelist.

Result:

A statistically significant reduction in the appearance of crow's feet, fine lines and wrinkles was observed by the expert grader on those who used the pillowcases containing Cupron copper oxide impregnated yarn. **The reduction represented a 93% mean improvement compared to the placebo pillowcase.**

No statistically significant improvement in the appearance of crow's feet, fine lines or wrinkles was observed for the placebo pillowcase users.

Some Background on Copper

Copper is an essential trace element. The recommended daily allowance of copper is 0.9 mg (1). Copper is safe for humans, as demonstrated by the widespread and prolonged use of copper intrauterine devices (2) and over-the-counter wound healing treatments (3;4). The risk of adverse reactions due to dermal contact with copper is extremely low (5). A phase I clinical trial found that applications of ointment preparations containing copper in concentrations up to 20% did not cause any adverse reactions or toxicity (6).

A durable platform technology was developed, which introduces copper oxide to textile fibers (7;8). The copper-impregnated textiles cause no skin sensitization or irritation (8-10).

We hypothesized that sleeping on pillowcases containing Cupron copper oxide would have a significant positive cosmetic effect on the individuals using them. In the present study we demonstrate in a double blind, placebo controlled study that sleeping on pillowcases containing Cupron copper oxide reduces the appearance of wrinkles, crow's feet and fine lines.

Test Methods

Test Items

Two test items were included in the study: a beige, cotton/polyester pillowcase containing 0.4% (weight/weight) Cupron copper oxide particles, and a placebo control, light green cotton/polyester pillowcase not containing copper oxide. There were no differences in the construction, structure, and feel of the two test items. In order to have everyone equal with regards to their skin care, each panelist was also given one bottle of Neutrogena® Oil-Free Fresh Moisturizer and one bar of Neutrogena® facial soap to use during the test procedure, in place of their regular facial soap and moisturizer. Panelists were also given one bottle of Arm & Hammer detergent to launder the pillowcases.

Test Participants

Sixty-three volunteers (60 women and 3 men), aged 35-65, were enrolled in the study. Each panelist was to read, understand and sign a written Informed Consent Form and complete a brief Medical History Form.

Inclusion Criteria

1. Males and females between the ages of 35 and 65 in general good health.
2. Individuals with a fine line/wrinkle score of ñ5ò (noticeable) or greater at the crowôs feet area around the eyes.
3. Individuals who slept on their side (right or left side).
4. Individuals who agreed to use Neutrogena® cleanser and moisturizer in place of their regular cleanser and moisturizer for the duration of the study.
5. Individuals who read, understood and signed the Informed Consent form.
6. Individuals with the ability to follow the study directions, to participate in the study, to return for all visits and to apply the product as per instructions.

Exclusion Criteria

1. Women who were pregnant, planning a pregnancy, lactating and/or nursing a child.
2. Individuals with visible skin disease that might have interfered with the evaluations.
3. Individuals with sunburn, suntan on the face or planning a vacation with sun-exposure or planning the use of a tanning booth during the study.
4. Individuals engaged in a concurrent research project of a facial product.
5. Individuals taking medications which might have interfered with the test results including the use of steroidal/non-steroidal anti-inflammatory drugs or antihistamines.
6. Individuals who had undergone a laser resurfacing or dermabrasion procedure on the face in the past 2 years, or a chemical face peel (deep peel in the past 1 year; superficial peel in the past 2 months).
7. Individuals with acne, active atopic dermatitis/eczema or psoriasis.
8. Individuals who had a surgical ñcosmeticò procedure on the face within the past 10 years.

9. Treatment or history of any type of cancer.
10. Individuals who were under treatment for asthma or diabetes.
11. Individuals with a known sensitivity to cosmetics or personal care products.

Study Outline

The study was designed as a 4-week study, in which the pillowcases were used by each of the test panelists.

Panelists reported to the Testing Facility for the baseline visit. A trained technician evaluated crowôs feet, fine lines and wrinkles on the face of each panelist. An irritation assessment of the face was conducted by a trained technician at the start of the study and every evaluation visit.

Enrolled panelists were assigned to the green pillowcase cell or the beige pillowcase, based on a randomization. Each panelist that was enrolled was provided with a Neutrogena® cleansing bar and moisturizer to be used during the entire test procedure. Additionally, each panelist was supplied with a detergent (Arm & Hammer Essentials™) to be used to launder the pillowcase. Panelists were instructed to launder the pillowcase as they normally would and to record the number of launderings the pillowcase received.

Panelists were given a pillowcase, Neutrogena® products, laundry detergent, use instructions and a diary. Panelists were instructed to report to the Testing Facility after 4 weeks of product use for additional evaluations. The panelists were instructed not to use the moisturizer on the day of their visit.

Evaluations of efficacy were based on a comparison of baseline vs. each observation period for the green pillowcase and the beige pillowcase. Additionally, a comparison between the green and beige pillowcases was conducted.

Randomization and Comparison Baseline Evaluations

The 63 panelists that were empanelled for the study were randomly selected for the 2 groups. No participant knew which pillowcase was the active or placebo product. None of the expert graders or clinical technical staff involved in the study knew the identity of the pillowcase. Panelists reported to the Testing Facility with a freshly washed ñclean faceò (without wearing face/eye area cosmetics or having applied any facial skin care products) for baseline evaluations.

Evaluation of Crow's Feet Fine Lines and Wrinkles

At each visit, an expert grader evaluated fine lines and wrinkles at the crowôs feet area of each panelist according to the scale below.

0 = None; 1-3 = Slight; 4-6 = Noticeable; 7-9 = Very Noticeable

Results and Discussion

Determination of positive cosmetic effect by an Expert Grader

The following table presents a summary of the mean crowôs feet, fine lines and wrinkles scores.

Expert Grader Evaluation of Crow's Feet Area Fine Lines/Wrinkles Evaluation Baseline & Week4				
Pillowcases	**Containing Cupron Copper Oxide Impregnated Yarn**		**With No Cupron Yarn**	
Parameter	**Baseline**	**Week 4**	**Baseline**	**Week 4**
Mean Score ± S.D.	5.9 ± 0.9	4.9 ± 0.9	5.8 ± 1.0	5.3 ± 0.9
n	31	31	31	31
p* value		<0.001		0.004
% Panelists Improving		75%		54%
% Mean Improvement		16.2%		8.4%

**Statistically significant difference from baseline*

When compared with baseline, the expert grader evaluated that in 75% of the panelists there was a reduction of crow's feet, fine lines and wrinkles after using a moisturizing cream and pillowcases containing Cupron copper oxide impregnated yarn for 4 weeks.

The improvement observed with the pillowcase containing Cupron Copper-oxide Impregnated Yarn was statistically significant ($p \leq 0.010$) when compared with baseline. Pillowcases containing Cupron copper oxide impregnated yarn resulted in a 93% mean improvement in facial fine lines and wrinkles as compared to the placebo pillowcase. Almost 40% more of the panelists using the moisturizer and cleaning soap plus the Cupron pillowcase showed improvement over those using the moisturizer and cleaning soap and the placebo pillowcase.

The results of this study demonstrates that sleeping on pillowcases containing at least 0.4% weight/weight copper oxide particles has a positive cosmetic effect on several cosmetic characteristics, such as reducing the appearance of wrinkles and fine lines. This positive effect was **in addition** of the positive effect that moisturizing creams and cleaning soaps have.

No irritation or a single adverse reaction was noted during this study, as well as in previous studies. This is in accordance to the very low risk of any adverse reaction due to dermal contact with copper (11).

A possible concern may be the inhalation of copper oxide particles. However, in an experiment using good laboratory practices (GLP) conducted by an independent laboratory (Nelson Laboratories, Salt Lake City, Utah, USA), human inhalation conditions were simulated for 5 hours and the amount of copper particles released from copper oxide impregnated fabrics containing 7.5 times the amount of copper oxide than the tested Cupron copper oxide pillowcases (i.e. in fabrics containing 3% (weight/weight) copper oxide particles) was determined.

The amount of copper particles measured was negligible and well below the USA Occupational Safety and Health Administration (OSHA) permissible exposure limits (PEL) for copper (data not shown), indicating that pillowcases containing 0.4% copper oxide (weight/weight) do not pose any risk due to possible inhalation of copper particles.

In addition, although copper is an essential element (12) and although copper oxide is found in multivitamin pills and dietary supplements, an experiment using GLP was conducted in an independent laboratory (Nelson Laboratories) in which the amount of copper eluting from a fabric impregnated with 7.5 times the amount of copper found in the tested Cupron copper oxide pillowcases into simulated saliva was determined. This experiment simulates an extreme unlikely scenario whereby secreted saliva coming into contact with the pillowcases during sleep may be ingested. The amount of copper that eluted into the saliva was below the minimal risk level (MRL) for copper oral exposure, determined to be 0.01mg/kg/day by the Agency for Toxic Substances and Disease Registry of the U.S. Department of Health and Human Services, indicating that even a fabric with 7.5 times as much copper as that used in this study would not pose a risk due to possible consumption of the copper that may elute into saliva.

How Does it Work

Why does sleeping on a Cupron pillowcase have a positive effect on the skin? A possible explanation for the reduction in wrinkles and fine lines, and improvement of the overall appearance when sleeping on the Cupron pillowcases may be that the copper ions are liberated into the moisture found between the face and the pillowcase, interacting naturally to enhance the skinôs beautiful appearance. Accordingly, several commercial facial creams contain copper as their active ingredient (e.g. Neutrogena Visibly Firm® Face Lotion SPF 20).

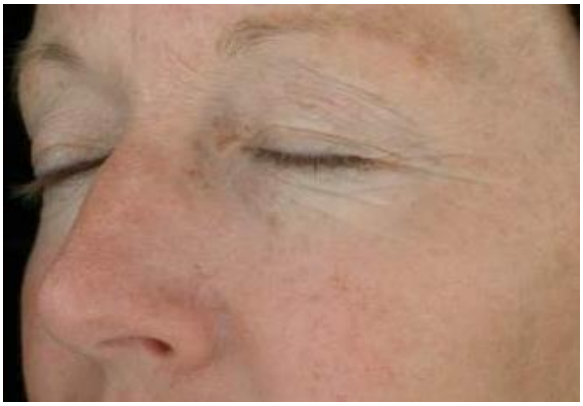
In conclusion, this study confirms our hypothesis that sleeping on pillowcases made with Cupron technology does have a significant positive cosmetic effect.

Here are two sets of pictures from two different subjects demonstrating the difference in the appearance of wrinkles and fine lines after only 4 weeks of sleeping on the pillowcase containing Cupron copper oxide.

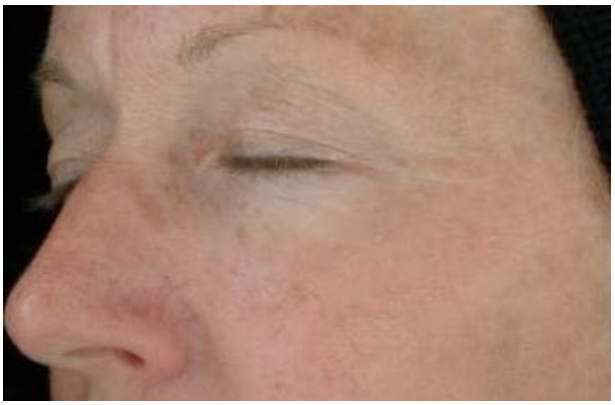
BEGINNING OF STUDY

AFTER 4 WEEKS

BEGINNING OF STUDY



AFTER 4 WEEKS



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