

Double-Blind, Parallel, Randomized Clinical Trial to Determine the Efficacy in Improving Cosmetic Attributes of Facial Skin when Using Cupron (Copper-Oxide Containing) Pillowcases

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Site: Kaplan Medical Center, Rehovot, Israel. Kaplan Medical Center is a teaching hospital, that belongs to the Clalit Israeli Hospital Network, affiliated to the Hadassah and Hebrew University of Jerusalem Medical School. (<http://www.kmc.org.il/>).

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Study Coordinator: Dr. Gadi Borkow



**Double-Blind, Parallel, Randomized Clinical Trial to Determine the
Efficacy in Improving Cosmetic Attributes of Facial Skin when Using
Cupron (Copper-Oxide Containing) Pillowcases**

STUDY REPORT

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Summary

Fifty-seven individuals, (55 women and two men), completed a 4 week, double blind, parallel, randomized clinical study. The participants used either copper-oxide containing pillowcases or pillowcases not containing copper-oxide (the “placebo control pillow cases”). Photographs were taken by a professional photographer of each participant at three times: The beginning (baseline) of the Trial, and at 2 and 4 weeks after the commencement of the Trial.

An expert grader evaluated the face for the effect on the following cosmetic facial skin attributes of those individuals using both the copper-oxide containing pillowcases and the placebo control pillowcases: wrinkles; crowsfeet/fine lines; blemishes; skin glow (defined as “shining skin”); texture; and general (or overall) appearance (defined as “skin that appeared generally healthy and without damage and wear-and-tear due to the ravages of time, sun-exposure, etc.”). These qualities were evaluated at the baseline, 2, and 4 weeks.

When comparing the copper-oxide containing pillowcases with the placebo pillowcases, the copper-oxide containing pillowcases performed statistically significantly better than the placebo control pillowcases for the following facial attributes: wrinkles, crowsfeet/fine lines, and general appearance, at both 2 and 4 weeks. The copper-oxide containing pillowcases performed statistically significantly better for texture at 4 weeks than the placebo control pillowcases.

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1. Aim of Trial/Study

The aim of the trial/study was to confirm that sleeping on pillowcases containing Cupron fibers had a statistically significant cosmetic effect on the skin of the individuals sleeping on them versus individuals sleeping on placebo control pillowcases.

2. Hypothesis

Copper plays a key role in many of the processes of skin regeneration. We hypothesized that sleeping on fabrics containing copper oxide impregnated fibers would have a positive and statistically significant cosmetic effect on the skin of the individuals sleeping on them versus those individuals sleeping on placebo control pillowcases.

3. General Trial Description

A double-blind, parallel, randomized, clinical trial of the copper-oxide containing pillow cases against placebo control pillowcases was conducted for a period of 4 weeks.

4. Trial Participants

Fifty-eight healthy individuals (56 women and 2 men), aged 30-60, were enrolled. Most of the trial participants are staff members of the Kaplan Medical Hospital (Laboratory and Medical Personnel). One trial participant dropped out of the Trial for personal reasons before the end of the Trial.

5. Test Items

Two test items were included in the study. Test Item 1, the copper-oxide containing pillowcase, was a pillow case in which 100% of the polyester fibers contained 0.4% (weight/weight) copper oxide. The copper oxide content of Test Item 1 was verified by an independent laboratory, The Analytical Laboratory of the Faculty of Agricultural, Food and Environmental Quality Sciences of the Hebrew University of Jerusalem. Test item 2, the placebo control pillowcase, was a pillowcase of the same appearance made of polyester fibers, but not containing copper oxide. There were no differences in the construction, structure, and feel of the two Test Items.

6. Randomization

Each one of the trial participants was given a number. Twenty nine of the trial participants were randomly selected for Group A and the other 29 trial participants were randomly selected for Group B. Group A and Group B were given either Test Item 1 or 2 during the Trial. No trial participant knew what the meaning of Test Item 1 or Test Item 2 was, i.e., they did not know if they belonged to the “test” group or to the “placebo control” group. In addition, the Expert Grader (Dr. Anna Lyakhovitsky, MD, Dermatologist), who graded the cosmetic facial skin attributes of the trial participants at the end of the trial, did not know which participants belonged to which group, or to which Test Item the participants had been exposed.

7. Trial Details

1. All 58 healthy volunteers (trial participants) were enrolled in the study at Day 0 (Week 0).
2. Each trial participant was randomly assigned to Group A or to Group B.
3. Photographs of the front and both sides of the faces were taken at Day 0 by a professional Photographer (Gideon Boaz). Each photo was marked with the participant code number, with the area of the face photographed (front, left, or right), and the date the photo was taken.
4. Trial participants were given 2 pillow cases, either Test Item 1 or Test Item 2, according to the Group to which they belonged.
5. Trial participants were instructed to use only the pillowcases given to them (the Test Items), and not their regular pillowcases, during the period of the Study.
6. Trial participants were instructed to use (wash, store, etc.) the Test Items in the same way as they would use their regular pillowcases, but without using a fabric softener during the washing or drying cycle.
7. Trial participants were instructed not to use moisturizers or other facial creams on their face during the night throughout the Trial period.
8. Trial participants were photographed by the same professional photographer at 2 and 4 weeks from the commencement of the study. The lightning conditions were the same as those taken at Week 0. Each photo was marked with the participant

code number, with the area of the face photographed (front, left, or right), and the date the photo was taken.

9. The photographs of the trial participants were examined by the Expert Grader at the end of the 4 weeks Trial by comparing the front photos taken at Weeks 0, 2 and 4 side by side, then by comparing the left side photos taken at Weeks 0, 2 and 4 side by side, and finally by comparing the right side photos taken at Week 0, 2 and 4 side by side, for each one of Trial Participant. A score for each of the cosmetic facial skin attributes specified in Section 8 was given (See Appendix A).

8. Facial Skin Attributes Examined

1. The Expert Grader graded each trial participant's facial skin attributes (see below) according¹ to standard cosmetic/dermatologic scores² of 1: Absent; 2: Mild; 3: Moderate; 4: Severe; and 5: Extreme. These ratings were given at Weeks 0, Week 2, and Week 4 of the Trial (See Appendix A, Page 11).
2. The following skin attributes were graded:
 - Wrinkles;
 - Crowsfeet/Fine lines;
 - Blemishes;
 - Skin Glow (defined as “shining skin”);
 - Texture;
 - General (or Overall) Appearance (defined as “skin that appeared generally healthy and without damage and wear-and-tear due to the ravages of time, sun-exposure, etc.”).

¹ Letter from Dr. Anna Lyakhovitsky. According to another independent dermatologist consulted, Dr. Anna Lyakhovitsky's definition of “skin glow” is unusual. A more common definition would be the “healthy skin appearance” definition used to define “General Appearance.” The latter is more properly defined as “skin glow” for cosmetic purposes.

² Lindqvist et al., *Plas Reconstr Surg* 115: 282, 2005; Traikovich S.S. *Arch Otolaryngol Head Neck Surg* 125: 1091, 1999; Narins et al., *Dermatol Surg* 29: 588, 2003.

9. Data Analysis

1. Data analysis was performed by MediStat Ltd. (Statistics in Medicine, Tel Aviv, Israel).
2. One of the trial participants did not finish the Trial for personal reasons. Her data was not included in the analysis.
3. A total of 54 scores (6 facial skin attributes x 3 photos of the face x 3 times) per trial participant were given.
4. For all facial skin attributes, a numerically decreasing score (i.e. from 3 to 2 or from 4 to 1) was considered an improvement in that facial skin attribute. When the movement was 1 on the scale, a grade of 1 was given (i.e. from 3 to 2 or from 2 to 1). When the movement was 2 on the scale, a grade of 2 was given (i.e. from 3 to 1 or from 4 to 2). No movement along the scale received a score of 0. A numerical increase in the scale (deterioration) received a correspondingly negative score.
5. Statistical Wilcoxon scores (rank sums) and chi-square tests were used to compare between Expert Grader scores for Test Item 1 and Test Item 2 at baseline Week 0 to compare the differences at Week 2 and Week 4, respectively, from the baseline (i.e., Week 2 versus Week 0 and Week 4 versus Week 0) per each examined facial skin attribute.

10. Tables of Statistical Analyses

Table 1: Overall summary → Wilcoxon scores (rank sums) and chi-square comparison between groups for changes from baseline

	2 Weeks		4 Weeks	
	<i>Wilcoxon - Rank Sums Test</i>	<i>Chi-Square Test</i>	<i>Wilcoxon - Rank Sums Test</i>	<i>Chi-Square Test</i>
Wrinkles	<0.001	<0.001	<0.001	<0.001
Fine Lines	<0.001	<0.001	<.0001	0.0001
Blemishes	0.6349	0.6279	0.2659	0.2615
Glow	0.9405	0.9381	0.3668	0.3928
Texture	0.1964	0.1915	<0.05	<0.05
Overall Appearance	<0.001	<0.001	<0.001	<0.001

Table 2: Wilcoxon scores (rank sums) comparison between groups for changes from baseline

	2 Weeks				4 Weeks			
	Front	Right	Left	Total	Front	Right	Left	Total
Wrinkles	0.0500	0.0860	0.0390	0.0005	0.2129	0.0258	0.0280	0.0005
Fine Lines	0.1030	0.0636	0.0047	0.0003	0.1337	0.0031	0.0521	0.0002
Blemishes	0.3685	1.0000	0.9572	0.6349	0.3906	0.7785	0.4780	0.2659
Glow	0.8908	0.8751	0.8207	0.9405	0.5674	0.4918	0.7830	0.3668
Texture	0.0995	0.1918	0.5073	0.1964	0.0455	0.2503	0.2648	0.0135
Overall Appearance	0.0802	0.0267	0.0802	0.0008	0.0372	0.0037	0.0293	<.0001

Table 3: Chi-square for Wilcoxon comparison between groups for changes from baseline

	2 Weeks				4 Weeks			
	Front	Right	Left	Total	Front	Right	Left	Total
Wrinkles	0.0331	0.0590	0.0318	0.0002	0.1717	0.0221	0.0221	0.0003
Fine Lines	0.0915	0.0539	0.0027	0.0002	0.1219	0.0021	0.0541	0.0001
Blemishes	0.3401		0.9349	0.6279	0.3725	0.7626	0.4624	0.2615
Glow	0.8792	0.8618	0.8062	0.9381	0.6028	0.5596	0.7090	0.6028
Texture	0.0860	0.1731	0.4861	0.1915	0.0377	0.2504	0.2504	0.0128
Overall Appearance	0.0690	0.0204	0.0690	0.0006	0.0303	0.0021	0.0233	<.0001

11. Conclusions

There was a statistically significant reduction of the appearance of facial wrinkles and crowsfeet/fine lines and statistically significant improvement in the texture and overall appearance of facial skin when consistently sleeping for 4 weeks on 0.4% (weight/weight) copper-oxide containing pillowcases (the Cupron pillowcases) versus the placebo control pillowcases. In most trial participants, this statistically significant effect was already noticeable within 2 weeks of using the copper-oxide containing pillowcases.

Appendix A

Cosmetic Trial – Grade Page

Participant Number:

Date:

Week: 0	<u>Front Side</u>	<u>Right Side</u>	<u>Left side</u>
	None → Severe	None → Severe	None →
Severe			
Wrinkles	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Crowsfeet/Fine Lines	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Blemishes	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Skin Glow	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Texture	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
General Appearance	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

Week: 2	<u>Front Side</u>	<u>Right Side</u>	<u>Left side</u>
	None → Severe	None → Severe	None →
Severe			
Wrinkles	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Crowsfeet/Fine Lines	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Blemishes	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Skin Glow	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Texture	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
General Appearance	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

Week: 4	<u>Front Side</u>	<u>Right Side</u>	<u>Left side</u>
	None → Severe	None → Severe	None →
Severe			
Wrinkles	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Crowsfeet/Fine Lines	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Blemishes	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Skin Glow	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Texture	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
General Appearance	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

Examined by: _____.