

## Measurement of Skin Hydration after a Single Application

### Summary

Study Sponsor .....: **Asam GmbH & Co. Betriebs KG**  
Altenzeller Weg 16  
92339 Beilngries  
Germany

Performance of Test .....: Derma Consult Concept GmbH  
and Evaluation by Von-Weichs-Str. 9A  
53121 Bonn

Supervisors of Study .....: Dr. rer. nat. H. P. Nissen  
Dr. med. H. Prieur  
Drs. B. Nissen

Study Code .....: DCC06K045

Test Product .....: The test product, which was coded as follows, was provided by  
M. Asam GmbH & Co. Betriebs KG:  
A. Vinolift Anti-Age Straffungscreme

Subjects .....: Number of individuals.: 20  
Sex .....: female  
Age range .....: 25-62 years (average: 40,6)

Test Area .....: Inner sides of forearms (randomized location)

Application .....: Single, controlled Application

Test Period .....: July 2006

Test Parameters .....: Determination of *skin hydration* with Corneometer CM 825 PC  
(Courage & Khazaka GmbH, Cologne)

- Time of Evaluation.....: Baseline measurement at start & after single product application of the test product:
- 2 hours after the application
  - 4 hours after the application
  - 6 hours after the application
  - 8 hours after the application
  - 24 hours after the application
- Evaluation .....: Descriptive statistics (average, median, minimum, maximum, variance, standard error, standard deviation); ANOVA, Tukey HSD
- Results .....: The test product was found to statistically significantly increase skin hydration after a single application and to have a 24 hour moisturization effect.

## Methods

### *Measurement of Skin Hydration (Corneometry)*

The Corneometer CM 825 PC (Courage and Khazaka, Cologne, Germany) registers the electrical capacitance of the skin surface. The capacitance is expressed digitally in arbitrary units (a.u.). The probe head (7x7 mm) consisting of a condenser was applied to the skin surface at constant pressure (3.5 N). The measuring principle is based on distinctly different dielectric constants of water (approximately 81) and most other materials (less than seven). Five measurements were performed on each test area and the mean was used to define the hydration state of the stratum corneum. Corneometer used in this study: S/N 26 96 1206.

### Performance of Test

The subjects were selected from the Derma Consult Concept GmbH database. They were informed about importance and meaning of the study. Written informed consent was obtained from all the subjects prior to entry into the trial. The following criteria were used for selection of subjects:

for inclusion in study:

- female ( $\geq 18$  years of age)
- clinically healthy

for exclusion from study:

- skin diseases
- pregnancy

The subjects of this study were between 25-62 years of age (average: 40,6). They could withdraw from study at any time without giving any reason.

Subjects were instructed not to use any topical preparations on the test areas starting from seven days prior to testing and until the end of the test. For cleansing, water or a mild syndet (Eubos<sup>®</sup> flüssig – blau; manufacturer: Dr. Hobein, D-53340 Meckenheim-Merl, Germany) was allowed only (whole study inclusive the run-in phase; supplied by Derma Consult Concept GmbH).

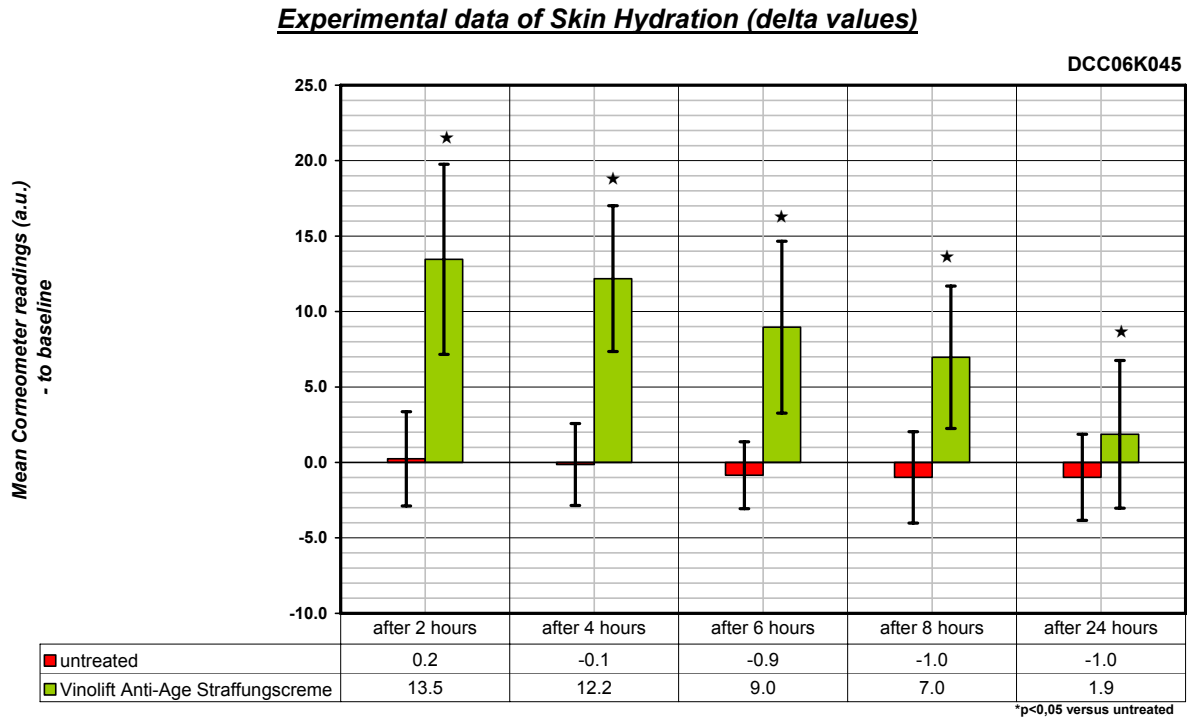
Prior to the controlled application of the test product (randomized location) by a staff member of Derma Consult Concept GmbH (approximately 2 mg/cm<sup>2</sup>; 30 seconds of massaging the product into the skin), measurements were taken at clearly defined sites of the inner sides of the forearms. One area remained untreated and served as control. Subjects were instructed not to cover the test area by clothing during the first 20 minutes after product application and in case the product was not taken into the skin completely, remaining product was removed with the soft paper towel by a Derma Consult staff member (not required in majority of subjects). Further measuring was performed 2, 4, 6, 8 and 24 hours following the single treatment (adaptation time: 30 min, room temperature: 21±1°C, relative humidity: 50± 5%). Subjects were asked to avoid bodily exertion and water contact.

### Biometry

Measurement data is automatically computerised and after validity check and quality assurance stored centrally in a database. Evaluation is conducted using the software NAG<sup>®</sup> Statistical Add-Ins for Excel – NAG Ltd., United Kingdom. The data were analyzed by Wilcoxon Rank Test. The 0.05 level was selected as the point of minimal acceptance of statistical significance.

## Results

Evaluated are changes in the hydration values in the treated area in comparison to the changes in the untreated area. An increase in the measurement value corresponds to an increase in skin hydration. The absolute changes by area and time point are displayed in figure one below.



*Fig. 1:  $\Delta$  Skin Hydration Values*

Following the application of the test product, a steep, statistically significant, increase in skin hydration was observed in the product treated area ( $p < 0.05$ ) as compared to the changes in the untreated condition. Over time the effect diminished, yet remained statistically significant until the last measurement 24 hours after the single application.

The test product was found to significantly increase skin hydration after a single application and to have a 24 hour moisturization effect. The respective measured changes as percentages relative to the initial condition and with consideration of the changes in the untreated area are reported in figure two below.

**Increase in Skin Hydration relative to initial conditions and to untreated**

DCC06K045

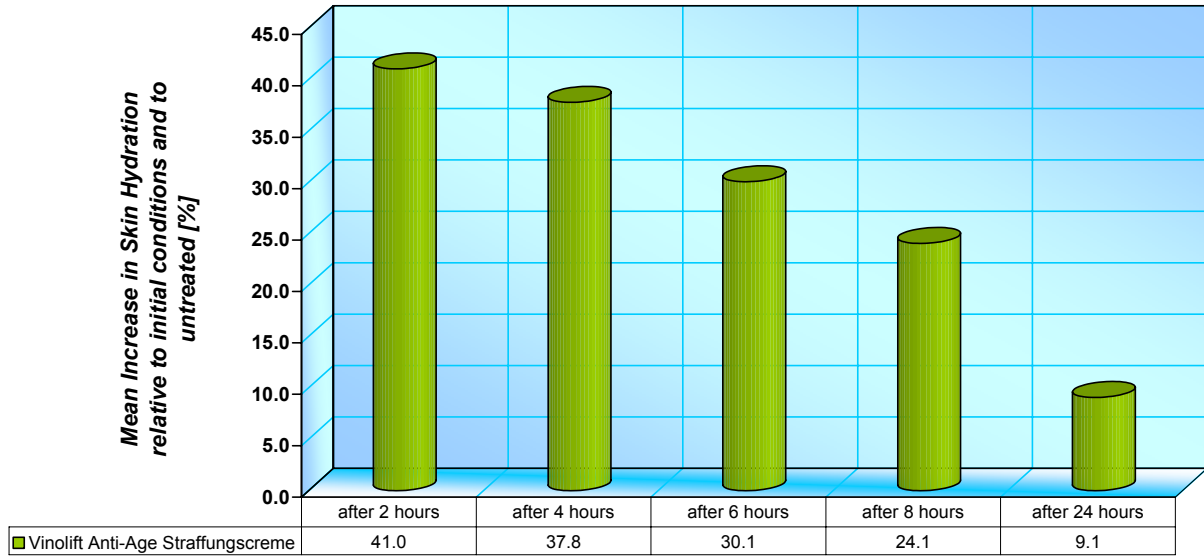


Fig. 2: Increase in Skin Hydration in %

## Incompatibility

No incompatibility was observed in any of the volunteers.

Signature:

Drs. B. Nissen Manager Derma Consult Concept
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Signature:

Dr. H. P. Nissen Chemist – Ph.D.
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Signature:

Dr. med. H. Prieur Dermatologist - Allergist
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Enclosures: Measuring values, statistics, summary statistics, graphic representations

**Experimental data of Skin Hydration, DCC06K045**

Corneometer readings (a.u.)

	start		after 2 hours		after 4 hours		after 6 hours		after 8 hours		after 24 hours	
	untr.	A	untr.	A	untr.	A	untr.	A	untr.	A	untr.	A
1	27.2	31.2	26.6	55.0	26.0	54.6	27.2	55.4	29.0	46.2	27.6	36.2
2	33.6	36.4	33.4	42.2	29.2	44.2	31.4	41.4	29.2	37.2	29.0	30.2
3	29.8	32.0	33.4	53.2	34.2	49.0	33.4	48.2	31.4	46.8	35.6	41.0
4	27.6	31.4	22.2	32.6	27.6	38.4	26.2	35.6	30.6	36.0	25.2	23.8
5	32.2	27.8	31.6	40.6	31.0	36.8	29.6	28.0	30.8	29.4	30.4	28.6
6	35.2	36.0	36.4	48.8	36.0	48.0	34.2	46.0	34.2	44.0	35.6	38.2
7	29.0	33.2	30.8	48.8	31.2	50.2	27.8	41.2	25.4	39.2	24.8	35.2
8	32.2	33.2	30.8	47.8	28.8	49.2	31.4	48.6	28.0	45.4	31.0	37.8
9	38.6	33.8	47.0	49.6	34.8	46.8	37.2	45.4	31.4	40.8	37.2	31.4
10	24.2	37.8	26.0	48.8	27.2	49.4	26.4	47.6	26.6	45.6	23.0	38.6
11	25.6	29.2	28.0	45.2	27.4	39.0	27.6	38.2	23.0	30.6	25.4	31.4
12	29.4	26.6	26.6	36.8	25.2	37.6	26.6	36.0	27.4	31.2	25.8	29.6
13	27.6	25.8	31.6	38.8	26.8	38.6	24.0	33.6	27.2	34.4	24.6	27.0
14	26.0	31.4	26.0	46.6	30.0	44.8	29.2	37.0	31.0	41.0	30.4	40.4
15	36.0	38.4	38.4	64.4	35.2	52.2	35.2	49.6	32.2	45.4	32.6	32.8
16	40.2	38.4	40.4	49.4	40.4	46.4	40.0	41.6	39.4	42.0	39.4	41.8
17	33.4	32.4	31.2	40.4	30.2	36.4	28.2	37.2	30.8	33.6	30.6	32.2
18	31.8	34.0	28.8	42.4	34.8	46.2	30.8	42.8	34.2	44.6	35.2	42.8
19	32.6	32.0	29.2	53.2	32.4	51.6	31.2	46.2	32.8	46.2	32.8	40.2
20	30.4	30.0	29.0	35.6	31.4	35.2	28.0	30.6	28.2	30.8	26.6	29.0
<b>Average</b>	31.1	32.6	31.4	46.0	31.0	44.7	30.3	41.5	30.1	39.5	30.1	34.4
<b>S.D.</b>	4.3	3.7	5.7	7.6	4.0	6.0	4.1	7.0	3.6	6.1	4.8	5.5
<b>Median</b>	31.1	32.2	30.8	47.2	30.6	46.3	29.4	41.5	30.7	40.9	30.4	34.0

**Experimental data of Skin Hydration, DCC06K045**

delta Corneometer readings (a.u.)

	after 2 hours t1-t0		after 4 hours t2-t0		after 6 hours t3-t0		after 8 hours t4-t0		after 24 hours t5-t0	
	untr.	A	untr.	A	untr.	A	untr.	A	untr.	A
1	-0.6	23.8	-1.2	23.4	0.0	24.2	1.8	15.0	0.4	5.0
2	-0.2	5.8	-4.4	7.8	-2.2	5.0	-4.4	0.8	-4.6	-6.2
3	3.6	21.2	4.4	17.0	3.6	16.2	1.6	14.8	5.8	9.0
4	-5.4	1.2	0.0	7.0	-1.4	4.2	3.0	4.6	-2.4	-7.6
5	-0.6	12.8	-1.2	9.0	-2.6	0.2	-1.4	1.6	-1.8	0.8
6	1.2	12.8	0.8	12.0	-1.0	10.0	-1.0	8.0	0.4	2.2
7	1.8	15.6	2.2	17.0	-1.2	8.0	-3.6	6.0	-4.2	2.0
8	-1.4	14.6	-3.4	16.0	-0.8	15.4	-4.2	12.2	-1.2	4.6
9	8.4	15.8	-3.8	13.0	-1.4	11.6	-7.2	7.0	-1.4	-2.4
10	1.8	11.0	3.0	11.6	2.2	9.8	2.4	7.8	-1.2	0.8
11	2.4	16.0	1.8	9.8	2.0	9.0	-2.6	1.4	-0.2	2.2
12	-2.8	10.2	-4.2	11.0	-2.8	9.4	-2.0	4.6	-3.6	3.0
13	4.0	13.0	-0.8	12.8	-3.6	7.8	-0.4	8.6	-3.0	1.2
14	0.0	15.2	4.0	13.4	3.2	5.6	5.0	9.6	4.4	9.0
15	2.4	26.0	-0.8	13.8	-0.8	11.2	-3.8	7.0	-3.4	-5.6
16	0.2	11.0	0.2	8.0	-0.2	3.2	-0.8	3.6	-0.8	3.4
17	-2.2	8.0	-3.2	4.0	-5.2	4.8	-2.6	1.2	-2.8	-0.2
18	-3.0	8.4	3.0	12.2	-1.0	8.8	2.4	10.6	3.4	8.8
19	-3.4	21.2	-0.2	19.6	-1.4	14.2	0.2	14.2	0.2	8.2
20	-1.4	5.6	1.0	5.2	-2.4	0.6	-2.2	0.8	-3.8	-1.0
<b>Average</b>	0.2	13.5	-0.1	12.2	-0.9	9.0	-1.0	7.0	-1.0	1.9
<b>S.D.</b>	3.1	6.3	2.7	4.8	2.2	5.7	3.0	4.7	2.9	4.9
<b>Median</b>	-0.1	12.9	-0.1	12.1	-1.1	8.9	-1.2	7.0	-1.3	2.1

**Increase in Skin Hydration relative to initial conditions and to untreated, DCC06K045**

corrected Corneometer readings (a.u.) [%]

	after 2 hours		after 4 hours		after 6 hours		after 8 hours		after 24 hours	
	untr.	A	untr.	A	untr.	A	untr.	A	untr.	A
1	-2.2	78.5	-4.4	79.4	0.0	77.6	6.6	41.5	1.5	14.6
2	-0.6	16.5	-13.1	34.5	-6.5	20.3	-13.1	15.3	-13.7	-3.3
3	12.1	54.2	14.8	38.4	12.1	38.5	5.4	40.9	19.5	8.7
4	-19.6	23.4	0.0	22.3	-5.1	18.4	10.9	3.8	-8.7	-15.5
5	-1.9	47.9	-3.7	36.1	-8.1	8.8	-4.3	10.1	-5.6	8.5
6	3.4	32.1	2.3	31.1	-2.8	30.6	-2.8	25.1	1.1	5.0
7	6.2	40.8	7.6	43.6	-4.1	28.2	-12.4	30.5	-14.5	20.5
8	-4.3	48.3	-10.6	58.8	-2.5	48.9	-13.0	49.8	-3.7	17.6
9	21.8	25.0	-9.8	48.3	-3.6	37.9	-18.7	39.4	-3.6	-3.5
10	7.4	21.7	12.4	18.3	9.1	16.8	9.9	10.7	-5.0	7.1
11	9.4	45.4	7.0	26.5	7.8	23.0	-10.2	15.0	-0.8	8.3
12	-9.5	47.9	-14.3	55.6	-9.5	44.9	-6.8	24.1	-12.2	23.5
13	14.5	35.9	-2.9	52.5	-13.0	43.3	-1.4	34.8	-10.9	15.5
14	0.0	48.4	15.4	27.3	12.3	5.5	19.2	11.3	16.9	11.7
15	6.7	61.0	-2.2	38.2	-2.2	31.4	-10.6	28.8	-9.4	-5.1
16	0.5	28.1	0.5	20.3	-0.5	8.8	-2.0	11.4	-2.0	10.8
17	-6.6	31.3	-9.6	21.9	-15.6	30.4	-7.8	11.5	-8.4	7.8
18	-9.4	34.1	9.4	26.4	-3.1	29.0	7.5	23.6	10.7	15.2
19	-10.4	76.7	-0.6	61.9	-4.3	48.7	0.6	43.8	0.6	25.0
20	-4.6	23.3	3.3	14.0	-7.9	9.9	-7.2	9.9	-12.5	9.2
<b>Average</b>	0.6	41.0	0.1	37.8	-2.4	30.1	-2.5	24.1	-3.0	9.1
<b>S.D.</b>	9.8	17.4	9.0	17.2	7.6	17.6	9.8	13.9	9.6	10.1
<b>Median</b>	-0.3	38.3	-0.3	35.3	-3.4	29.7	-3.6	23.9	-4.3	8.9
<b>Impr.*</b>	-	100	-	100	-	100	-	100	-	80

\* % of subjects with realtive improvement in test area as compared to initial condition and corrected by changes in untreated area

## Descriptive Statistics of Skin Hydration, DCC06K045

### start

	untr.	A
Valid cases	20.0	20.0
Mean	31.1	32.6
Std. error of mean	1.0	0.8
Variance	18.4	13.3
Std. Deviation	4.3	3.7
Variation Coefficient	0.1	0.1
Minimum	24.2	25.8
Maximum	40.2	38.4
Median	31.1	32.2

### after 2 hours

	untr.	A
Valid cases	20.0	20.0
Mean	31.4	46.0
Std. error of mean	1.3	1.7
Variance	32.9	57.2
Std. Deviation	5.7	7.6
Variation Coefficient	0.2	0.2
Minimum	22.2	32.6
Maximum	47.0	64.4
Median	30.8	47.2

### after 4 hours

	untr.	A
Valid cases	20.0	20.0
Mean	31.0	44.7
Std. error of mean	0.9	1.4
Variance	15.6	36.6
Std. Deviation	4.0	6.0
Variation Coefficient	0.1	0.1
Minimum	25.2	35.2
Maximum	40.4	54.6
Median	30.6	46.3

### after 6 hours

	untr.	A
Valid cases	20.0	20.0
Mean	30.3	41.5
Std. error of mean	0.9	1.6
Variance	16.5	48.9
Std. Deviation	4.1	7.0
Variation Coefficient	0.1	0.2
Minimum	24.0	28.0
Maximum	40.0	55.4
Median	29.4	41.5

**after 8 hours**

	<b>untr.</b>	<b>A</b>
Valid cases	20.0	20.0
Mean	30.1	39.5
Std. error of mean	0.8	1.4
Variance	13.0	37.4
Std. Deviation	3.6	6.1
Variation Coefficient	0.1	0.2
Minimum	23.0	29.4
Maximum	39.4	46.8
Median	30.7	40.9

**after 24 hours**

	<b>untr.</b>	<b>A</b>
Valid cases	20.0	20.0
Mean	30.1	34.4
Std. error of mean	1.1	1.2
Variance	22.7	30.6
Std. Deviation	4.8	5.5
Variation Coefficient	0.2	0.2
Minimum	23.0	23.8
Maximum	39.4	42.8
Median	30.4	34.0

## Wilcoxon Rank Test of Skin Hydration, DCC06K045

### start - comparison of absolute values

	untr. - A
Rank sum (positive)	67
Z-value	-1.4003
Significance	0.1620
non-zero observations	20

### after 2 hours - comparison of changes from initial condition

	untr. - A
Rank sum (positive)	0
Z-value	-3.9013
Significance	0.0000
non-zero observations	20

### after 4 hours - comparison of changes from initial condition

	untr. - A
Rank sum (positive)	0
Z-value	-3.9013
Significance	0.0000
non-zero observations	20

### after 6 hours - comparison of changes from initial condition

	untr. - A
Rank sum (positive)	0
Z-value	-3.9013
Significance	0.0000
non-zero observations	20

### after 8 hours - comparison of changes from initial condition

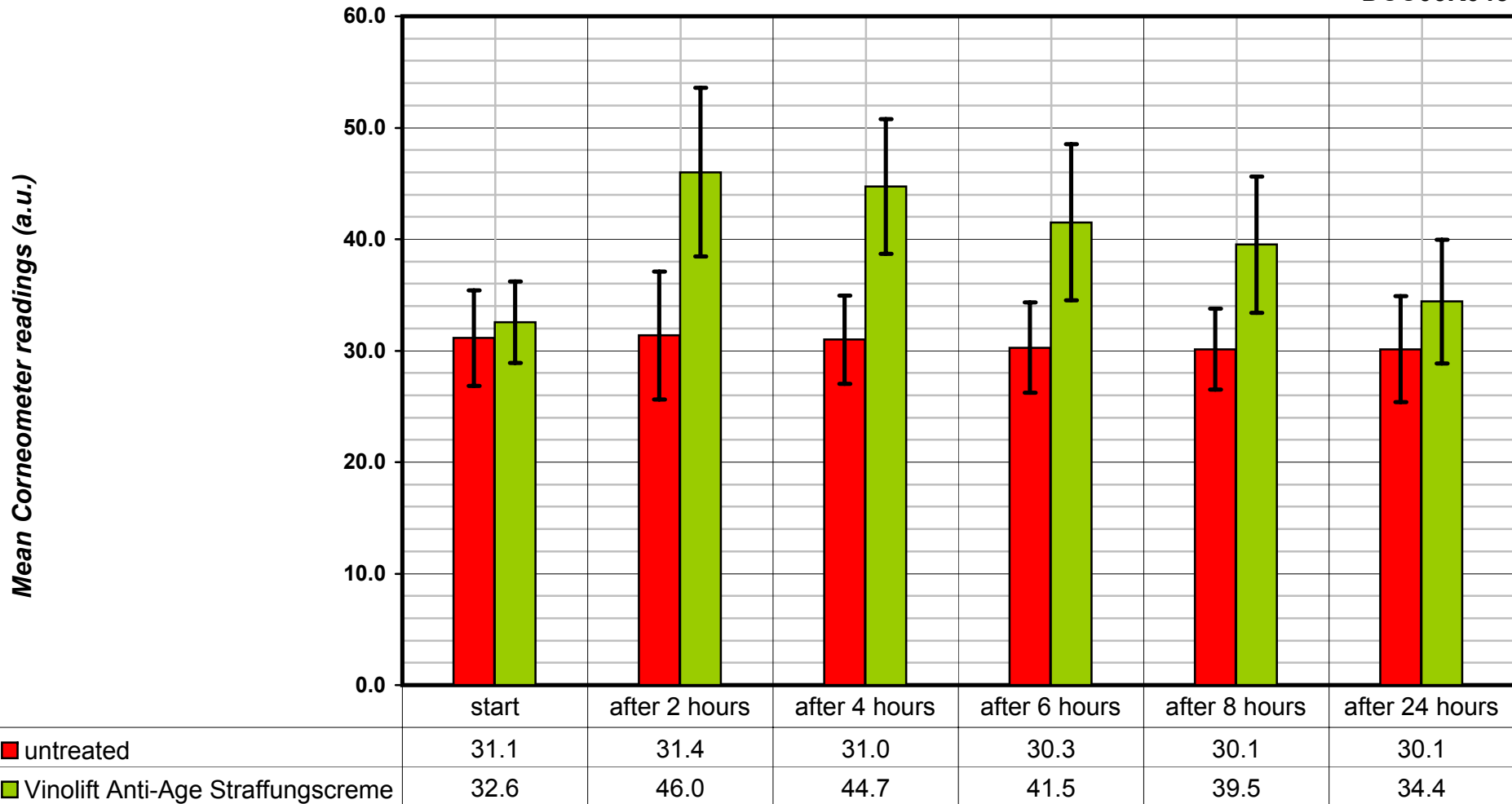
	untr. - A
Rank sum (positive)	0
Z-value	-3.9013
Significance	0.0000
non-zero observations	20

### after 24 hours - comparison of changes from initial condition

	untr. - A
Rank sum (positive)	23
Z-value	-3.0426
Significance	0.0012
non-zero observations	20

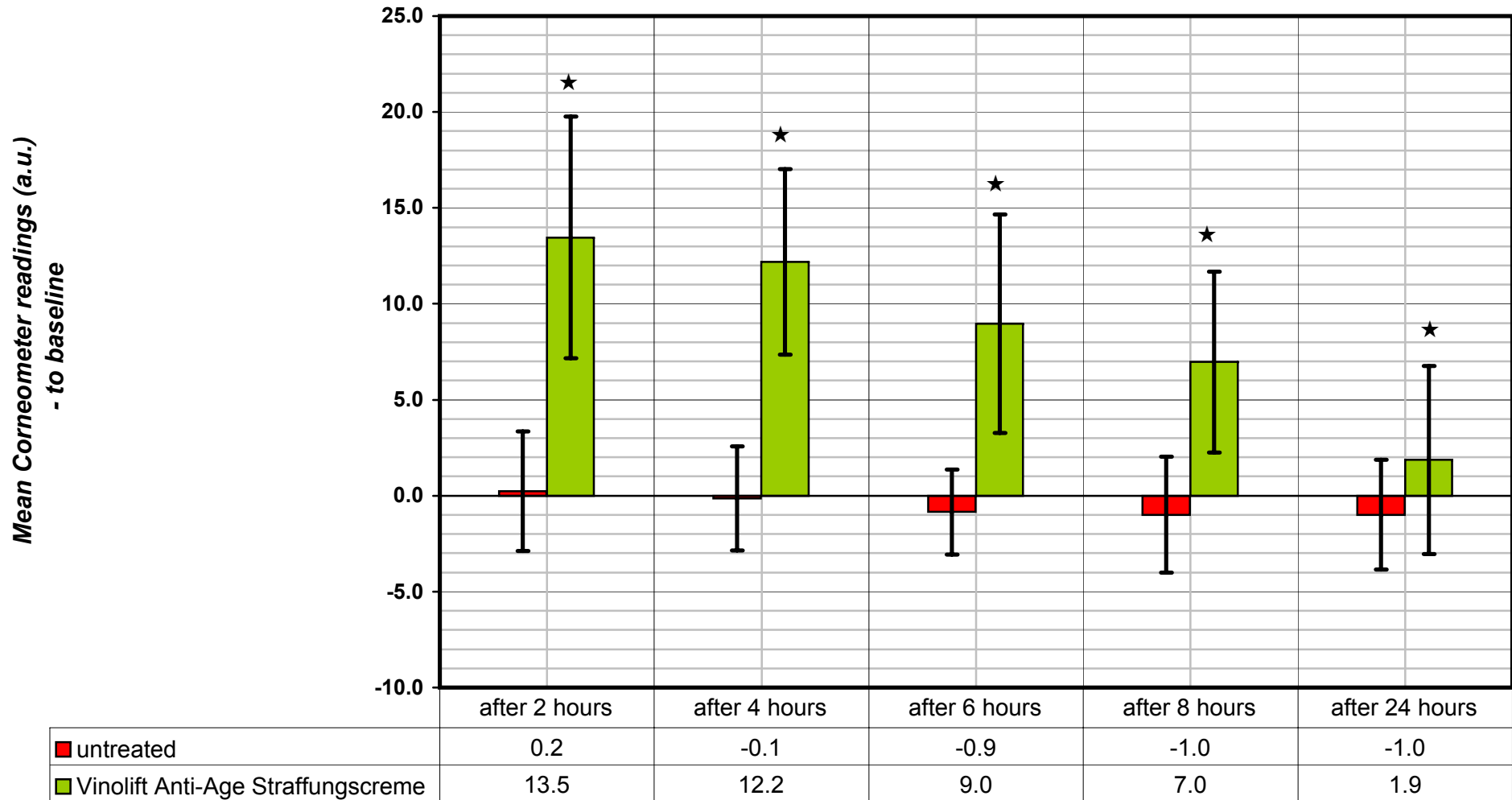
## Experimental data of Skin Hydration

DCC06K045



## Experimental data of Skin Hydration (delta values)

DCC06K045



\*p<0,05 versus untreated

**Increase in Skin Hydration relative to initial conditions and to untreated**

DCC06K045

