

## Efficacy Test Conducted With One Product

### Summary

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

Date of Order.....: 29.06.2005

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

Supervisors of Study .....: H. P. Nissen, PhD  
Dr. H. Prieur, Dermatologist – Allergist  
Drs. B. Nissen

Study Code .....: DCC05W042

Test Product .....: The test product, which was coded as follows, was provided by  
ampucom:

A. M. Asam Aufbau Ampullenkur (supplied 12.07.2005 as “OPC  
+ Vitamin C Aufbau Ampulle by ampucom, C. Höhner)

Subjects .....: Number of individuals.: 20  
Sex.....: female  
Age range .....: 37-63 years (average: 44,3)

Test Area .....: Inner sides of forearms  
Face

Application.....: Duration....: 14 days (user trial/skin hydration measurement)  
28 days (cell renewal determination)  
Frequency.: twice daily

Test Period .....: July / August 2005

Test Parameters .....: 1. Determination of *skin hydration* with Corneometer CM 825 PC (Courage & Khazaka GmbH, Cologne)

2. Determination of cell renewal time

3. Subjective evaluation by questionnaire

Design of Study .....: **Day 0**  
Determination of the parameters in the test areas  
First test product application

**Day 7**  
Determination of skin hydration 8-12 hours following the last daily test product application

**Day 14**  
Determination of skin hydration and evaluation of fluorescenceskin hydration 8-12 hours following the last daily test product application; distribution and collection of questionnaire

**Day 16 until Day 28**  
Evaluation of the fluorescence every other day until subsided

Evaluation .....: Descriptive statistics (average, median, minimum, maximum, variance, standard error, standard deviation); Wilcoxon Rank Test

Results .....: **Skin Hydration**  
The test product was found to statistically significantly increase skin hydration.

**Cell renewal**  
The tested product was found to statistically significantly reduce cell renewal time.

**User Trial**  
The subjects rated the product and its application experience not too enthusiastically.

## **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). Three 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.

### ***Determination of Cell Renewal Time***

A 5% suspension of dansyl chloride in petrolatum was applied to a small circular area on the inner side of the forearms in the respective test areas on occlusive adhesive patches for 24h prior to the start of the study. The level of fluorescence was assessed visually from day 14 on every other day under UV illumination until the skin was no longer fluorescent.

### ***Subjective Evaluation / Questionnaire***

Questionnaire design and evaluation were conducted using Keypoint 4.1 (Cambridge Software Publishing, UK). In the design of the questionnaire and the wording of the items, specific attention was paid to comprehensibility and appropriate vocabulary, as well as the volunteers' ability to articulate the answers. For maximum compliance and ease in evaluation and to additionally minimize item nonresponse by making it easier for subjects to complete the questionnaire, closed dichotomous and multichotomous questions were used, the latter mostly in the form of a Likert scale (expression of agreement to disagreement to fixed statements). The questionnaire is included in its original form in the appendix.

## **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. 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 37-63 years of age (average: 44,3). 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).

One day prior to the start of the study, a 5% suspension of dansyl chloride in petrolatum was applied to small circular fields on the inner side of the forearms in each respective test area on occlusive adhesive patches for 24h. After removal of the occlusion and prior to the first application of the test product, measurements were taken at clearly defined sites of the inner sides of the forearms. One area remained untreated and served as control. Further measurement of skin hydration was performed after 7 and 14 days of application 8-12 skin hydration 8-12 hours following the last daily application (adaptation time: 30 min, room temperature:  $21\pm 1^{\circ}\text{C}$ , relative humidity:  $50\pm 5\%$ ). The subjects used the test product (approximately  $2\text{ mg/cm}^2$ ) twice daily (in the morning and evening) and in a manner corresponding as largely as possible to that to be practised by the future consumer in the test area on the forearm and on their face for subjective evaluation by means of a questionnaire distributed after 14 days of application.

On the inner sides of the forearms, application continued for another 14 days, and fluorescence was assessed visually every other day starting from day 14 on until no longer detectable in both the treated and untreated condition.

## **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**

### ***Skin Hydration***

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.

**Experimental data of Skin Hydration (delta values)**

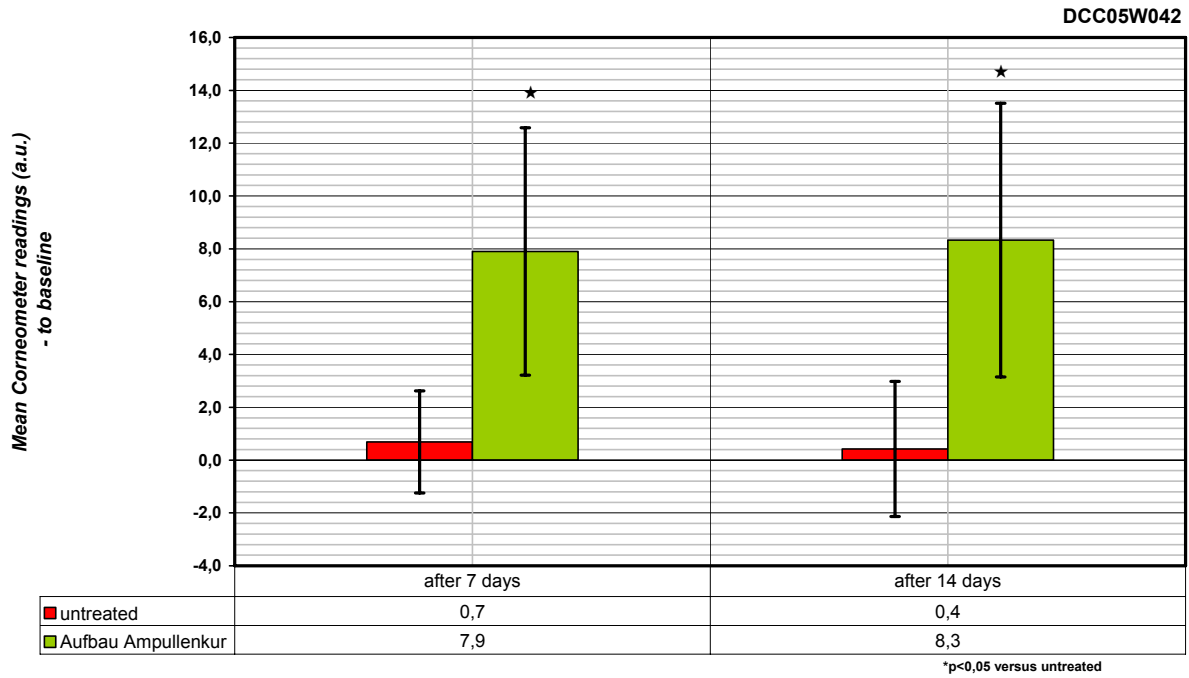


Fig. 1:  $\Delta$  Skin Hydration Values

After both 14 and 28 days of treatment, a statistically significant ( $p < 0,05$ ) increase in skin hydration was observed in the product treated test area as compared to the changes in the untreated area. The test product was found to increase skin hydration. The respective changes in skin hydration in the treated areas 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**

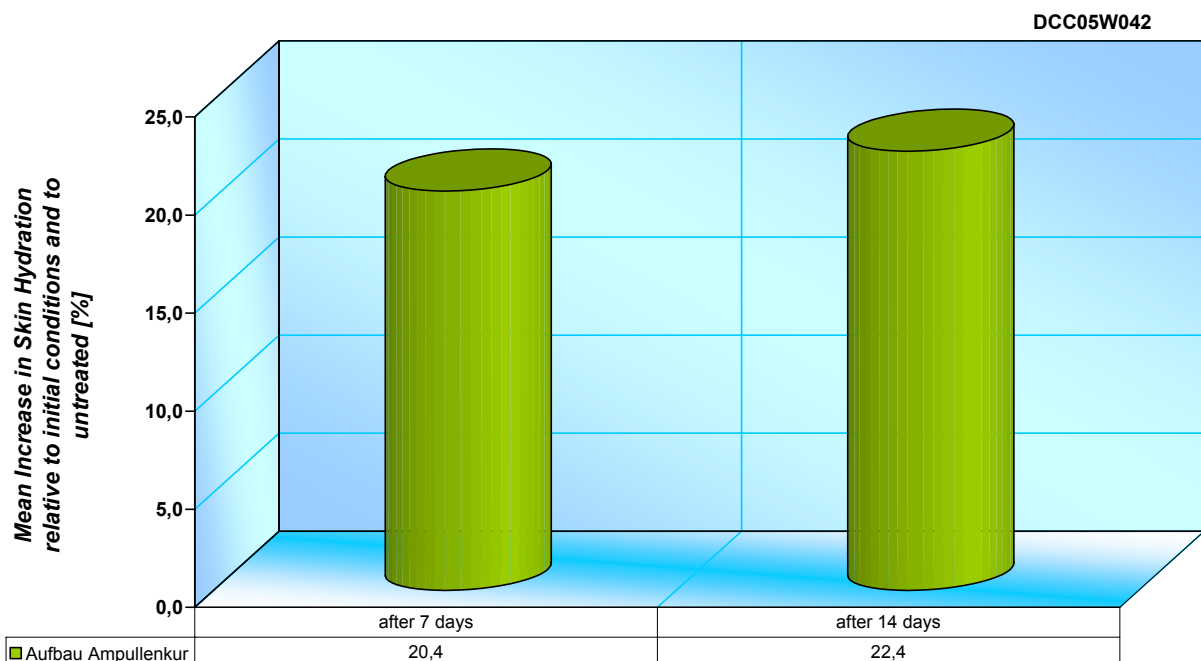


Fig. 2: Increase in Skin Hydration in %

## Cell Renewal

Evaluated is the difference in cell renewal time in days between the treated and the untreated area. The absolute renewal time by area is shown below in figure three.

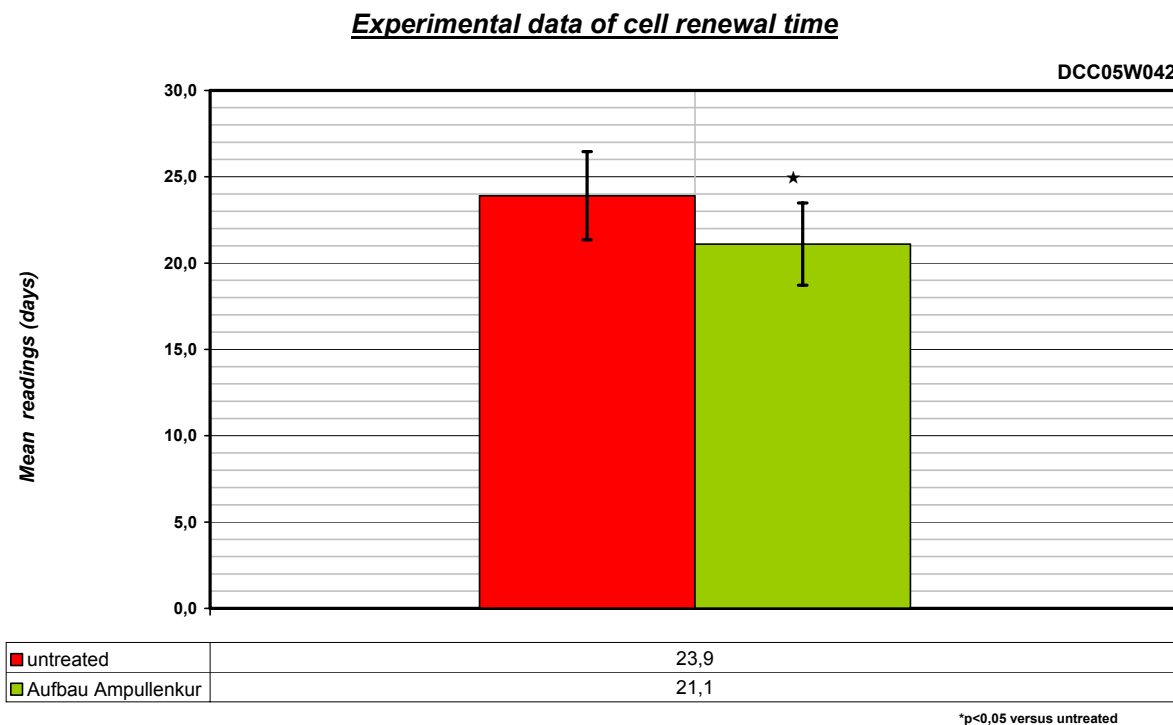


Fig. 3: Cell renewal time

## User Trial Results

After 14 days of regular use, the test product was received rather divergent by the subjects, overall, however, not too enthusiastically. A full graphical review can be found in the appendix.

On the positive side, no incompatibilities were observed and the general application of the product was perceived positively with unanimous agreement that the product is easy to spread (100%) and a great majority finding the product to be taken into the skin quickly (85%) and with lesser degree of approval to create a pleasant skin sensation (65%), to calm and to refresh the skin (50%).

The view on the scent of the product was mixed with 50% finding the product scent very good or good, 25% average and another 25% not liking it. If at all, it as found to be too faint to exactly right.

With regard to the effects of the product, there was wide agreement that the product increased skin hydration (80%), however, with regard to other effects the views were divergent with a relatively high percentage of subjects being undecided: Still the majority found the product to have made their skin softer (55%) and smoother (50%), however, with regard to their skin being more vital/fresh (45%), more firm (45%) and their wrinkles to have been visibly reduced (20%) the product did not manage to convince the majority.

This also carries through to the overall rating of the product with the subjects giving an average school grade of 2.9 (German system: 1=very good; 6=insufficient) and only 30% answering that they would probably/certainly continue to use the product and recommend the product to others.

## Incompatibility

No incompatibility was observed in any of the volunteers. One subject (No.1) quit the study before the initial measurement and was immediately replaced.

Signature:

Dr. med. H. Prieur Dermatologist - Allergist
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Signature:

Drs. B. Nissen Manager Derma Consult Concept
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Signature:

Dr. H. P. Nissen Chemist – Ph.D.
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Enclosures: Measuring values, statistics, summary statistics, graphic representations

**Experimental data of Skin Hydration, DCC05W042**

Corneometer readings (a.u.)

	start		after 7 days		after 14 days	
	untr.	A	untr.	A	untr.	A
1	28,2	23,8	28,6	24,4	26,8	26,0
2	30,4	33,0	31,8	42,2	34,2	42,6
3	39,0	40,0	38,4	43,2	37,0	43,8
4	35,6	34,8	36,2	44,0	38,2	40,0
5	36,0	38,0	36,4	51,2	38,0	54,8
6	21,8	25,0	25,2	28,4	24,2	27,4
7	34,4	37,6	38,4	42,6	39,0	43,8
8	33,0	37,6	36,4	54,8	37,6	55,0
9	35,6	33,2	32,0	31,8	33,6	45,8
10	37,8	36,8	38,2	44,6	37,8	47,6
11	36,4	34,0	37,8	45,0	34,0	39,6
12	34,8	34,4	34,6	38,8	34,6	35,2
13	39,0	37,4	39,0	47,8	39,0	47,2
14	35,4	35,2	36,0	45,4	39,4	49,8
15	36,0	33,6	37,8	45,2	34,4	47,6
16	34,2	30,6	36,0	42,8	30,6	36,4
17	34,8	32,0	31,4	35,6	32,4	34,2
18	34,0	33,2	33,4	41,4	34,8	47,0
19	40,4	39,2	42,4	51,8	40,4	47,2
20	33,8	32,4	34,4	38,8	33,0	37,4
<b>Average</b>	<b>34,5</b>	<b>34,1</b>	<b>35,2</b>	<b>42,0</b>	<b>35,0</b>	<b>42,4</b>
<b>S.D.</b>	<b>4,1</b>	<b>4,2</b>	<b>4,0</b>	<b>7,5</b>	<b>4,2</b>	<b>7,9</b>
<b>Median</b>	<b>35,1</b>	<b>34,2</b>	<b>36,1</b>	<b>43,0</b>	<b>34,7</b>	<b>43,8</b>

**Experimental data of Skin Hydration, DCC05W042**

delta Corneometer readings (a.u.)

after 7 days  
t1-t0after 14 days  
t2-t0

	untr.	A	untr.	A
1	0,4	0,6	-1,4	2,2
2	1,4	9,2	3,8	9,6
3	-0,6	3,2	-2,0	3,8
4	0,6	9,2	2,6	5,2
5	0,4	13,2	2,0	16,8
6	3,4	3,4	2,4	2,4
7	4,0	5,0	4,6	6,2
8	3,4	17,2	4,6	17,4
9	-3,6	-1,4	-2,0	12,6
10	0,4	7,8	0,0	10,8
11	1,4	11,0	-2,4	5,6
12	-0,2	4,4	-0,2	0,8
13	0,0	10,4	0,0	9,8
14	0,6	10,2	4,0	14,6
15	1,8	11,6	-1,6	14,0
16	1,8	12,2	-3,6	5,8
17	-3,4	3,6	-2,4	2,2
18	-0,6	8,2	0,8	13,8
19	2,0	12,6	0,0	8,0
20	0,6	6,4	-0,8	5,0
<b>Average</b>	0,7	7,9	0,4	8,3
<b>S.D.</b>	1,9	4,7	2,6	5,2
<b>Median</b>	0,6	8,7	0,0	7,1

**Increase in Skin Hydration relative to initial conditions and to untreated, DCC05W042**

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

	after 7 days		after 14 days	
	untr.	A	untr.	A
1	1,4	1,1	-5,0	14,2
2	4,6	23,3	12,5	16,6
3	-1,5	9,5	-5,1	14,6
4	1,7	24,8	7,3	7,6
5	1,1	33,6	5,6	38,7
6	15,6	-2,0	11,0	-1,4
7	11,6	1,7	13,4	3,1
8	10,3	35,4	13,9	32,3
9	-10,1	5,9	-5,6	43,6
10	1,1	20,1	0,0	29,3
11	3,8	28,5	-6,6	23,1
12	-0,6	13,4	-0,6	2,9
13	0,0	27,8	0,0	26,2
14	1,7	27,3	11,3	30,2
15	5,0	29,5	-4,4	46,1
16	5,3	34,6	-10,5	29,5
17	-9,8	21,0	-6,9	13,8
18	-1,8	26,5	2,4	39,2
19	5,0	27,2	0,0	20,4
20	1,8	18,0	-2,4	17,8
<b>Average</b>	<b>2,3</b>	<b>20,4</b>	<b>1,5</b>	<b>22,4</b>
<b>S.D.</b>	<b>6,1</b>	<b>11,6</b>	<b>7,7</b>	<b>13,8</b>
<b>Median</b>	<b>1,7</b>	<b>24,0</b>	<b>0,0</b>	<b>21,7</b>
<b>Impr.*</b>	<b>-</b>	<b>95</b>	<b>-</b>	<b>95</b>

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

## Descriptive Statistics of Skin Hydration, DCC05W042

### start

	untr.	A
Valid cases	20,0	20,0
Mean	34,5	34,1
Std. error of mean	0,9	0,9
Variance	16,8	17,5
Std. Deviation	4,1	4,2
Variation Coefficient	0,1	0,1
Minimum	21,8	23,8
Maximum	40,4	40,0
Median	35,1	34,2

### after 7 days

	untr.	A
Valid cases	20,0	20,0
Mean	35,2	42,0
Std. error of mean	0,9	1,7
Variance	15,7	57,0
Std. Deviation	4,0	7,5
Variation Coefficient	0,1	0,2
Minimum	25,2	24,4
Maximum	42,4	54,8
Median	36,1	43,0

### after 14 days

	untr.	A
Valid cases	20,0	20,0
Mean	35,0	42,4
Std. error of mean	0,9	1,8
Variance	17,7	62,7
Std. Deviation	4,2	7,9
Variation Coefficient	0,1	0,2
Minimum	24,2	26,0
Maximum	40,4	55,0
Median	34,7	43,8

## Wilcoxon Rank Test of Skin Hydration, DCC05W042

### start - comparison of absolute values

	untr. - A
Rank sum (positive)	127,5
Z-value	0,8217
Significance	0,4142
non-zero observations	20

### after 7 days - comparison of changes from initial condition

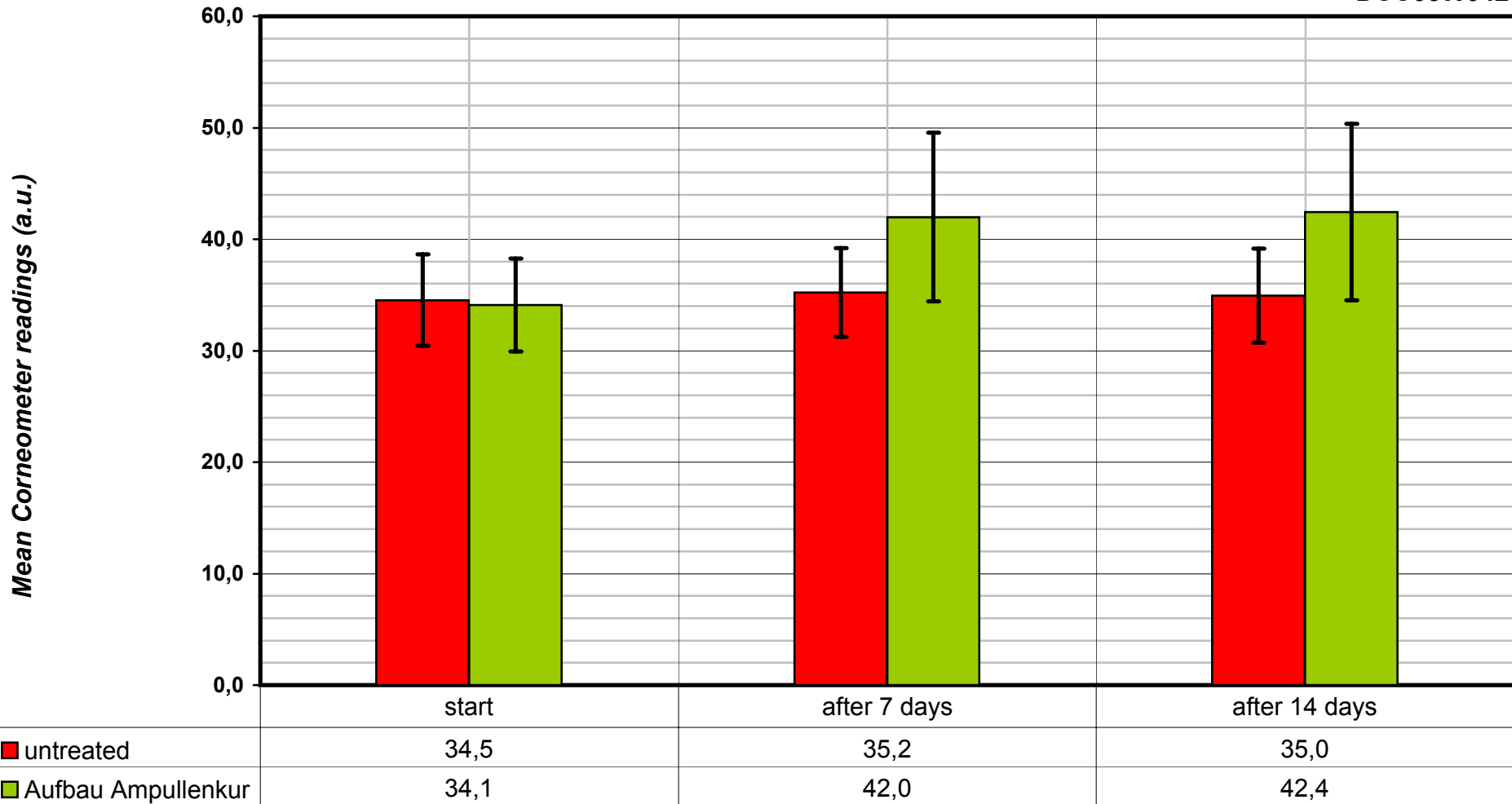
	untr. - A
Rank sum (positive)	0
Z-value	-3,8029
Significance	0,0000
non-zero observations	19

### after 14 days - comparison of changes from initial condition

	untr. - A
Rank sum (positive)	0
Z-value	-3,8037
Significance	0,0000
non-zero observations	19

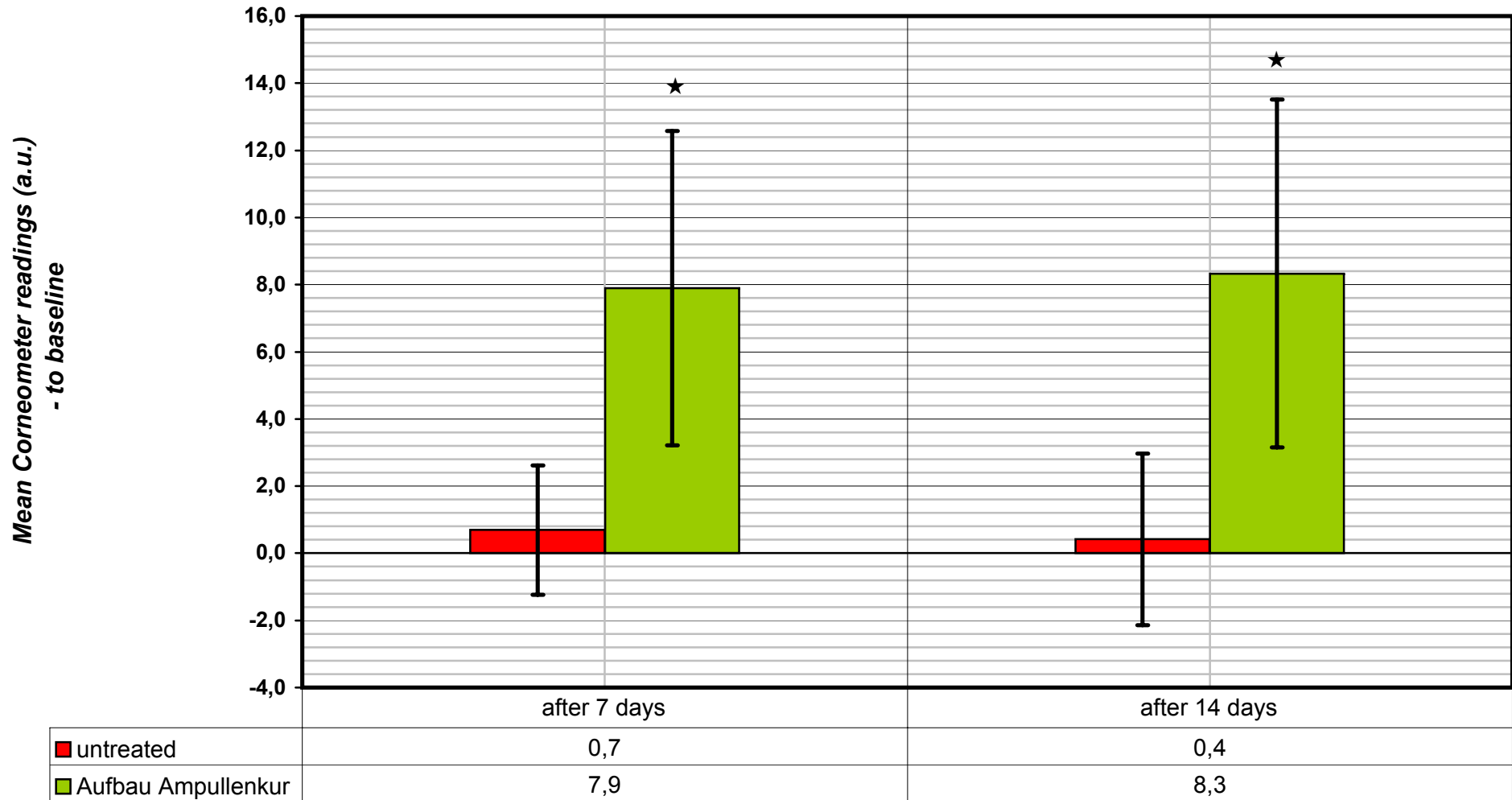
## Experimental data of Skin Hydration

DCC05W042



## Experimental data of Skin Hydration (delta values)

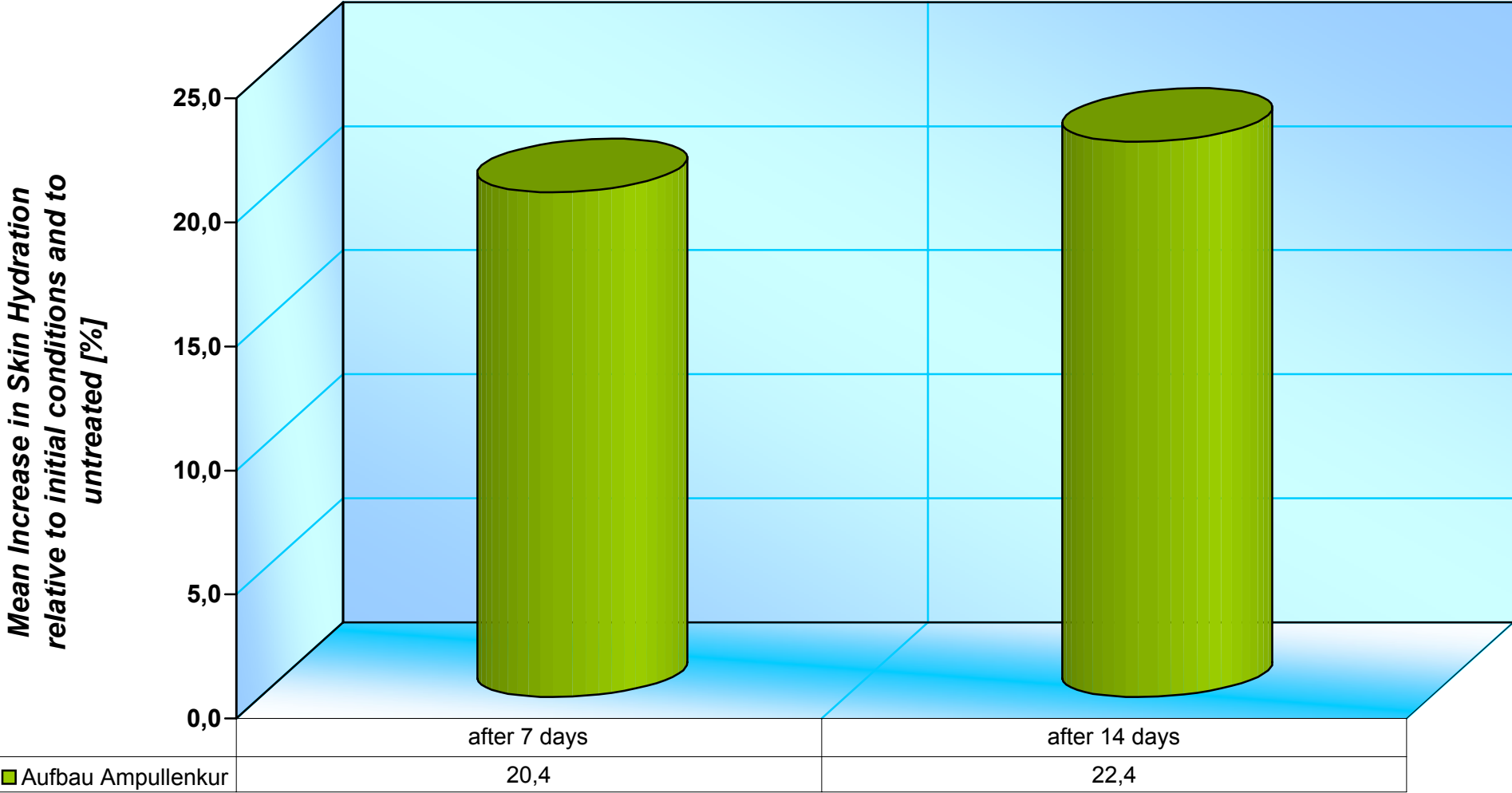
DCC05W042



\*p<0,05 versus untreated

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

DCC05W042



**Experimental data of cell renewal time, DCC05W042**

Days until fluorescence could no longer be detected

	<b>untr.</b>	<b>A</b>
1	20	18
2	26	22
3	24	22
4	24	20
5	26	24
6	24	24
7	18	16
8	22	20
9	26	20
10	24	22
11	22	18
12	26	20
13	22	22
14	20	18
15	24	22
16	26	22
17	26	24
18	24	24
19	28	24
20	26	20
<b>Average</b>	<b>23,9</b>	<b>21,1</b>
<b>S.D.</b>	<b>2,6</b>	<b>2,4</b>
<b>Median</b>	<b>24,0</b>	<b>22,0</b>

## Descriptive Statistics of cell renewal time, DCC05W042

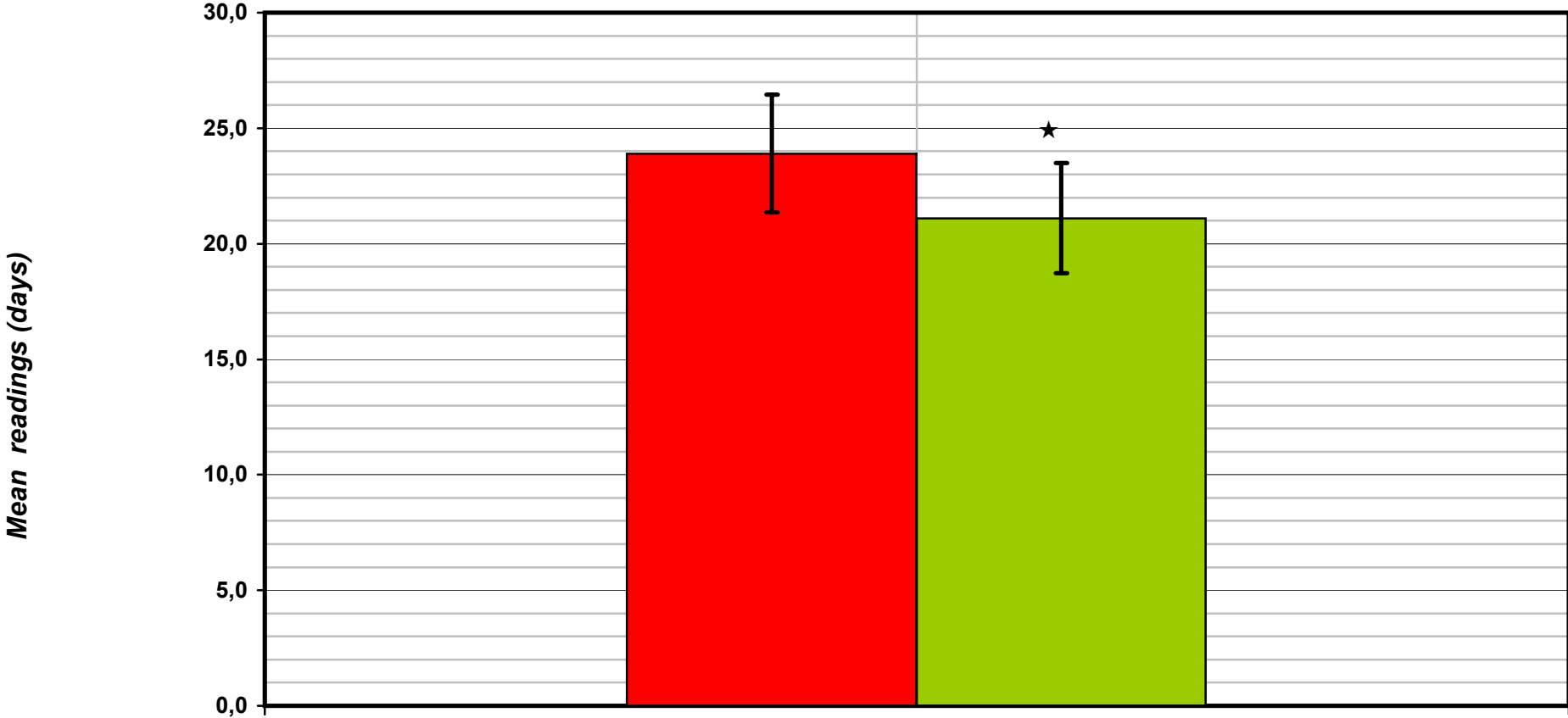
	untr.	A
Valid cases	20,0	20,0
Mean	23,9	21,1
Std. error of mean	0,6	0,5
Variance	6,5	5,7
Std. Deviation	2,6	2,4
Variation Coefficient	0,1	0,1
Minimum	18,0	16,0
Maximum	28,0	24,0
Median	24,0	22,0

Wilcoxon Rank Test of cell renewal time, DCC05W042

	untr. - A
Rank sum (positive)	153
Z-value	3,6725
Significance	0,0000
non-zero observations	17

Experimental data of cell renewal time

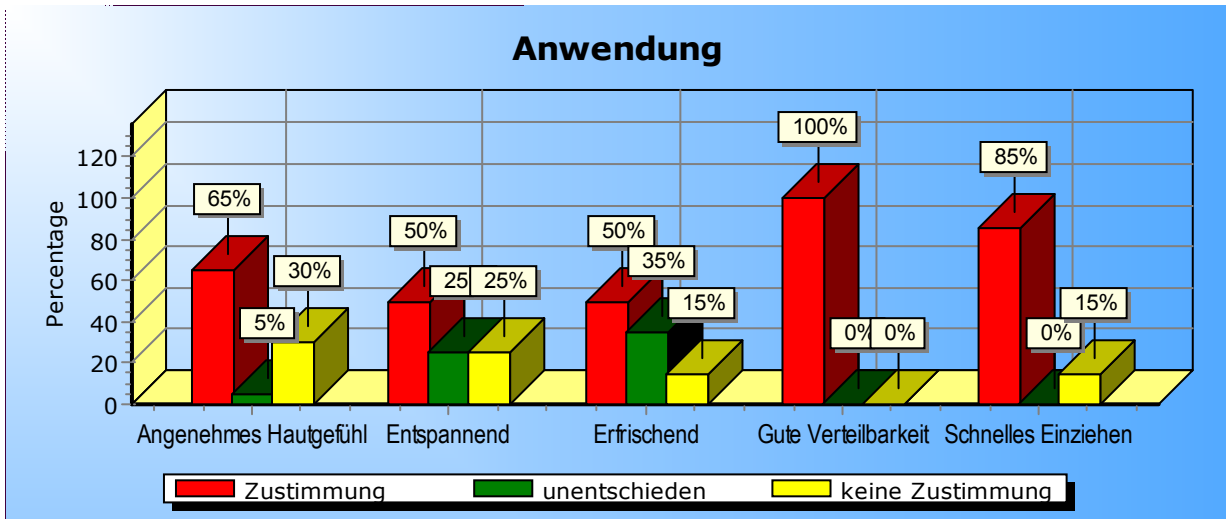
DCC05W042



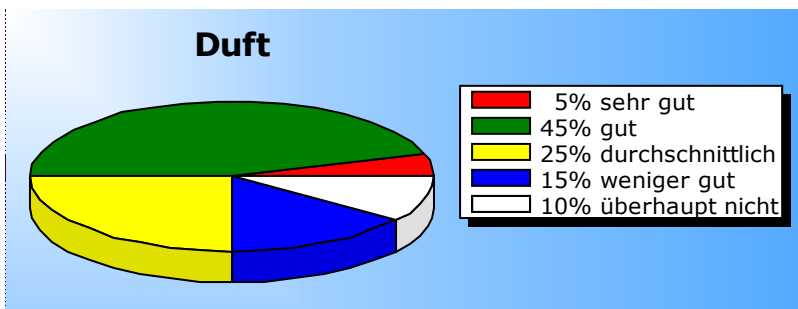
■ untreated	23,9
■ Aufbau Ampullenkur	21,1

\*p<0,05 versus untreated

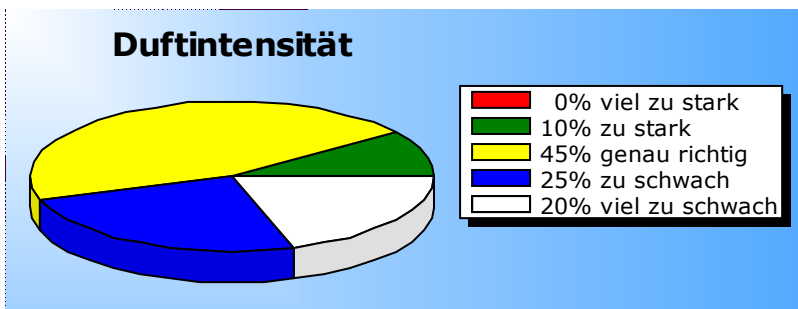
# Anwendungstest mit "M. Asam Aufbau Ampullenkur "



Block 1



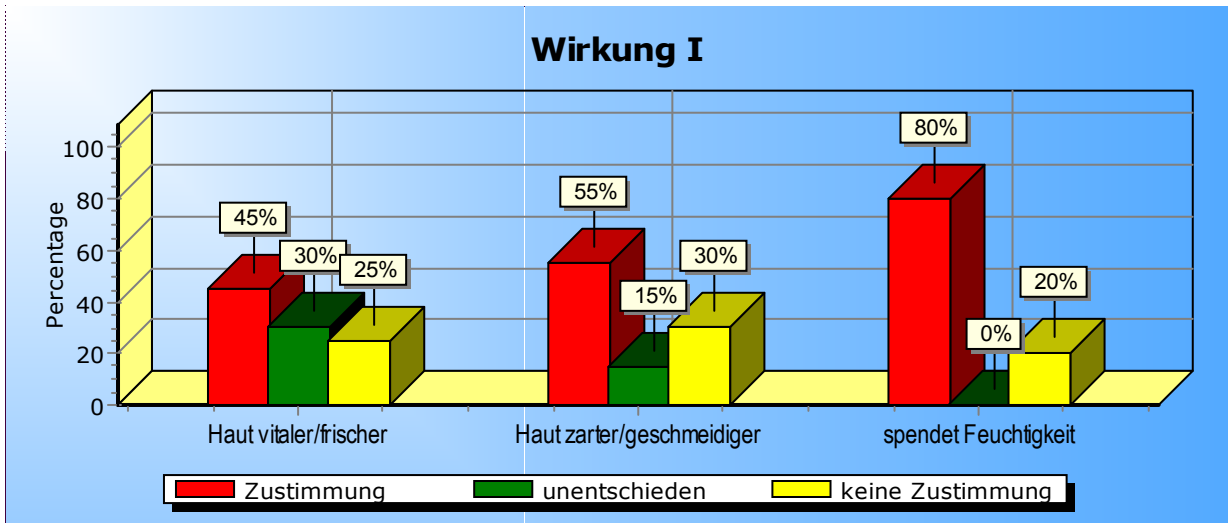
Frage 2



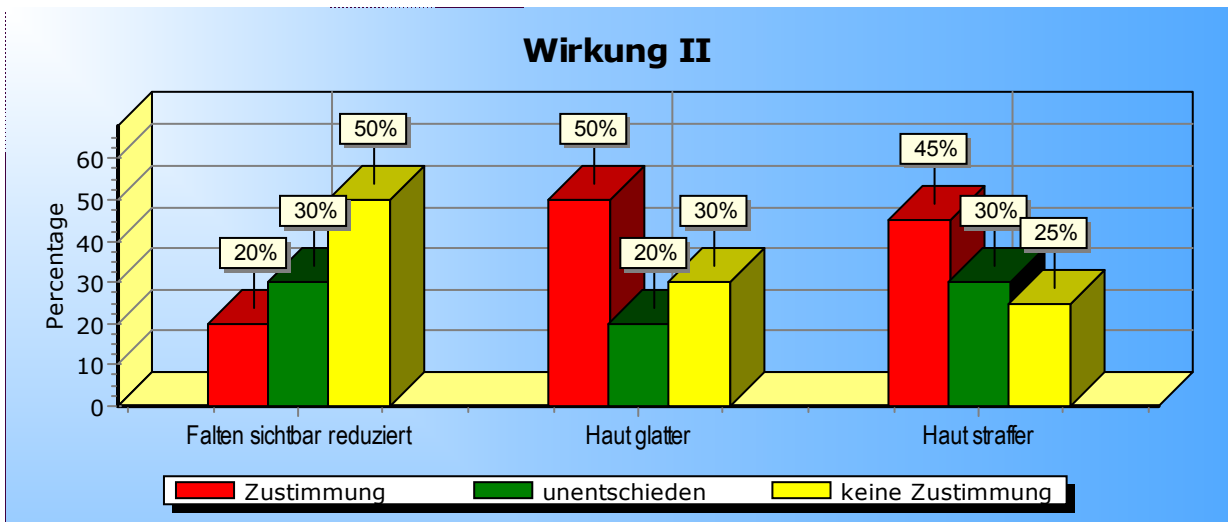
Frage 3

Duft/Duftintensität frequency - row % - col %	viel zu stark	zu stark	genau richtig	zu schwach	viel zu schwach	Total
sehr gut	0 0% 0%	0 0% 0%	1 100% 11%	0 0% 0%	0 0% 0%	1 5%
gut	0 0% 0%	1 11% 50%	5 56% 56%	1 11% 20%	2 22% 50%	9 45%
durchschnittlich	0 0% 0%	0 0% 0%	3 60% 33%	2 40% 40%	0 0% 0%	5 25%
weniger gut	0 0% 0%	1 33% 50%	0 0% 0%	2 67% 40%	0 0% 0%	3 15%
überhaupt nicht	0 0% 0%	0 0% 0%	0 0% 0%	0 0% 0%	2 100% 50%	2 10%
Total	0 0%	2 10%	9 45%	5 25%	4 20%	20

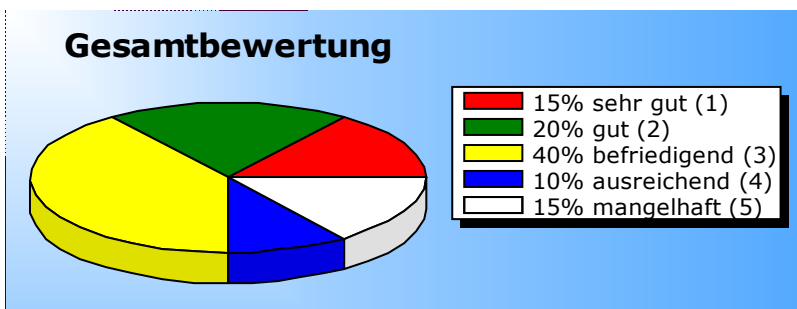
Kreuztabelle Frage 2 / Frage 3



Block 4.1



Block 4.2

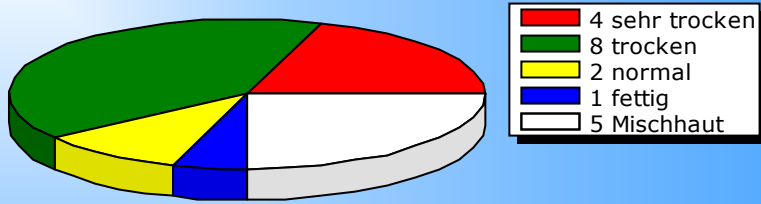


Frage 5

Question	Count	Min	Max	Mean
Gesamtbewertung	20,00	1,00	5,00	2,90

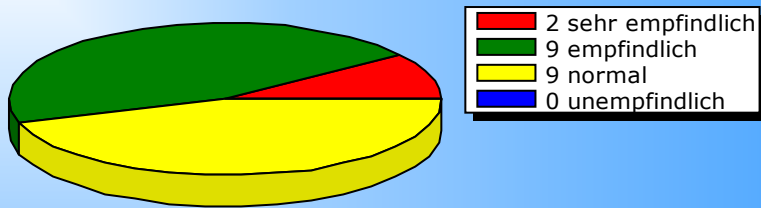
Tabelle Frage 5

### Hauttyp (Selbsteinsch.)



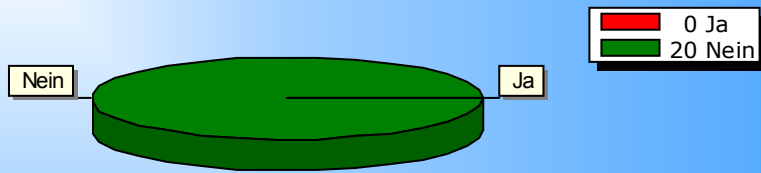
Frage 6

### Empfindlichkeit



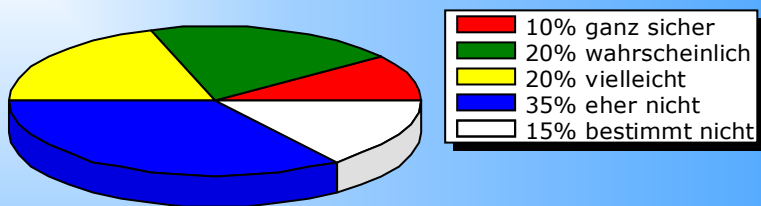
Frage 7

### Vertragen (Ja/Nein)



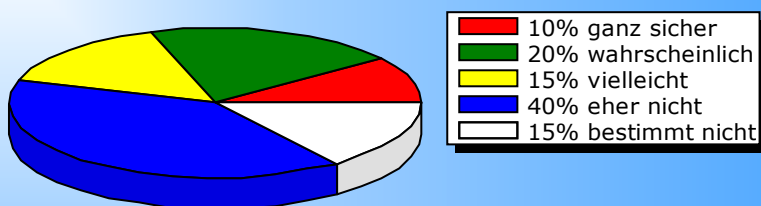
Frage 8

### Würde weiterverwenden



Frage 9

### Würde weiterempfehlen



# Anwendungstest - Gesichtspflege

Vielen Dank für Ihre Teilnahme an dieser Kosmetikstudie. Nachdem Sie Gelegenheit hatten das Testprodukt kennenzulernen, möchten wir Sie nun bitten uns einige Fragen zu Ihren Eindrücken zu beantworten:

## Anwendung - Eindrücke vom Gebrauch

Block 1. Bitte bewerten Sie Ihre Zustimmung zu folgenden Aussagen über die Anwendung des Testproduktes.

	stimme voll und ganz zu	stimme eher zu	unentschieden	stimme eher nicht zu	stimme überhaupt nicht zu
Das Testprodukt lässt sich gut verteilen.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Das Testprodukt zieht schnell in die Haut ein.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Das Testprodukt vermittelt ein angenehmes Hautgefühl.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nach der Anwendung fühlt sich meine Haut entspannt an.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nach der Anwendung fühlt sich meine Haut erfrischt an.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Frage 2. Der Duft des Produktes gefällt mir:

- sehr gut
- gut
- durchschnittlich
- weniger gut
- überhaupt nicht

Frage 3. Die Intensität des Duftes ist:

- viel zu stark
- zu stark
- genau richtig
- zu schwach
- viel zu schwach

## Wirkung - Eindrücke der Wirkung

Block 4. Bitte bewerten Sie Ihre Zustimmung zu folgenden Aussagen über die Wirkung des Testproduktes.

	stimme voll und ganz zu	stimme eher zu	unentschieden	stimme eher nicht zu	stimme überhaupt nicht zu
Das Testprodukt spendet meiner Haut Feuchtigkeit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Meine Haut ist straffer geworden.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Meine Haut ist zarter & geschmeidiger geworden.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Meine Haut ist glatter geworden	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Falten wurden sichtbar reduziert.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Meine Haut wirkt vitaler und frischer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Frage 5. **Bitte geben Sie dem Testprodukt eine Schulnote:**

- sehr gut (1)
- gut (2)
- befriedigend (3)
- ausreichend (4)
- mangelhaft (5)

Frage 6. **Wie würden Sie Ihre Haut im Gesicht bezeichnen? Als...**

- sehr trocken
- fettig
- trocken
- Mischhaut
- normal

Frage 7. **Wie würden Sie Ihre Haut in Gesicht einschätzen? Als...**

- sehr empfindlich
- empfindlich
- normal
- unempfindlich

Frage 8. **Traten während der Anwendung des Testproduktes irgendwelche Probleme (z.B. Juckreiz oder Rötungen) auf?**

- Ja
- Nein

**Wenn ja, beschreiben Sie bitte die aufgetretenen Probleme kurz:**

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**Bitte nehmen Sie bei der Beantwortung der folgenden Fragen an, dass sich der Preis für das Testprodukt im Rahmen dessen bewegt, was Sie normalerweise für eine Gesichtspflege ausgeben.**

Frage 9. **Würden Sie das Testprodukt gerne weiterverwenden?**

- ganz sicher
- wahrscheinlich
- vielleicht
- eher nicht
- bestimmt nicht

Frage 10. **Würden Sie das Testprodukt weiterempfehlen?**

- ganz sicher
- wahrscheinlich
- vielleicht
- eher nicht
- bestimmt nicht

**Vielen Dank für Ihre Mitarbeit.**