

Measurement of Skin Hydration after a Single Application (Cosmetic Study)

Summary

Study Sponsor: **Temmentec AG**
Lütoldstrasse 6
3454 Sumiswald
Switzerland

Date of Order.....: 05.10.2017

Performance of Test: Derma Consult Concept GmbH
and Evaluation by Hermann-Wandersleb-Ring 4
53121 Bonn
Germany

Supervisors of Study: Dr. med. H. Prieur, Dermatologist – Allergist
B. Nissen, Manager Derma Consult Concept

Study Code: DCC17K137GR2

Test Product: The test product, which was coded as follows, was provided by
Temmentec AG in October 2017:

E. Rivoli Le Visage Masque Reparatteur Torstone
(lab-01086.5/24.08.17)

Control.....: Untreated

Subjects: Number of individuals.: 20
Sex.....: female
Age range: 19-60 years (average: 41,4)

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

Application.....: Single, controlled Application

Test Period: November 2017

Test Parameter.....: Determination of *skin hydration* with Corneometer MPA 5 CPU (Courage & Khazaka GmbH, Cologne)

Time of Evaluation.....: Baseline measurement at start & after application of the test product:

- 2 hours after the application
- 4 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); Wilcoxon Rank test

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 MPA 5 CPU (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 10359198; probe S/N 11284693.

Performance of Test

The subjects were selected from the Derma Consult 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 (≥ 18 years of age)
- ability to comply with the requirements of the study
- fundamentally clinically healthy

for exclusion from study:

- skin diseases or any other medical condition interfering with the objectives of the study
- planned medical treatment during study period
- pregnancy

The subjects of this study were between 19-60 years of age (average: 41,4). They could withdraw from the study at any time without giving any reason. They were instructed not to use any topical preparations on the test areas starting from seven days prior to testing (preconditioning phase) and until the end of the test. For cleansing during the preconditioning phase, water or a mild syndet (Eubos[®] flüssig – blau; manufacturer: Dr. Hobein, D-53340 Meckenheim-Merl, Germany; supplied by Derma Consult) was allowed only.

Prior to the controlled application of the test product (randomized location) by a staff member of Derma Consult (approximately 4 mg/cm² - increased product amount over regular leave-on products because of the product type – mask; 15 minutes after application, residue was first massaged into the skin with light pressure and after 20 minutes any residue still remaining was removed with soft paper towels using tapping motions), measurements were taken at clearly defined sites on the inner sides of the forearms. One area remained untreated and served as control. The subjects were instructed not to cover the test areas by clothing during the first 20 minutes after product application. Further measuring was performed 2, 4, 8 and 24 hours following product application. The subjects were asked to avoid bodily exertion and water contact with the test areas.

All measurements were conducted after adaptation to the controlled environmental conditions of the test institute (room temperature: 21±1°C, relative humidity: 45±5%).

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[®] 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.

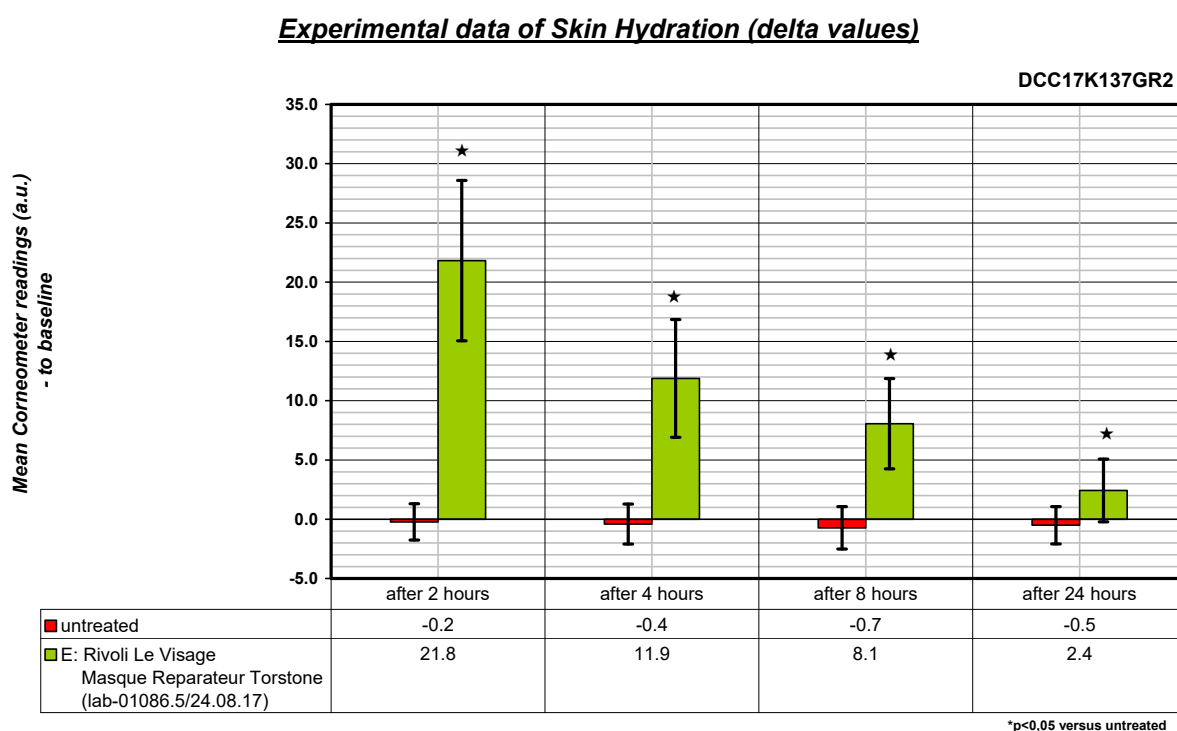


Fig. 1: Δ Skin Hydration Values

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 was found to be statistically significant in the product treated area until the final measurement 24 hours after application. A positive effect of the test product treatment could be detected after 8 hours in 100% and after 24 hours in 90% of the study participants.

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

DCC17K137GR2

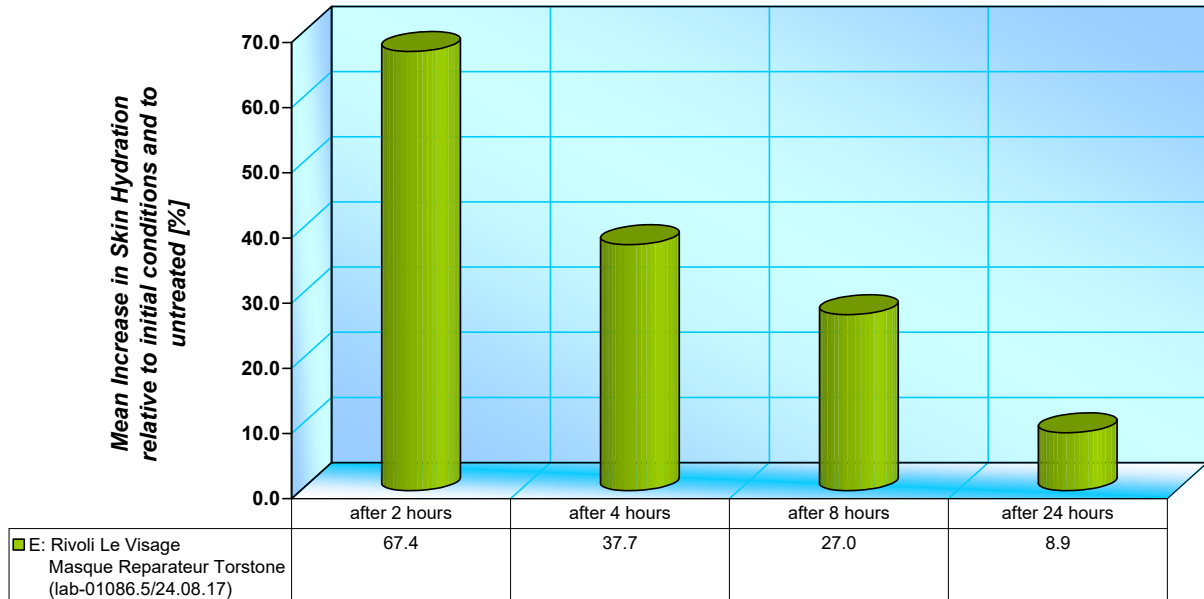


Fig. 2: Increase in Skin Hydration in %

Incompatibility

No incompatibility was observed in or reported by any of the volunteers.

Signature:

B. Nissen Manager Derma Consult Concept
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Signature:

Dr. med. H. Prieur Dermatologist - Allergist

Enclosures: Measuring values, statistics, summary statistics, graphic representations

Experimental data of Skin Hydration, DCC17K137GR2

Corneometer readings (a.u.)

	start		after 2 hours		after 4 hours		after 8 hours		after 24 hours	
	untr.	E	untr.	E	untr.	E	untr.	E	untr.	E
1	31.0	27.8	31.1	55.1	31.1	47.8	31.2	40.1	32.1	34.5
2	34.6	33.9	33.4	53.6	32.5	51.5	34.0	44.6	35.4	38.2
3	35.6	34.6	32.2	54.8	34.8	40.3	34.7	40.6	32.4	37.5
4	34.3	33.8	33.1	61.3	33.1	46.0	32.5	36.5	34.8	34.8
5	37.6	36.8	37.9	49.2	35.4	42.9	34.3	38.7	35.1	38.8
6	34.9	34.1	31.9	41.7	33.4	37.3	33.7	36.2	34.8	34.7
7	34.5	33.4	34.1	48.5	34.3	44.5	33.4	39.0	33.4	32.4
8	31.3	33.1	32.7	50.4	32.4	38.9	32.6	38.6	29.8	37.3
9	37.4	35.9	36.2	48.5	35.0	46.1	36.8	43.3	36.9	34.9
10	23.1	24.0	24.9	45.7	24.0	37.7	23.4	34.6	24.4	23.8
11	38.7	36.0	37.9	67.0	36.8	49.3	36.6	44.7	36.8	38.2
12	36.1	34.3	36.8	57.2	36.6	44.7	35.8	41.7	34.8	33.7
13	34.3	33.6	36.2	67.6	36.5	57.4	33.8	49.9	35.6	37.2
14	33.9	36.4	32.6	66.0	34.0	51.5	31.3	47.3	31.9	40.8
15	30.3	29.4	31.9	48.6	32.7	41.9	34.1	39.6	31.1	33.5
16	37.5	34.4	37.2	56.5	34.4	42.8	33.7	37.9	35.5	32.5
17	34.0	37.7	34.4	65.7	34.0	47.8	33.8	45.9	32.6	39.8
18	24.8	26.6	26.6	51.9	27.3	40.2	26.5	37.1	26.5	33.8
19	37.4	35.1	35.8	54.6	35.5	46.1	35.0	43.8	35.4	36.9
20	35.5	30.6	35.2	54.0	34.7	44.4	35.0	42.8	37.3	36.7
Average	33.8	33.1	33.6	54.9	33.4	45.0	33.1	41.1	33.3	35.5
S.D.	4.1	3.6	3.4	7.4	3.1	5.1	3.2	4.1	3.4	3.6
Median	34.6	34.0	33.8	54.3	34.2	44.6	33.8	40.4	34.8	35.8

Experimental data of Skin Hydration, DCC17K137GR2

delta Corneometer readings (a.u.)

	after 2 hours t1-t0		after 4 hours t2-t0		after 8 hours t3-t0		after 24 hours t4-t0	
	untr.	E	untr.	E	untr.	E	untr.	E
1	0.2	27.3	0.1	20.0	0.3	12.3	1.1	6.7
2	-1.3	19.7	-2.1	17.6	-0.7	10.7	0.8	4.3
3	-3.4	20.2	-0.8	5.7	-0.9	6.0	-3.2	3.0
4	-1.3	27.5	-1.3	12.2	-1.9	2.6	0.5	0.9
5	0.3	12.4	-2.2	6.1	-3.3	1.9	-2.5	2.0
6	-3.0	7.6	-1.5	3.2	-1.2	2.1	0.0	0.6
7	-0.4	15.1	-0.2	11.1	-1.1	5.7	-1.1	-0.9
8	1.4	17.3	1.2	5.8	1.3	5.5	-1.4	4.2
9	-1.2	12.6	-2.4	10.1	-0.5	7.4	-0.5	-1.0
10	1.7	21.7	0.9	13.7	0.2	10.6	1.3	-0.2
11	-0.9	31.0	-1.9	13.3	-2.1	8.7	-1.9	2.2
12	0.7	22.8	0.5	10.4	-0.3	7.3	-1.3	-0.6
13	1.8	33.9	2.2	23.8	-0.5	16.2	1.2	3.6
14	-1.3	29.6	0.1	15.1	-2.6	10.9	-2.0	4.4
15	1.7	19.2	2.5	12.5	3.9	10.2	0.8	4.1
16	-0.3	22.1	-3.1	8.4	-3.8	3.5	-2.0	-1.8
17	0.4	28.0	0.0	10.1	-0.2	8.2	-1.3	2.2
18	1.9	25.3	2.6	13.6	1.8	10.6	1.8	7.2
19	-1.6	19.5	-2.0	11.0	-2.4	8.8	-2.1	1.8
20	-0.2	23.4	-0.8	13.7	-0.5	12.1	1.9	6.0
Average	-0.2	21.8	-0.4	11.9	-0.7	8.1	-0.5	2.4
S.D.	1.5	6.8	1.7	5.0	1.8	3.8	1.6	2.7
Median	-0.3	21.9	-0.5	11.7	-0.6	8.4	-0.8	2.2

Increase in Skin Hydration relative to initial conditions and to untreated, DCC17K137GR2

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

	after 2 hours		after 4 hours		after 8 hours		after 24 hours	
	untr.	E	untr.	E	untr.	E	untr.	E
1	0.6	97.8	0.4	71.7	0.8	43.5	3.7	20.6
2	-3.6	61.9	-6.2	58.2	-1.9	33.6	2.2	10.6
3	-9.5	67.9	-2.2	18.7	-2.4	19.8	-9.0	17.6
4	-3.7	85.0	-3.7	39.8	-5.5	13.3	1.3	1.4
5	0.9	32.9	-5.8	22.3	-8.8	13.8	-6.6	11.9
6	-8.6	30.8	-4.3	13.7	-3.4	9.5	-0.1	1.9
7	-1.0	46.4	-0.5	33.9	-3.3	20.3	-3.2	0.4
8	4.5	47.6	3.8	13.6	4.3	12.4	-4.6	17.2
9	-3.1	38.2	-6.4	34.6	-1.4	21.9	-1.3	-1.6
10	7.5	83.0	4.0	53.3	1.0	43.0	5.5	-6.5
11	-2.2	88.3	-5.0	41.9	-5.5	29.6	-5.0	11.2
12	2.0	64.5	1.4	28.8	-0.8	22.1	-3.6	1.7
13	5.4	95.5	6.4	64.2	-1.6	49.8	3.6	7.0
14	-3.8	85.0	0.2	41.4	-7.7	37.6	-5.8	17.8
15	5.6	59.6	8.1	34.4	12.8	21.7	2.8	11.2
16	-0.9	65.2	-8.3	32.8	-10.2	20.5	-5.4	0.0
17	1.2	73.2	-0.1	26.9	-0.6	22.4	-3.9	9.7
18	7.5	87.9	10.3	41.0	7.1	32.7	7.1	20.2
19	-4.3	59.9	-5.2	36.7	-6.5	31.5	-5.6	10.7
20	-0.7	77.0	-2.1	47.0	-1.3	40.9	5.3	14.4
Average	-0.3	67.4	-0.8	37.7	-1.7	27.0	-1.1	8.9
S.D.	4.8	20.4	5.2	15.7	5.4	11.6	4.8	7.9
Median	-0.8	66.6	-1.3	35.7	-1.7	22.3	-2.2	10.7
Impr.*	-	100	-	100	-	100	-	90

* % 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, DCC17K137GR2

start

	untr.	E
Valid cases	20.0	20.0
Mean	33.8	33.1
Std. error of mean	0.9	0.8
Variance	16.6	13.0
Std. Deviation	4.1	3.6
Variation Coefficient	0.1	0.1
Minimum	23.1	24.0
Maximum	38.7	37.7
Median	34.6	34.0

after 2 hours

	untr.	E
Valid cases	20.0	20.0
Mean	33.6	54.9
Std. error of mean	0.8	1.7
Variance	11.7	54.7
Std. Deviation	3.4	7.4
Variation Coefficient	0.1	0.1
Minimum	24.9	41.7
Maximum	37.9	67.6
Median	33.8	54.3

after 4 hours

	untr.	E
Valid cases	20.0	20.0
Mean	33.4	45.0
Std. error of mean	0.7	1.1
Variance	9.5	25.8
Std. Deviation	3.1	5.1
Variation Coefficient	0.1	0.1
Minimum	24.0	37.3
Maximum	36.8	57.4
Median	34.2	44.6

after 8 hours

	untr.	E
Valid cases	20.0	20.0
Mean	33.1	41.1
Std. error of mean	0.7	0.9
Variance	10.2	16.4
Std. Deviation	3.2	4.1
Variation Coefficient	0.1	0.1
Minimum	23.4	34.6
Maximum	36.8	49.9
Median	33.8	40.4

after 24 hours

	untr.	E
Valid cases	20.0	20.0
Mean	33.3	35.5
Std. error of mean	0.8	0.8
Variance	11.4	13.3
Std. Deviation	3.4	3.6
Variation Coefficient	0.1	0.1
Minimum	24.4	23.8
Maximum	37.3	40.8
Median	34.8	35.8

Wilcoxon Rank Test of Skin Hydration, DCC17K137GR2

start - comparison of absolute values

	untr. - E
Rank sum (positive)	144
Z-value	1.4373
Significance	0.1536
non-zero observations	20

after 2 hours - comparison of changes from initial condition

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

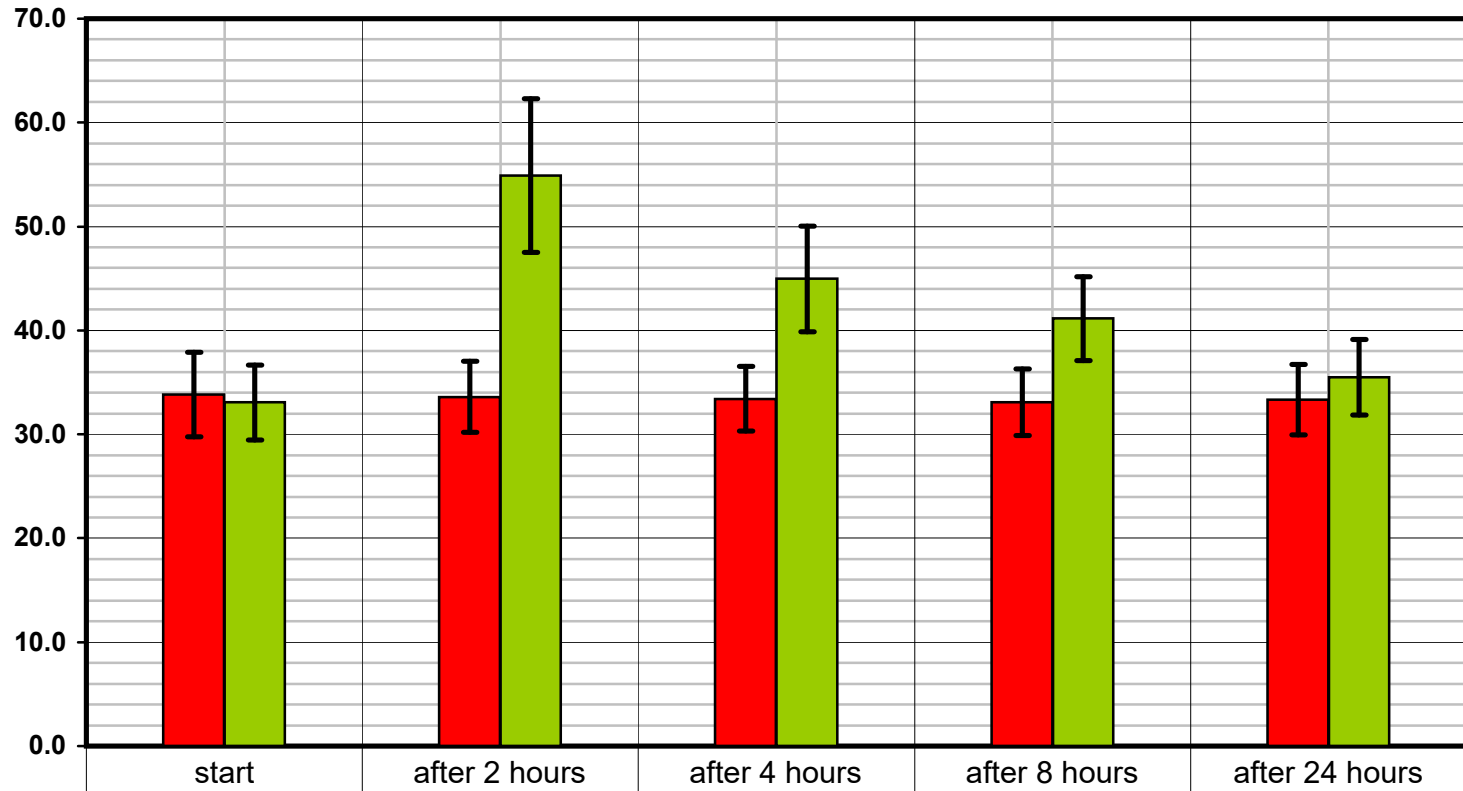
after 24 hours - comparison of changes from initial condition

	untr. - E
Rank sum (positive)	11
Z-value	-3.4906
Significance	0.0001
non-zero observations	20

Experimental data of Skin Hydration

DCC17K137GR2

Mean Corneometer readings (a.u.)



■ untreated

33.8

33.6

33.4

33.1

33.3

■ E: Rivoli Le Visage
Masque Reparateur Torstone
(lab-01086.5/24.08.17)

33.1

54.9

45.0

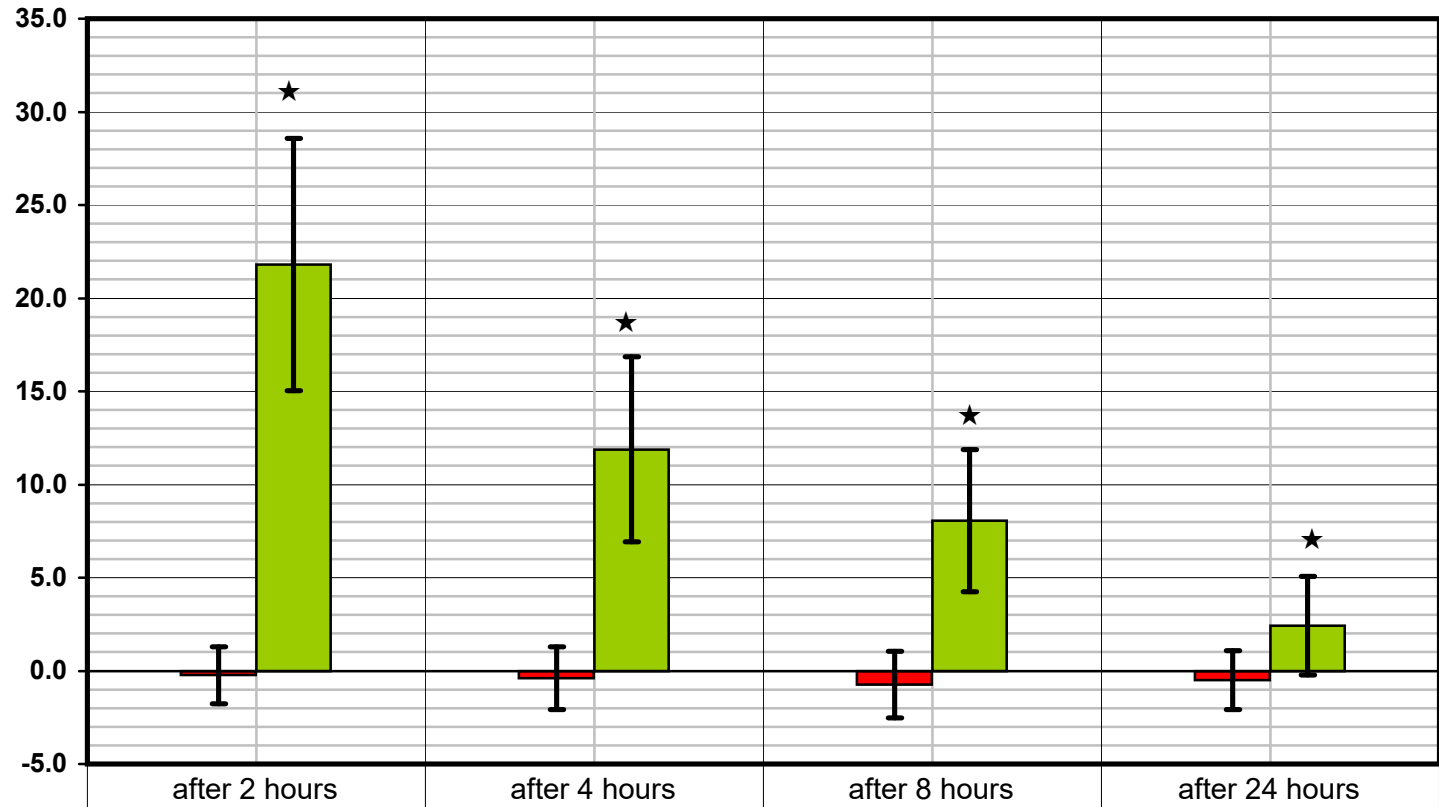
41.1

35.5

Experimental data of Skin Hydration (delta values)

DCC17K137GR2

Mean Corneometer readings (a.u.)
- to baseline



■ untreated

■ E: Rivoli Le Visage
Masque Reparateur Torstone
(lab-01086.5/24.08.17)

*p<0,05 versus untreated

Increase in Skin Hydration relative to initial conditions and to untreated

DCC17K137GR2

