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Concept
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Date: 09.07.2020

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

Summary

Study Sponsor: **IBREA GLOBAL CO., LTD.**
2F, 220, INHYANG-RO, GOCHON-EUP
GIMPO-SI, GYEONGGI-DO
KOREA

Date of Order.....: 21.05.2020

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: DCC20K055GR1

Test Product.....: The test product, which was coded as follows, was provided by
IBREA GLOBAL CA., LTD. in May 2020:

A. iBrea Skin Relief Ultra Hydrating Body Lotion
(Lot No: MWL 0219-5; Date: 20.05.13)

Control.....: Untreated

Subjects: Number of individuals.: 20
Sex: female
Age range: 23-63 years (average: 40,4)

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

Application.....: Single, controlled Application

Test Period.....: July 2020

manager: Boris Nissen
bank account: Sparkasse KölnBonn BIC: COLSDE33XXX
IBAN: DE89 3705 0198 1902 2876 38

district court Bonn HRB 12566
VAT-REG.No. DE 209873944
Tax No. 205/5711/0927

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:

- 4 hours after the application
- 8 hours after the application
- 24 hours after the application
- 48 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 09372310; probe S/N 09341843.

Performance of Test

To respect the SARS-CoV-2 related legal requirements in place at the time of conduct of the study, a contact minimized study protocol was employed.

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 23-63 years of age (average: 40,4). 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 and a mild syndet (Eubos® flüssig – blau; manufacturer: Dr. Hobein, D-53340 Meckenheim-Merl, Germany; supplied by Derma Consult) were allowed only.

Prior to the controlled application of the test product (randomized location) by a staff member of Derma Consult (approximately 2 mg/cm²; 30 seconds of massaging the product into the skin), measurements were taken at clearly defined sites on the inner sides of the forearms. One additional 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 and, in case the product was not taken into the skin completely, to gently remove residue with soft paper towels under guidance and supervision by a Derma Consult staff member (not required by any of the subjects). Further measuring was performed 4, 8, 24 and 48 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±2°C, relative humidity: 45±10%).

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.

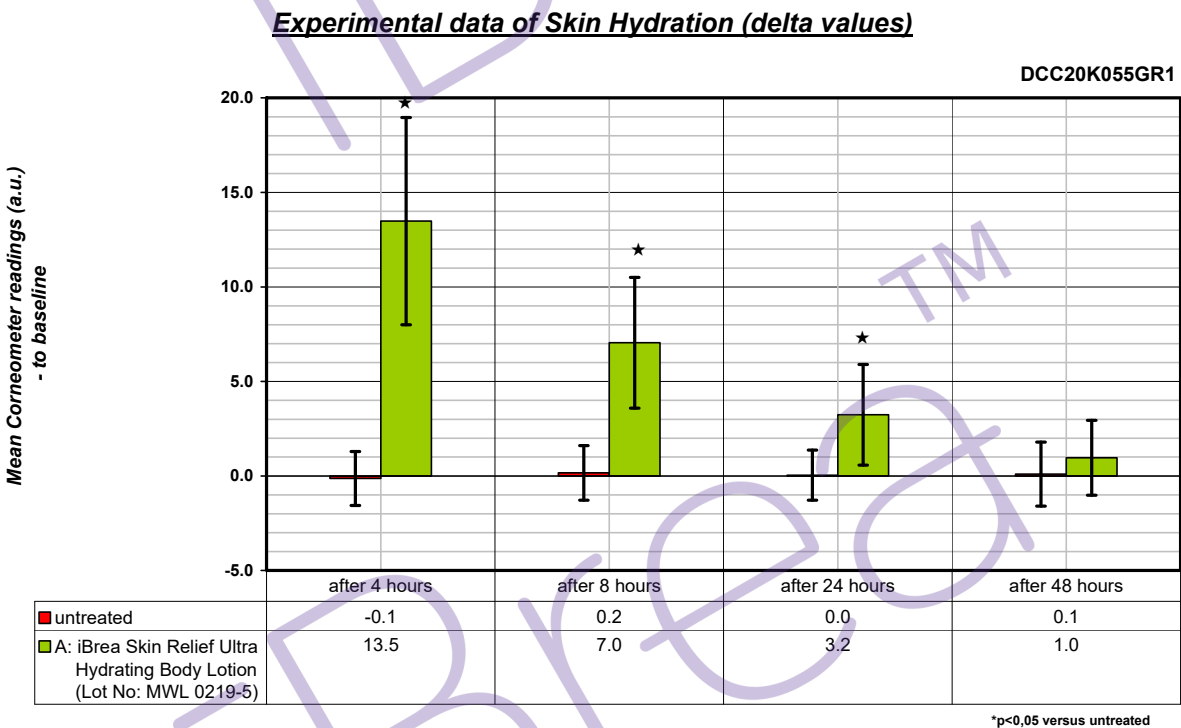


Fig. 1: Δ Skin Hydration Values

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 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 80% 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.

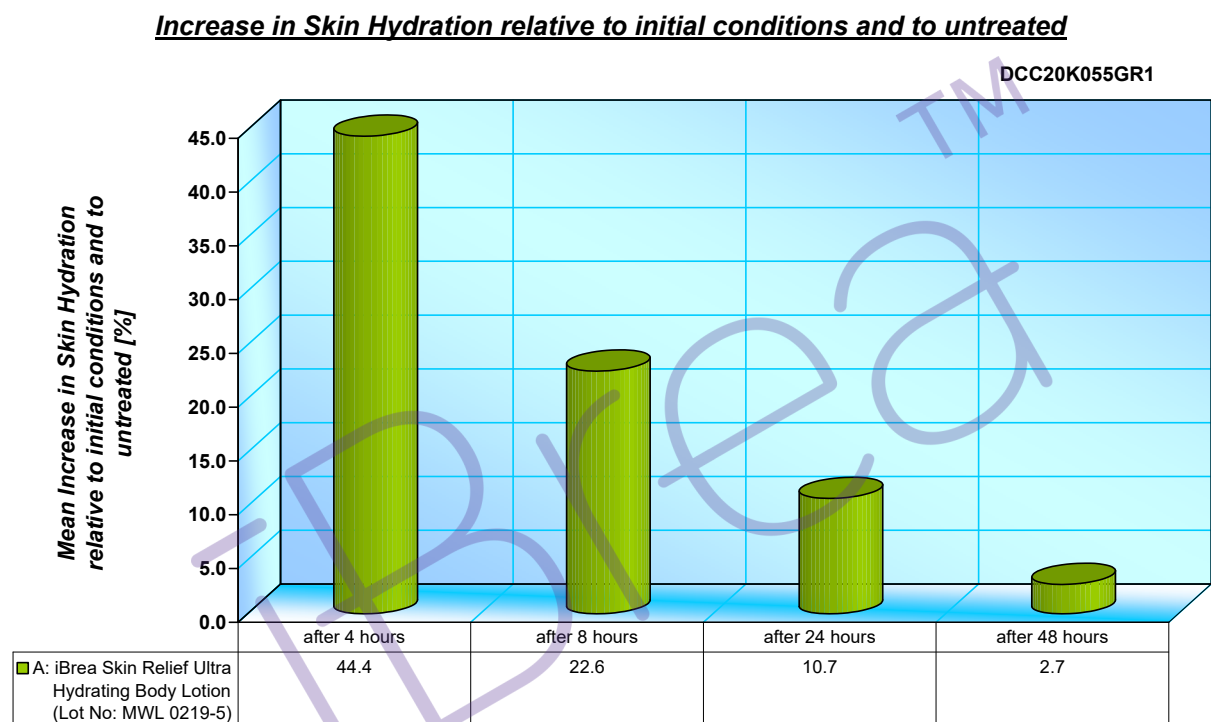


Fig. 2: Increase in Skin Hydration in %

Incompatibility

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

Signature:

B. Nissen
Manager Derma Consult Concept

Signature:

Dr. med. H. Prieur
Dermatologist - Allergist

Experimental data of Skin Hydration, DCC20K055GR1

Corneometer readings (a.u.)

	start		after 4 hours		after 8 hours		after 24 hours		after 48 hours	
	untr.	A	untr.	A	untr.	A	untr.	A	untr.	A
1	26.4	25.6	26.0	37.6	27.8	33.9	25.8	29.4	26.4	27.5
2	32.8	29.7	32.4	40.2	31.7	35.2	32.7	32.6	32.1	30.4
3	27.3	27.7	27.3	38.9	25.4	34.3	29.4	32.9	27.2	29.4
4	33.3	32.9	33.3	41.0	30.9	37.8	30.4	36.3	32.3	34.2
5	32.5	33.7	34.3	42.8	33.4	40.2	33.9	39.1	35.2	34.8
6	31.1	28.6	30.2	43.3	30.2	40.4	29.4	32.7	29.0	31.6
7	30.4	34.8	31.0	52.1	31.8	45.8	32.7	40.4	30.3	38.5
8	31.3	29.6	29.7	45.6	29.8	34.9	30.1	33.0	28.4	26.9
9	25.4	28.1	28.3	51.5	27.0	40.3	26.7	35.8	29.9	34.2
10	30.6	25.0	29.7	44.4	28.9	33.2	29.9	31.4	30.5	24.2
11	29.4	27.9	26.5	35.9	29.4	28.1	28.6	27.1	28.7	26.2
12	31.4	33.3	31.6	45.5	32.2	36.4	31.6	33.1	31.9	32.7
13	25.8	31.0	24.8	46.6	25.0	40.1	26.5	35.3	26.0	32.1
14	25.6	26.6	25.3	32.8	26.5	31.0	25.9	28.4	24.7	27.2
15	33.4	38.4	33.7	63.2	33.6	48.6	34.0	36.6	36.0	38.9
16	36.0	36.3	36.2	48.0	36.2	41.5	37.3	36.5	36.2	38.0
17	31.6	31.3	31.2	41.6	32.3	33.9	31.7	31.4	31.0	29.7
18	36.9	31.6	34.1	40.7	39.3	37.7	37.1	35.1	37.7	32.2
19	33.2	32.2	35.5	40.3	35.8	38.4	31.4	35.0	34.5	33.5
20	34.7	32.4	35.3	54.3	35.3	45.8	35.0	39.3	33.3	33.7
Average	31.0	30.8	30.8	44.3	31.1	37.9	31.0	34.1	31.1	31.8
S.D.	3.4	3.5	3.5	7.0	3.8	5.1	3.4	3.6	3.6	4.2
Median	31.3	31.1	31.1	43.0	31.3	37.8	30.9	34.1	30.7	32.2

Experimental data of Skin Hydration, DCC20K055GR1

delta Corneometer readings (a.u.)

	after 4 hours t1-t0		after 8 hours t2-t0		after 24 hours t3-t0		after 48 hours t4-t0	
	untr.	A	untr.	A	untr.	A	untr.	A
1	-0.4	12.0	1.4	8.3	-0.6	3.8	0.0	1.8
2	-0.4	10.5	-1.1	5.6	-0.1	2.9	-0.7	0.7
3	0.0	11.2	-1.9	6.6	2.0	5.2	-0.1	1.7
4	-0.1	8.1	-2.4	4.9	-2.9	3.4	-1.0	1.3
5	1.8	9.1	1.0	6.5	1.4	5.4	2.7	1.1
6	-0.9	14.7	-0.9	11.8	-1.8	4.1	-2.1	3.0
7	0.6	17.3	1.4	11.0	2.3	5.5	-0.1	3.7
8	-1.6	16.0	-1.5	5.3	-1.2	3.4	-2.9	-2.7
9	2.9	23.4	1.6	12.2	1.3	7.7	4.5	6.1
10	-0.9	19.4	-1.7	8.2	-0.7	6.4	-0.1	-0.9
11	-2.9	8.0	0.0	0.1	-0.7	-0.8	-0.7	-1.7
12	0.3	12.3	0.8	3.2	0.2	-0.2	0.5	-0.6
13	-1.0	15.6	-0.9	9.1	0.6	4.3	0.1	1.1
14	-0.3	6.2	0.9	4.4	0.3	1.8	-0.9	0.6
15	0.3	24.8	0.2	10.2	0.6	-1.8	2.6	0.6
16	0.2	11.6	0.2	5.2	1.3	0.2	0.2	1.7
17	-0.4	10.3	0.7	2.6	0.0	0.1	-0.7	-1.6
18	-2.7	9.1	2.4	6.1	0.3	3.5	0.8	0.6
19	2.2	8.2	2.6	6.3	-1.8	2.9	1.2	1.4
20	0.6	22.0	0.6	13.4	0.4	7.0	-1.3	1.3
Average	-0.1	13.5	0.2	7.0	0.0	3.2	0.1	1.0
S.D.	1.4	5.5	1.4	3.5	1.3	2.7	1.7	2.0
Median	-0.2	11.8	0.4	6.4	0.2	3.4	-0.1	1.1

Increase in Skin Hydration relative to initial conditions and to untreated, DCC20K055GR1

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

	after 4 hours		after 8 hours		after 24 hours		after 48 hours	
	untr.	A	untr.	A	untr.	A	untr.	A
1	-1.4	48.2	5.4	26.9	-2.3	17.2	0.1	7.1
2	-1.2	36.5	-3.4	22.1	-0.4	10.3	-2.0	4.5
3	0.1	40.3	-7.1	30.9	7.5	11.4	-0.3	6.5
4	-0.2	24.8	-7.3	22.2	-8.7	19.0	-3.1	7.1
5	5.5	21.5	3.0	16.3	4.2	11.7	8.3	-4.9
6	-2.8	54.1	-2.9	44.0	-5.7	19.9	-6.9	17.2
7	1.8	47.8	4.5	27.0	7.6	8.3	-0.4	11.1
8	-5.2	59.1	-4.9	22.8	-4.0	15.4	-9.3	0.1
9	11.6	71.8	6.3	37.3	5.3	22.3	17.6	4.2
10	-2.9	80.3	-5.6	38.3	-2.2	27.6	-0.3	-3.2
11	-9.7	38.2	-0.1	0.6	-2.5	-0.5	-2.3	-3.8
12	0.8	36.0	2.6	6.9	0.6	-1.1	1.5	-3.3
13	-3.9	54.3	-3.3	32.8	2.5	11.5	0.5	3.0
14	-1.1	24.4	3.4	13.2	1.3	5.4	-3.7	6.0
15	0.9	63.8	0.7	25.9	1.7	-6.4	7.7	-6.3
16	0.4	31.6	0.7	13.7	3.6	-2.9	0.5	4.1
17	-1.3	34.2	2.2	6.1	0.1	0.3	-2.1	-3.1
18	-7.4	36.2	6.6	12.6	0.7	10.2	2.2	-0.2
19	6.7	18.7	7.8	11.8	-5.4	14.3	3.7	0.6
20	1.7	66.2	1.7	39.8	1.0	20.5	-3.9	7.9
Average	-0.4	44.4	0.5	22.6	0.2	10.7	0.4	2.7
S.D.	4.8	17.5	4.7	12.3	4.3	9.3	5.8	6.0
Median	-0.6	39.3	1.2	22.5	0.6	11.5	-0.3	3.5
Impr.*	-	100	-	100	-	80	-	65

* % 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, DCC20K055GR1

start

	untr.	A
Valid cases	20.0	20.0
Mean	31.0	30.8
Std. error of mean	0.8	0.8
Variance	11.6	12.5
Std. Deviation	3.4	3.5
Variation Coefficient	0.1	0.1
Minimum	25.4	25.0
Maximum	36.9	38.4
Median	31.3	31.1

after 4 hours

	untr.	A
Valid cases	20.0	20.0
Mean	30.8	44.3
Std. error of mean	0.8	1.6
Variance	12.6	49.2
Std. Deviation	3.5	7.0
Variation Coefficient	0.1	0.2
Minimum	24.8	32.8
Maximum	36.2	63.2
Median	31.1	43.0

after 8 hours

	untr.	A
Valid cases	20.0	20.0
Mean	31.1	37.9
Std. error of mean	0.9	1.2
Variance	14.7	26.5
Std. Deviation	3.8	5.1
Variation Coefficient	0.1	0.1
Minimum	25.0	28.1
Maximum	39.3	48.6
Median	31.3	37.8

after 24 hours

	untr.	A
Valid cases	20.0	20.0
Mean	31.0	34.1
Std. error of mean	0.8	0.8
Variance	11.7	12.6
Std. Deviation	3.4	3.6
Variation Coefficient	0.1	0.1
Minimum	25.8	27.1
Maximum	37.3	40.4
Median	30.9	34.1

after 48 hours

	untr.	A
Valid cases	20.0	20.0
Mean	31.1	31.8
Std. error of mean	0.8	0.9
Variance	13.3	17.2
Std. Deviation	3.6	4.2
Variation Coefficient	0.1	0.1
Minimum	24.7	24.2
Maximum	37.7	38.9
Median	30.7	32.2

Wilcoxon Rank Test of Skin Hydration, DCC20K055GR1

start - comparison of absolute values

	untr. - A
Rank sum (positive)	116
Z-value	0.3920
Significance	0.7012
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 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

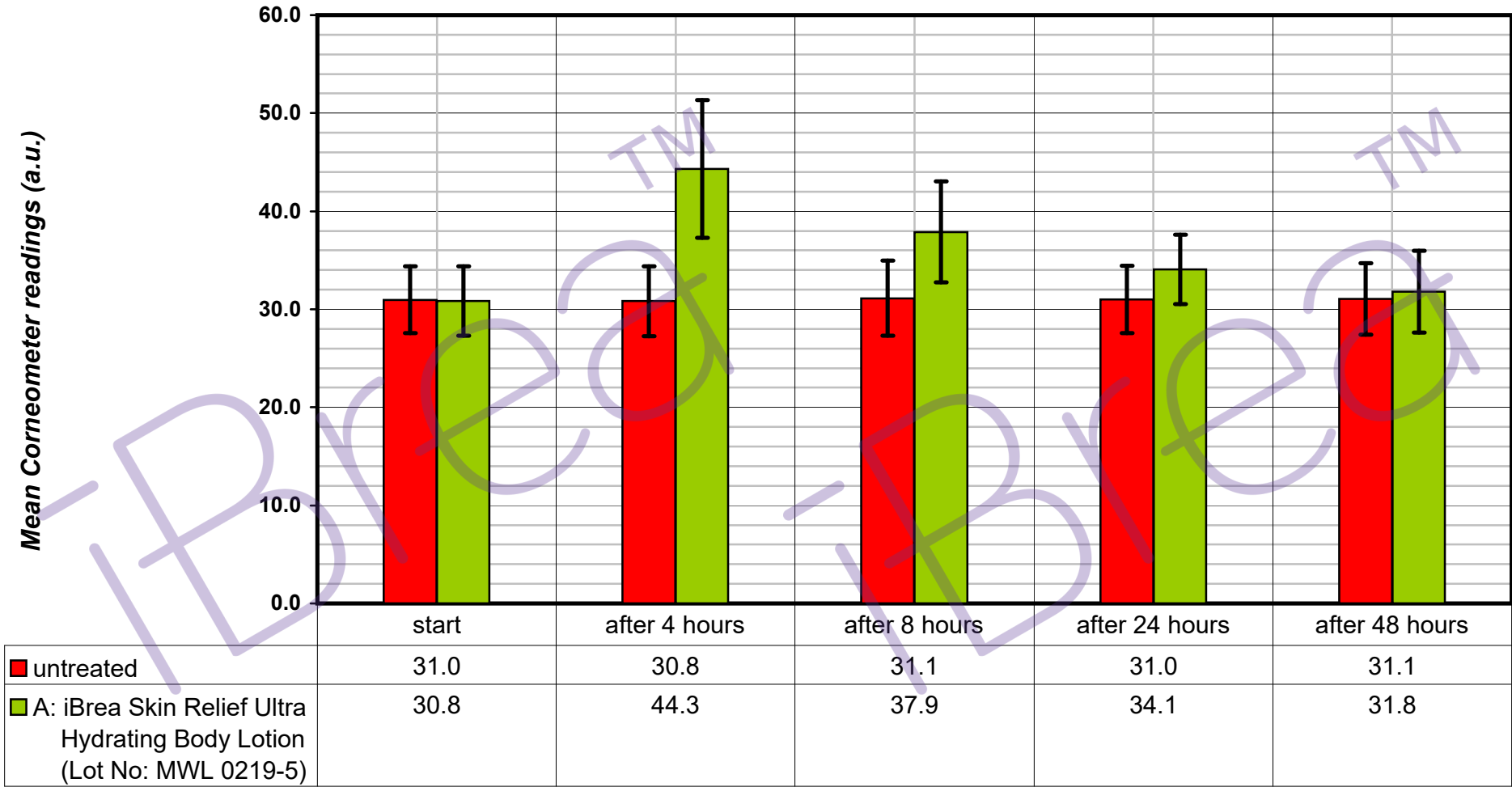
	untr. - A
Rank sum (positive)	15
Z-value	-3.3413
Significance	0.0003
non-zero observations	20

after 48 hours - comparison of changes from initial condition

	untr. - A
Rank sum (positive)	55.5
Z-value	-1.8295
Significance	0.0651
non-zero observations	20

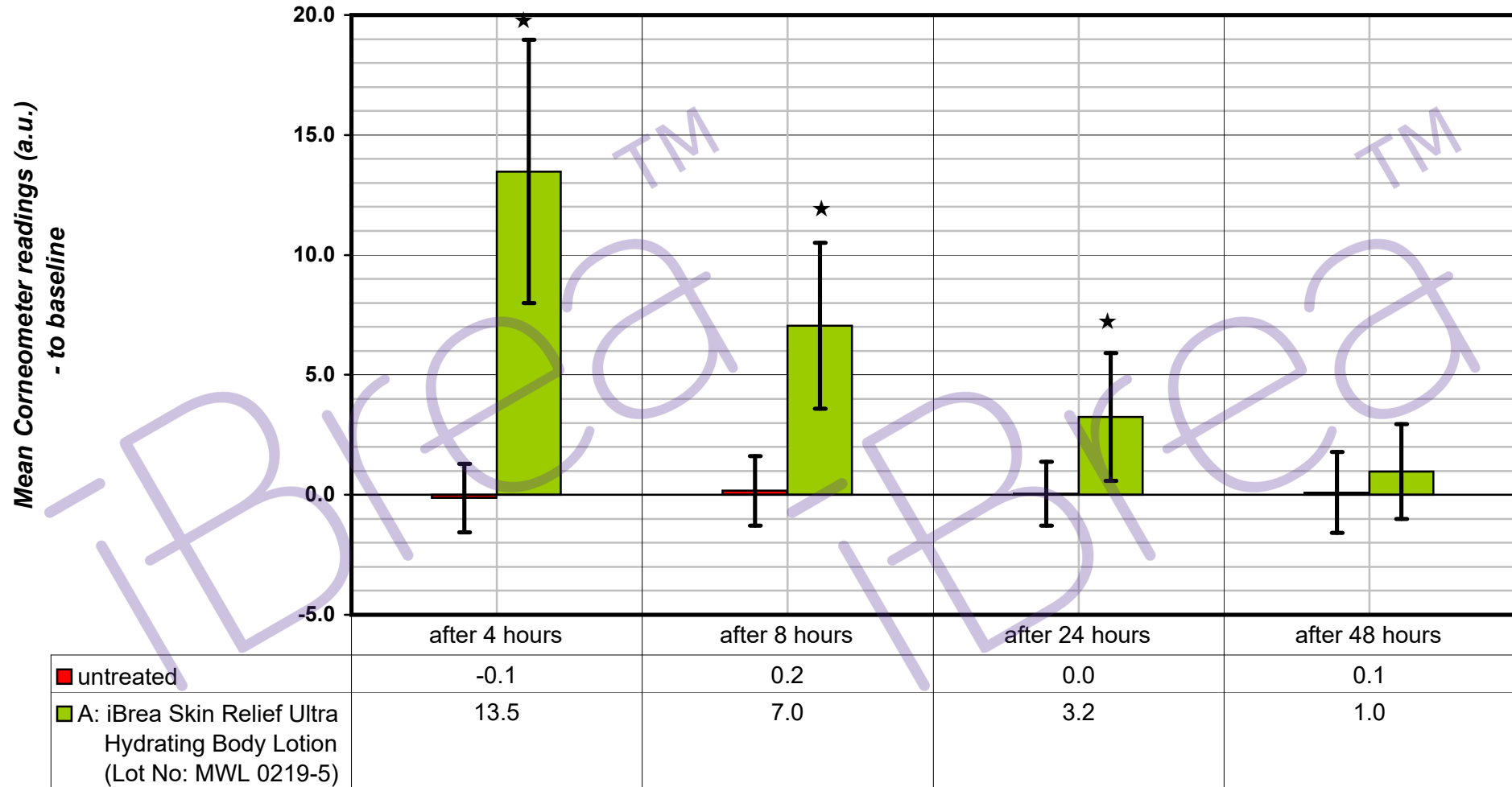
Experimental data of Skin Hydration

DCC20K055GR1



Experimental data of Skin Hydration (delta values)

DCC20K055GR1



*p<0,05 versus untreated

Increase in Skin Hydration relative to initial conditions and to untreated

DCC20K055GR1

