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Date: 14.02.04

Evaluation Of The Protective Efficacy Of Two Test Products Against Sodium Dodecyl Sulphate-Induced Skin Irritation (TEWL, Redness)

Summary

Study Sponsor .....: **OMNIMEDICA AG**
Wagistr. 13
CH-8952 Schlieren
Switzerland

Date of Order.....: 13.01.04

Performance of Test .....: Derma Consult GmbH
and Evaluation by Brunnenstrasse 61
53347 Alfter

Supervisor of Study.....: Dr. med. H. Prieur
Dr. H. P. Nissen Ph.D.

Test Products.....: The test products were provided by OMNIMEDICA:
1. 4Protection System Body Lotion
2. Ebenol® - 0,25% Hydrocortisone acetate (Strathmann AG)

Subjects .....: Number of individuals.: 20
Sex.....: female
Age range .....: 22 - 52 years

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

Application.....: Duration....: 9 days
Frequency.: twice daily

Test Period.....: February 2004

Test Parameters	1. Determination of *Transepidermal Waterloss (TEWL)* by means of Tewameter TM 210 (Courage + Khazaka GmbH, Cologne)
.....	2. Determination of skin redness with Chromameter CR 300 (Minolta, Japan)
Time of Evaluation.....	- before treatment with sodium dodecyl sulfate (SDS) - 4 hours after SDS treatment
Evaluation.....	Descriptive statistics: mean, median, minimum, maximum, variance, standard error, standard deviation; Wilcoxon test
Results	The two products protected the skin in this test model against the damaging effects (TEWL, skin redness) of sodium dodecyl sulphate (SDS) treatment.

Methods

Measurement of TEWL

Measurements of TEWL were performed with the Tewameter TM 210 (Courage & Khazaka, Cologne, Germany). The Tewameter is a device to measure the water evaporation of skin surfaces based on the diffusion principle discovered by A. Fick in 1885. The TEWL is calculated automatically and expressed digitally in g/m^2h. Measurements were carried out in accordance with the guidelines of the Standardisation group of the European Contact Dermatitis Society (Pinnagoda et al. Contact Dermatitis 1990, **22**, 164-178). Each value was the average of three measurements.

Measurement of Skin Redness

By means of Chromametry, brightness, reddening, and blanching effects on the skin can be assessed in a standardized manner. A color shade is defined three dimensionally by brightness, hue, and saturation. Chromametry permits the synchronous determination of these three parameters. The chromameter's measurement attachment contains a high-power xenon flash-lamp that guarantees uniform and constant illumination of the measurement area. A dual-beam procedure ensures reproducibility of standard illumination from measurement to measurement. For the color analysis, only the vertically reflected light is conducted to six highly sensitive silicon photodiodes. The illumination system, comprised of xenon flash lamps and silicon photodiodes, is adapted by filter to the CIE's (Commission Internationale de l'Eclairage) internationally standardized spectral-response curve and detects the smallest aberrations in the spectral composition of the reflected xenon light. Chromameter CR 300 uses several measurement systems. With an eye to the task at hand, the measurements were taken exclusively in the L*a*b* colorimetry system (also designated as CIELAB system). L* represents the brightness, while a* and b* the hue and color saturation. a* shows the position on the red-green axis and b* on the yellow-blue axis. An increase in the reddening is shown by an increase in the a* value. The values are internationally defined absolute values. Measurements were done

according to the guidelines of the European Society of Contact Dermatitis (Fullerton et al., Guidelines for measurement of skin colour and erythema. Contact Dermatitis 1996: **35**; 1-10). Each value was the average of three measurements.

Performance of Test

Subjects were informed about importance and meaning of the study. Written informed consent was obtained from all the subjects prior to entry into the trial. Subjects were instructed not to use any topical preparations on the test areas starting from three days prior to testing until end of test. Following criteria were used for selection of subjects:

for inclusion in study:
- age range >18 years
- clinically healthy

for exclusion from study:
- skin diseases
- pregnancy

Measurements were carried out at a temperature of 20° C ± 1° C and a relative humidity of 50 % ± 10 %. Subjects were accustomed to ambient conditions for 30 min prior to any measurement. The test was carried out on the volar forearms. The samples were applied for a period of one week twice daily (in the morning and in the evening) randomised on the forearms, one area remained untreated and served as control. The dose of application was about 2 mg/cm^2 (application with a syringe for fine dosage: Omnifix® - F 1ml; manufacturer: Braun Melsungen AG, Germany). On day 7 the initial measurements were done 8-12h after the last daily application. Skin irritation was induced in the test sites by applying Sodium Dodecyl Sulphate (SDS, purity: 99%; Tupker et al., Guidelines on sodium lauryl sulfate - SLS exposure tests. Contact Dermatitis, 1997, **37**; 53-69) 2% in distilled water under occlusive plastic chambers (Hill Top Chamber®: diameter: 19mm) supplied with a non-woven Webril® pad for 24h. occlusion. After 24h hours, occlusion was removed and the skin was wiped with a soft paper towel to remove remaining solution, rinsed with tape water and gently dried with a soft paper towel. Four hours later redness and TEWL were recorded. Use of other cosmetic products or drugs was restricted on the test areas throughout the whole study.

Biometry

Measuring data are centrally computerised after validity check and quality assurance. Evaluation is done using the software WinSTAT® Add-in for Excel – R. K. Fitch, Germany. Data were analyzed by Wilcoxon Test. A comparison of the results of each time point versus untreated was carried out. The 0.05 level was selected as the point of minimal acceptance statistical significance.

Results

TEWL

The TEWL increased after SDS treatment. The increase of the TEWL was lower in the treated areas in comparison to the untreated area ($p<0,05$). The two products were equivalent in increasing the TEWL only minimal. The average values (in g/hm²) were shown in fig. 1.

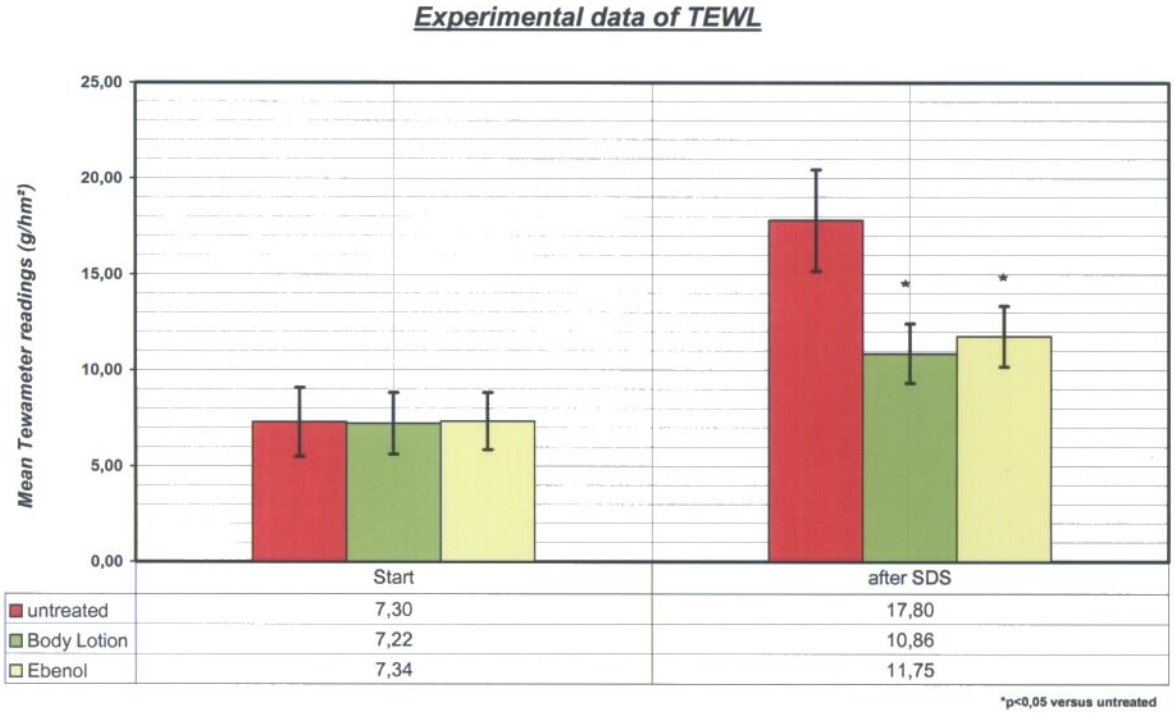


Fig. 1: TEWL

Skin Redness

Skin redness increased after SDS exposure. The increase of skin redness was lower in the treated areas in comparison to the untreated area ($p<0,05$). The two products were equivalent in increasing skin redness only minimal. The average values (in a*) were shown in fig. 2.

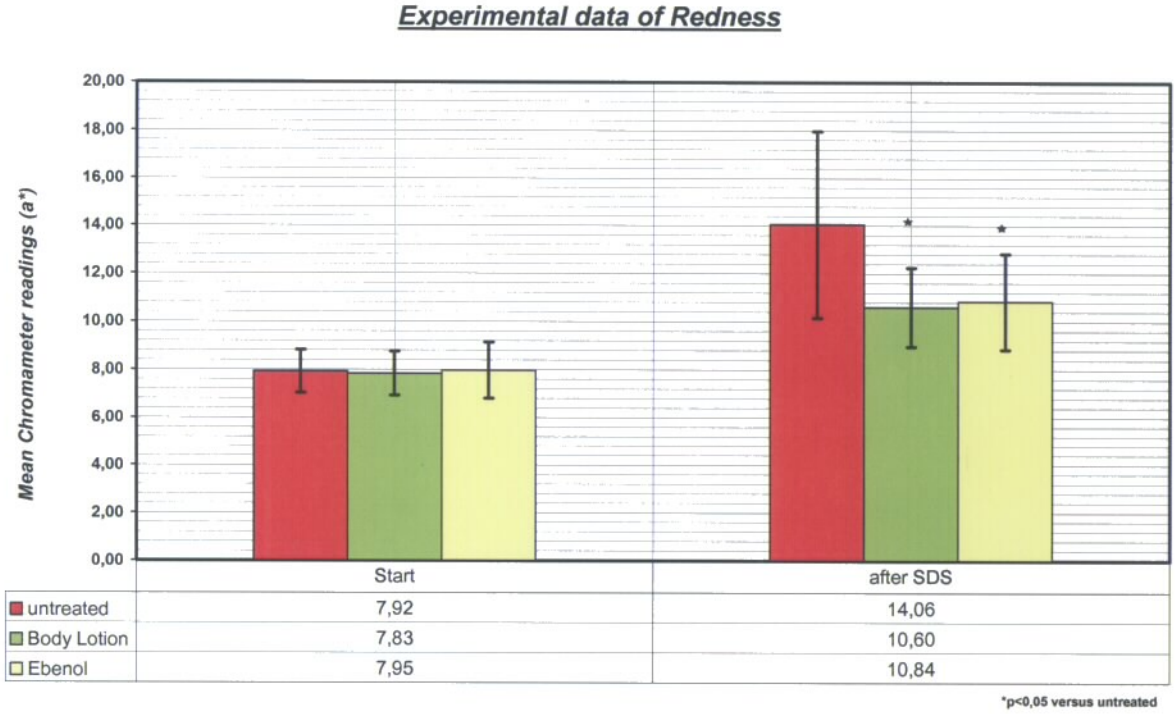


Fig. 2: Redness

Incompatibility

No incompatibility was observed in any of the subjects.

Signature:

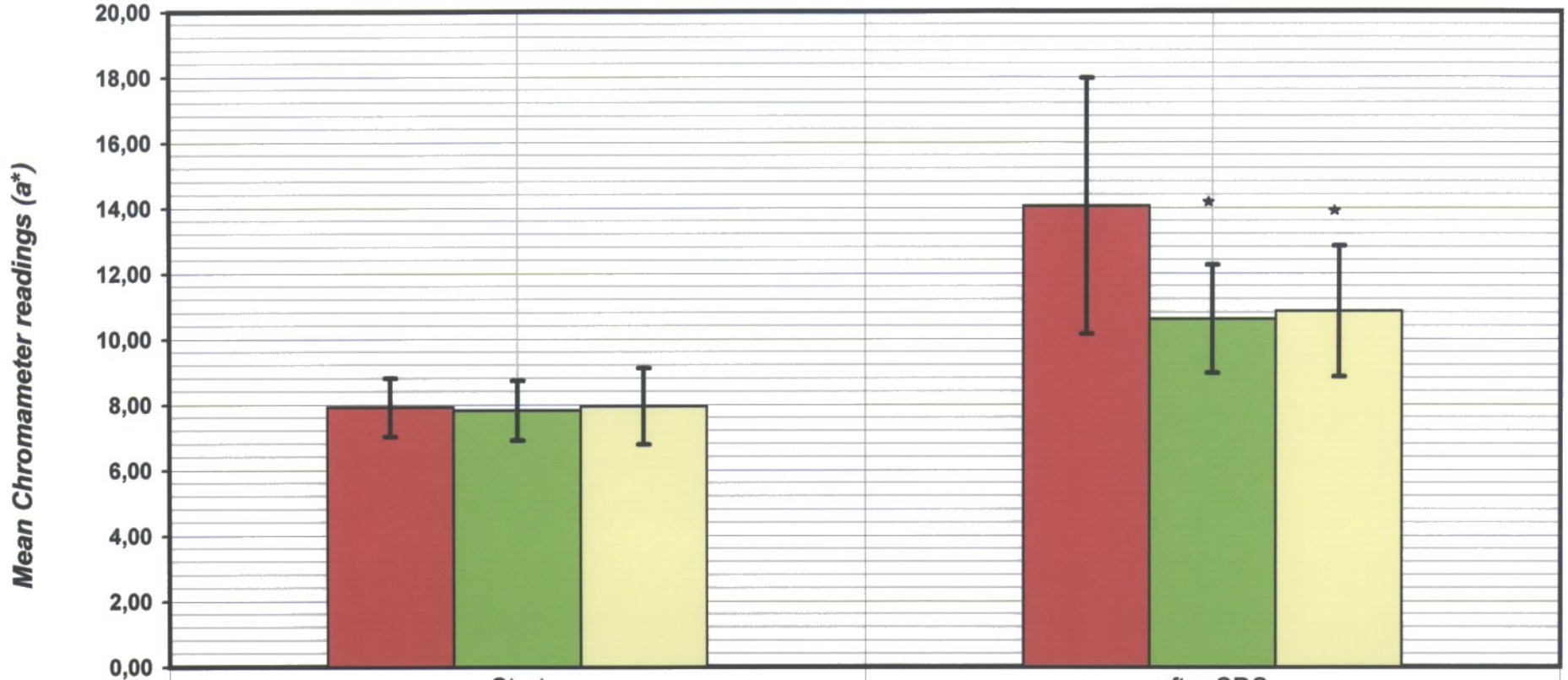
Dr. H.-P. Nissen
Chemist – Ph.D.

Signature:

Dr. med H. Prieur
Dermatologist - Allergist

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

Experimental data of Redness



	Start	after SDS
untreated	7,92	14,06
Body Lotion	7,83	10,60
Ebenol	7,95	10,84

*p<0,05 versus untreated

Experimental data of Redness.

Chromameter readings (a*)

	Start			after SDS		
	untr.	A	B	untr.	A	B
1	7,89	8,56	8,14	23,59	12,54	10,60
2	8,56	7,99	7,63	11,47	10,22	11,27
3	7,56	8,91	6,03	12,79	11,05	13,78
4	8,34	7,87	7,32	22,65	12,87	11,09
5	8,67	8,34	9,30	16,40	12,32	13,99
6	8,78	7,83	7,54	11,54	10,76	9,79
7	7,67	8,32	7,32	11,69	10,00	9,53
8	8,45	7,08	7,56	10,74	11,85	11,94
9	7,43	8,13	9,12	14,16	8,82	14,09
10	9,53	6,13	6,43	11,87	7,63	6,87
11	9,16	7,03	7,09	11,54	7,76	8,31
12	7,01	7,76	9,69	10,12	8,35	8,54
13	7,11	9,07	9,76	13,29	11,54	11,12
14	7,15	7,34	7,87	10,17	9,52	9,72
15	6,12	6,09	8,76	13,57	11,32	9,65
16	8,75	8,15	9,54	20,20	12,09	11,95
17	8,00	9,35	7,12	14,10	12,32	12,07
18	7,65	7,65	6,43	12,98	9,36	8,55
19	8,17	8,47	9,20	15,98	9,65	11,24
20	6,45	6,47	7,23	12,38	12,11	12,76
Average	7,92	7,83	7,95	14,06	10,60	10,84
S.D.	0,89	0,92	1,16	3,90	1,65	1,99
Median	7,95	7,93	7,60	12,89	10,91	11,11

Descriptive Statistics of Redness,

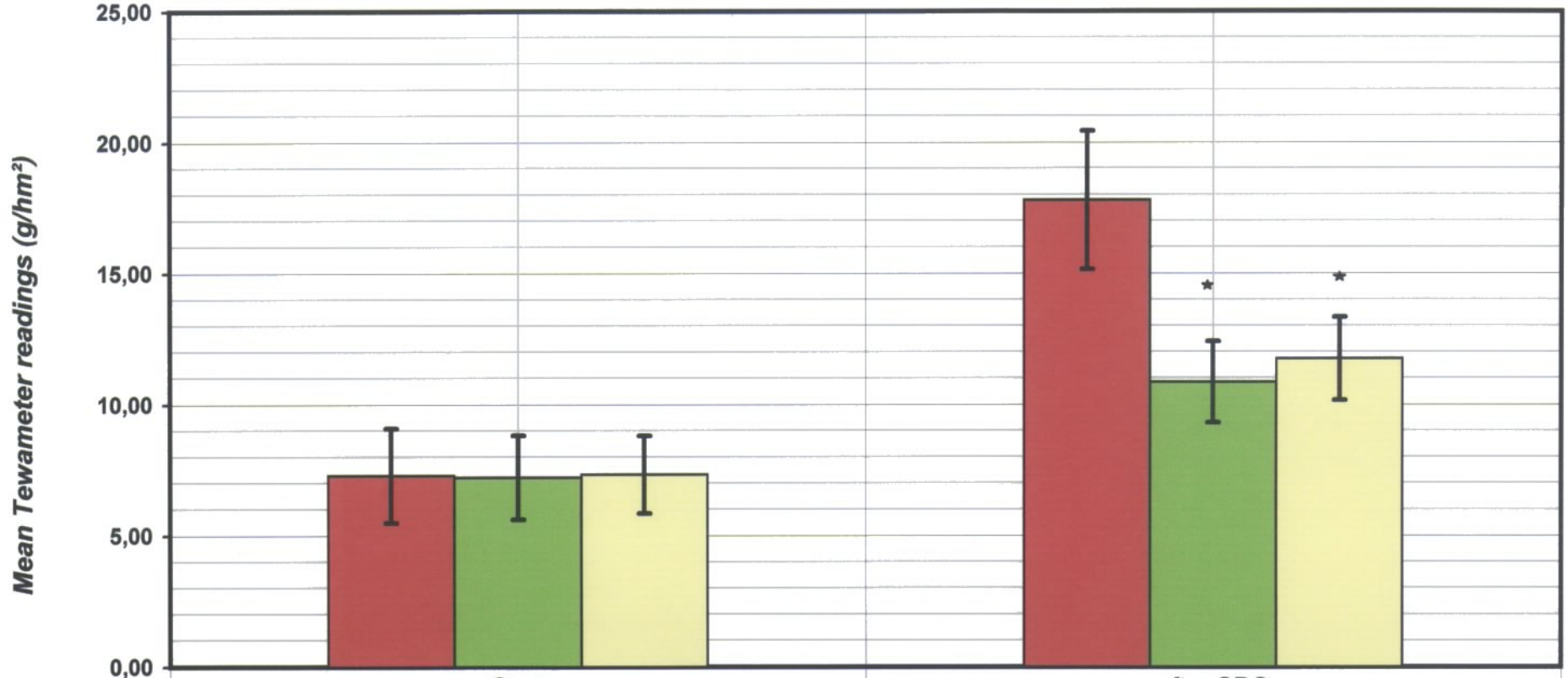
Start

	untr.	A	B
Valid cases	20,0	20,0	20,0
Mean	7,9	7,8	8,0
Std. error of mean	0,2	0,2	0,3
Variance	0,8	0,8	1,4
Std. Deviation	0,9	0,9	1,2
Variation Coefficient	0,1	0,1	0,1
Minimum	6,1	6,1	6,0
Maximum	9,5	9,4	9,8
Median	7,9	7,9	7,6

after SDS

	untr.	A	B
Valid cases	20,0	20,0	20,0
Mean	14,1	10,6	10,8
Std. error of mean	0,9	0,4	0,4
Variance	15,2	2,7	4,0
Std. Deviation	3,9	1,7	2,0
Variation Coefficient	0,3	0,2	0,2
Minimum	10,1	7,6	6,9
Maximum	23,6	12,9	14,1
Median	12,9	10,9	11,1

Experimental data of TEWL



	Start	after SDS
untreated	7,30	17,80
Body Lotion	7,22	10,86
Ebenol	7,34	11,75

*p<0,05 versus untreated

Experimental data of TEWL.

Tewameter readings (g/hm²)

	Start			after SDS		
	untr.	A	B	untr.	A	B
1	7,90	8,70	8,50	16,70	13,20	13,50
2	7,40	5,90	8,30	21,60	7,40	11,60
3	9,40	3,90	8,50	17,50	11,20	12,60
4	6,50	7,40	9,40	10,90	11,90	11,70
5	9,40	6,40	7,80	22,40	12,50	14,70
6	6,40	7,30	5,90	18,50	12,40	12,50
7	4,90	4,90	7,60	19,80	13,20	11,70
8	9,30	6,90	9,50	19,80	8,00	15,20
9	9,30	7,40	4,90	17,50	10,00	10,40
10	5,30	8,90	9,00	18,50	11,10	10,90
11	8,40	4,90	6,40	16,50	8,90	10,30
12	5,90	9,50	8,30	18,60	9,90	13,40
13	3,90	7,90	8,30	18,60	11,30	10,60
14	9,30	8,30	6,40	18,10	11,90	12,70
15	5,60	7,60	4,90	16,80	11,40	10,40
16	8,30	7,90	6,40	19,60	10,80	9,40
17	9,30	4,90	8,40	15,70	10,90	10,50
18	5,30	9,40	7,10	18,70	10,30	11,60
19	8,20	8,40	5,80	17,50	10,90	9,70
20	5,90	7,90	5,30	12,70	10,00	11,60
Average	7,30	7,22	7,34	17,80	10,86	11,75
S.D.	1,80	1,60	1,48	2,64	1,55	1,58
Median	7,65	7,50	7,70	18,30	11,00	11,60

Wilcoxon Rank Test of Redness,

Start

	untr. - A	untr. - B	A - B
Rank sum (positive)	94	111	86
Z-value	-0,0201	0,2053	-0,6907
Significance	0,9843	0,8408	0,4980
non-zero observations	19	20	20

after SDS

	untr. - A	untr. - B	A - B
Rank sum (positive)	206	196	103,5
Z-value	3,7519	3,3786	-0,0373
Significance	0,0000	0,0002	0,9643
non-zero observations	20	20	20

Wilcoxon Rank Test of TEWL,

Start

	untr. - A	untr. - B	A - B
Rank sum (positive)	96	106	100,5
Z-value	0,0201	0,0187	-0,1494
Significance	0,9762	0,9787	0,8769
non-zero observations	19	20	20

after SDS

	untr. - A	untr. - B	A - B
Rank sum (positive)	209	209	64,5
Z-value	3,8639	3,8643	-1,4940
Significance	0,0000	0,0000	0,1350
non-zero observations	20	20	20

Descriptive Statistics of TEWL,

Start

	untr.	A	B
Valid cases	20,0	20,0	20,0
Mean	7,3	7,2	7,3
Std. error of mean	0,4	0,4	0,3
Variance	3,3	2,6	2,2
Std. Deviation	1,8	1,6	1,5
Variation Coefficient	0,2	0,2	0,2
Minimum	3,9	3,9	4,9
Maximum	9,4	9,5	9,5
Median	7,7	7,5	7,7

after SDS

	untr.	A	B
Valid cases	20,0	20,0	20,0
Mean	17,8	10,9	11,8
Std. error of mean	0,6	0,3	0,4
Variance	7,0	2,4	2,5
Std. Deviation	2,6	1,5	1,6
Variation Coefficient	0,1	0,1	0,1
Minimum	10,9	7,4	9,4
Maximum	22,4	13,2	15,2
Median	18,3	11,0	11,6