STUDY 235/10/00: RESULTS

EVALUATION of LENITIVE EFFECT and of EFFICACY in RESTORING SKIN BARRIER PROPERTIES after SKIN IRRITATION INDUCED by SODIUM LAURYL SULFATE

TransEpidermalWaterLoss

Table 1: Means and standard deviations

TEWL	T_0	T_{24h}	T_{48h}	T_{72h}	T_{96h}
EMULSION at 5% MYRTILLUS OIL	12.0 *± 2.5*	28.8 *± 9.1*	26.1 *± 9.4*	20.3 *± 6.3*	16.5 *± 4.0*
EMULSION at 2% MIRTYLLUS OIL	11.9 *± 2.5*	27.3 *± 9.2*	25.9 *± 10.9*	19.2 *± 6.7*	15.0 *± 5.1*
PLACEBO	12.1 *± 2.5*	31.3 *± 7.8*	28.1 *± 9.8*	21.1 *± 8.1*	18.0 *± 6.6*
UNTREATED	12.0 *± 2.9*	31.3 *± 8.5*	28.3 *± 9.0*	21.7 *± 6.5*	17.8 *± 4.9*

Table 2: Mean variations and standard deviations

TEWL	$T_{24h}-T_0$	$T_{48h}-T_0$	$T_{72h}-T_0$	$T_{96h}-T_0$
EMULSION at 5% MYRTILLUS OIL	16.8 *± 8.4*	14.1 *± 9.5*	8.3 *± 6.5*	4.5 *± 4.6*
EMULSION at 2% MIRTYLLUS OIL	15.4 *± 9.3*	14.0 *± 10.7*	7.3 *± 6.8*	3.1 *± 5.7*
PLACEBO	19.2 *± 7.8*	16.0 *± 10.4*	9.0 *± 8.4*	5.9 *± 6.9*
UNTREATED	19.3 *± 8.1*	16.3 *± 8.7*	9.7 *± 6.3*	5.8 *± 4.5*

Table 3: Statistical comparison between baseline and the following times (Variance analysis and Bonferroni test)

TEWL	T_0 vs T_{24h}	T_0 vs T_{48h}	T_0 vs T_{72h}	T_0 vs T_{96h}
EMULSION at 5% MYRTILLUS OIL	p < 0.0001	p < 0.0001	p = 0.001	p > 0.05
EMULSION at 2% MIRTYLLUS OIL	p < 0.0001	p < 0.0001	p < 0.01	p > 0.05
PLACEBO	p < 0.0001	p < 0.0001	p < 0.001	p < 0.05
UNTREATED	p < 0.0001	p < 0.0001	p = 0.0001	p = 0.05

The statistically significant increase of the TEWL values observed in all the four sites 24 hours after the SLS application, underlines that a damage in the skin barrier has occurred. The damage is still evident 48 hours after SLS-application, even if the decrease of the values at the subsequent checks shows a gradual recovery of the skin properties.

EMULSIONE at 2% MYRTILLUS OIL and **EMULSION at 5% MYRTILLUS OIL**: the barrier damage is statistically significant at the checks T_{24h}, T_{48h}, T_{72h} while, after 96 hours from the SLS application, the increase of TEWL values is not statistically significant. This indicates that after 96 hours the skin barrier function has been recovered.

PLACEBO and **CONTROL AREA**: the barrier damage is statistically significant until 96 hours after the SLS application. This indicates that, at the end of the study, the skin barrier function has not been recovered yet.

Table 4: Statistical comparison among the variations recorded in the treated and in the control/placebo areas (Variance Analysis and Bonferroni test)

TEWL	EMULSION at 5% MYRTILLUS OIL vs EMULSION at 2% MYRTILLUS OIL vs PLACEBO vs UNTREATED
T_{24h}-T_0	p > 0.05
T_{48h}-T_0	p > 0.05
T_{72h}-T_0	p > 0.05
T_{96h}-T_0	p > 0.05

The statistical comparison among the variations recorded in the four areas does not show any statistically significant difference at any control time.

Therefore, there is not a significant difference between the areas treated with the products and the control/placebo areas as regards the recovery of the skin barrier function.

SKIN REDNESS (a* parameter)

Table 5: Means and standard deviations

a* parameter	T_0	T_{24h}	T_{48h}	T_{72h}	T_{96h}
EMULSION at 5% MYRTILLUS OIL	7.00 ± 1.09	10.78 ± 2.00	10.93 ± 2.02	10.21 ± 2.16	9.40 ± 1.60
EMULSION at 2% MIRTYLLUS OIL	7.25 ± 1.09	11.16 ± 2.05	10.89 ± 1.92	9.87 ± 1.25	9.01 ± 1.09
PLACEBO	7.47 ± 1.16	11.78 ± 2.00	11.78 ± 2.32	10.52 ± 1.97	10.36 ± 1.87
UNTREATED	7.29 ± 0.89	11.42 ± 3.03	11.17 ± 2.29	10.43 ± 2.38	9.72 ± 1.63

Table 6: Mean variations and standard deviations

a* parameter	$T_{24h}-T_0$	$T_{48h}-T_0$	$T_{72h}-T_0$	$T_{96h}-T_0$
EMULSION at 5% MYRTILLUS OIL	3.78 ± 2.39	3.93 ± 2.19	3.21 ± 2.30	2.40 ± 1.96
EMULSION at 2% MIRTYLLUS OIL	3.91 ± 1.84	3.64 ± 2.21	2.62 ± 1.67	1.76 ± 1.45
PLACEBO	4.31 ± 2.01	4.31 ± 2.36	3.05 ± 2.21	2.89 ± 1.78
UNTREATED	4.13 ± 2.92	3.88 ± 2.22	3.14 ± 2.39	2.43 ± 1.79

Table 7: Statistical comparison between baseline and the following times (Variance analysis and Bonferroni test)

a* parameter	T_0 vs T_{24h}	T_0 vs T_{48h}	T_0 vs T_{72h}	T_0 vs T_{96h}
EMULSION at 5% MYRTILLUS OIL	$p < 0.0001$	$p < 0.0001$	$p < 0.0001$	$p < 0.0001$
EMULSION at 2% MIRTYLLUS OIL	$p < 0.0001$	$p < 0.0001$	$p < 0.0001$	$p < 0.01$
PLACEBO	$p < 0.0001$	$p < 0.0001$	$p < 0.0001$	$p < 0.0001$
UNTREATED	$p < 0.0001$	$p < 0.0001$	$p < 0.0001$	$p < 0.001$

In all the areas the increase in the skin redness values is statistically significant for all the duration of the test.

This indicates that at the end of the study the basal situation has not been recovered yet.

Table 8: Statistical comparison among the variations recorded in the treated and in the control/placebo areas (Variance Analysis and Bonferroni test)

a* parameter	EMULSION at 5% MYRTILLUS OIL vs EMULSION at 2% MYRTILLUS OIL vs PLACEBO vs UNTREATED
$T_{24h}-T_0$	p > 0.05
$T_{48h}-T_0$	p > 0.05
$T_{72h}-T_0$	p > 0.05
$T_{96h}-T_0$	p > 0.05

The statistical comparison among the variations recorded in the four areas does not show any statistically significant difference at any control time.

Therefore, there is not a significant difference between the areas treated with the products and the control/placebo areas as regards the recovery of the lenitive effect.