Evaluation of the IN VIVO COSMECEUTICAL EFFICACY of MF III of Switzerland Blue Cell Extract Serum Gel. Moisturiser

One-and Two-Month Skin Cosmeceutical Efficacy Test Results

Clinical Study Report Nr. CTE43A

Independent Clinical Study directed & headed by:

Prof. Dr. Alain Béguin

Clinical Skin Testing Department
Swiss Skin Testing Institute
Neuchâtel (SWITZERLAND)

October-December, 2005

Demography

- Venue of study: Neuchâtel Switzerland period: Summer
- Eight-weeks study
- 29 healthy women, Caucasian skin type
- Skin phototype II *(Fitzpatrick)*
- Ages 30-64
- Mean age 52.1 ± 8.6 y
- Study is monocentric *(no placebo)*
- Volenteers nor research conducting staff personnel are aware of the product nor its name throughout the study.

Age Group 30-34	Age Group 35-39	Age Group 40-44	Age Group 45-49	Age Group 50-54	Age Group 55-60	Age Group 61-64
Sch 30 (27*)		Alz 41 (1*)	Egg 47 (8*)	Aud 53 (2*)	Bau 60 (3*)	Bau 60 (3*)
		Hug 42 (13*)	Fra 45 (9*)	Bro 53 (6*)	Cec 60 (7*)	Bec 64 (4*)
		Jun 42 (14*)	Lamb 48 (18*)	Ghy 50 (11*)	Lama 56 (17*)	Bol 63 (5*)
		Kut 43 (16*)	Lup 48 (19*)	Kob 52 (15*)	Riz 56 (26*)	Gal 62 (10*)
		Ton 45 (28*)	Pul 48 (24*)	Mer 53 (21*)		Gir 62 (12*)
			Rie 49 (25*)			Mei 64 (20*)
						Noi 62 (22*)
						Wed 62 (29*)

* *Code numbers of each different women.*

Measurement
And treatment schedules

Study phase	Screening	Test		
		Day 1	Day 29	Day 57
Volunteer's recruitment, information and informed consent	●			
Inclusion and exclusion criteria, concomitant medication	●			
Instructions, product handing over, visual evaluation and bioengineering measurements, first test product application		●		
Visual evaluation and bioengineering measure-ments, compliance check			●	●
Hand-over of questionnaire			●	
Visual evaluation and bioengineering measure-ments, compliance check, check of remaining, unused softgels, back hand-over of questionnaire				●
Administrative work		●		●
Study termination				●

Protocol:

- **Room temperature = (22.5 ± 1.5) °C**
- **Relative air humidity = (50 ± 10) %**

	Measuring conditions (mean values ± SD)					
	Day 1		Day 29		Day 57	
	Temp (°C)	RH (%)	Temp (°C)	RH (%)	Temp (°C)	RH (%)
Measured values (Means ± SD)	**22.4 ± 0.8**	**52.6 ±2.9**	**21.3 ± 0.6**	**52.8 ± 4.3**	**21.8 ± 1.0**	**46.3 ± 4.5**

Legend: **Temp**: temperature; **RH**: relative humidity; **SD**: Std. deviation

The measuring room conditions were ensured at each visit, thus conforming to the protocol.

Test Parameters

Test Parameters No.

1. **Moisture**
2. **Transepidermal water loss**
3. **Firmness**
4. **Epidermis+dermis density**
5. **Sebum**
6. **Skin microrelief** *(roughness)*
7. **Wrinkle depth** *(microtopography)*

Clinical Skin measurement devices :

– Corneometer® CM 825
(Courage & Khazaka, skin moisturisation)

– Sebumeter® SM 810
(Courage & Khazaka, sebum)

– Reviscometer® RVM 600
(Courage & Khazaka, elasticity/firmness)

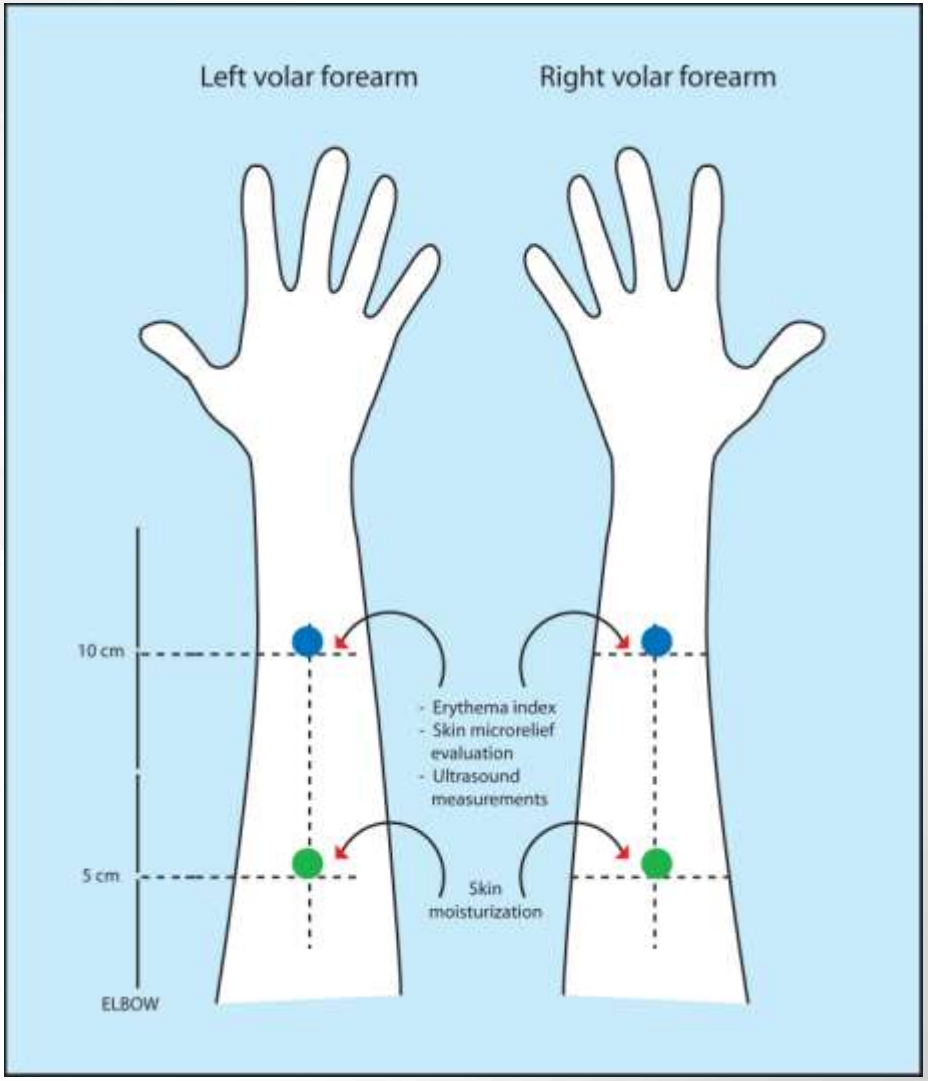
– Dermalab® TEWL
(Cortex Technology, TEWL)

– DermaScan® C
(Cortex Technology, dermis density)

– Visioscan® VC 98
(Courage & Khazaka, skin microrelief evaluation)

– Talysurf® CLI 1000
(Taylor Hobson, wrinkle microtopography)

Measurement areas and sequences



Measurement areas and sequences *(continued)*

Moisture
– left forearm *(5x)*
– right forearm *(5x)*

↓

Sebum
– left nose side *(1x)*
– right nose side *(1x)*

↓

Skin microrelief *(roughness)*
– left forearm *(3x)*
– right forearm *(3x)*

↓

Firmness *(forearms)*
– left forearm *(3x)*
– right forearm *(3x)*

↓

Measurement areas and sequences *(continued)*

TEWL – **left forearm** ***(1x)***
– **right forearm** ***(1x)***

Firmness – **left temple** ***(crow's foot, 3x)***
(face) – **right temple** ***(crow's foot, 3x)***

Epidermis+dermis – **left cheek** ***(1x)***
density *(face)* – **right cheek** ***(1x)***

for 8 randomly selected volunteers only

Wrinkle depth – **left crow's feet** ***(1x)***
(microtopography, face)

Selected measurement devices

Combi-3
(Courage & Khazaka)

- **Moisture**
- **Sebum**

DermaScan C
(Cortex Technology)

- **Dermis density**

Selected measurement devices (continued)

Visioscan
(Courage & Khazaka)

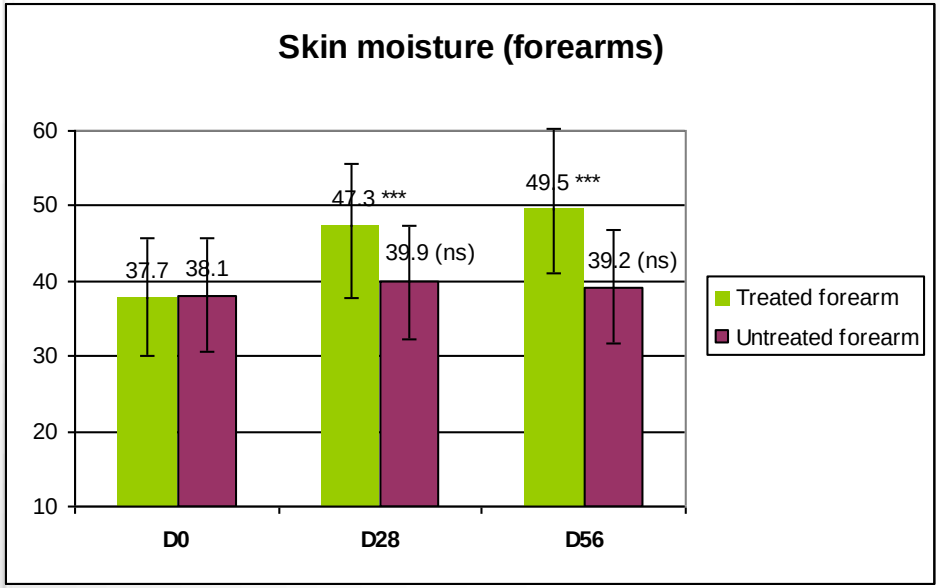
- **Skin microrelief**

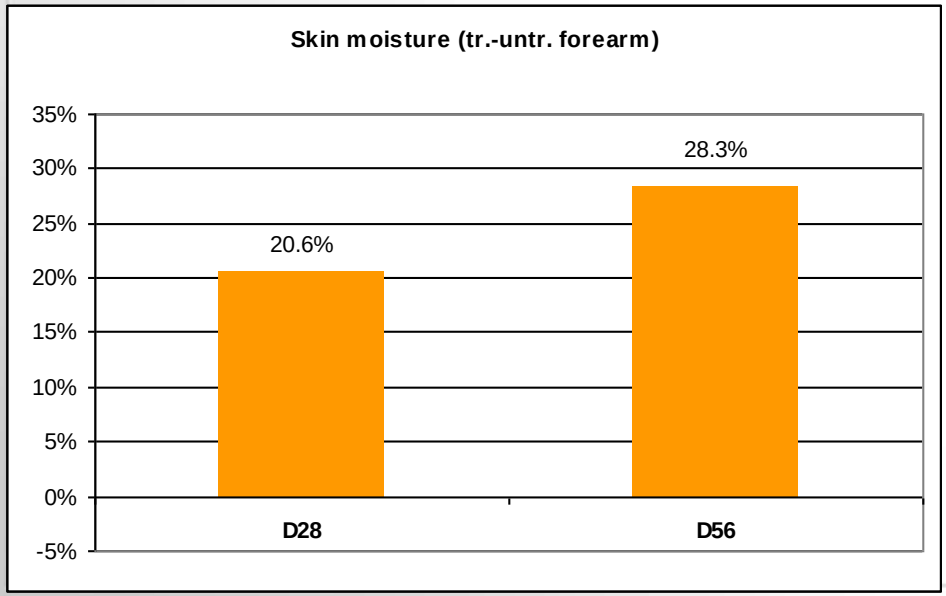
Dermalab TEWL
(Cortex Technology)

- **Transepidermal water loss**

Moisture, forearms - *CONCLUSION ON RESULTS*

	Skin hydration: Mean values (± SD; Corneometer units)			Permutation statistics	Permutation statistics
	Day 0	Day 28	Day 56	Day 28 vs. Day 0	Day 56 vs. Day 0
Treated forearm	37.7 ± 7.9	47.3 ± 8.4	49.5 ± 10.8	p < 0.0001 *** extr. significant	p < 0.0001 *** extr. significant
Untreated forearm	38.1 ± 7.6	39.9 ± 9.5	39.2 ± 8.6	p = 0.09 (ns) unsignificant	p = 0.27 (ns) unsignificant
Mean difference (treated vs. untreated, Corneometer units)	-0.4	7.4	10.3		
Ratio to D0 (treated) (%)		20.6%	28.3%		





Test Parameters No: 1 *(continued)* (on moisture, forearms)

RESULTS

Skin moisture before (D0) and during twice daily treatment with the test product *(Corneometer units; Means ± SD)*

%-Changes in skin moisture treated – untreated *(out of means)*

Test Parameters No: 1
(on moisture, forearms)

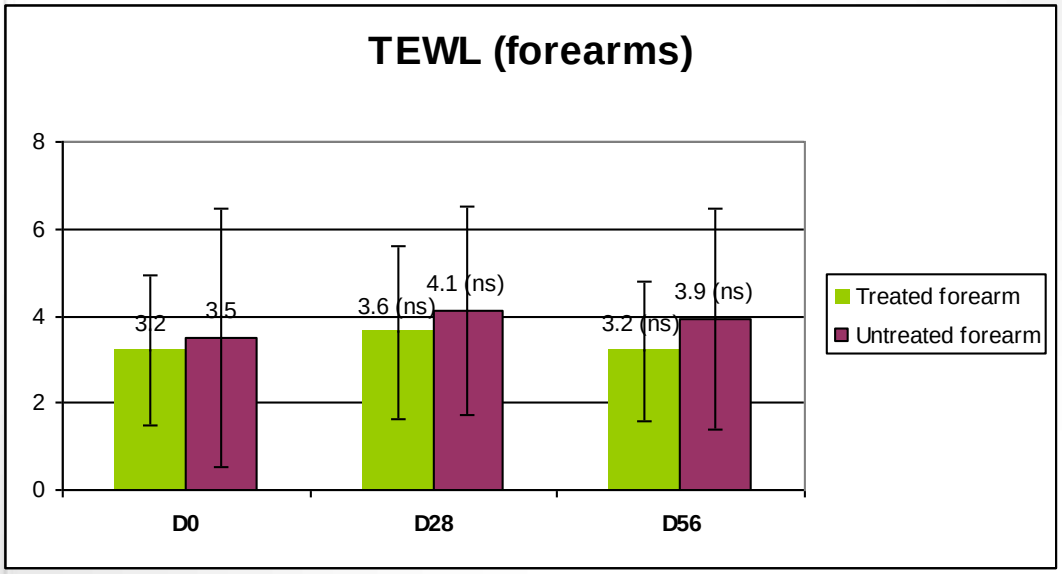
CONCLUSION ON RESULTS

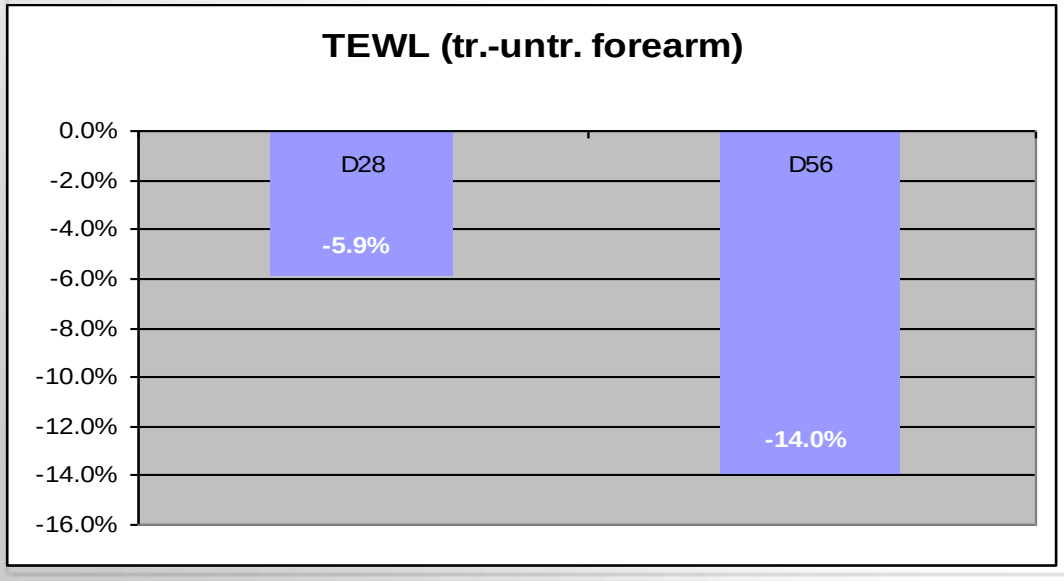
- **The test product <u>significantly increases</u> skin moisture by <u>21%</u> *(at 28 days).***
- **The test product <u>significantly increases</u> skin moisture by <u>28%</u> *(at 56 days).***
- **Results are statistically <u>extremely significant</u> on the treated forearm and unsignificant on the untreated forearm.**
- **The test product has therefore a <u>very good moisturising effect.</u>**

Test Parameters No: 2 *(Continued)*
(on Transepidermal Water l\Loss TEWL, forearms)

RESULTS

	Evolution of TEWL: Mean values (± SD; g/m^2 x h)			Permutation statistics	Permutation statistics
	Day 0	Day 28	Day 56	Day 28 vs. Day 0	Day 56 vs. Day 0
Treated forearm	3.2 ± 1.7	3.6 ± 2.0	3.2 ± 1.6	p = 0.14 (ns) unsignificant	p = 0.50 (ns) unsignificant
Untreated forearm	3.5 ± 3.0	4.1 ± 2.4	3.9 ± 2.5	p = 0.17 (ns) unsignificant	p = 0.25 (ns) unsignificant
Mean difference (tr. vs. untr., Cutometer units)	-0.3	-0.5	-0.8		
Ratio to D0 (treated, %)		-5.9%	-14.0%		





Test Parameters No: 2 *(Continued)* (on Transepidermal Water Loss TEWL, forearms)

RESULTS

Transepidermal water loss before (D0) and during twice daily treatment with the test product *(g/m² x h; Means ± SD)*

%-Changes in transepidermal water loss treated – untreated *(out of means)*

Test Parameters No: 2
(on Transepidermal Water Loss TEWL, forearms)
CONCLUSION ON RESULTS

- **The TEWL results show that the test product has no negative side effects on the skin *(no skin damage).***

- **However, this product strengthens the skin barrier properties and makes the skin more resistent towards TEWL. This point has to be considered as indicative only, as the overall TEWL changes are statistically unsignificant.**

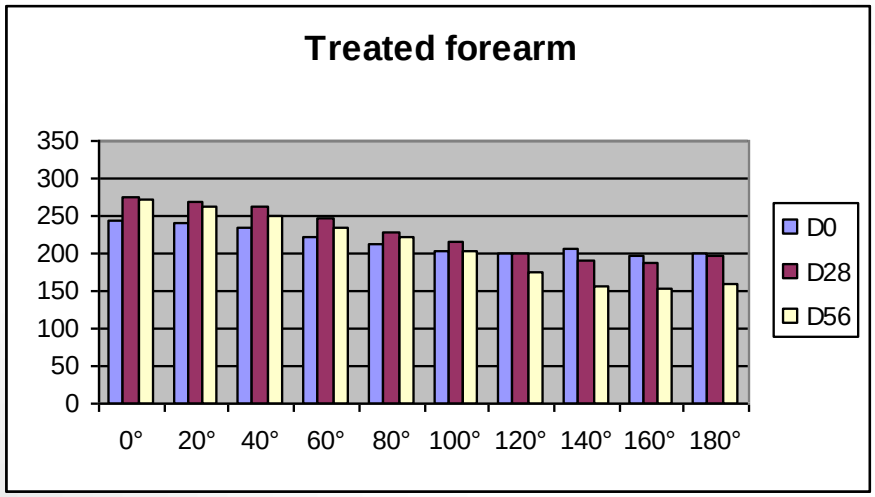
Test Parameters No: 3 (on firmness, forearms)

RESULTS

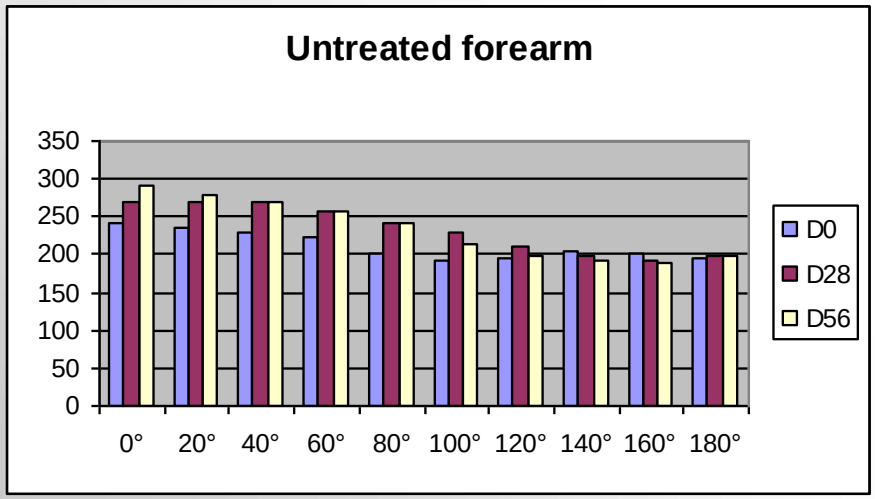
	Evolution of firmness (Treated forearm; Mean values; Reviscometer units)										Permutation statistics	Permutation statistics
	0°	20°	40°	60°	80°	100°	120°	140°	160°	180°	Day 28 vs. Day 0	Day 56 vs. Day 0
Day 0	242.4	241.6	235.1	222.2	212.5	202.8	199.6	207.1	198.3	198.8	Values at 180°	Values at 180°
Day 28	276.4	268.9	262.2	247.7	228.8	215.1	200.2	190.0	188.0	195.4	p = 0.432 (ns)	p = 0.038 *
Day 56	272.3	263.3	249.5	234.5	222.7	203.0	173.8	157.7	152.1	158.8	unsignificant	significant
(Day 0 - Day 28) /Day 0	-14.0%	-11.3%	-11.5%	-11.5%	-7.7%	-6.1%	-0.3%	8.2%	5.1%	1.7%		
(Day 0 - Day 56) /Day 0	-12.4%	-9.0%	-6.1%	-5.5%	-4.8%	-0.1%	12.9%	23.8%	23.3%	20.1%		

	Evolution of firmness (Untreated forearm; Mean values; Reviscometer units)										Permutation statistics	Permutation statistics
	0°	20°	40°	60°	80°	100°	120°	140°	160°	180°	Day 28 vs. Day 0	Day 56 vs. Day 0
Day 0	242.9	236.1	229.6	221.6	201.4	191.4	196.4	203.2	201.5	194.1	Values at 180°	Values at 180°
Day 28	270.8	270.5	268.3	255.7	241.2	230.6	209.5	198.3	191.9	199.0	p = 0.420 ns	p = 0.438 ns
Day 56	291.6	278.9	270.2	256.2	242.5	212.3	197.9	190.6	187.9	197.7	unsignificant	unsignificant
(Day 0 – Day 28) /Day 0	-11.4%	-14.6%	-16.8%	-15.4%	-19.7%	-20.5%	-6.7%	2.4%	4.8%	-2.5%		
(Day 0 - Day 56) /Day 0	-20.0%	-18.1%	-17.7%	-15.6%	-20.4%	-10.9%	-0.8%	6.2%	6.8%	-1.8%		

Test Parameters No: 3
(Continued)
(on firmness, forearms)
RESULTS



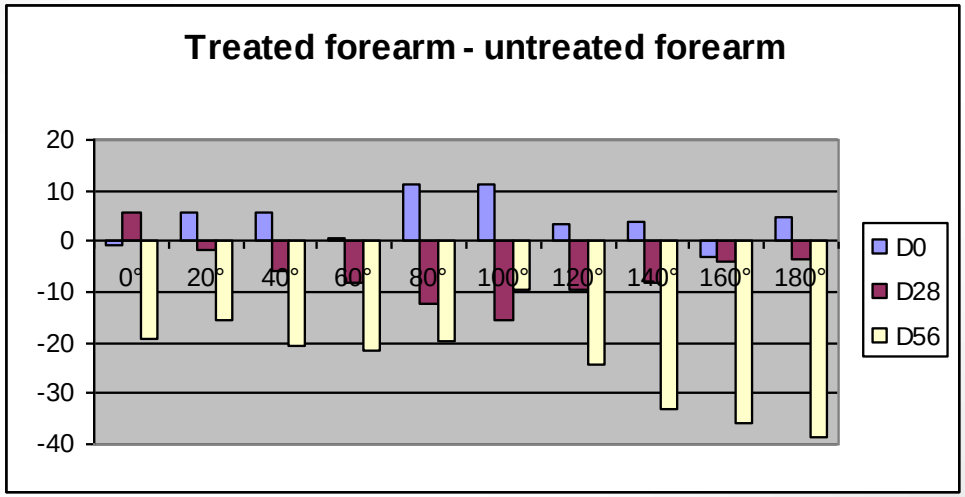
RRTM changes (D0) and during twice daily treatment with the test product *(RRTM units; Treated forearm; Means)*



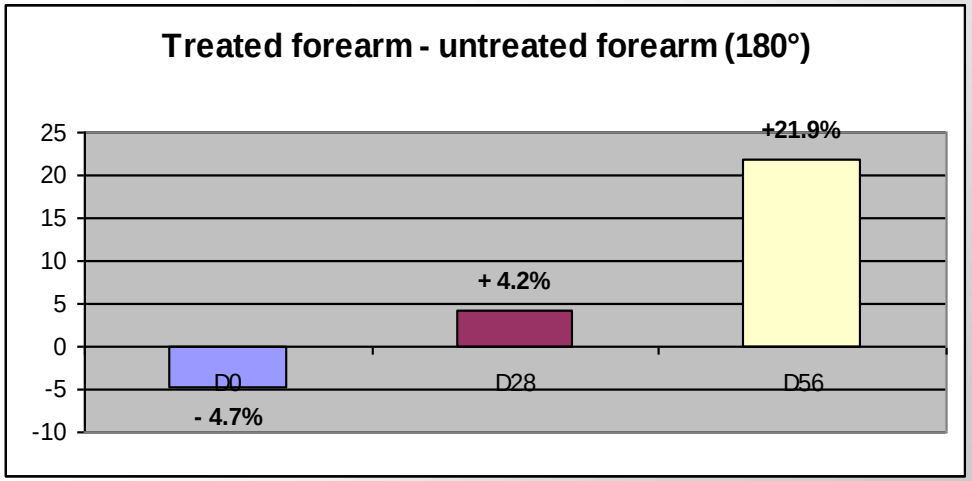
RRTM changes (D0) and during twice daily treatment with the test product *(RRTM units; Untreated forearm; Means)*

Test Parameters No: 3
(Continued)
(on firmness, forearms)
RESULTS

Overall %-changes in RRTM
(forearms, based on mean values)



%-Changes in RRTM at 180°
(forearms, based on mean values)
= percentages of firmness increase



Test Parameters No: 3
(on firmness, forearms)

CONCLUSION ON RESULTS

- **The RRTM results on the forearms obviously show that the treatment has a very good firming effect, which was measured on the treated forearm.**
- **Maximum percentage of improvement at 180°: + 22% after 8 weeks.**
- **Results are statistically significant on the treated forearm at 8 weeks and unsignificant on the untreated forearm.**

Test Parameters No: 3 (on firmness, neck)

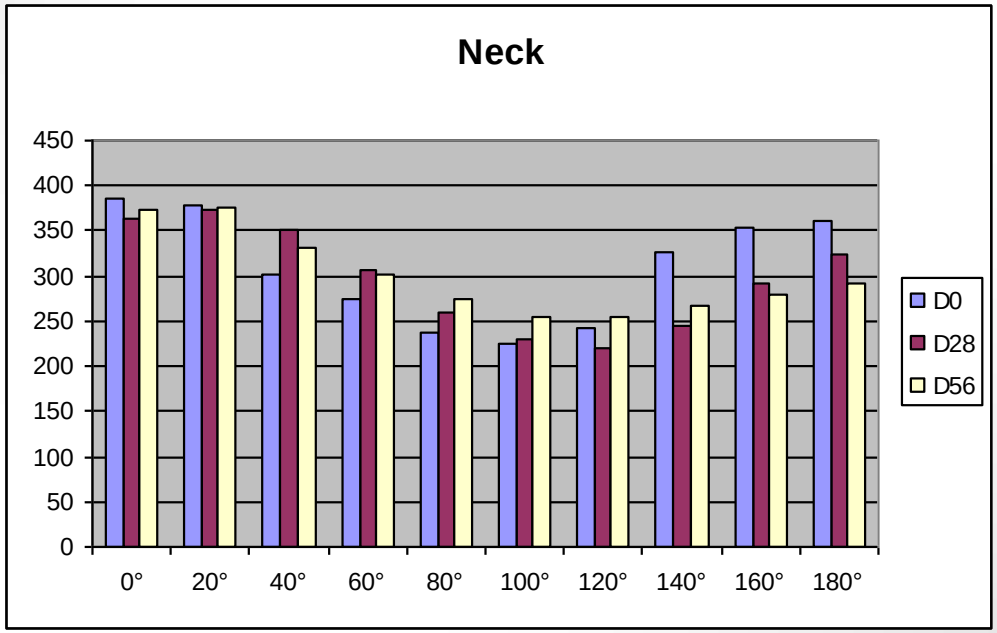
RESULTS

	Evolution of firmness (Neck; Mean values; Reviscometer units)										Permutation statistics	Permutation statistics
	0°	20°	40°	60°	80°	100°	120°	140°	160°	180°	Day 28 vs. Day 0	Day 56 vs. Day 0
Day 0	386.9	378.9	302.0	273.4	238.5	225.1	241.4	326.8	353.3	362.0	Values at 180°	Values at 180°
Day 28	364.1	373.4	350.2	306.2	258.6	229.9	221.1	244.3	290.5	323.4	p = 0.048 *	p = 0.005 *
Day 56	372.7	375.0	331.2	301.7	274.4	254.2	254.6	267.2	279.4	291.1	significant	very significant
(Day 0 –Day 28) /Day 0	5.9%	1.4%	-15.9%	-12.0%	-8.5%	-2.1%	8.4%	25.3%	17.8%	10.7%		
(Day 0-Day 56) /Day 0	3.7%	1.0%	-9.7%	-10.3%	-15.1%	-12.9%	-5.5%	18.2%	20.9%	19.6%		

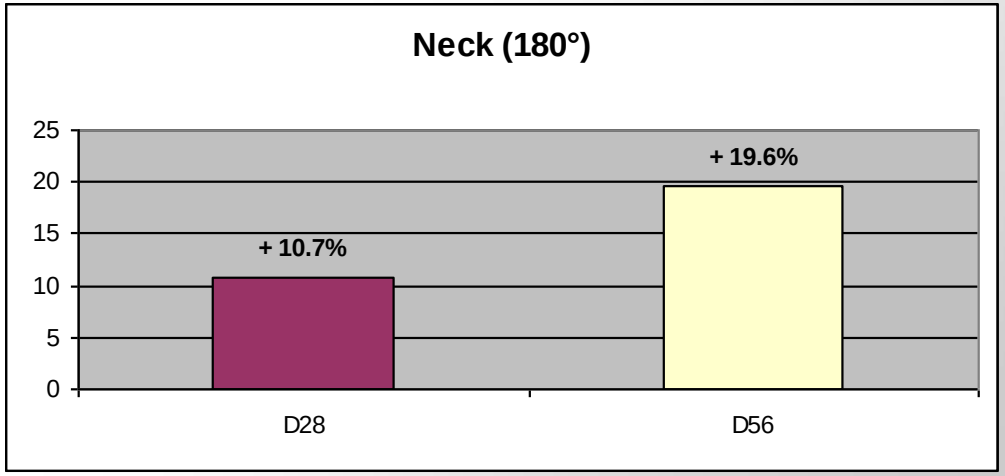
Test Parameters No: 3
(Continued)
(on firmness, neck)

RESULTS

Overall %-changes in RRTM
(neck, based on mean values)



%-Changes in RRTM at 180°
(neck, based on mean values)
= percentages of firmness increase



Test Parameters No: 3 (on firmness, neck)

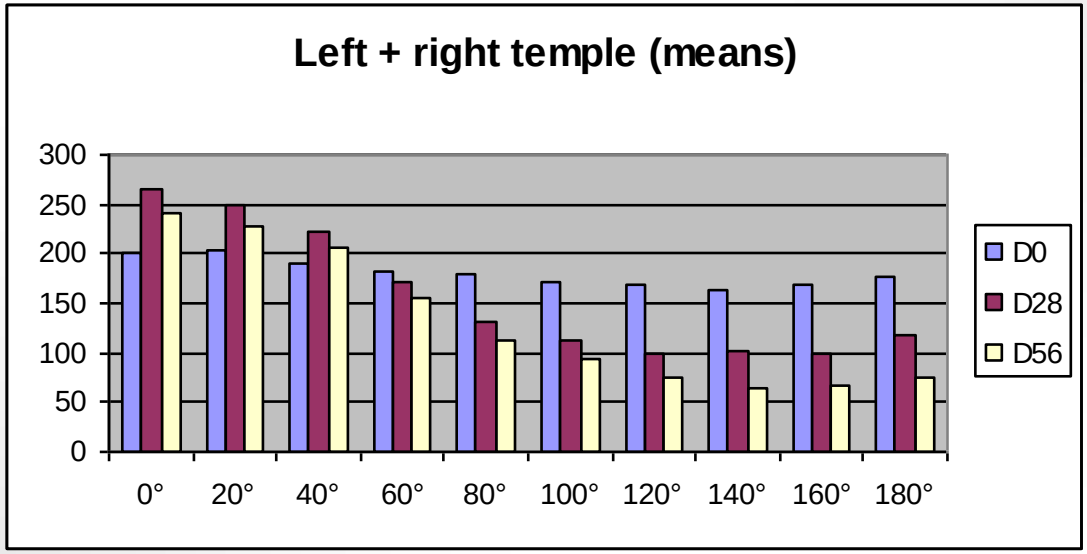
CONCLUSION ON RESULTS

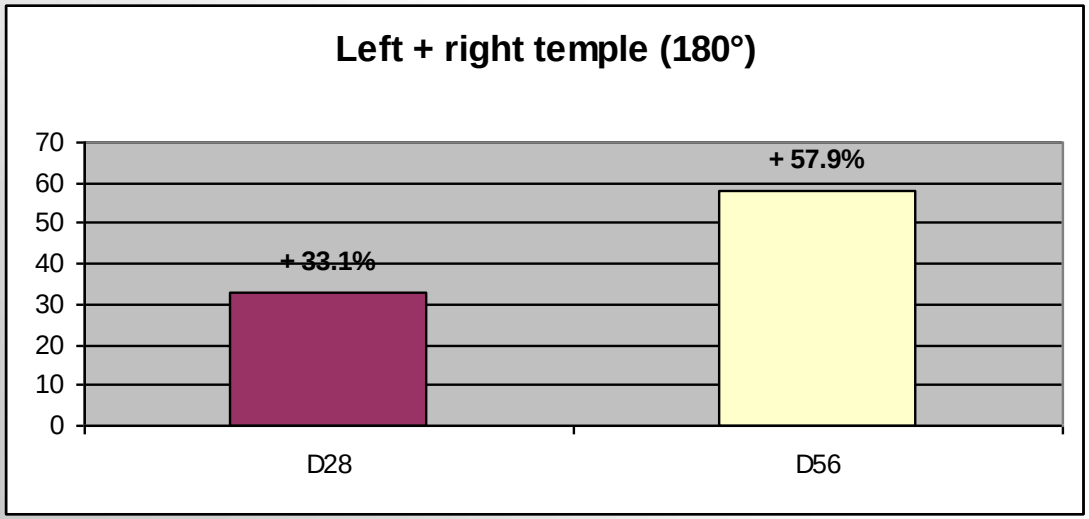
- **Here also, the RRTM results on the neck show a steady increase of firmness during the treatment, thus showing a good firming effect on the neck.**
- **Maximum percentage of improvement at 180°: + 20% after 8 weeks.**
- **Results are statistically significant 4 weeks and very significant at 8 weeks.**

Test Parameters No: 3 (on firmness, temples)

RESULTS

	Evolution of firmness (Left+right temple; Means; Reviscometer units)										Permutation statistics	Permutation statistics
	0°	20°	40°	60°	80°	100°	120°	140°	160°	180°	Day 28 vs. Day 0	Day 56 vs. Day 0
Day 0	200.8	203.2	190.0	181.4	179.4	171.7	167.5	162.4	168.4	176.9	Values at 180°	Values at 180°
Day 28	264.3	250.0	222.8	172.6	130.6	112.6	100.4	102.9	99.3	118.4	p = 0.001 **	p < 0.0001 ***
Day 56	241.4	227.1	206.0	156.6	113.3	94.3	76.1	63.5	66.2	74.4	very significant	extr. significant
(Day 0-Day 28) /Day 0	-31.6%	-23.0%	-17.3%	4.8%	27.2%	34.4%	40.1%	36.7%	41.0%	33.1%		
(Day 0-Day 56) /Day 0	-20.2%	-11.7%	-8.4%	13.6%	36.9%	45.1%	54.5%	60.9%	60.7%	57.9%		





Test Parameters No: 3
(Continued)
(on firmness, temples)

RESULTS

Overall %-changes in RRTM
(temples, based on mean values)

%-Changes in RRTM at 180°
(temples, based on mean values)
= percentages of firmness increase

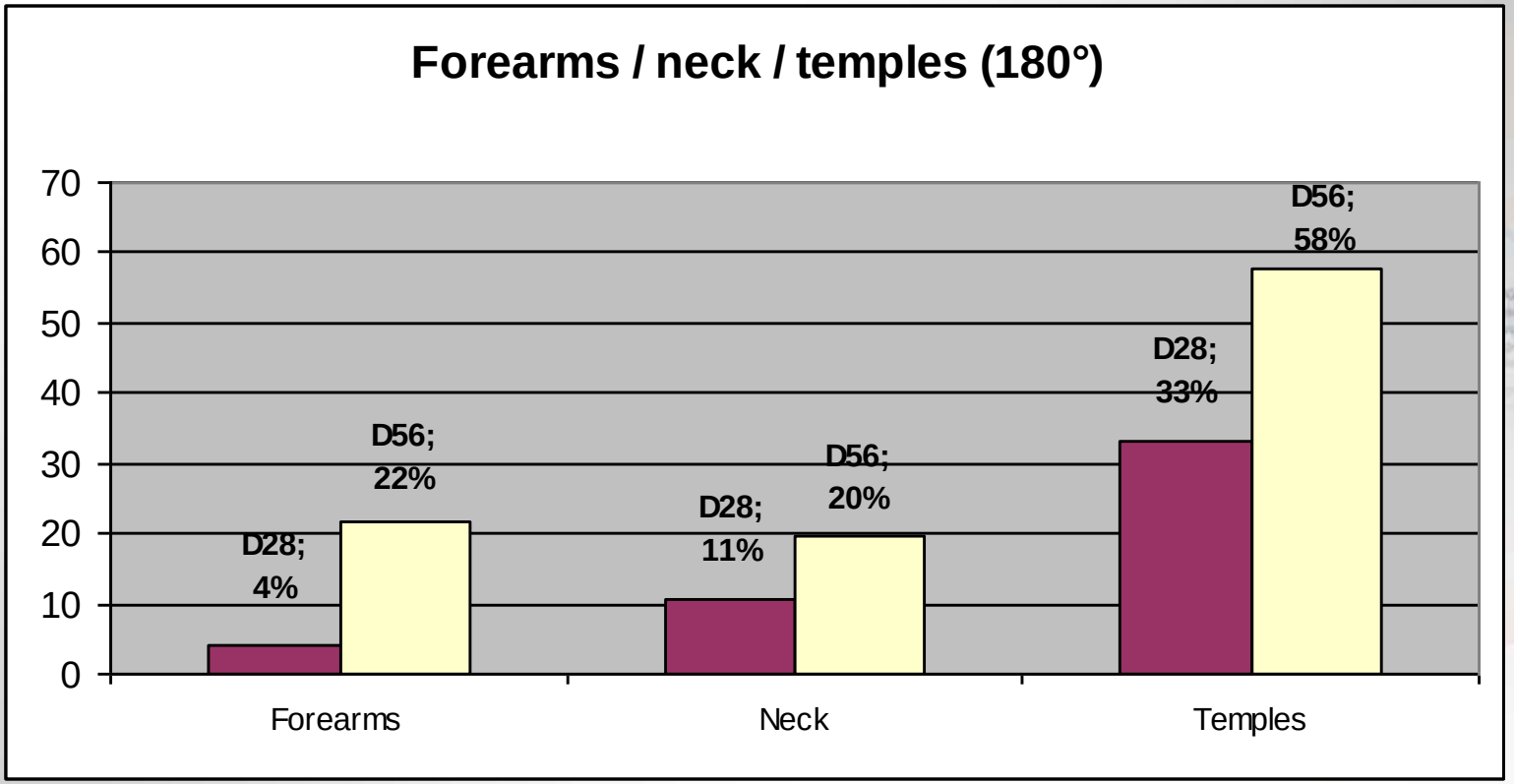
Test Parameters No: 3 (on firmness, temples)

CONCLUSION ON RESULTS

- **RRTM results on the temples show the most important increase of firmness of the 3 measured areas, thus showing a very good firming effect on the temples.**
- **Maximum percentage of improvement at 180°: + 58% after 8 weeks.**
- **Results are statistically very significant at 4 weeks and extremely significant at 8 weeks.**

Test Parameters No: 3
(on firmness, foreams, neck & temples: summarized data)

FINAL CONCLUSION ON RESULTS

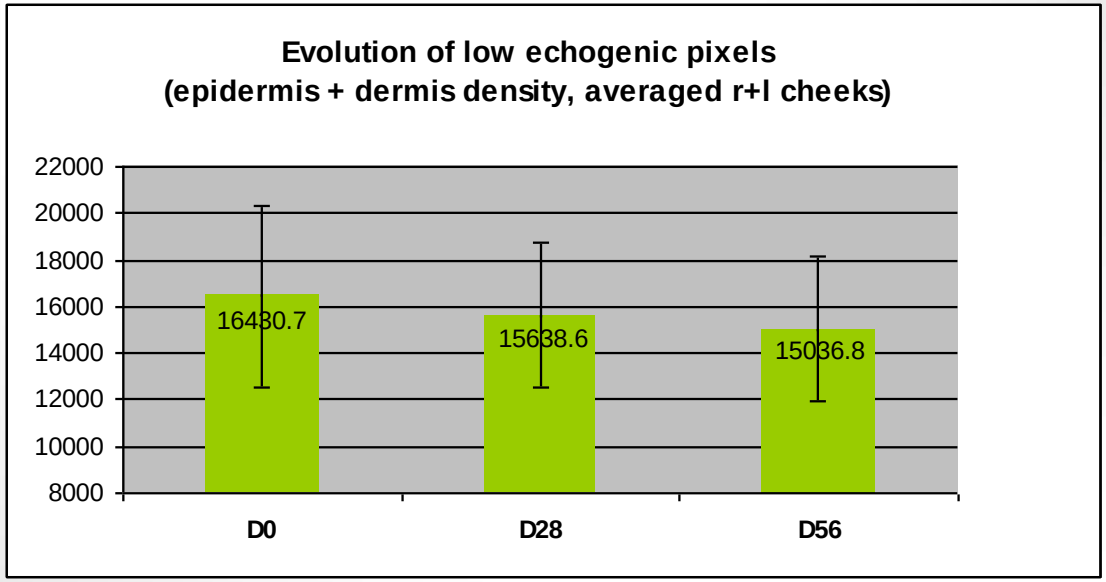


Comparative %-changes in RRTM at 180° on the forearms, neck and temples (based on mean values)
= comparative percentages of firmness increase at 4 and 8 weeks

- **Out of these results it appears that the test product delivers its strongest effect on the facial skin.**

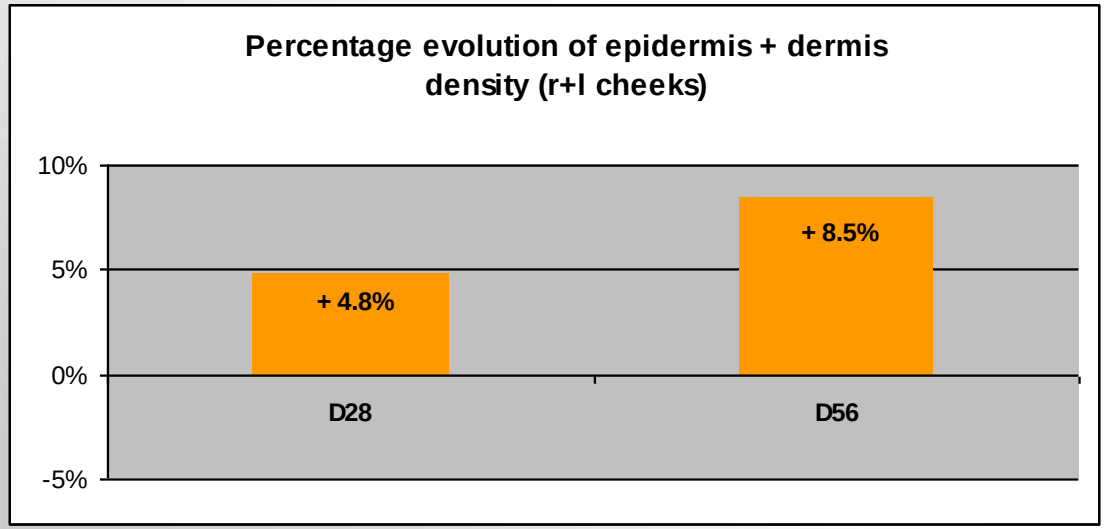
Test Parameters No: 4
(on epidermis+dermis density, cheeks)
RESULTS

	Epidermis+dermis density: Mean values (± SD; LEPs units)			Permutation statistics	Permutation statistics
	Day 0	Day 28	Day 56	Day 28 vs. Day 0	Day 56 vs. Day 0
Means (right + left cheek)	16430.7 ± 3884.4	15638.6 ± 3462.8	15036.8 ± 80.8	p = 0.07 (ns) unsignificant	p = 0.009 ** very significant
Difference versus Day 0 (DermaScan LEPs units)	-	-792.1	-1393.9		
Difference versus Day 0 (% LEPs units)	-	-4.8%	-8.5%		
Difference versus Day 0 (% density)	-	4.8%	8.5%		



Test Parameters No: 4 *(Continued)* (on epidermis+dermis density, cheeks) *RESULTS*

Low echogenic pixels (LEPs) before (D0) and during twice daily treatment with the test product (DermaScan pixel units; Means ± SD)



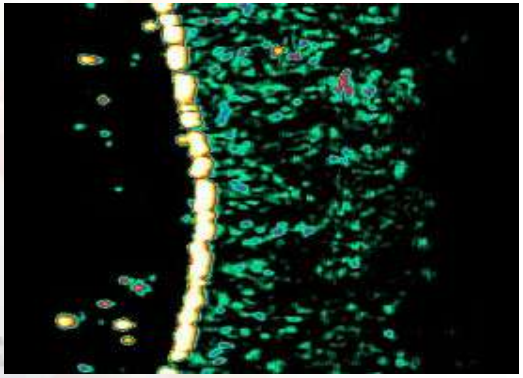
%-Changes in the LEPs of the skin ultrasound imaging during twice daily treatment with the test product (Means) = percentages of epidermis+dermis density increase

Test Parameters No: 4 *(Continued)*
(on epidermis+dermis density, cheeks)

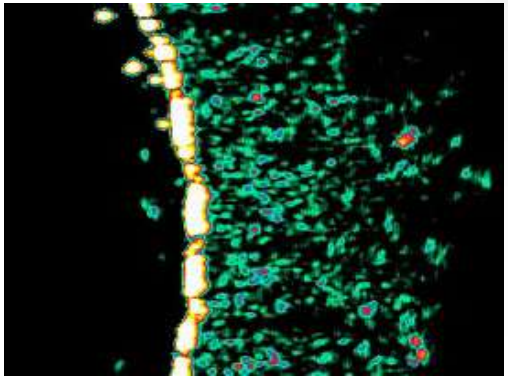
RESULTS

Vol. #8/205155/ Egg Ge

Day 0 / Right cheek

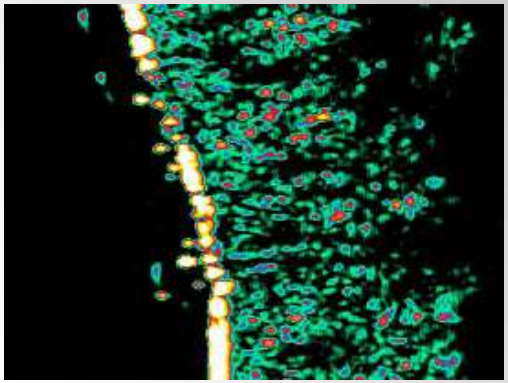


Day 28 / Right cheek



+ 9 %

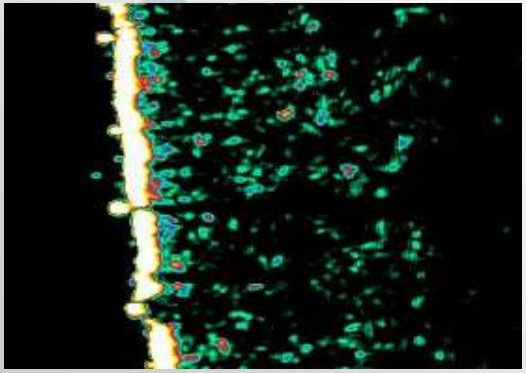
Day 56 / Right cheek



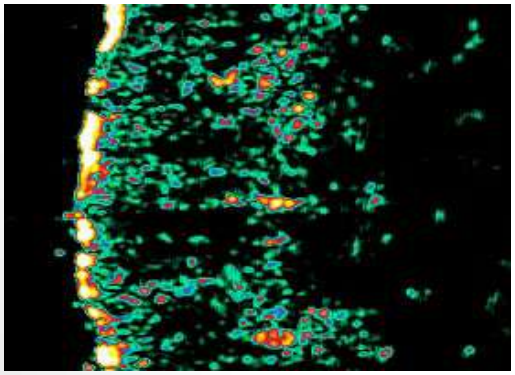
+ 24 %

Vol. #11/205397/ Ghy Ma

Day 0 / Right cheek

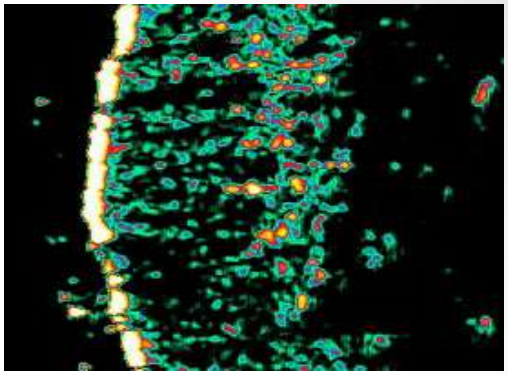


Day 28 / Right cheek



+ 20 %

Day 56 / Right cheek



+ 28 %

Test Parameters No: 4
(on epidermis+dermis density, cheeks)

CONCLUSION ON RESULTS

- **The treatment produces an increase of dermis density on the cheeks after 4 weeks (+4.8%) and after 8 weeks (+8.5%).**
- **Results are statistically unsignificant at 4 weeks and very significant at 8 weeks.**

Test Parameters No: 5
(on sebum, nose side, oily skin subgroup)

RESULTS

Oily skin subgroup:

15 volunteers with ref. sebum casual level >= 150 µg/cm^2

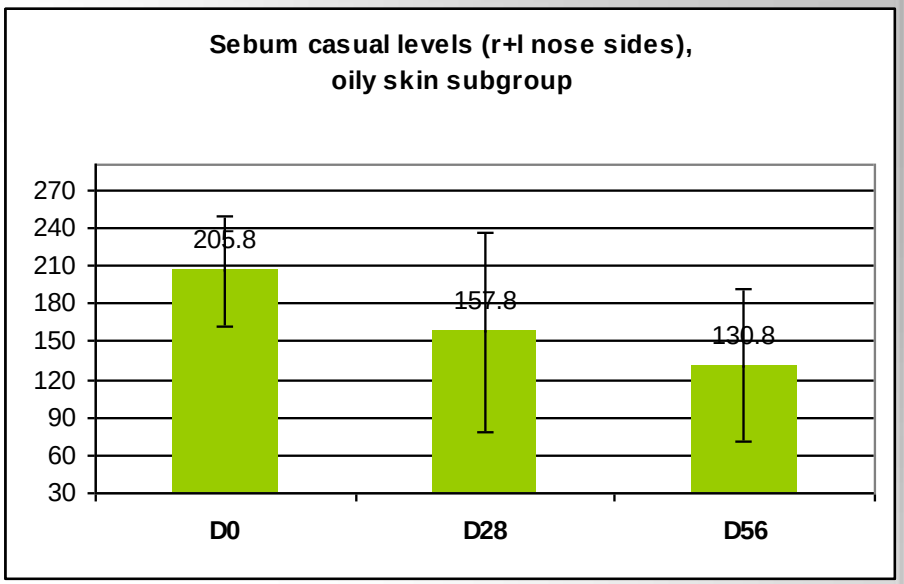
Oily skin subgroup (15 volunteers, ref. val. >= 150 µg/cm^2)	Evolution of sebum casual level: Mean values (± SD; µg/cm^2)			Permutation statistics	Permutation statistics
	Day 0	Day 28	Day 56	Day 28 vs. Day 0	Day 56 vs. Day 0
Left + right nose side	205.8 ± 44.1	157.8 ± 78.8	130.8 ± 60.8	p = 0.03 * significant	p = 0.001 ** very significant
Ratio to Day 0 (%)	-	-23.3%	-36.4%		

Test Parameters No: 5 *(Continued)* (on sebum, nose side, oily skin subgroup)

RESULTS

Oily skin subgroup

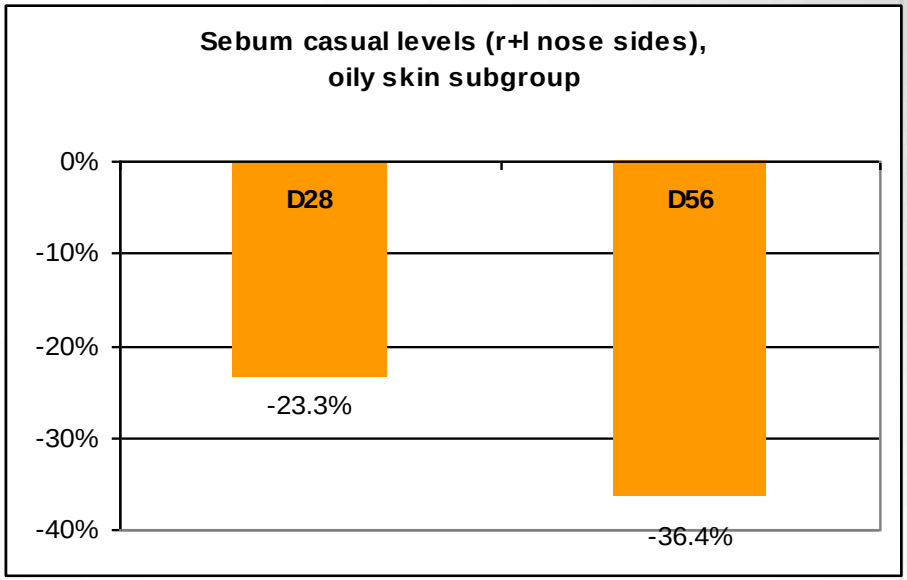
Sebum casual level before (D0) and during twice daily treatment with the test product (µg/cm^2; Means ± SD)



Oily skin subgroup

%-Changes in the sebum casual level during twice daily treatment with the test product (Means)

= percentages of sebum casual level decrease



Test Parameters No: 5
(on sebum, nose side, oily skin subgroup)

CONCLUSION ON RESULTS

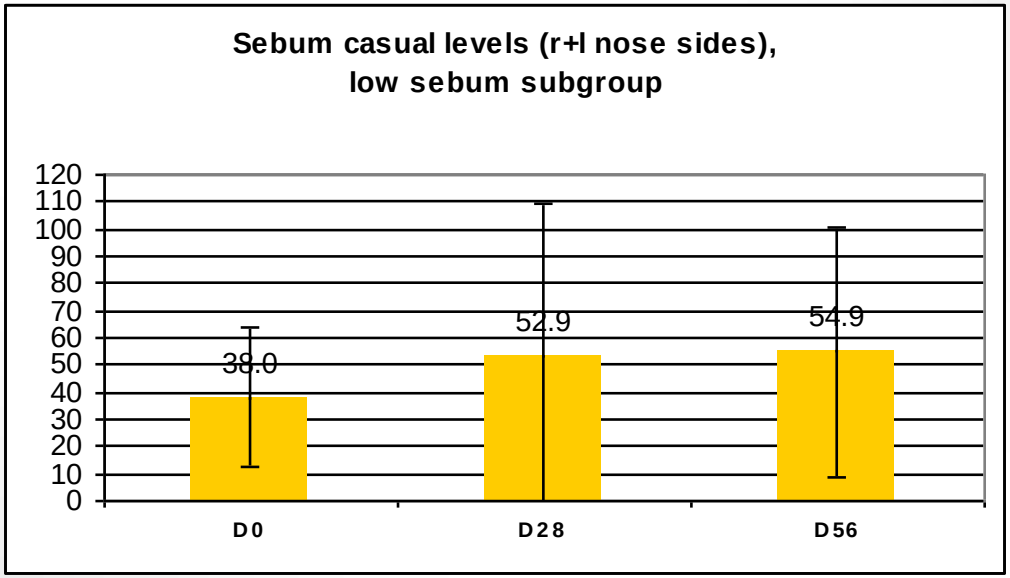
- **An important average decrease of sebum casual levels was measured on the nose side of the oily skin subgroup of participants.**
- **A seboregulation process is clear: after 8 weeks of treatment the sebum level is normalized. The test product normalizes oily skins within 8 weeks.**
- **Results are statistically significant at 4 weeks and very significant at 8 weeks.**

Test Parameters No: 5
(on sebum, nose side, low-sebum skin subgroup)

RESULTS

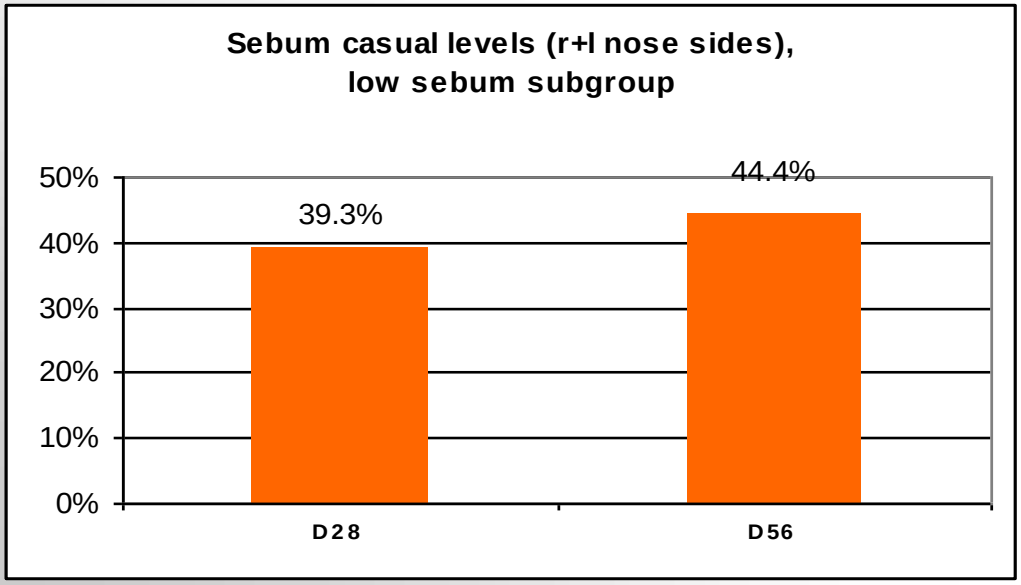
Low-sebum skin subgroup:
8 volunteers with ref. sebum casual level < 100 µg/cm^2

Low-sebum skin subgroup (8 vol., ref. val. < 100 µg/cm^2)	Evolution of sebum casual level: Mean values (± SD; µg/cm^2)			Permutation statistics	Permutation statistics
	Day 0	Day 28	Day 56	Day 28 vs. Day 0	Day 56 vs. Day 0
Left + right nose side	38.0 ± 25.7	52.9 ± 56.9	54.9 ± 45.7	p = 0.27 (ns) unsignificant	p = 0.08 * significant
Ratio to Day 0 (%)	-	39.3%	44.4%		



Test Parameters No:5
(Continued)
(on sebum, nose side, low-sebum skin subgroup)
RESULTS

Low-sebum subgroup
Sebum casual level before (D0) and during twice daily treatment with the test product (µg/cm^2; Means ± SD)



Low-sebum subgroup
%-Changes in the sebum casual level during twice daily treatment with the test product (Means)
= percentages of sebum casual level increase

Test Parameters No: 5
(on sebum, nose side, low-sebum skin subgroup)

CONCLUSION ON RESULTS

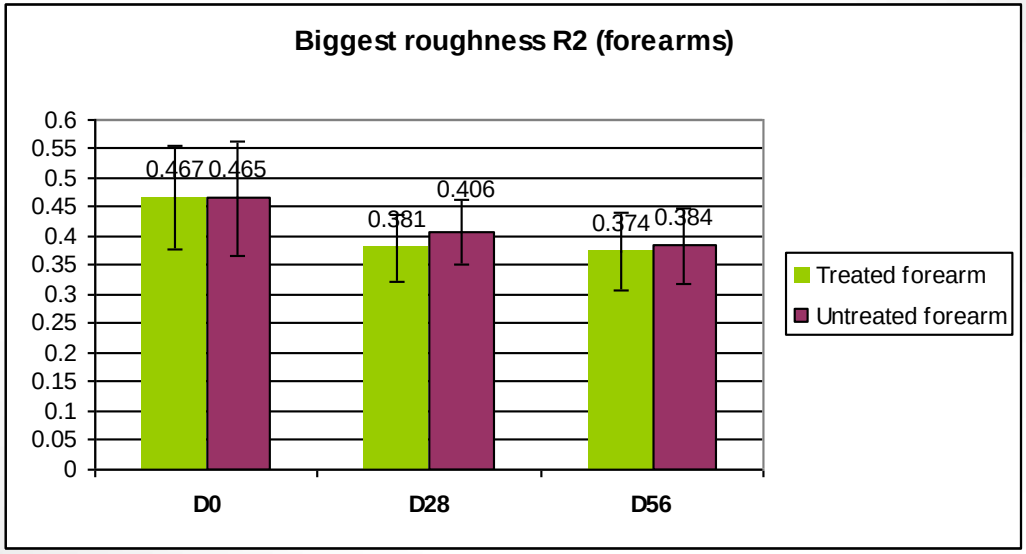
- **In the low-sebum skin subgroup, an interesting increase of sebum casual levels was measured, towards normalization values.**

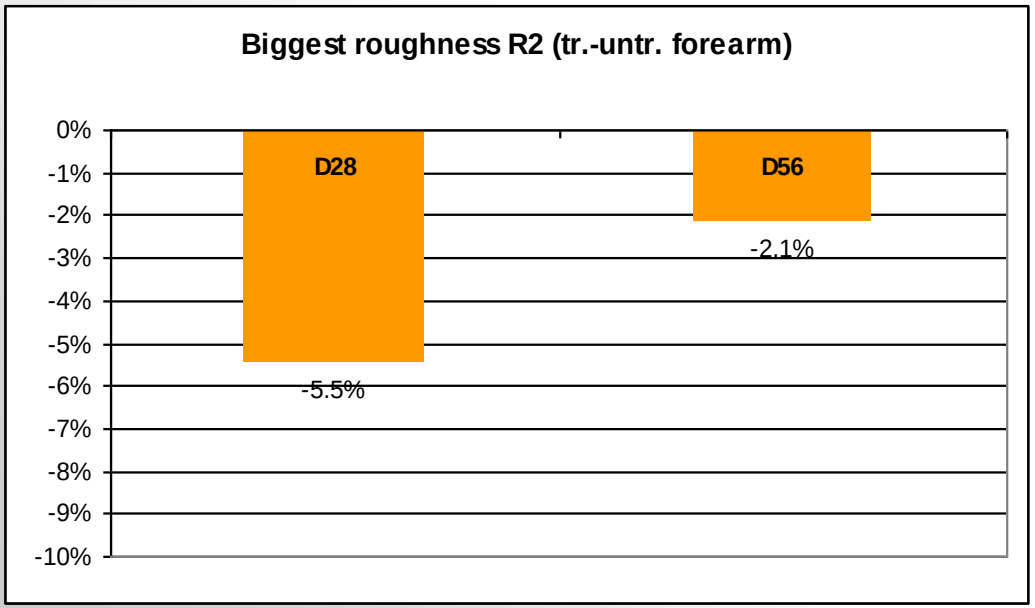
- **Results are statistically unsignificant at 4 weeks and significant at 8 weeks.**

Test Parameters No: 6
(on skin microrelief (roughness), forearms)

RESULTS

	Biggest roughness R2: Mean values (± SD; Visioscan units)			Permutation statistics	Permutation statistics
	Day 0	Day 28	Day 56	Day 28 vs. Day 0	Day 56 vs. Day 0
Treated forearm	0.468 ± 0.093	0.381 ± 0.053	0.377 ± 0.065	p < 0.0001 *** very significant	p = 0.0001 *** very significant
Untreated forearm	0.467 ± 44.1	0.406 ± 78.8	0.387 ± 60.8	p = 0.0003 *** very significant	p = 0.0001 *** very significant
Mean difference (treated vs. untreated, Visioscan units)	0.002	-0.026	-0.010		
Ratio to Day 0 (%)		-5.5%	-2.1%		





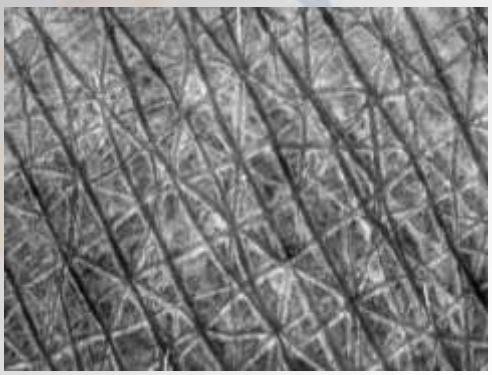
Test Parameters No: 6
(Continued)
(on skin microrelief (roughness), forearms)
RESULTS

Superficial skin roughness (Parameter R2/biggest roughness) before (D0) and during twice daily treatment with the test product *(Visioscan units; Means ± SD)*

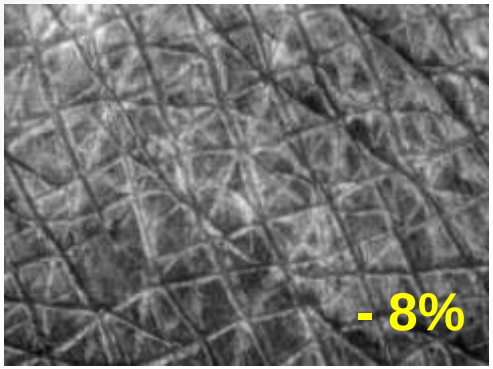
%-Changes in the superficial roughness of the skin *(Parameter R2/biggest roughness)* during twice daily treatment with the test product *(Means)*
= percentages of skin roughness decrease

Test Parameters No: 6 *(Continued)*
(on skin microrelief (roughness), forearms)

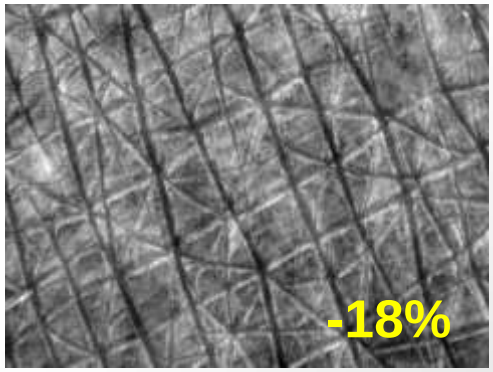
RESULTS



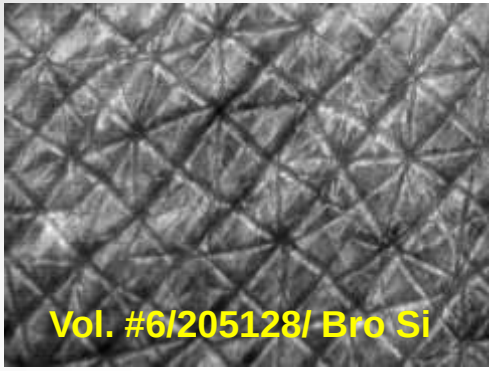
Day 0/Right side (untreated)



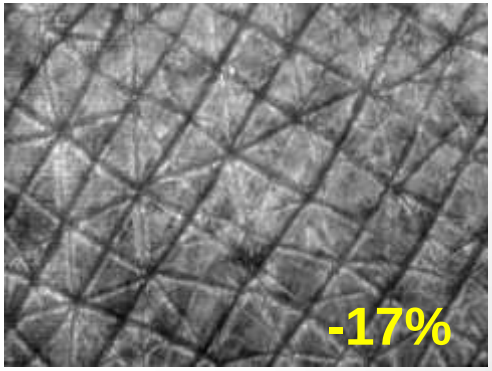
Day 28/Right side (untreated)



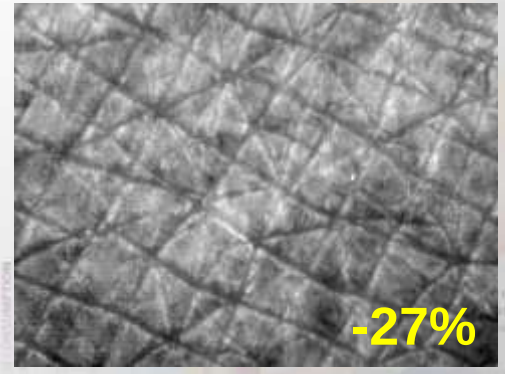
Day 56/Right side (untreated)



Day 0/Left side (treated)



Day 28/Left side (treated)



Day 56/Left side (treated)

Test Parameters No: 6
(on skin microrelief (roughness), forearms)

CONCLUSION ON RESULTS

- **On the treated forearm a continuous process of roughness reduction takes place at 4 and 8 weeks *(difference treated–untreated = –5.5% and –2.1%, respectively).* The intensity reduction at D56 is probably due to worse external conditions *(dryer weather, winter).***
- **Results were statistically very significant for both treated and untreated forearms.**

Test Parameters No: 7
(on wrinkle depth (microtopography, left crow's feet)

RESULTS

- **For 8 randomly selected volunteers, silicone replicas were taken on the crow's feet *(left face side)* at D0, D28 *(4 weeks)* and D56 *(8 weeks).***
- **The profile of the mould was measured by laser profilometry**
- **The average wrinkle depth was calculated.**

Photography of a silicone print
(example, Intercosmetica© 2005)

Test Parameters No: 7 *(Continued)*
(on wrinkle depth (microtopography, left crow's feet)

RESULTS

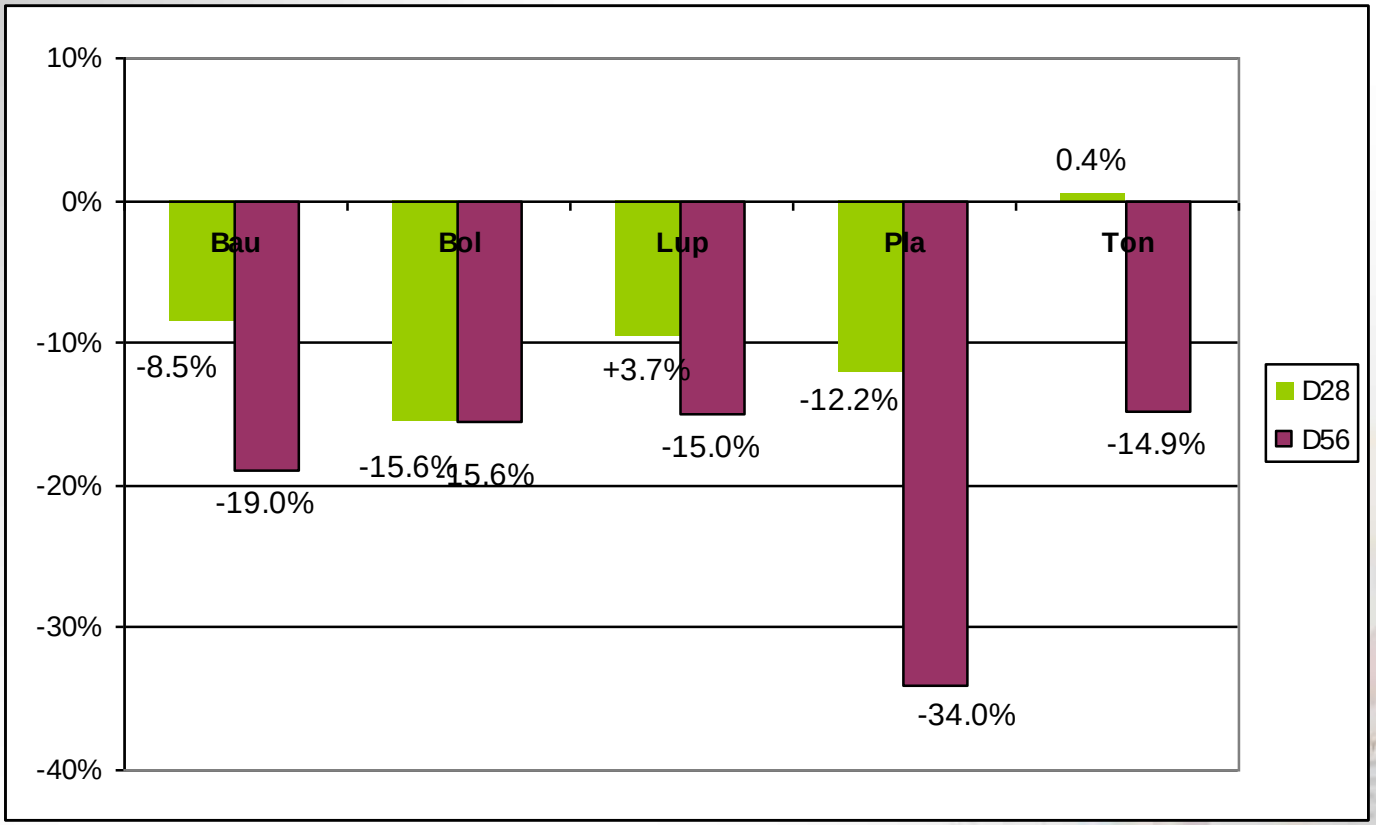
- **5 volunteers out of 8 presented wrinkle depth reductions.**

Wrinkle depth results (Left eyeside; Crow's feet; mm; 8 subjects)						
Vol.# and ID			Age (years)	Day 0	Day 28	Day 56
3.	205109	Bau Cl	60	0.305	0.279	0.247
5.	205357	Bol An	63	0.083	0.070	0.070
9.	205521	Fra Na	45	0.823	0.956	0.820
14.	205301	Jun Vi	42	0.190	0.202	0.153
19.	205452	Lup Mo	48	0.301	0.272	0.256
23.	204012	Pla Ja	52	0.303	0.265	0.200
24.	204051	Pul Na	48	0.397	0.422	0.488
28.	205270	Ton Pa	45	0.605	0.608	0.515

Average wrinkle depth results	Mean values (±SD; Left eyeside; Crow's feet; mm; 8 subjects)		
	Day 0	Day 28	Day 56
Left eyeside	0.435	0.459	0.423
	±0.209	±0.263	±0.248

Test Parameters No: 7 *(Continued)*
(on wrinkle depth (microtopography, left crow's feet)

RESULTS



%-Changes in the wrinkle depth (crow's feet area, mm) of the skin during twice daily treatment with the test product

= percentages of wrinkle depth reduction

Test Parameters No: 7
(on wrinkle depth (microtopography, left crow's feet)

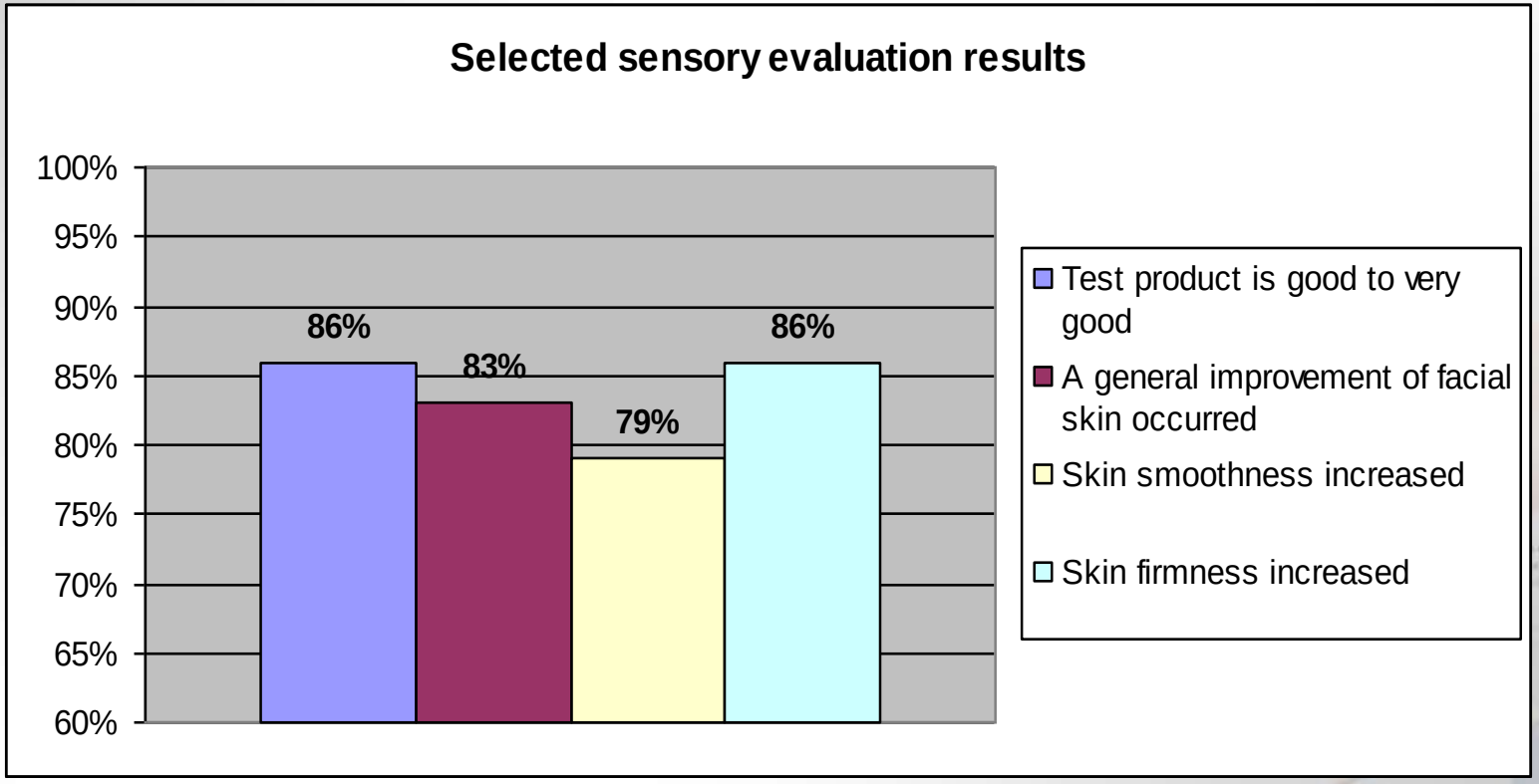
CONCLUSION ON RESULTS

- **Among the 5 positive volunteers, reduction amplitudes were distributed between 8.5% and 34%.**

Test Parameters No: 7 (on sensory evaluation)

RESULTS

- **A general improvement in the skin of the face was quoted by 24 out of 29 volunteers (83%).**
- **23 volunteers (79%) noted an increase in skin smoothness.**
- **25 volunteers (86%) noted an increase in skin firmness.**
- **The test product was rated as a good to very good product by 86% of the volunteers.**



CONCLUSION ON RESULTS

In conclusion:

- **An important process of skin replenishment took place during the treatment, on two skin levels**

(1) On top of the skin: reduction of crow's feet wrinkles (up to 34%) and microwrinkles (smoothening effect).
Additionally, with a 8-week moisturization by 30%, the test product is a very good moisturiser.

(2) Below the skin, in the papillar and reticular dermis, dermis density was increased.

- **The test product also provides a real seboregulating effect, which was especially observed in oily skin subjects.**

- **The test product is safe and non irritating. No TEWL increase was observed.**

CONCLUSIONS (Continued)

- **The overwhelming majority of volunteers (83%) noted a general improvement of the facial skin.**
- **86% of the volunteers rated the test product as good or very good.**
  No participant rated it as bad or very bad.

COMPARATIVE IN VIVO REVISCOMETER-RRTM AND ULTRASONOGRAPHY TECHNIQUES TO ASSESS THE ANTI-AGEING EFFICACY OF THE NOVEL MFIII® OF SWITZERLAND BLUECELL EXTRACT SERUM GEL

Alain Béguin

Cosmetic Skin Testing Department, Intercosmetica Neuchâtel SA, 2008 Neuchâtel, Switzerland

ABSTRACT

The anti-ageing properties of a new facial care treatment, *MF III®* of Switzerland Bluecell Extract Serum Gel, were investigated using the shear wave propagation method (multi-angle measurements) and the high-frequency skin ultrasonography. A 2-month cosmetic efficacy study was conducted with 29 healthy female volunteers, aged between 30 and 64 (mean 52 years). Results showed continuous and statistically significant reductions of resonance running time (RRT) on the temples and volar forearms, which corresponded to skin firmness increases, and indicated a strong anisotropic situation, especially on the temples. In parallel to that, a continuous, statistically significant dermis density increase was assessed on the face by ultrasonography.

INTRODUCTION

It has been shown in literature that classical cutometry measurements cannot always correctly describe skin elasticity and firmness changes [1,2]. As a valuable alternative, the shear wave propagation method can precisely assess about changes in firmness and present the angular anisotropic properties of skin, as related to Langer's lines [3]. Since the new *MF III®* of Switzerland Bluecell Extract Serum Gel was shown to be effective in improving certain aspects of ageing skin [4], it was interesting to compare the firming activity of this product in different skin areas and to relate it to the redensification of dermis, as measured by ultrasonography. RRT measurements were made on volar forearms (treated vs. untreated) and on the temples; ultrasound measurements were made on one cheek. The aim of the present work was to evaluate and compare the intensities of such anti-ageing effects according to the skin area.

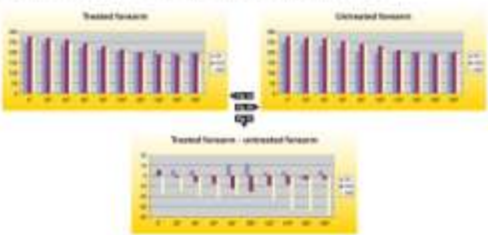


Figure 1 – RRT evolution on volar forearms, during twice daily treatment with the test product (RRT units) (1a) Treated (1b) Untreated (1c) Treated-untreated

RESULTS

29 healthy female volunteers with Caucasian skin type (ages 30-64) participated in a 2-month open efficacy study, applying the *MF III®* of Switzerland Bluecell Extract Serum Gel twice daily on the whole face an on one volar forearm. RRT measurements, using the Reviscometer® RVM 600 (Courage & Khazaka, Germany), were made in two skin areas, the volar forearms (VF) and the temples. In each of them 10 RRT values were recorded with angle increments of 20°, thus covering an angular field of 180°; the 0° reference angle was set in the vertical axis from foot to head. High-frequency ultrasonography measurements on the left cheek were made using a 20-MHz DermaScan® C device (Cortex Technology, Denmark), set on B-mode. VF: differences after-before and treated-untreated indicated continuous and statistically significant decreases of RRT. After 2 months of treatment the strongest RRT reduction was observed at 180°: -21.9%, and the lowest one at 0°: -7.6%, both assessing about a firming effect; untreated forearms gave non-significant results. Temples: after 2 months results were -57.9% RRT at 180° and +20.2% RRT at 0°; the most important firming effect was seen on the temples. Ultrasonography: on the cheek a statistically significant average increase of 8.5% dermis density was obtained after 2 months of treatment.

DISCUSSION

During the 2-month treatment period significant and constant increases in firmness were measured on the treated VF and the temples. A particularly strong anisotropy in the data was observed for the temples (Fig. 2), as compared to VF (Fig. 1a-1c). On the temples, especially between 140° and 180°, important RRT decreases between 30% and 40% were observed after 1 month, and decreases between 55% and 70% were obtained after 2 months (Table 1). Comparatively, results obtained between 0° and 40° were not significant (Fig. 2, [4]). The important firmness observed in high angles is correlated with the improved density measured on the face. On VF a firming effect was also evidenced, but it appears that the skin substructure of the VF area was less subject to a firming effect than temples (max. 24%, Table 1). Hence, important differences in anisotropy and firming evolution between VF and facial skin (temples) must be outlined. Obviously, however, it appears that the active ingredients of the *MF III®* of Switzerland Bluecell Serum Gel help successfully fighting against ageing signs such as laxity and loss of dermis density, especially on the face.

	[illegible]		[illegible]		[illegible]	
	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Table 1 – Comparative evolution of firmness on volar forearms and temples. 2 selected angles with highest response. Percentage differences to baseline. RRT units [illegible] (significant, ** very significant, *** extremely significant, ns non-significant)*

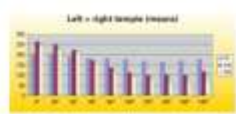


Figure 2 – RRT evolution on temples, during twice daily treatment with the test product (RRT units)

CONCLUSIONS

This study showed that an important and continuous skin firming effect was delivered by the test product during 2 months, and was evidenced on the temples by RRT measurements. A strong anisotropy was outlined there. Ultrasonography measurement, showing dermis density increases, confirmed these results. RRT measurements on VF showed that firmness increases represent max. 1/3 of the values observed on the temples, and that anisotropy was much less important. As a matter of fact VF skin can be considered as representative of facial skin for surface parameters (e.g. moisture or TEWL); internal skin parameters (e.g. firmness or viscoelasticity) reveal important differences with facial skin, thus showing that VF are not entirely representative of facial skin, in such cases.

REFERENCES

[1] E. Ruvolo, N. Kollias, Aging the elastic parameters of human epidermis: the role of Langer's lines and skin anisotropy, Poster presentation for Johnson & Johnson Consumer and Personal Products Worldwide, 2005 World Congress of Noninvasive Studies of the Skin, Wilmington, DE, USA (2005).

[2] D. Khazaka, News in the Field of Elasticity Measurement, Cosmetic Science Conference, Düsseldorf, Germany (2001).

[3] J.L. Nizet, C. Piérard-Franchimont, G.E. Piérard, Influence of Body Posture and Gravitational Forces on Shear Wave Propagation in the Skin, Dermatology 2001, 202, 177-180.

[4] A. Béguin, unpublished data (2005).

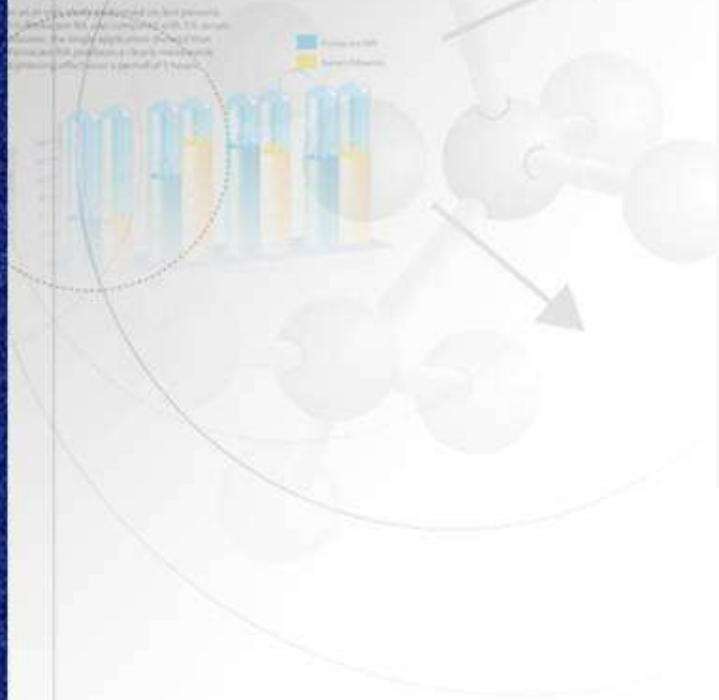
For more information of Clinical Study, contact info@mf3.ch

This Clinical Study Finding was presented at

APGI* Skin and Formulation 2nd Symposium in Versailles, France, October 9-10, 2006

***APGI is a member of the FIP (Fédération Internationale Pharmaceutique) and of the EUFEPS (European Federation of Pharmaceutical Sciences)**

Thank You



Brought to you exclusively by:

Laboratoires Dom AVMM Suisse

Leutschenbachstrasse 95,
8050 Zurich, Switzerland.
Fax: +41 44 274 2424

www.mf3swiss.com