



UNIVERSITA' DEGLI STUDI DI PAVIA
DIPARTIMENTO DI MEDICINA INTERNA E TERAPIA MEDICA
(Direttore: Prof. Plinio Richelmi)



**Evaluation of the anti-wrinkles power of a professional cosmetic treatment
through a clinical test**

**Apparecchiatura utilizzata: JetPeel3
Manipolo utilizzato: Manipolo a 3 uscite JTP-N01
Prodotto: BTX - NAT**

TAVTECH LTD.

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SUMMARY

Scope of this clinical test is to evaluate the cosmetic power of a treatment and its acceptability, in particular we have evaluated :

- the elasticizing power
- the firming power
- the moisturizing power
- the anti-wrinkle power
- the brightening power
- the softening power of the treatment.

This test was performed by a professional operator and overseen by a dermatologist, both members of Bio Basic Europe staff : 20 female panellists, with an age between 30 and 60 years were recruited to be submitted to 6 treatments (twice a week).

During this period specific clinical (skin softness, skin smoothness, skin brightness, skin compactness, macro-wrinkles visibility variation) and instrumental (moisturization, elasticity, compactness, wrinkles depth and surface) parameters have been evaluated.

At the end of the study volunteers self-evaluations have been also taken. The score they gave is according to the VNS scale (0-10 where 0 is the minimum value and 10 the maximum one).

From the results obtained it can be said that the treatment has proved to help in reducing wrinkles visibility.

In particular, after 6 treatments , we obtained the following results:

- Skin elasticity improves of 18%
- Skin compactness improves of 19% after
- Skin moisturization improves of 14%
- Wrinkles depth decreases of 11%
- Wrinkles VOLUME decreases of 21%
- Skin brightness improves in the 100% of the panelists
- Visibility of macro-wrinkles decreases in the 77.7% of the panelists
- Skin softness improves in the 77.7% of the panelists
- Very good acceptability



EXPERIMENTAL PART

Report no. **1309F04F**

Title

Evaluation of the anti-wrinkles power of a professional cosmetic treatment through a clinical test

Scope

Through the test one can evaluate if the tested cosmetic treatment has got any anti-wrinkles cosmetic power.

Contract information

- Technical report performed by BIO BASIC EUROPE s.r.l. and Università degli Studi di Pavia.
- Final technical report written by BIO BASIC EUROPE s.r.l. on behalf of TAVTECH LTD.

**Sponsor**

TAVTECH LTD.

Monitor

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Test subjects

20* female subjects, with an age between 30 and 60 years, have been selected for the test, following the undermentioned inclusion criteria:

- good state of general health
- no dermatopathies
- no pharmacological treatment in progress
- promise not to change the usual daily routine

Drop out

1. Volunteer n. 6:

She stopped the test at the third treatment: an abrasion on the eye contour area (on the left half face) have been advised. This undesired effect was probably due to the extreme sensitivity of the skin to the dermoabrasion.

2. Volunteer n. 12:

She stopped the test at the fifth treatment: an abrasion on the eye contour area (on the left half face) have been advised. This undesired effect was probably due to the extreme sensitivity of the skin to the dermoabrasion



METHOD OF EXECUTION

The whole treatment is carried out from a professional esthetician : volunteers are exposed to a treatment in cabin twice per week, for a total of 6 treatments.

PROCEDURE FOR EACH TREATMENT

- 1) Remove make-up
- 2) Prepare face skin

Device: JetPeel

Device with 3 exits JTP-N01

Product applied: physiological saline (sodium chloride 0,9%)

Duration: 11 minutes

Carry out an accurate dermabrasion of the face accelerating the physiological saline micronized drops with the device. Keep the device at a 2 cm distance from the face skin and with an inclination between 45 and 90 degrees.

- 3) Transdermal and painless vehiculation of the 10% BTX - NAT solution

Device: JetPeel

Device with 3 exits JTP-N01

Product applied: Time 4 Jet BTX - NAT 10%

Duration: 9 minutes

Vehiculate the BTX - NAT solution accelerating the BTX - NAT solution micronized drops with the device. Keep the device at a 0.5-1 cm distance from the face skin and with an inclination between 45 and 90 degrees.

EXECUTION OF THE TEST

INSTRUMENTAL PARAMETERS

- **Skin elasticity and skin compactness*** measurement are taken with the **elastometer CUTOMETER® – MPA 580**

* Skin elasticity was measured with Cutometer®. Before the test, it was necessary to standardize the measuring technique, of the level (maximum 500 mBar) and of the time of suction, with subsequent release, as well as the number of repeated measurements in the same test area (maximum 9). For this research, a suction cycle of 1 second at 500 mBar followed by a releasing cycle of one second was selected.

Regarding the elastometric measurement, the skin surface was aspirated from the depression induced by the machine into the aperture of the elastometer's measuring probe.

Depth of skin penetration inside the probe was measured by an optic sensor.

Linkage to a PC allowed the data obtained to be displayed, stored and printed. Cutaneous elasticity reflects the skin's potential capacity (measured in mm) for retraction.

A graph shows the deformation curve of skin undergoing aspiration, and includes two components (see the figure).

- An elastic component (U_e), which corresponds to the part of the curve that rises rapidly, and is reversible to the deformation;
- A plastic component (U_v), which corresponds to the part of the curve that rises slowly and is not completely reversible to the deformation.

- The total distension of the skin obtained at the end of an aspiration cycle is defined as skin extensibility ($U_f=R_0$): **this parameter is a skin compactness index**

- During the releasing phase, the quantity of deformation remaining in the skin can be observed (U_a-U_r =residual deformation).

Cutaneous elasticity is defined as the ratio:

- o **Elasticity= U_a/U_f (R2)**

Which represents the recovery degree of the maximum deformation reached, whose values range between 0 and 1 (maximum elasticity).

- Skin **moisturization**** is measured with CORNEOMETER® CM 850

**Corneometry measures the electric capacity of the skin surface that is related to skin moisture: indeed both electric capacity and the conductance of biological tissue change according to the water content, i.e. they increase if the water content increases. This instrument translates the electrical parameters in moisturization units (scale: 0÷130)

- **Wrinkles surface,depth,volume** *** studied with VisoFace Quick[®] and elaborated with and elaborated with Skin Surface Analyzer SSA***

***Wrinkle surface (mm²) of the wrinkle
Wrinkles depth (AU) of the wrinkle
Wrinkle Volume (mm²xAU) of the wrinkle

CLINICAL PARAMETERS

- Skin softness
- Skin smoothness
- Skin compactness
- Skin brightness
- Macro-Wrinkles variation

The readings are taken:

- at [t0] (basal value): before the first treatment
- at [t1]: first treatment
- at [t3]: third treatment
- at [t6]: sixth treatment

The readings are taken by the experimenter in the medical studio, then analysed and reported in a graph.

SELF-EVALUATION:

Volunteers opinions are also taken at the end of the last treatment[t6].

This self-evaluation was performed according to VNS scale where 0 is the minimum value and 10 is the maximum one.

EVALUATION AND RECKONING OF THE INSTRUMENTAL RESULTS

The statistical analysis has been performed using Student « t » test: we decided to fix the threshold of acceptability at 5 % .

EVALUATION OF CLINICAL PARAMETRS

The statistical analysis has been performed using Friedman test: we decided to fix the threshold of acceptability at 5 %

To carry out a statistical survey and to be able to evaluate the skin variations in a specific period of time, the following skin parameters have been analyzed:

Skin softness		Skin compactness	
Skin is rough	Insufficient	not compact (skin with very low uniformity and density)	Insufficient
Skin is not very soft	Sufficient	little compact (skin with low uniformity and density)	Sufficient
Skin is fairly soft	Fairly good	Quite compact (skin with a fairly good uniformity and density)	Fairly good
Skin is soft	Good	compact (uniform skin with a normal density)	Good
Skin is very soft	Very good	very compact (uniform skin with a good density)	Very good

Skin brightness Macro Wrinkles variation Skin smoothness	
No variation (in comparison with the beginning of the experimentation)	Absent
Slight variation (in comparison with the beginning of the experimentation)	Slight
Fairly good variation (in comparison with the beginning of the experimentation)	Fairly good
Significant variation (in comparison with the beginning of the experimentation)	Good
Very Significant variation (in comparison with the beginning of the experimentation)	Good Very

Summarizing Tables of the Values

CLINICAL AND INSTRUMENTAL PARAMETERS

Elasticità cutanea <i>Skin elasticity</i>				
Rif. Vol Vol. ref	t0	t 1st treatment	t 3rd treatment	t 6th treatment
1	0,430	0,675	0,657	0,681
2	0,624	0,500	0,643	0,708
3	0,579	0,598	0,787	0,788
4	0,605	0,659	0,692	0,685
5	0,591	0,471	0,585	0,606
7	0,612	0,672	0,663	0,682
8	0,756	0,800	0,782	0,763
9	0,625	0,684	0,761	0,745
10	0,724	0,783	0,772	0,787
11	0,463	0,586	0,563	0,610
13	0,460	0,514	0,538	0,590
14	0,703	0,707	0,715	0,745
15	0,706	0,725	0,791	0,841
16	0,607	0,693	0,658	0,670
17	0,483	0,576	0,606	0,618
18	0,541	0,591	0,601	0,620
19	0,514	0,553	0,562	0,579
20	0,415	0,418	0,439	0,551
Media Average	0,580	0,623	0,656	0,682
Dev. STD	0,103513501	0,106248181	0,099905398	0,083378302
Test t student	sign 95% (val. est. +-2,110)	1,220170026	2,251812815	3,246382555
		NO	YES	YES

Skin elasticity improves of 18% after 6th treatments (statistically significant)

Compattezza cutanea <i>Skin compactness</i>				
Rif. Vol Vol. ref	t0	t 1st treatment	t 3rd treatment	t 6th treatment
1	0,228	0,197	0,187	0,160
2	0,201	0,195	0,184	0,157
3	0,291	0,285	0,267	0,254
4	0,223	0,202	0,190	0,145
5	0,255	0,261	0,223	0,236
7	0,186	0,157	0,140	0,118
8	0,131	0,152	0,124	0,118
9	0,255	0,209	0,211	0,223
10	0,195	0,191	0,185	0,141
11	0,241	0,228	0,225	0,199
13	0,197	0,201	0,163	0,153
14	0,185	0,171	0,180	0,165
15	0,198	0,182	0,180	0,161
16	0,282	0,251	0,263	0,266
17	0,393	0,382	0,324	0,332
18	0,179	0,151	0,138	0,145
19	0,258	0,246	0,221	0,217
20	0,287	0,294	0,294	0,183
Media Average	0,233	0,220	0,206	0,187
Dev. STD	0,05885201	0,05907404	0,05422204	0,05719948
Test t student	sign 95% (val. est. +-2,110)	-0,6501238	-1,43149	-2,3320616
		NO	NO	YES

Skin compactness improves of 19% after 6th treatments (statistically significant)

Skin moisturization				
Vol. ref	t0	t 1st treatment	t 3rd treatment	t 6th treatment
1	52,300	54,400	51,800	58,800
2	49,900	54,600	57,200	58,600
3	50,300	59,400	56,900	58,100
4	46,600	49,400	53,200	55,100
5	61,900	70,300	65,700	67,500
7	46,800	55,600	54,200	58,100
8	55,800	64,400	65,800	60,700
9	56,800	60,500	65,000	59,100
10	53,100	63,800	62,400	60,600
11	57,300	64,400	67,000	70,500
13	57,200	63,300	68,400	64,600
14	39,800	43,500	44,100	48,500
15	48,400	50,100	53,200	56,100
16	46,000	58,300	57,200	58,100
17	49,400	46,800	53,200	52,000
18	48,100	53,900	59,800	50,200
19	46,300	50,100	52,700	52,900
20	52,500	53,500	52,700	55,100
<i>Average</i>	51,028	56,461	57,806	58,033
Dev. STD	5,373771329	7,122552326	6,660195389	5,635287977
Test t student	sign 95% (val. est. +2,110)	2,583591114	3,360178852	3,81699088
		YES	yes	yes

Skin moisturization improves of 14% after 6 treatments (statistically significant)

PROFONDITA' DELLE RUGHE - WRINKLES DEPTH(au)				
Rif. Vol Vol. ref	t0	t 1st treatment	t 3rd treatment	t 6th treatment
1	16,190	16,082	15,336	14,440
2	14,420	13,930	13,170	11,250
3	15,260	15,020	14,820	13,850
4	13,240	13,005	12,180	12,250
5	15,950	15,620	14,600	14,514
7	11,580	11,320	11,080	9,780
8	14,530	14,310	12,910	12,780
9	17,950	17,620	16,600	16,514
10	13,560	13,330	13,240	13,010
11	13,120	12,740	12,050	11,420
13	14,940	14,610	13,860	11,950
14	11,030	10,750	10,850	10,910
15	11,530	11,260	11,040	10,750
16	12,930	12,540	12,170	12,050
17	14,180	12,850	12,780	12,662
18	11,580	10,990	10,600	10,100
19	12,200	11,680	11,870	11,620
20	11,270	11,170	11,070	9,620
<i>Media Average</i>	13,637	13,268	12,790	12,193
Dev. STD	1,952431365	1,972175695	1,707366634	1,807411166
Test t student	sign 95% (val. est. +-2,110)	-0,563361373	-1,384408031	-2,302462454
		NO	no	si/yes

Wrinkles depth decreases of 11% after 6 treatments (statistically significant)

SUPERFICIE DELLE RUGHE - WRINKLES SURFACE - mm²				
Rif. Vol Vol. ref	t0	t 1st treatment	t 3rd treatment	t 6th treatment
1	27,350	30,190	28,610	23,380
2	30,660	27,820	26,154	24,154
3	42,610	40,230	39,520	37,920
4	37,880	37,820	35,020	34,850
5	34,620	35,000	33,670	30,880
7	38,750	37,410	35,260	33,100
8	38,750	38,245	33,160	32,280
9	49,190	49,250	46,350	44,400
10	49,190	46,350	44,400	44,100
11	34,940	33,640	31,590	28,540
13	46,530	44,180	42,720	39,430
14	50,920	49,110	46,240	44,250
15	42,710	39,100	38,210	38,920
16	58,410	53,210	50,090	51,230
17	59,630	59,760	56,400	54,100
18	44,150	43,450	42,760	40,970
19	33,850	33,280	29,700	27,840
20	40,170	39,620	34,500	34,630
Media Average	42,239	40,981	38,575	36,943
Dev. STD	8,889677075	8,248428693	8,094781417	8,643117064
Test t student	sign 95% (val. est. +-2,110)	-0,44013353	-1,29302296	-1,81234802
		NO	no	no

Wrinkles surface decreases of 13% after 6 treatments (no statistically significant)

VOLUME DELLE RUGHE - WRINKLES VOLUME (au x mm²)				
<i>Panellist code</i>	t0	t1	t3	t6
1	0,44	0,49	0,44	0,34
2	0,44	0,39	0,34	0,27
3	0,65	0,60	0,59	0,53
4	0,50	0,49	0,43	0,43
5	0,55	0,55	0,49	0,45
7	0,45	0,42	0,39	0,32
8	0,56	0,55	0,43	0,41
9	0,88	0,87	0,77	0,73
10	0,67	0,62	0,59	0,57
11	0,46	0,43	0,38	0,33
13	0,70	0,65	0,59	0,47
14	0,56	0,53	0,50	0,48
15	0,49	0,44	0,42	0,42
16	0,76	0,67	0,61	0,62
17	0,85	0,77	0,72	0,69
18	0,51	0,48	0,45	0,41
19	0,41	0,39	0,35	0,32
20	0,45	0,44	0,38	0,33
Media Average	0,574	0,542	0,493	0,451
Dev. STD	0,143911	0,132358	0,124809	0,131855
Test t student	sign 95% (val. est. +-2,110)	-0,69625	-1,80469	-2,67133
		NO	no	yes

Wrinkles volume decreases of 21% after 6 treatments (statistically significant)

Compattezza cutanea		Skin compactness		
Panellist code	t0	t1 - 1st treatment	t3 - 3rd treatment	t6 - 6th treatment
1	Insufficiente/Insufficient	Insufficiente/Insufficient	Sufficiente/Sufficient	Discreto/Fairly good
2	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good	Buono/Good
3	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good
4	Discreto/Fairly good	Discreto/Fairly good	Buono/Good	Ottimo/very good
5	Sufficiente/Sufficient	Sufficiente/Sufficient	Discreto/Fairly good	Discreto/Fairly good
7	Discreto/Fairly good	Discreto/Fairly good	Buono/Good	Buono/Good
8	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good
9	Sufficiente/Sufficient	Discreto/Fairly good	Buono/Good	Buono/Good
10	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good	Buono/Good
11	Sufficiente/Sufficient	Sufficiente/Sufficient	Discreto/Fairly good	Buono/Good
13	Sufficiente/Sufficient	Sufficiente/Sufficient	Buono/Good	Buono/Good
14	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good
15	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good	Ottimo/very good
16	Sufficiente/Sufficient	Sufficiente/Sufficient	Sufficiente/Sufficient	Sufficiente/Sufficient
17	Insufficiente/Insufficient	Sufficiente/Sufficient	Discreto/Fairly good	Discreto/Fairly good
18	Sufficiente/Sufficient	Sufficiente/Sufficient	Buono/Good	Buono/Good
19	Sufficiente/Sufficient	Sufficiente/Sufficient	Buono/Good	Buono/Good
20	Insufficiente/Insufficient	Insufficiente/Insufficient	Insufficiente/Insufficient	Buono/Good

STATISTICAL ANALYSIS

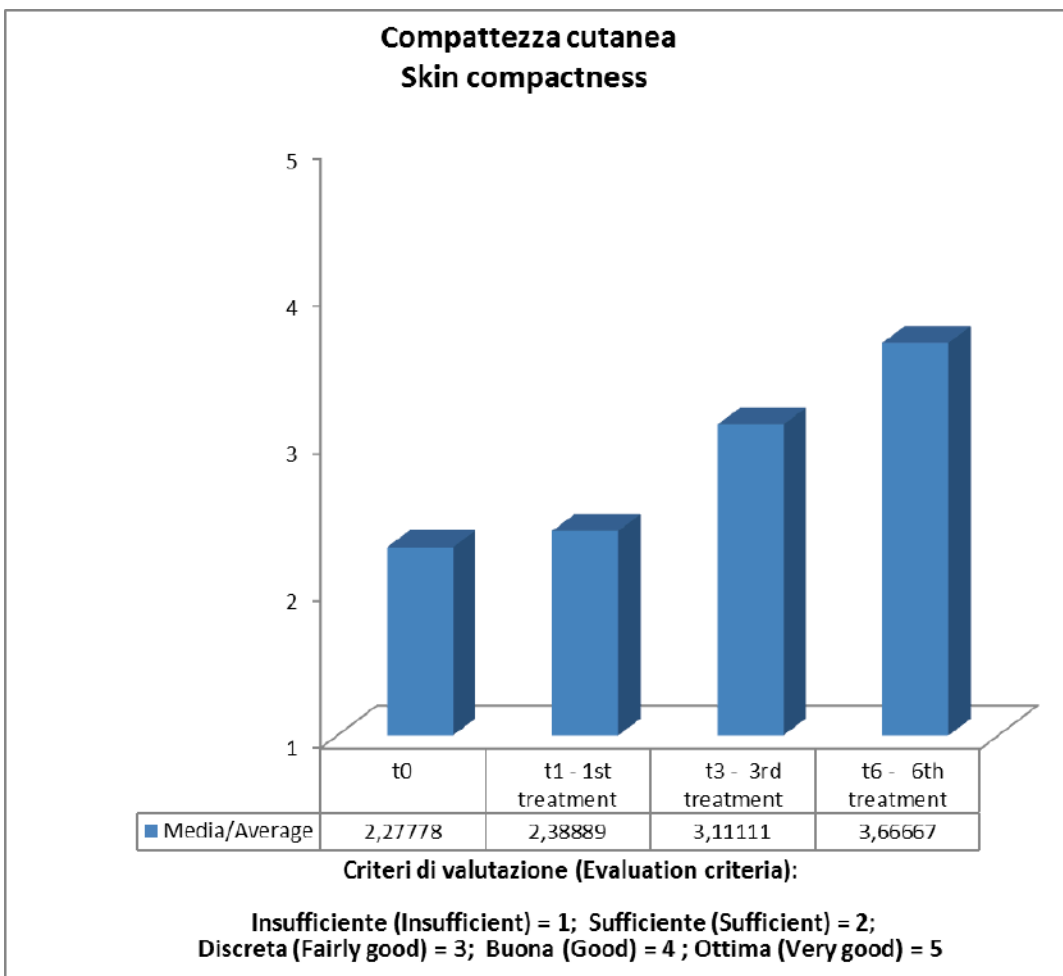
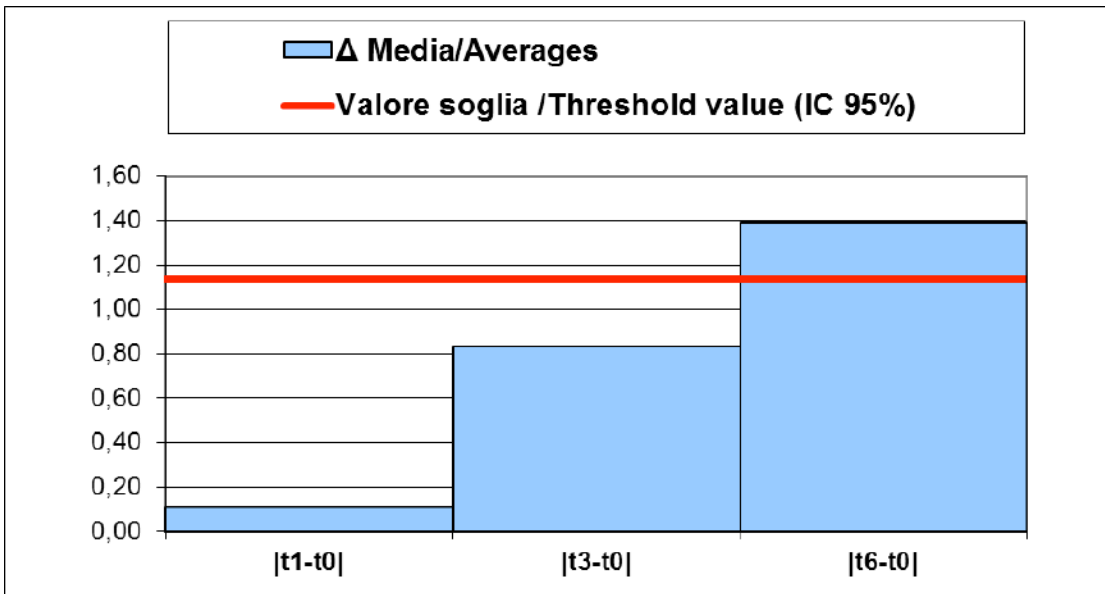
The Friedman Test allows the statistical analysis of non parametric data. (Cosmetic news, 130, January/February (30-32). A score between 1-5 is given to the experimenter evaluations (Insufficient, Sufficient, Fairly good, Good, Very good). For each period average values are calculated. The test is significant if the average differences are bigger than the threshold value (Interval Confidence 95%)

ANALISI STATISTICA

Per la valutazione statistica di dati non parametrici (scores) non indipendenti si è utilizzato il Test di Friedman (Cosmetic news, 130, January/February (30-32)). Ad ogni giudizio dello sperimentatore (Insufficiente, Sufficiente, Discreto, Buono, Ottimo) viene assegnato un punteggio da 1 a 5. Per ogni intervallo di tempo si sommano i punteggi attribuiti ad ogni singolo volontario e si calcolano le relative medie. A questo punto si valutano le differenze tra le diverse medie. Le variazioni tra le medie risultano essere significative se superano il valore soglia definito (Intervallo di confidenza 95%).

1,14	t1-t0	t3-t0	t6-t0
	0,11	0,83	1,39
	NO	no	SI'/YES

Skin compactness improves in the 77.7% of the panellists after the 6 treatment (statistically significant)



Luminosità cutanea		Skin brightness		
Panellist code	t0	t1 - 1st treatment	t3 - 3rd treatment	t6 - 6th treatment
1	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good	Buona/Good
2	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good	Buona/Good
3	Discreta/Fairly good	Buona/Good	Buona/Good	Buona/Good
4	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good	Buona/Good
5	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good	Buona/Good
7	Discreta/Fairly good	Discreta/Fairly good	Buona/Good	Ottima/very good
8	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good	Buona/Good
9	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good	Buona/Good
10	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good	Buona/Good
11	Discreta/Fairly good	Discreta/Fairly good	Buona/Good	Buona/Good
13	Leggera/Slight	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good
14	Leggera/Slight	Leggera/Slight	Discreta/Fairly good	Buona/Good
15	Nessuna/Absent	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good
16	Nessuna/Absent	Leggera/Slight	Leggera/Slight	Leggera/Slight
17	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good	Discreta/Fairly good
18	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good	Discreta/Fairly good
19	Nessuna/Absent	Leggera/Slight	Discreta/Fairly good	Discreta/Fairly good
20	Leggera/Slight	Discreta/Fairly good	Buona/Good	Buona/Good

STATISTICAL ANALYSIS

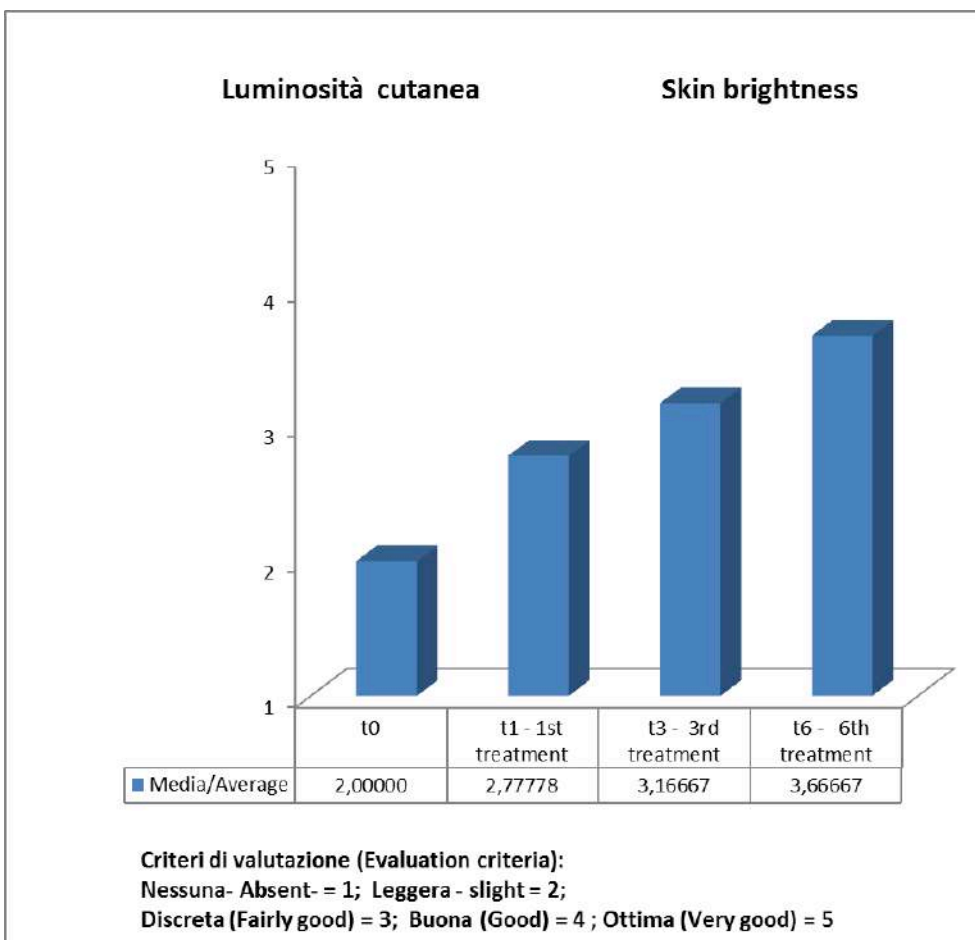
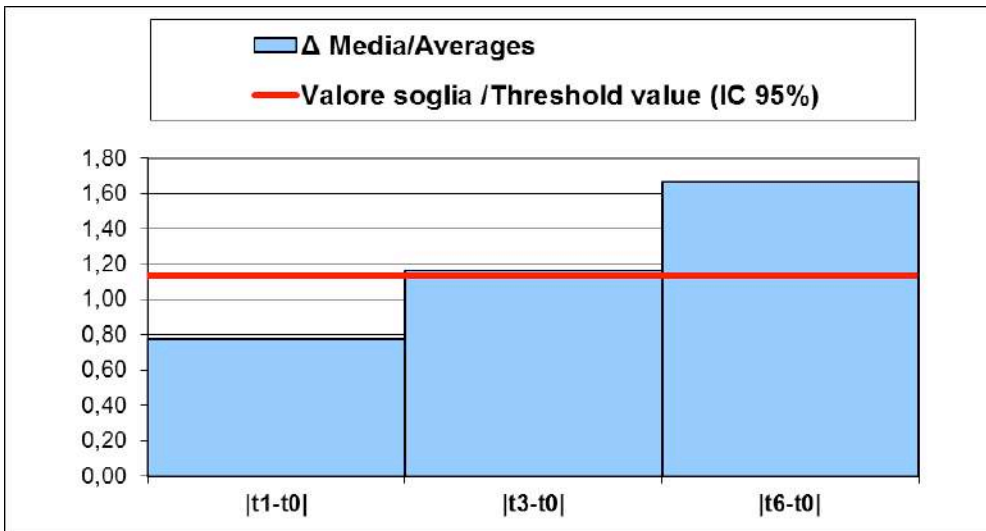
The Friedman Test allows the statistical analysis of non parametric data. (Cosmetic news, 130, January/February (30-32).
 A score between 1-5 is given to the experimenter evaluations (Variation: Absent, Slight, Fairly good, Good, Very good).
 (to=1) For each period average values are calculated. The test is significant if the average differences are bigger than the
 threshold value (Interval Confidence 95%)

ANALISI STATISTICA

Per la valutazione statistica di dati non parametrici (scores) non indipendenti si è utilizzato il Test di Friedman (Cosmetic news, 130, January/February (30-32)). Ad ogni giudizio dello sperimentatore (Variazione: Nessuna, leggera, Discreta, Buona, Ottima) viene assegnato un punteggio da 1 a 5. (to=1) Per ogni intervallo di tempo si sommano i punteggi attribuiti ad ogni singolo volontario e si calcolano le relative medie. A questo punto si valutano le differenze tra le diverse medie. Le variazioni tra le medie risultano essere significative se superano il valore soglia definito (Intervallo di confidenza 95%).

1,14	t1-t0	t3-t0	t6-t0
	0,78	1,17	1,67
	NO	SI'/YES	SI'/YES

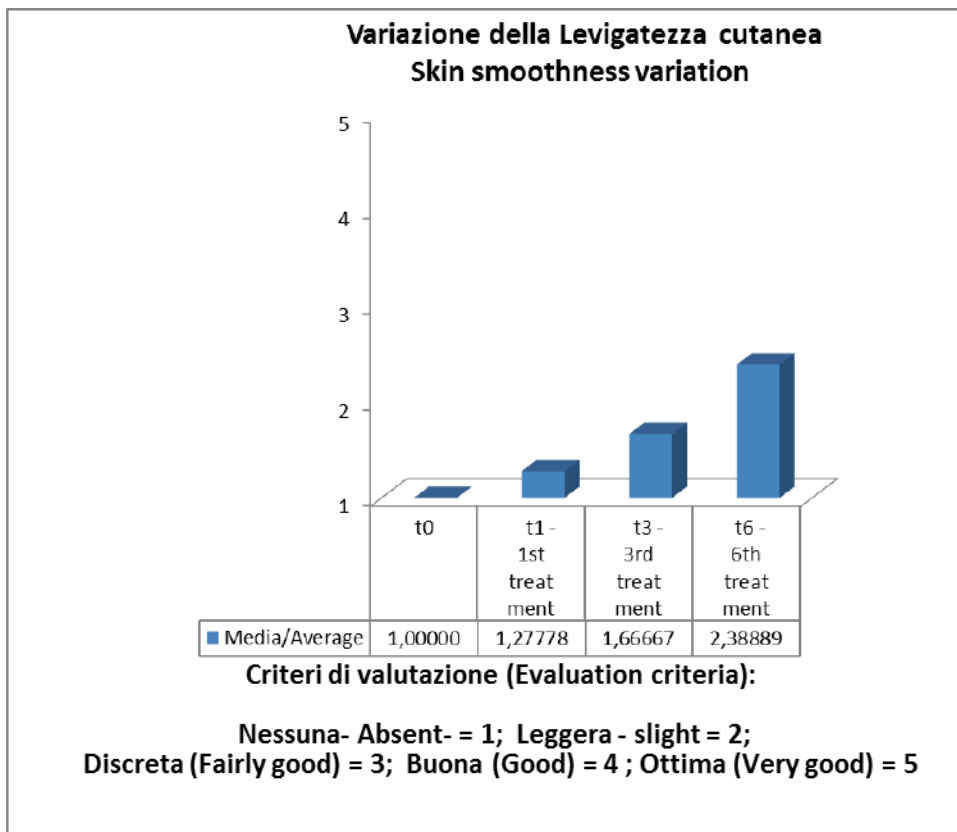
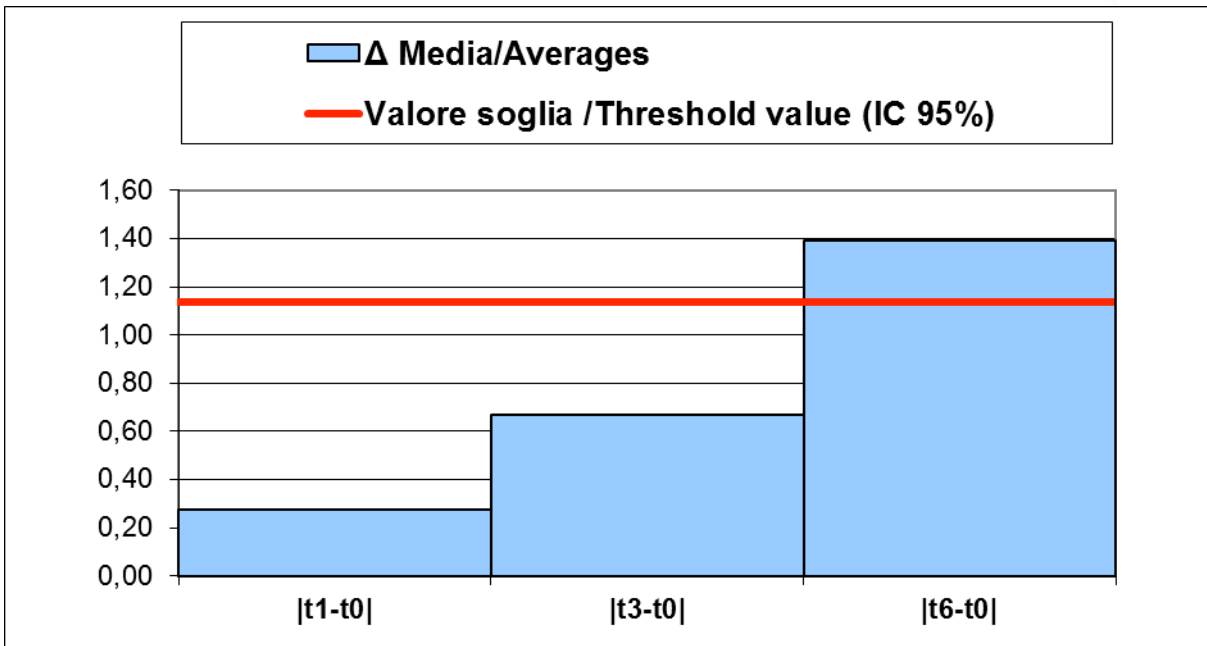
Skin brightness improves in the 100% of the panellists after the 6 treatment (statistically significant)



Variazione della Levigatezza cutanea		Skin smoothness variation		
Panellist code	t0	t1 - 1st treatment	t3 - 3rd treatment	t6 - 6th treatment
1	//	Nessuna/Absent	Leggera/Slight	Leggera/Slight
2	//	Nessuna/Absent	Leggera/Slight	Discreta/Fairly good
3	//	Nessuna/Absent	Nessuna/Absent	Leggera/Slight
4	//	Nessuna/Absent	Leggera/Slight	Leggera/Slight
5	//	Nessuna/Absent	Leggera/Slight	Leggera/Slight
7	//	Leggera/Slight	Discreta/Fairly good	Buona/Good
8	//	Nessuna/Absent	Leggera/Slight	Discreta/Fairly good
9	//	Nessuna/Absent	Nessuna/Absent	Leggera/Slight
10	//	Nessuna/Absent	Nessuna/Absent	Nessuna/Absent
11	//	Leggera/Slight	Leggera/Slight	Leggera/Slight
13	//	Leggera/Slight	Leggera/Slight	Discreta/Fairly good
14	//	Nessuna/Absent	Nessuna/Absent	Nessuna/Absent
15	//	Nessuna/Absent	Leggera/Slight	Discreta/Fairly good
16	//	Nessuna/Absent	Nessuna/Absent	Nessuna/Absent
17	//	Nessuna/Absent	Nessuna/Absent	Discreta/Fairly good
18	//	Nessuna/Absent	Nessuna/Absent	Leggera/Slight
19	//	Leggera/Slight	Leggera/Slight	Buona/Good
20	//	Leggera/Slight	Leggera/Slight	Discreta/Fairly good

STATISTICAL ANALYSIS			
<p>The Friedman Test allows the statistical analysis of non parametric data. (Cosmetic news, 130, January/February (30-32). A score between 1-5 is given to the experimenter evaluations (Variation:Absent,Slight, Fairly good, Good, Very good). (to=1)For each period average values are calculated. The test is significant if the average differences are bigger than the threshold value (Interval Confidence 95%)</p>			
ANALISI STATISTICA			
<p>Per la valutazione statistica di dati non parametrici (scores) non indipendenti si è utilizzato il Test di Friedman (Cosmetic news, 130, January/February (30-32)). Ad ogni giudizio dello sperimentatore (Variazione: Nessuna, leggera, Discreta, Buona, Ottima) viene assegnato un punteggio da 1 a 5 . (to=1) Per ogni intervallo di tempo si sommano i punteggi attribuiti ad ogni singolo volontario e si calcolano le relative medie. A questo punto si valutano le differenze tra le diverse medie. Le variazioni tra le medie risultano essere significative se superano il valore soglia definito (Intervallo di confidenza 95%).</p>			
1,14	t1-t0	t3-t0	t6-t0
	0,28	0,67	1,39
	NO	no	SI'/YES

Skin smoothness improves in the 100% of the panellists after the 6 treatment (statistically significant)



Riduzione della visibilità delle macrorughe / Macrowrinkles variation

Rif. Volontario Panellist code	t0	t1 - 1st treatment	t3 - 3rd treatment	t6 - 6th treatment
1	//	Nessuna/Absent	Leggera/Slight	Leggera/Slight
2	//	Leggera/Slight	Leggera/Slight	Buona/Good
3	//	Nessuna/Absent	Nessuna/Absent	Leggera/Slight
4	//	Nessuna/Absent	Leggera/Slight	Leggera/Slight
5	//	Nessuna/Absent	Nessuna/Absent	Leggera/Slight
7	//	Nessuna/Absent	Leggera/Slight	Leggera/Slight
8	//	Nessuna/Absent	Nessuna/Absent	Leggera/Slight
9	//	Nessuna/Absent	Nessuna/Absent	Nessuna/Absent
10	//	Nessuna/Absent	Nessuna/Absent	Nessuna/Absent
11	//	Leggera/Slight	Leggera/Slight	Discreta/Fairly good
13	//	Nessuna/Absent	Leggera/Slight	Buona/Good
14	//	Nessuna/Absent	Nessuna/Absent	Nessuna/Absent
15	//	Nessuna/Absent	Nessuna/Absent	Nessuna/Absent
16	//	Nessuna/Absent	Leggera/Slight	Leggera/Slight
17	//	Nessuna/Absent	Leggera/Slight	Leggera/Slight
18	//	Nessuna/Absent	Nessuna/Absent	Leggera/Slight
19	//	Nessuna/Absent	Leggera/Slight	Leggera/Slight
20	//	Nessuna/Absent	Nessuna/Absent	Discreta/Fairly good

STATISTICAL ANALISYS

The Friedman Test allows the statistical analysis of non parametric data. (Cosmetic news, 130, January/February (30-32).

A score between 1-5 is given to the experimenter evaluations (Variation:Absent,Slight, Fairly good, Good, Very good).

(to=1)For each period average values are calculated. The test is significant if the average differences are bigger than the threshold value (Interval Confidence 95%)

ANALISI STATISTICA

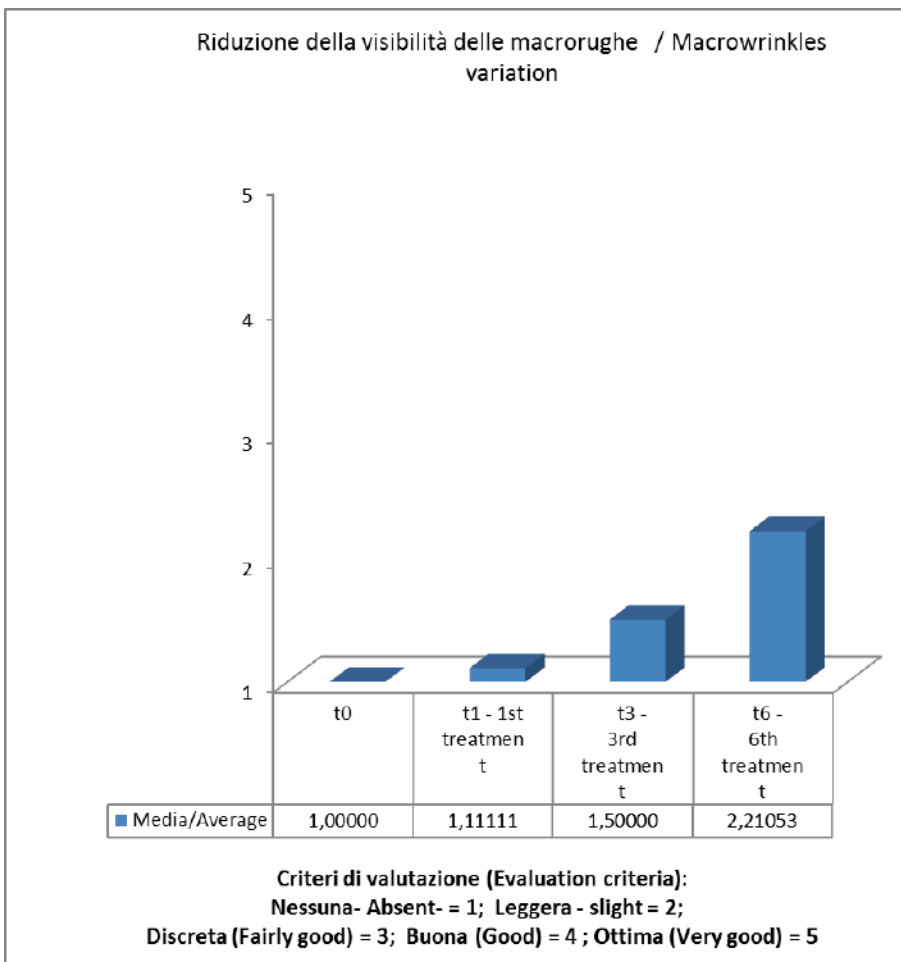
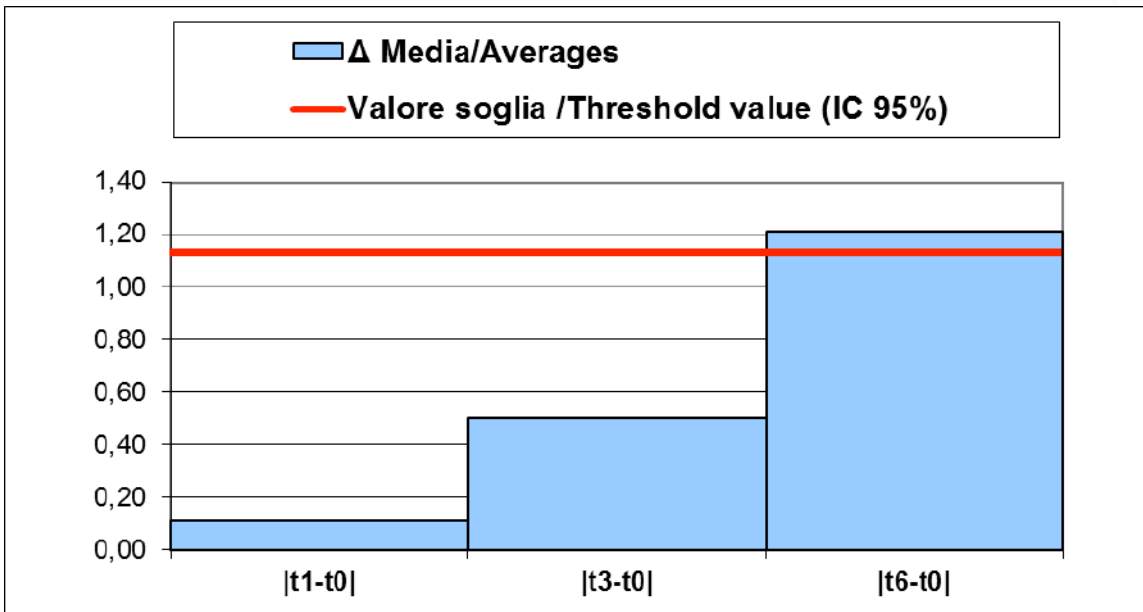
Per la valutazione statistica di dati non parametrici (scores) non indipendenti si è utilizzato il Test di Friedman (Cosmetic news, 130, January/February (30-32)). Ad ogni giudizio dello sperimentatore (Variazione: Nessuna, leggera, Discreta,

Buona, Ottima) viene assegnato un punteggio da 1 a 5 . (to=1) Per ogni intervallo di tempo si sommano i punteggi attribuiti ad ogni singolo volontario e si calcolano le relative medie. A questo punto si valutano le differenze tra le

diverse medie. Le variazioni tra le medie risultano essere significative se superano il valore soglia definito (Intervallo di confidenza 95%).

1,14	t1-t0	t3-t0	t6-t0
	0,11	0,50	1,11
	NO	no	SI'/YES

Macro-Wrinkles visibility decreases in the 77.7% of the panellists after the 6 treatment (statistically significant)



Morbidezza cutanea		Skin softness		
Panellist code	t0	t1 - 1st treatment	t3 - 3rd treatment	t6 - 6th treatment
1	Sufficiente/Sufficient	Sufficiente/Sufficient	Buono/Good	Buono/Good
2	Discreto/Fairly good	Discreto/Fairly good	Buono/Good	Buono/Good
3	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good
4	Discreto/Fairly good	Discreto/Fairly good	Buono/Good	Buono/Good
5	Sufficiente/Sufficient	Sufficiente/Sufficient	Discreto/Fairly good	Discreto/Fairly good
7	Discreto/Fairly good	Discreto/Fairly good	Buono/Good	Buono/Good
8	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good
9	Discreto/Fairly good	Discreto/Fairly good	Buono/Good	Buono/Good
10	Discreto/Fairly good	Discreto/Fairly good	Buono/Good	Buono/Good
11	Sufficiente/Sufficient	Sufficiente/Sufficient	Buono/Good	Buono/Good
13	Sufficiente/Sufficient	Sufficiente/Sufficient	Buono/Good	Buono/Good
14	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good	Discreto/Fairly good
15	Discreto/Fairly good	Discreto/Fairly good	Buono/Good	Buono/Good
16	Sufficiente/Sufficient	Sufficiente/Sufficient	Sufficiente/Sufficient	Sufficiente/Sufficient
17	Insufficiente/Insufficient	Insufficiente/Insufficient	Sufficiente/Sufficient	Discreto/Fairly good
18	Sufficiente/Sufficient	Sufficiente/Sufficient	Buono/Good	Buono/Good
19	Sufficiente/Sufficient	Sufficiente/Sufficient	Discreto/Fairly good	Buono/Good
20	Sufficiente/Sufficient	Sufficiente/Sufficient	Discreto/Fairly good	Buono/Good

STATISTICAL ANALYSIS

The Friedman Test allows the statistical analysis of non parametric data. (Cosmetic news, 130, January/February (30-32).

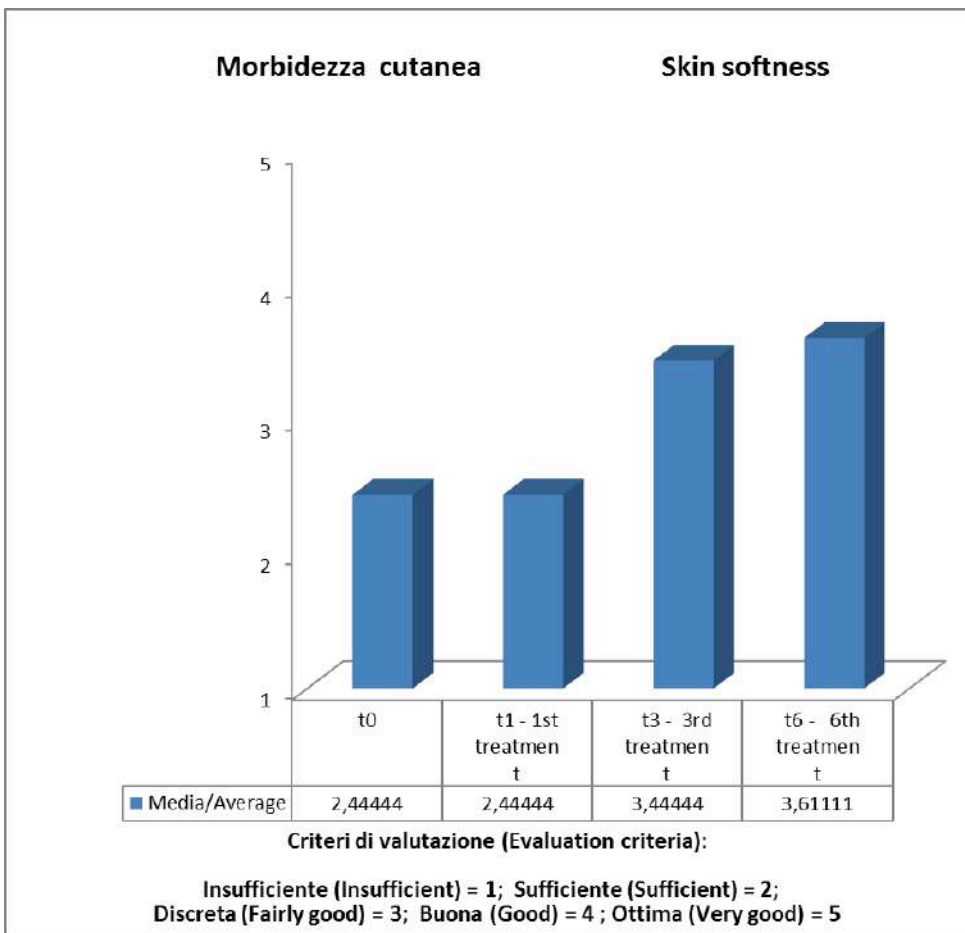
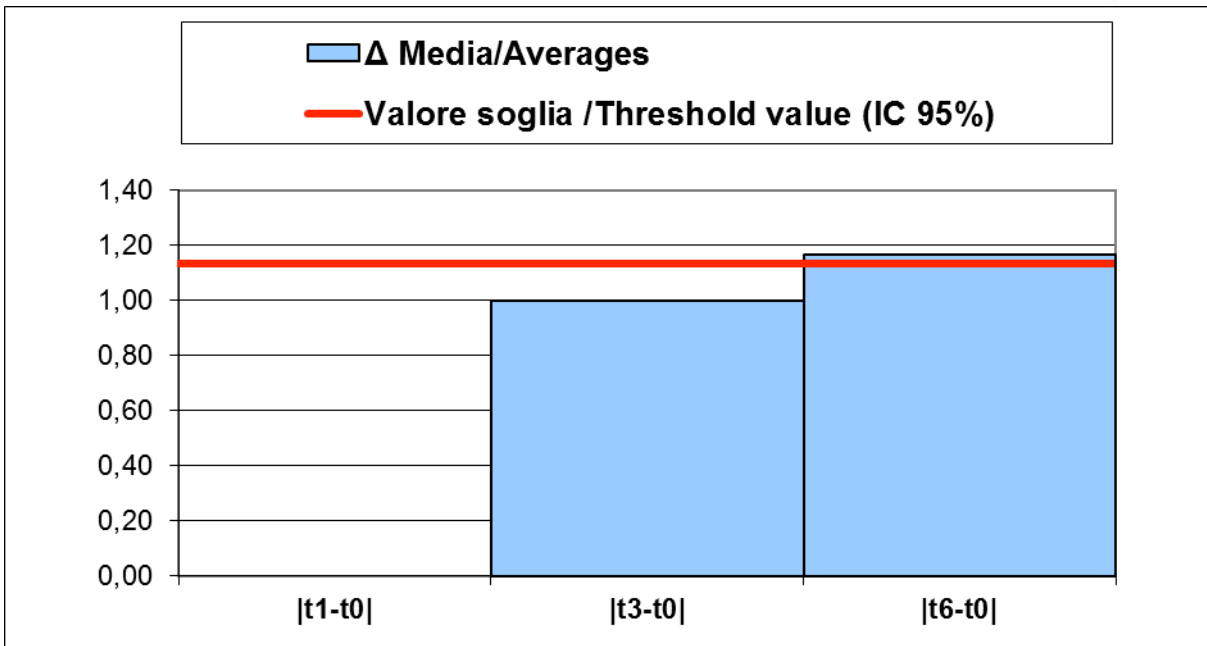
A score between 1-5 is given to the experimenter evaluations (Insufficient, Sufficient, Fairly good, Good, Very good). For each period average values are calculated. The test is significant if the average differences are bigger than the threshold value (Interval Confidence 95%)

ANALISI STATISTICA

Per la valutazione statistica di dati non parametrici (scores) non indipendenti si è utilizzato il Test di Friedman (Cosmetic news, 130, January/February (30-32)). Ad ogni giudizio dello sperimentatore (Insufficiente, Sufficiente, Discreto, Buono, Ottimo) viene assegnato un punteggio da 1 a 5. Per ogni intervallo di tempo si sommano i punteggi attribuiti ad ogni singolo volontario e si calcolano le relative medie. A questo punto si valutano le differenze tra le diverse medie. Le variazioni tra le medie risultano essere significative se superano il valore soglia definito (Intervallo di confidenza 95%).

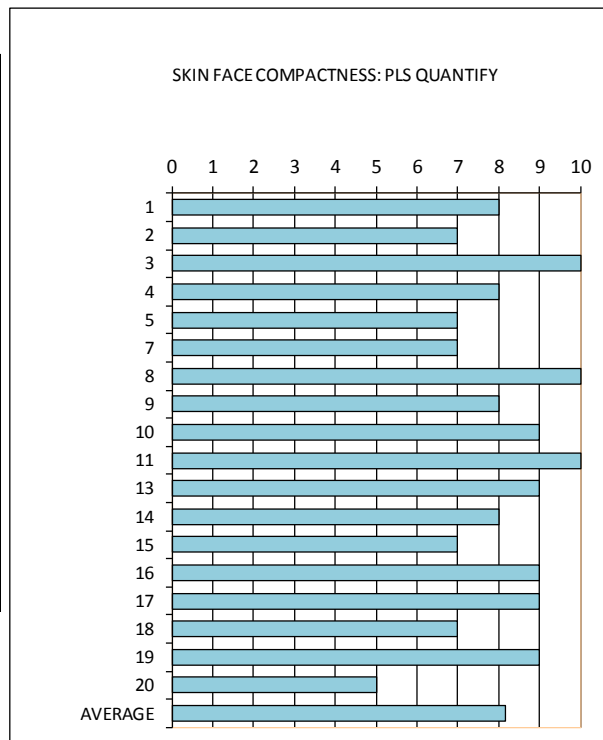
1,14	t1-t0	t3-t0	t6-t0
	0,00	1,00	1,17
	no	no	si/yes

Skin softness improves in the 77.7 % of the panellists after the 6 treatment (statistically significant)

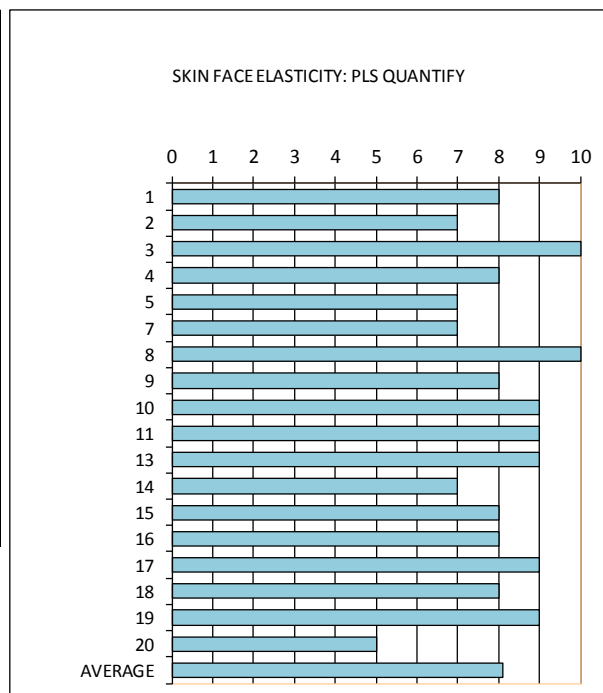


PANELLIST'S SELF EVALUATIONS

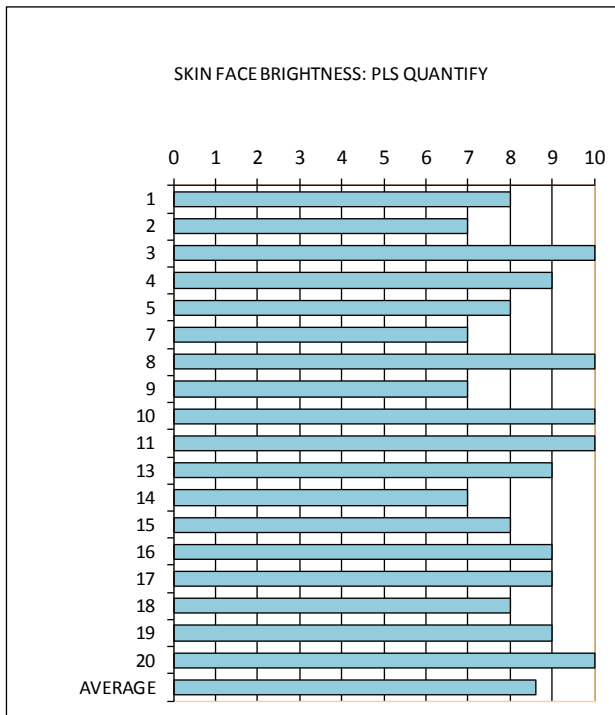
Panellist code	after 6 treatments
1	8
2	7
3	10
4	8
5	7
7	7
8	10
9	8
10	9
11	10
13	9
14	8
15	7
16	9
17	9
18	7
19	9
20	5
AVERAGE	8,17



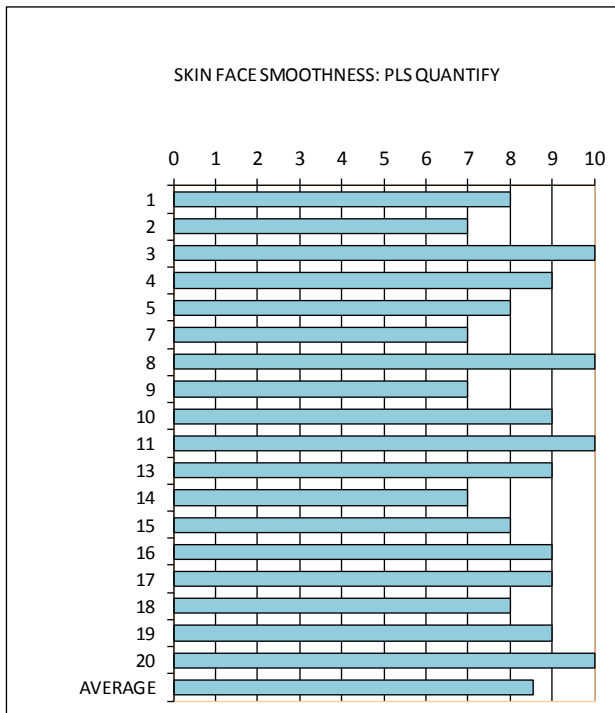
Panellist code	after 6 treatments
1	8
2	7
3	10
4	8
5	7
7	7
8	10
9	8
10	9
11	9
13	9
14	7
15	8
16	8
17	9
18	8
19	9
20	5
AVERAGE	8,11



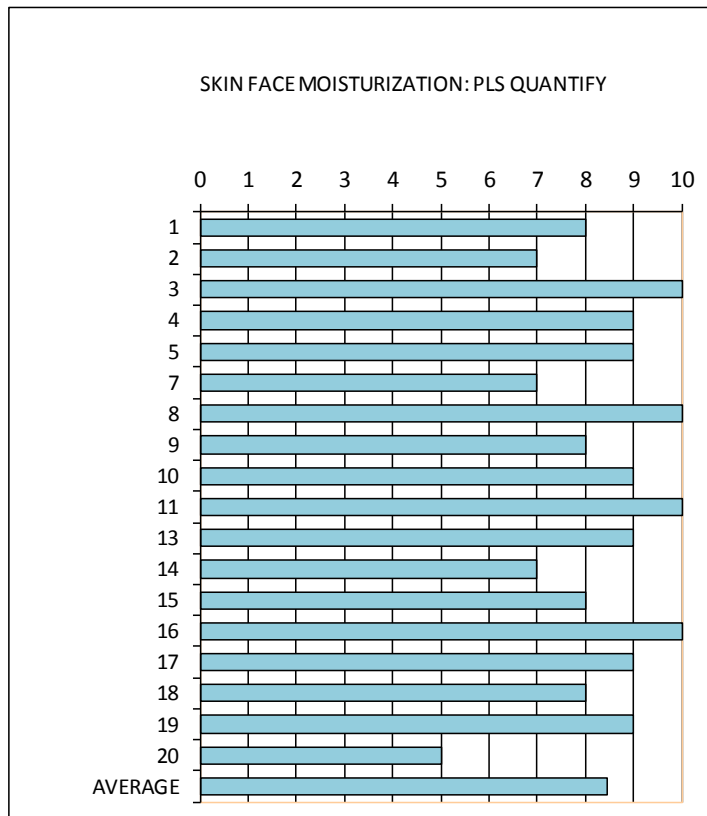
Panellist code	after 6 treatments
1	8
2	7
3	10
4	9
5	8
7	7
8	10
9	7
10	10
11	10
13	9
14	7
15	8
16	9
17	9
18	8
19	9
20	10
AVERAGE	8,61



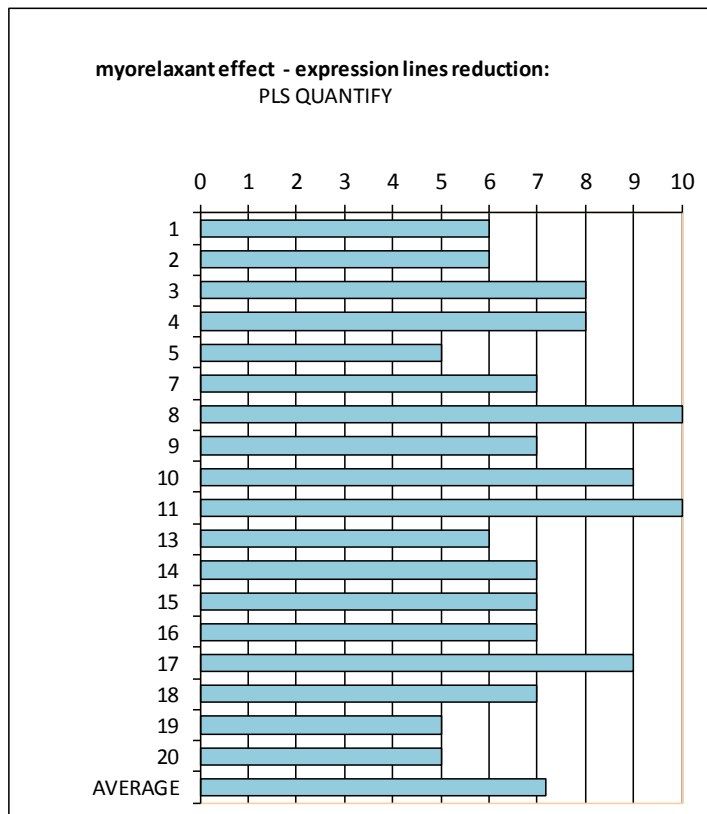
Panellist code	after 6 treatments
1	8
2	7
3	10
4	9
5	8
7	7
8	10
9	7
10	9
11	10
13	9
14	7
15	8
16	9
17	9
18	8
19	9
20	10
AVERAGE	8,56



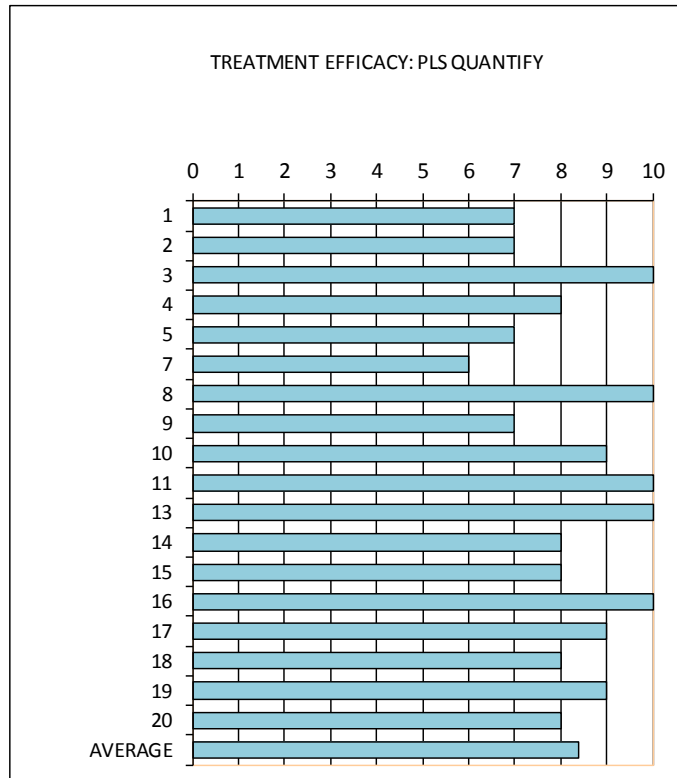
Panellist code	after 6 treatments
1	8
2	7
3	10
4	9
5	9
7	7
8	10
9	8
10	9
11	10
13	9
14	7
15	8
16	10
17	9
18	8
19	9
20	5
AVERAGE	8,44



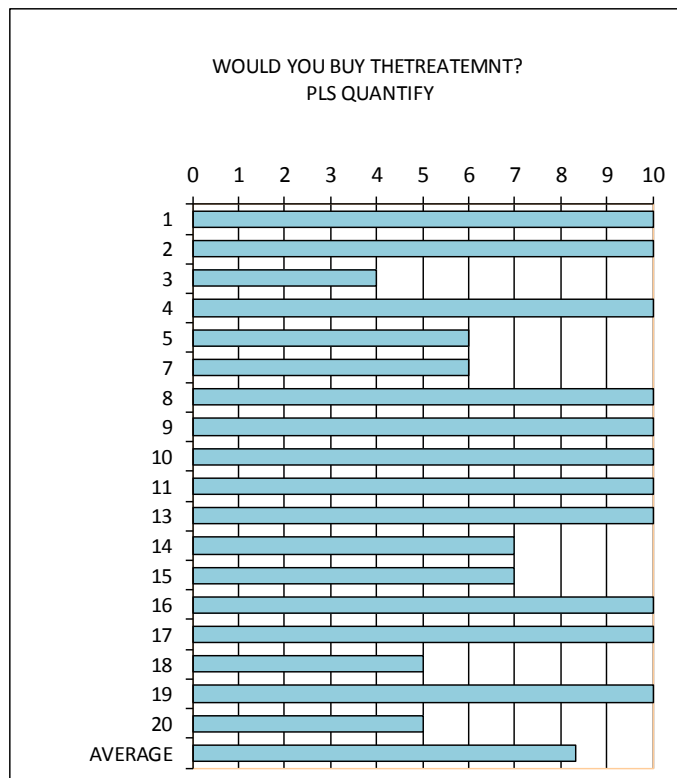
Panellist code	after 6 treatments
1	6
2	6
3	8
4	8
5	5
7	7
8	10
9	7
10	9
11	10
13	6
14	7
15	7
16	7
17	9
18	7
19	5
20	5
AVERAGE	7,17



Panellist code	after 6 treatments
1	7
2	7
3	10
4	8
5	7
7	6
8	10
9	7
10	9
11	10
13	10
14	8
15	8
16	10
17	9
18	8
19	9
20	8
AVERAGE	8,39



Panellist code	after 6 treatments
1	10
2	10
3	4
4	10
5	6
7	6
8	10
9	10
10	10
11	10
13	10
14	7
15	7
16	10
17	10
18	5
19	10
20	5
AVERAGE	8,33



CONCLUSIONS

According to the obtained results we can state that the treatment :

Apparecchiatura utilizzata: JetPeel3
Manipolo utilizzato: Manipolo a 3 uscite JTP-N01
Prodotto: BTX - NAT

can change in the period of treatment the instrumental and clinical parameters evaluated on the volunteers who underwent the clinical test. From the results obtained it can be said that the treatment has proved to help in reducing wrinkles visibility.

In particular, after 6 treatments:

Skin elasticity improves of 18%

- Skin compactness improves of 19% after
- Skin moisturization improves of 14%
- Wrinkles depth decreases of 11%
- Wrinkles VOLUME decreases of 21%
- Skin brightness improves in the 100% of the panelists
- Visibility of macro-wrinkles decreases in the 77.7% of the panelists
- Skin softness improves in the 77.7% of the panelists
- Very good acceptability

Experimenter

Dr. Fernando Marco BIANCHI

Monitor

Prof. Plinio RICHELMI

Quality Control

Dott. Claudio ANGELINETTA



Enclosure A : recruitment

Date (d/m/y) :

--	--	--	--	--	--

Volunteer no.:

--	--	--	--

Consent Form

Volunteer's initials

--	--	--	--

Title

Evaluation of the anti-wrinkles power of a professional cosmetic treatment through a clinical test

Sponsor

TAVTECH LTD.

Report no.1309F04F

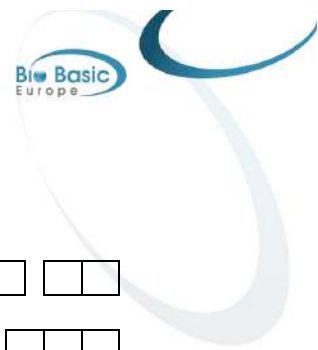
I confirm that the volunteer has read the enclosed informative form. The volunteer has had the opportunity to ask questions to which was given an exhaustive answer. The volunteer was explained the Objective, the method and the features of the clinical survey, benefits and possible discomforts. The volunteer has agreed to take part in the test.

Date:

--	--	--	--	--	--

Physician's name
(in block letters)

Physician's signature



Enclosure B : recruitment

Date (d/m/y) :

--	--	--	--	--	--

Volunteer no. :

--	--	--	--

Check of the inclusion and exclusion criteria

Volunteer's initials

--	--	--	--

Age: between 30 and 60 years old

SI	NO
YES	

Good state of general health

SI	NO
YES	

Absence of pharmacological treatment in progress until the selection

SI	NO
YES	

Promise not to change the usual daily routine

SI	NO
YES	

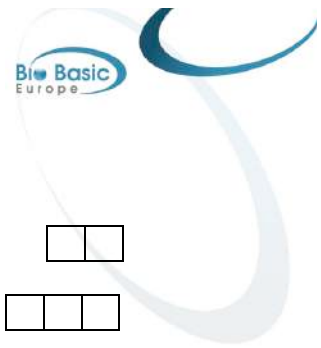
No psychological diseases

SI	NO
YES	

In compliance with the procedures mentioned in the survey the volunteer, after having been informed, has given his or her consent

SI	NO
YES	

ATTENTION: Just one mark indicating "no" is enough to bar the volunteer from the survey



Enclosure C : recruitment

Date (d/m/y) :

Volunteer no. :

Informative form

Volunteer's initials

Title

Evaluation of the anti-wrinkles power of a professional cosmetic treatment through a clinical test

Sponsor

TAVTECH LTD.

Report no.1309F04F

Introduction:

All tested cosmetic products have been formulated in accordance with REGULATION (EC) No1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products.

Scope

Through the test one can evaluate if the tested cosmetic treatment has got any anti-wrinkles cosmetic power.



Informative Form (Continuation)

The clinical data are strictly confidential

During or at the end of the test the promoters of the survey or some Health officers may have to examine your case file. The results could also be published . In any case your name will never be mentioned, unless if absolutely necessary and also in this case only to people - who like us - are subject to professional secrecy. All information gathered in the survey will remain strictly confidential and you won't be identified from it.

What happens, if you decide not to take part in the test ?

Your decision to take part in the test must be absolutely voluntary, you must not feel forced to. If you decide not to take part, you will neither run into any inconvenience nor lose any benefit which you enjoy at present. If you decide to interrupt the treatment, you can do it any time and you will neither run into any inconvenience nor lose any benefit you enjoy now. However, if you decide to interrupt it, you should inform your physician promptly and you had better come back for a check up. We ourselves reserve the right to interrupt the test if we feel it isn't any longer good for you.

You can ask questions or you can ask for an explanation any time before, during and after the treatment applying directly to:

Physician _____ Phone _____

who will attend you throughout the treatment.



Bibliography

Regulation (EC) no1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products.

Declaration of Helsinki - ethical principles for medical research involving human subjects

adopted by the 18th wma general assembly, Helsinki, Finland, June 1964, and consecutive amendments (last amendment: 59th wma general assembly, Seoul, October 2008)

Guidelines for the evaluation of the efficacy of cosmetic products, revised version may 2008

Cosmetics Europe – The personal care association -

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Via A. Panizzi, 10
MILANO ITALY