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Comparative evaluation of the skin tolerability, of the antiperspirant efficacy and of the acceptability of a cosmetic treatment through clinical test

JET PEEL TECHNOLOGY + JET SOLUTION SWEATLESS SERUM FUNCTIONAL LINE (active)
Vs
JET PEEL TECHNOLOGY + SERUM (placebo)

TAVTECH LTD

Report no. **1709G07F**

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SUMMARY

The purpose of this clinical test is to verify the skin tolerability and to evaluate the antiperspirant efficacy of a cosmetic treatment dedicated to the hyperhidrosis care.
Treatment acceptability is also evaluated.
This test was performed by a professional operator and monitored by a dermatologist, both members of Bio Basic Europe staff, as follows:
12 panellists, both male and female, with an age between 18 and 60 and with hyperhidrosis were recruited. Volunteers underwent 4 sessions (once per week for 28 consecutive days) of treatment performed by using the jet-peel technology in association with the active serum on the right armpit and with the placebo serum on the left armpit.
During the test, any changes affecting the skin such as erythema and oedema were recorded and the sweat amount produced in half working day (about 4 hour) was evaluated.
Moreover, all the evaluations given by volunteers in the sensorial test were collected after 28 days (after the four treatments using jet-peel) and at the end of this test. The score they gave is according to VNS scale (0-10 where 0 is the minimum value and 10 is the maximum value).
According to the results obtained in the volunteers who underwent the clinical test, we can state that the treatment has proved to have a good skin tolerability and a very good antiperspirant action.

EXPERIMENTAL PART

Report no 1709G07F

Title

Comparative evaluation of the skin tolerability, of the antiperspirant efficacy and of the acceptability of a cosmetic treatment through clinical test

Scope

The purpose of this clinical test is to verify the skin tolerability and to evaluate the antiperspirant efficacy of a cosmetic treatment dedicated to the hyperhidrosis care.
Treatment acceptability is also evaluated.

Legal information

In accordance with the current legislation and the declaration of Helsinki, all volunteers must be adequately informed of the aims, methods, clinical trial details, anticipated benefits and potential undesirable effects of the study. Each panellist must sign an informed consent form, which is managed and archived by applying the internal procedure of the Quality Management System of Bio Basic Europe S.r.l.

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.
- Experimentation performed at CDC - Dermo-clinic Research Institute

CLINICAL TEST FEATURES

Test subjects

12 subjects, both male and female, with an age between 18 and 60 years, were selected for the test, following the undermentioned inclusion criteria:

- hyperhidrosis;
- armpits depilated 24h prior the treatment (with razor or laser; not by using hair removal creams);

- good state of health/absence of psychological and/or cognitive disorders;
- no dermatopathies and allergic pathologies (to cosmetics or other specific excipient), or other pathologies (as unknown irritant responses);
- no ongoing pharmacological treatments that could affect the result of the test;
- no participations in other clinical trial during the previous 30 days;
- signature of the informed consent form.

Method of application of the samples

Panellists didn't use neither antiperspirants nor anti-bacterial or scented soaps during the 24 hours before the trial (wash-out period). They only used neutral soap for daily cleansing.

The treatment was performed as follows:

- 4 sessions (once per week for 28 consecutive days) of the jetpeel technology treatment performed by a professional operator (using the device in association with the active serum on the right armpit and with the placebo serum on the left armpit).

Blindness

This test was performed with a double-blind procedure:
the experimenter and the volunteers don't know which is the active products and which is the placebo product.

Ingredients (INCI):

JET SOLUTION SWEATLESS SERUM FUNCTIONAL LINE (active)

Aloe Barbadensis Leaf Juice, Aqua (Water), Propylene Glycol, Hamamelis Virginiana (Witch Hazel) Leaf Water, Methylpropanediol, Glycerin, Pentylene glycol, Acetyl Hexapeptide-8, Pentapeptide-18, Sodium Hyaluronate, Ginkgo Biloba Leaf Extract, Harpagophytum Procumbens Root Extract, Ruscus Aculeatus Root Extract, Aesculus Hippocastanum Seed Extract, Equisetum Arvense Extract, Achillea Millefolium Extract, Citric Acid, Caprylyl Glycol, Tetrasodium EDTA, Phenoxyethanol, Ethylhexylglycerin.

SERUM (placebo)

Sodio cloruro 9,0gr/1000 ml. Acqua per preparazioni iniettabili.

EXECUTION OF THE TEST

SKIN TOLERABILITY

The following clinical evaluations were assessed:

- skin alterations (erythema, edema)

ANTIPERSPIRANT EFFICACY

After having weight the disposable sweat pads by using the analytical balance, panellists put them under both armpits and keep them for half working day (about 4 hours).
After this period, the sweat pads are removed and the amount of sweat is evaluated gravimetrically by weighing them again.

The measurements and the evaluations are performed:

- at [t0] (basal value)
- at [t1]: after 3 weeks of treatment (before the 3rd jet peel session)
- at [t2]: after 5 weeks of treatment (1 week after the last jet peel session-the 4th one)
- at [t3]: after 56 days of treatment (1 month after the last jet peel session-the 4th one)
- at [t4]: after 84 days of treatment (2 months after the last jet peel session-the 4th one)

SELF-EVALUATION

Volunteers opinions were collected after the fourth session with jet peel technology [T2] and at the end of the test [T4]. This self-evaluation was performed according to VNS scale where 0 is the minimum value and 10 is the maximum value.

EVALUATION AND RECKONING OF THE RESULTS

ANTIPERSPIRANT EFFICACY

The statistical analysis was performed using two-sided Student « t » test.
We decided to fix the threshold of acceptability at 5%.

SKIN TOLERABILITY

The skin state of the volunteers during the treatment was evaluated.
To evaluate the variations of the skin parameters in a specific period, the following numerical values are given:

Skin alterations (erythema and oedema)			
Erythema		**Edema**	
No Erythema	0	No Edema	0
Slight Erythema (hardly visible)	1	Very slight Edema (hardly visible)	1
Clearly visible Erythema	2	Slight Edema	2
Moderate Erythema	3	Moderate Edema (about 1mm raised skin)	3
Serious Erythema (dark red with possible formation of light eschars)	4	Strong Edema (extended swelling even beyond the application area)	4

The variations of the skin parameters are reported in the summarizing tables and in the charts.

Summarizing Tables of the Values

SKIN TOLERABILITY

SKIN ALTERATIONS										
Panellist code	T0		T1		T2		T3		T4	
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0
Average	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

Slight side effects (redness) occurred soon after the jet peel device use.
These phenomena disappear few hours after the sessions.

ANTIPERSPIRANT ACTION

Active									
Ref. Vol.	Sweat amount (g)								
	T0	T1	T2	T3	T4	Δ T1-T0	Δ T2-T0	Δ T3-T0	Δ T4-T0
1	0,543	0,516	0,631	0,424	0,417	-0,027	0,088	-0,119	-0,126
2	0,658	0,506	0,433	0,457	0,402	-0,152	-0,225	-0,201	-0,256
3	0,266	0,195	0,130	0,136	0,156	-0,071	-0,136	-0,130	-0,110
4	0,795	0,854	0,796	0,696	0,768	0,059	0,001	-0,099	-0,027
5	0,180	0,178	0,220	0,249	0,256	-0,002	0,040	0,069	0,076
6	0,229	0,268	0,253	0,211	0,264	0,039	0,024	-0,018	0,035
7	0,405	0,392	0,373	0,469	0,448	-0,013	-0,032	0,064	0,043
8	0,684	0,717	0,623	0,559	0,439	0,033	-0,061	-0,125	-0,245
9	0,210	0,197	0,109	0,162	0,161	-0,013	-0,101	-0,048	-0,049
10	0,342	0,246	0,204	0,222	0,244	-0,096	-0,138	-0,120	-0,098
11	0,604	0,625	0,623	0,596	0,658	0,021	0,019	-0,008	0,054
12	0,667	0,643	0,572	0,574	0,650	-0,024	-0,095	-0,093	-0,017
Average	0,465	0,445	0,414	0,396	0,405	-0,020	-0,051	-0,069	-0,060

Survey times	Number of observations	Average	Standard deviation	p-value	Significance (p-value<0,05)
T0	12	0,465	0,2175		
T1	12	0,445	0,2317	0,266489	no
T2	12	0,414	0,2313	0,076105	no
T3	12	0,396	0,1922	0,014245	yes
T4	12	0,405	0,2019	0,087472	no

Comparing to the value obtained at T0 (basal value) , the sweat amount produced in a half working day (about 4 hours) decreases:

- of 4% at T1 (statistically significant)
- of 11% at T2 (statistically significant)
- **of 15% at T3 (statistically significant)**
- of 13% at T4 (statistically significant)

Placebo									
Ref. Vol.	Sweat amount (g)								
	T0	T1	T2	T3	T4	Δ T1-T0	Δ T2-T0	Δ T3-T0	Δ T4-T0
1	0,545	0,511	0,629	0,464	0,472	-0,034	0,084	-0,081	-0,073
2	0,636	0,516	0,463	0,493	0,484	-0,120	-0,173	-0,143	-0,152
3	0,253	0,169	0,197	0,155	0,202	-0,084	-0,056	-0,098	-0,051
4	0,824	0,862	0,829	0,751	0,773	0,038	0,005	-0,073	-0,051
5	0,190	0,150	0,240	0,275	0,249	-0,040	0,050	0,085	0,059
6	0,201	0,270	0,295	0,178	0,236	0,069	0,094	-0,023	0,035
7	0,392	0,419	0,366	0,434	0,461	0,027	-0,026	0,042	0,069
8	0,679	0,670	0,607	0,592	0,598	-0,009	-0,072	-0,087	-0,081
9	0,193	0,187	0,149	0,159	0,185	-0,006	-0,044	-0,034	-0,008
10	0,368	0,294	0,290	0,326	0,288	-0,074	-0,078	-0,042	-0,080
11	0,592	0,585	0,628	0,685	0,660	-0,007	0,036	0,093	0,068
12	0,679	0,673	0,635	0,693	0,641	-0,006	-0,044	0,014	-0,038
Average	0,463	0,442	0,444	0,434	0,437	-0,021	-0,019	-0,029	-0,025

Survey times	Number of observations	Average	Standard deviation	p-value	Significance (p-value<0,05)
T0	12	0,463	0,2237		
T1	12	0,442	0,2315	0,212966	no
T2	12	0,444	0,2177	0,417454	no
T3	12	0,434	0,2166	0,205071	no
T4	12	0,437	0,2024	0,24025	no

Comparing to the value obtained at T0 (basal value) , the sweat amount produced in a half working day (about 4 hours) decreases:

- of 4% at T1 (no statistically significant)
- of 4% at T2 (no statistically significant)
- of 6% at T3 (no statistically significant)
- of 5% at T4 (no statistically significant)

Comparison between right and left armpit

RIGHT AXILLA – ACTIVE vs LEFT AXILLA - PLACEBO			
Survey times	**Number of observations**	**p-value**	**Significance (p-value<0,05)**
T0	12	0,977016	no
T1	12	0,997642	no
T2	12	0,004478	yes
T3	12	0,004991	yes
T4	12	0,004995	yes

Before products use, no difference between the two areas was observed.

At T2, T3 and T4, statistically significant differences in means between the area treated with active products and the area treated with placebo products were observed. In particular, the sweat amount produced in a half working day (about 4 hours) decreases more in the area treated with the active product.

SELF-EVALUATIONS

Did you notice a sweating reduction?

Vol. Ref.	Active		Placebo	
	T2	T4	T2	T4
1	6	7	5	5
2	8	8	7	7
3	7	8	6	6
4	5	8	3	7
5	5	5	3	3
6	6	7	3	5
7	7	7	5	5
8	7	8	4	6
9	8	7	6	6
10	7	8	6	6
11	7	7	5	5
12	7	8	5	6
Average:	6,6	7,3	4,8	5,6

Did you notice a sweating reduction under stress conditions as well?

Vol. Ref.	Active		Placebo	
	T2	T4	T2	T4
1	7	7	5	5
2	8	8	6	8
3	8	7	6	6
4	6	7	3	6
5	6	7	3	3
6	7	7	3	5
7	8	7	5	5
8	8	8	5	6
9	8	7	6	6
10	8	9	6	7
11	6	6	3	3
12	7	8	5	6
Average:	7,25	7,33	4,7	5,5

CONCLUSIONS

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

JET PEEL TECHNOLOGY
+
JET SOLUTION SWEATLESS SERUM FUNCTIONAL LINE (active)

in the volunteers who underwent the clinical test, has proved to have a good skin tolerability and a very good antiperspirant action.

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