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Preliminary evaluation of the effect and of the acceptability of a cosmetic treatment through clinical test

MESOJET DESIGN + 73803 - SPAMED - JET TECH EUROPE ACNE SOLUTION

TAVTECH LTD

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SUMMARY

The purpose of this clinical test is to assess, on a preliminary basis, the effect of a cosmetic treatment in reducing the visibility of imperfections caused by acne and to evaluate its acceptability.
This test was performed by a professional operator and monitored by a dermatologist as follows:
10 panellists, both male and female, with an age between 16 and 30 years and with mild to moderate acne were recruited and underwent 4 sessions of the treatment (one every two days).
Before the treatment, after the first session and after the fourth session, the following instrumental and clinical parameters were evaluated: skin sebum, average skin pores area, blemish redness (erythema) and visibility of imperfections.
Moreover, all the evaluations given by volunteers in the sensorial test were collected 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 on a preliminary basis that the treatment has proved to have an effect reducing the visibility of imperfections caused by acne and a good acceptability.

EXPERIMENTAL PART

Report no 1801N17F

Title

Preliminary evaluation of the effect and of the acceptability of a cosmetic treatment through clinical test

Scope

The purpose of this clinical test is to assess, on a preliminary basis, the effect of a cosmetic treatment in reducing the visibility of imperfections caused by acne and to evaluate its acceptability.

In particular, the following instrumental and clinical parameters were evaluated: skin sebum, average skin pores area, blemish redness (erythema) and visibility of imperfections. Self-evaluations were also taken.

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

10 subjects, both male and female, with an age between 16 and 30 years, were selected for the test, following the undermentioned inclusion criteria:

- mild to moderate acne

- 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 underwent 4 sessions of the treatment (one every two days) performed a professional operator (using the device in association with the JET TECH EUROPE ACNE SOLUTION).

Ingredients (INCI):

73803 - SPAMED - JET TECH EUROPE ACNE SOLUTION

AQUA, BUTYLENE GLYCOL, ALOE BARBADENSIS LEAF JUICE, SEBACIC ACID, 10-HYDROXYDECANOIC ACID, 1,10-DECANEDIOL, PEG-40 HYDROGENATED CASTOR OIL, ETHOXYDIGLYCOL, GLYCERIN, PALMITOYL TRIPEPTIDE-8, PHYTIC ACID, HEPTAPEPTIDE-10, HYDROLYZED NETTLE LEAF EXTRACT, DEXTRAN, PHENOXYETHANOL, SODIUM OLEATE, GLYCINE SOJA OIL, DISODIUM EDTA, HYDROGENATED LECITHIN, POTASSIUM SORBATE, SODIUM SALICYLATE

EXECUTION OF THE TEST

INSTRUMENTAL PARAMETERS

- Measurements of **sebum** were taken by using **SEBUMETER® SM 815**

This is a direct measurement of the sebum secretion on skin and hair scalp.
The measurement principle is the photometric method, the grease spot photometer.
For the determination of the sebum, the measuring head of the cassette is inserted into the aperture of the device, where a photocell measures the transparency. The light transmission represents the sebum content on the surface of the measuring area. A microprocessor calculates the result, which is shown on the display in units from 0-350.

- Measurements of **average skin pores area** were performed by using Antera 3D® and the dedicated software Antera 3D®.

Antera 3D® is a camera able to capture images at high resolutions. Thanks to the use of an innovative method and complex mathematical algorithms, the device is able to acquire 3D images.
Antera 3D software allows to analyse volume and area of some characteristics of the skin which are deep-set in comparison to the normal skin surface. Therefore, this function allows to measure the average area of pores of a specific skin area. The measurements are expressed in mm^2.

- Measurements of **blemish redness (erythema)** were performed by using Antera 3D® and the dedicated software Antera 3D®.

Antera 3D software allows to measure the erythema index on a specific skin area. The measured value is the average concentration of hemoglobin per surface unit of the selected area.

CLINICAL PARAMETERS

- **Visibility of imperfections**

The measurements and the clinical evaluations were taken:

- at [t0] (basal value)
- After the first session of the treatment (20 minutes after the session) [T1]
- After the fourth session of the treatment (20 minutes after the session) [T4]

SELF-EVALUATIONS

Volunteers opinions were collected after the fourth session of the treatment [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

INSTRUMENTAL PARAMETERS

The statistical analysis was performed using Paired t-test: we decided to fix the threshold of acceptability at 5% .

CLINICAL PARAMETERS

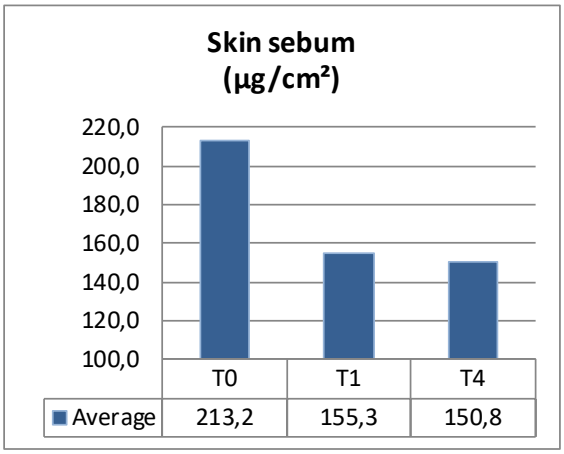
The statistical analysis was performed using the Wilcoxon test: we decided to fix the threshold of acceptability at 5%. To carry out a statistical survey and to be able to evaluate the skin variations in a specific period, the following parameters were analysed:

Visibility of imperfections	Opinion
No visible imperfections	Absent
Slightly visible imperfections	Slight
Moderately visible imperfections	Moderate
Evident imperfections	Evident
Very evident imperfections	Very evident

Summarizing Tables of the Values

INSTRUMENTAL and CLINICAL PARAMETERS

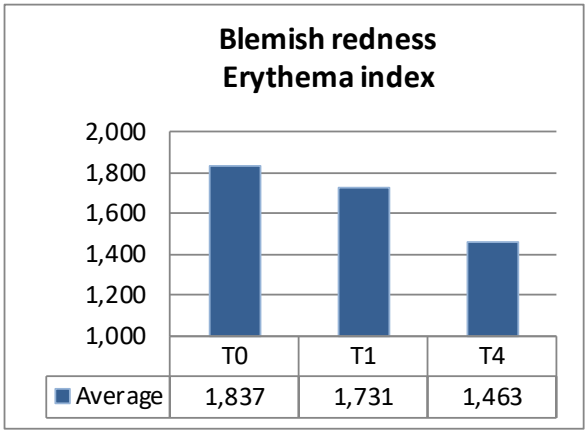
Skin sebum (µg/cm²)			
Vol. ref	**T0**	**T1**	**T4**
1	218,0	163,0	185,0
2	204,0	121,0	123,0
3	230,0	190,0	159,0
4	198,0	175,0	154,0
5	250,0	169,0	161,0
6	196,0	137,0	147,0
7	205,0	133,0	140,0
8	177,0	134,0	136,0
9	213,0	162,0	149,0
10	241,0	169,0	154,0
Average	213,2	155,3	150,8



Survey times	Number of observations	Average	Standard deviation	p-value	Significance (p-value<0,05)
T0	10	213,2	22,1650375		
T1	10	155,3	22,4452420	5,721E-06	**yes**
T4	10	150,8	16,6252820	3,921E-06	**yes**

Skin sebum reduces of:
- 27%, after the first session of the treatment (statistically significant)
- 29%, after the fourth session of the treatment (statistically significant)

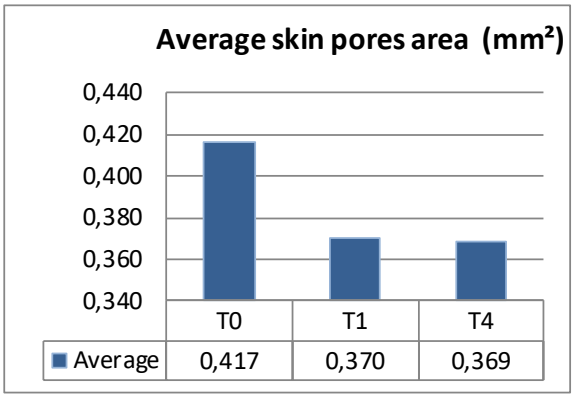
Blemish redness Erythema index			
Vol. ref	**T0**	**T1**	**T4**
1	1,581	1,393	1,399
2	2,072	1,958	1,515
3	1,703	1,528	1,537
4	1,740	1,787	1,766
5	1,724	1,645	1,250
6	1,856	1,668	1,361
7	2,027	1,868	1,520
8	1,825	1,744	1,384
9	1,680	1,609	1,232
10	2,157	2,105	1,661
Average	1,837	1,731	1,463



Survey times	Number of observations	Average	Standard deviation	p-value	Significance (p-value<0,05)
T0	10	1,837	0,1898966		
T1	10	1,731	0,2095441	0,0014936	**yes**
T4	10	1,463	0,1705906	0,0001841	**yes**

Blemish redness (erythema) reduces of:
- 6%, after the first session of the treatment (statistically significant)
- 20%, after the fourth session of the treatment (statistically significant)

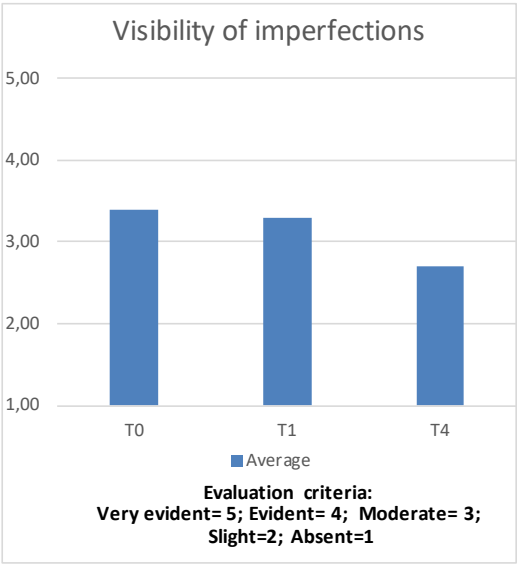
Average skin pores area (mm²)			
Vol. ref	**T0**	**T1**	**T4**
1	0,492	0,426	0,439
2	0,436	0,364	0,358
3	0,604	0,564	0,602
4	0,356	0,316	0,319
5	0,365	0,273	0,180
6	0,299	0,281	0,273
7	0,539	0,464	0,475
8	0,380	0,365	0,393
9	0,336	0,310	0,313
10	0,358	0,340	0,335
Average	0,417	0,370	0,369



Survey times	Number of observations	Average	Standard deviation	p-value	Significance (p-value<0,05)
T0	10	0,417	0,0986557		
T1	10	0,370	0,0909298	0,0005448	**yes**
T4	10	0,369	0,1168333	0,0233191	**yes**

Average skin pores area reduces of:
- 11%, after the first session of the treatment (statistically significant)
- 11%, after the fourth session of the treatment (statistically significant)

Visibility of imperfections			
Panellist code	**T0**	**T1**	**T4**
1	Moderate	Moderate	Moderate
2	Very evident	Very evident	Evident
3	Evident	Evident	Evident
4	Slight	Slight	Slight
5	Moderate	Moderate	Slight
6	Moderate	Slight	Slight
7	Evident	Evident	Moderate
8	Moderate	Moderate	Slight
9	Evident	Evident	Moderate
10	Moderate	Moderate	Slight
Average	Moderate 3,40	Moderate 3,30	Moderate 2,70

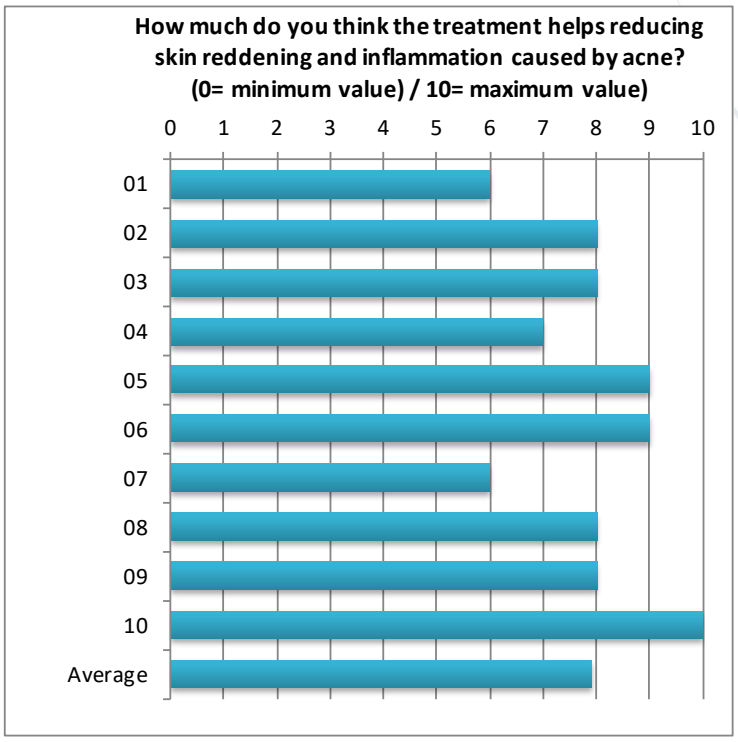


α	*0,05*	Code	2				Significance
T0 - T1	n	1	T	0	T-crit	--	**no**
T0 - T4	n	7	T	0	T-crit	2	**yes**

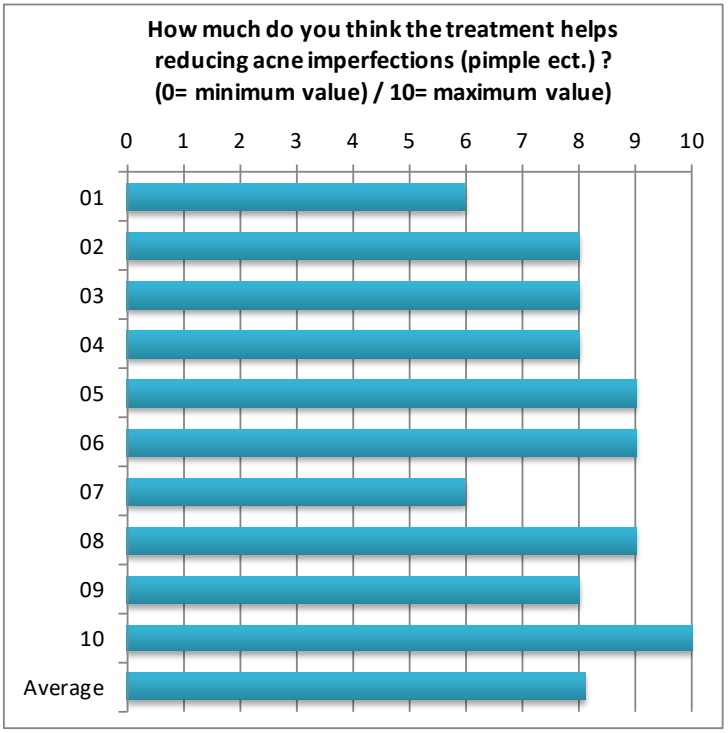
Visibility of imperfections reduces in the
- 5% of the volunteers after the first session of the treatment (no statistically significant)
- 70% of the volunteers, after the fourth session of the treatment (statistically significant)

SELF-EVALUATIONS

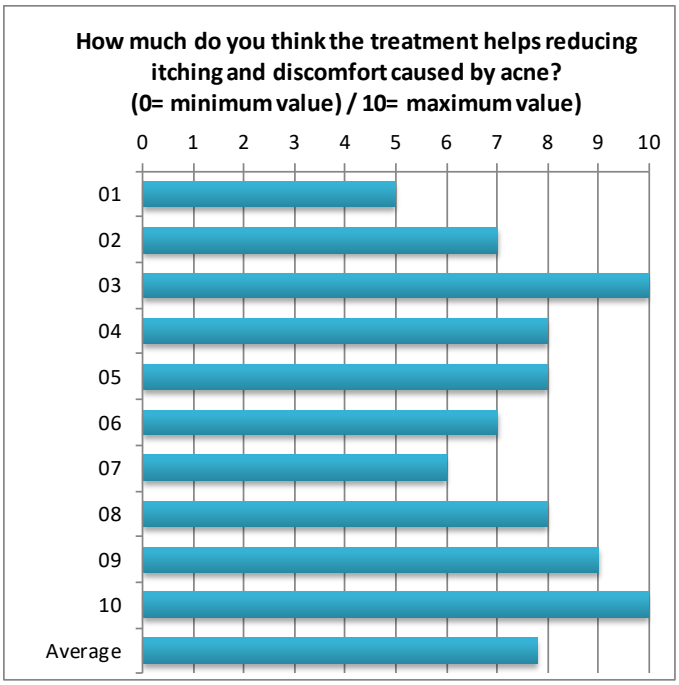
Vol. Ref.	T4
01	6
02	8
03	8
04	7
05	9
06	9
07	6
08	8
09	8
10	10
Average	7,9



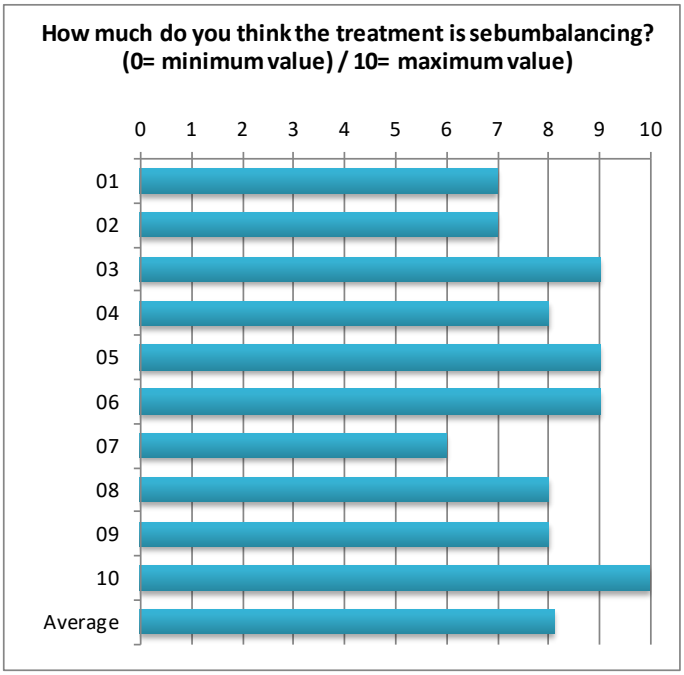
Vol. Ref.	T4
01	6
02	8
03	8
04	8
05	9
06	9
07	6
08	9
09	8
10	10
Average	8,1



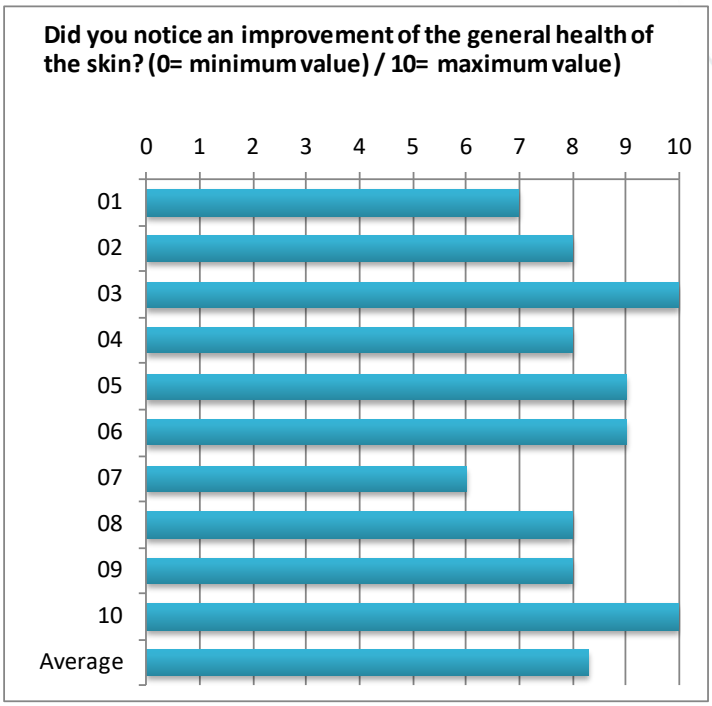
Vol. Ref.	T4
01	5
02	7
03	10
04	8
05	8
06	7
07	6
08	8
09	9
10	10
Average	7,8



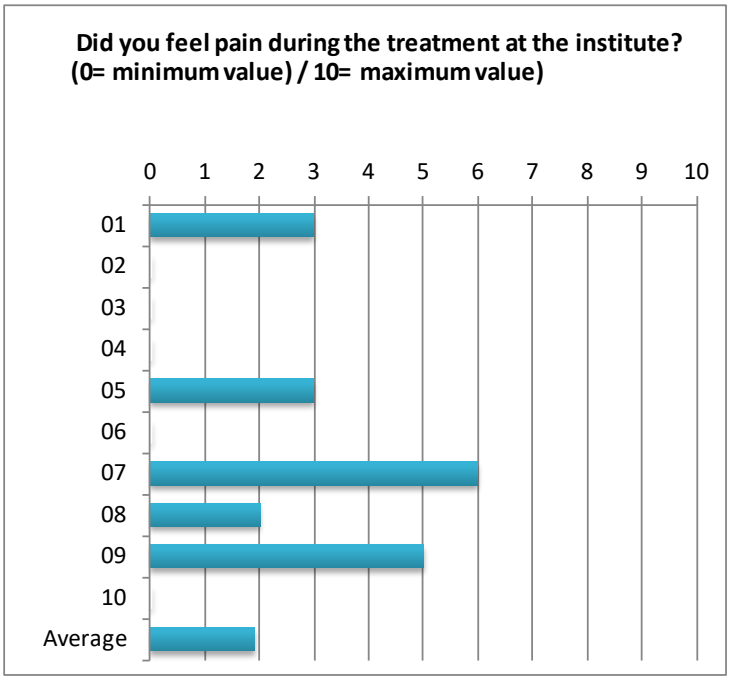
Vol. Ref.	T4
01	7
02	7
03	9
04	8
05	9
06	9
07	6
08	8
09	8
10	10
Average	8,1



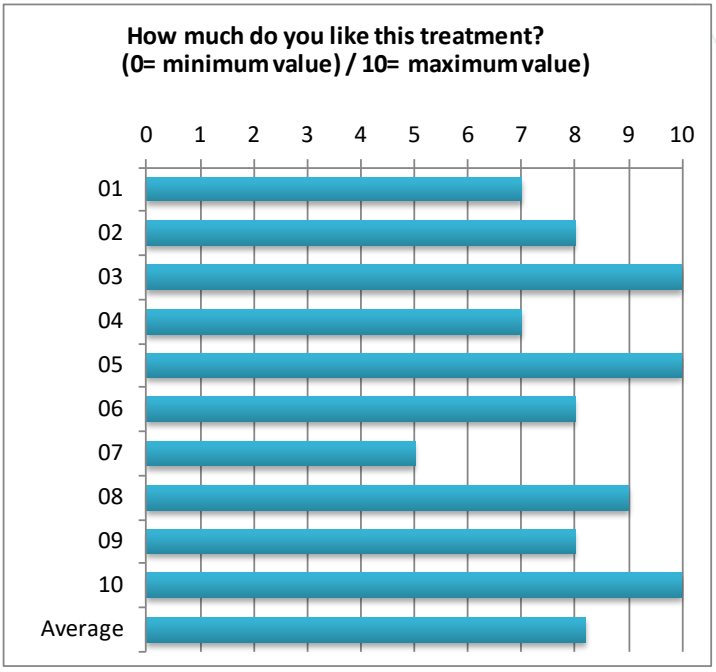
Vol. Ref.	T4
01	7
02	8
03	10
04	8
05	9
06	9
07	6
08	8
09	8
10	10
Average	8,3



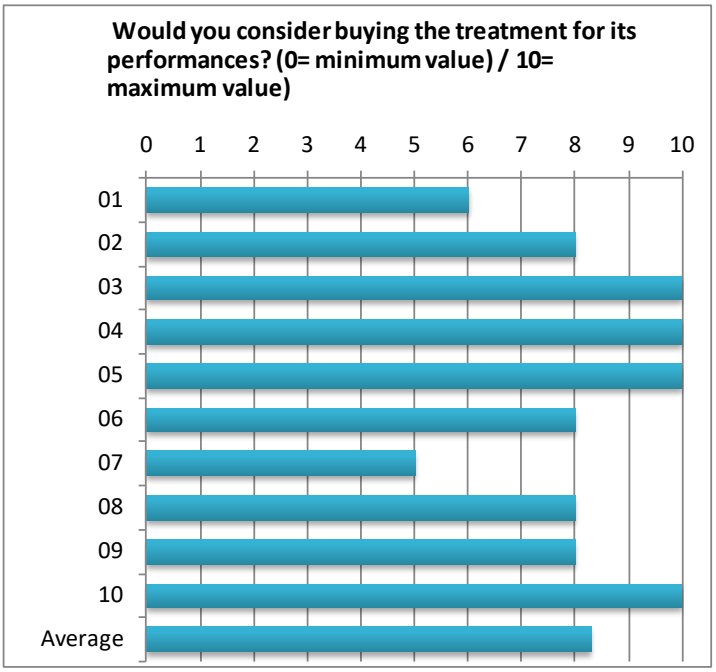
Vol. Ref.	T4
01	3
02	0
03	0
04	0
05	3
06	0
07	6
08	2
09	5
10	0
Average	1,90



Vol. Ref.	T4
01	7
02	8
03	10
04	7
05	10
06	8
07	5
08	9
09	8
10	10
Average	8,2



Vol. Ref.	T4
01	6
02	8
03	10
04	10
05	10
06	8
07	5
08	8
09	8
10	10
Average	8,3



CONCLUSIONS

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

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on a preliminary basis, has proved to have an effect reducing the visibility of imperfections caused by acne and a good acceptability.

Experimenter

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Quality Control

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