



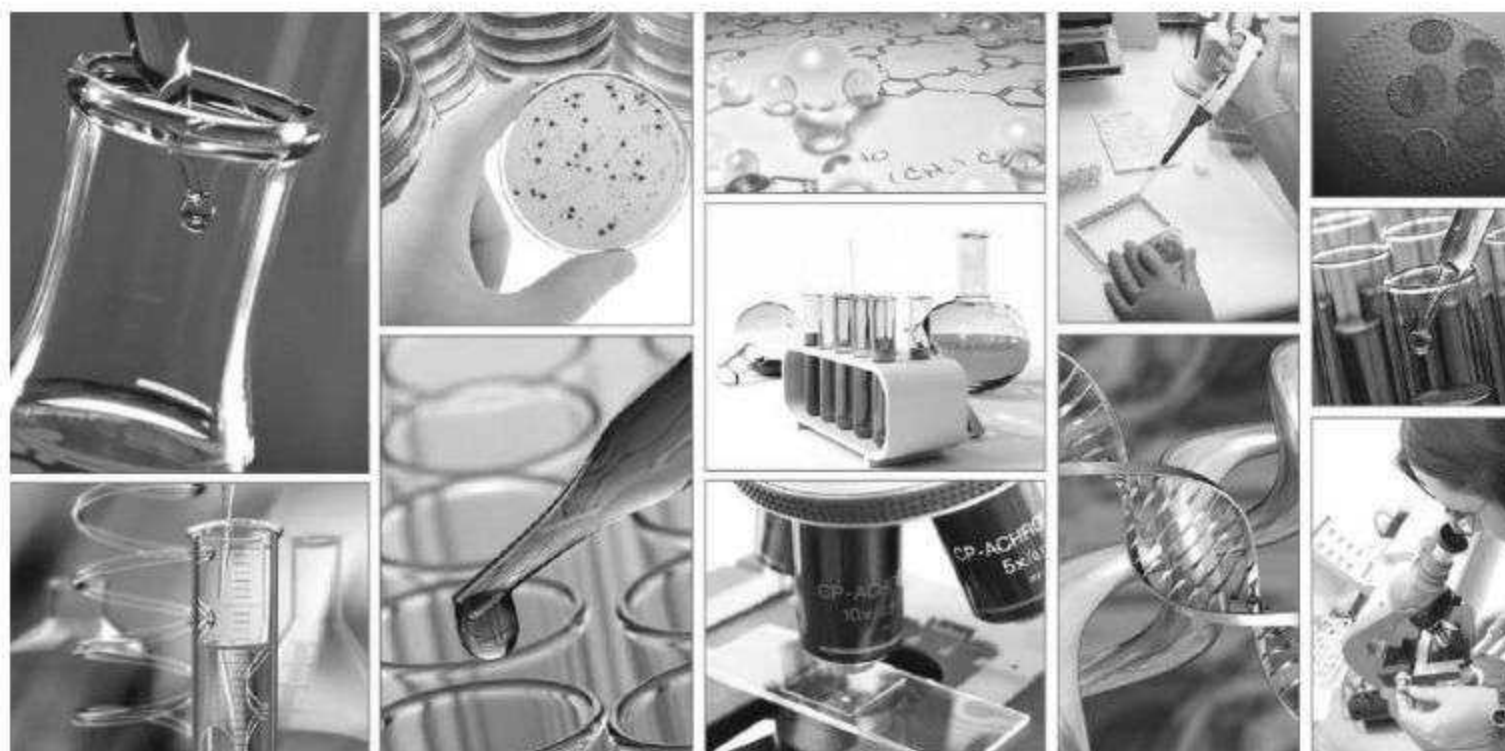
STUDY REFERENCES:

VV_ET-4/20DXT2(D)-A_703_21_001, VV_ET-SC/20DXT2(D)-B_703_21_001,

Study report - Version nº 1

EVALUATION OF THE EFFICACY OF A COSMETIC PRODUCT UNDER DERMATOLOGICAL CONTROL

- Subjective appreciation of organoleptic characteristics and efficacy



CUSTOMER: CHAMORRO BENAVIDES SAS BIC

TESTED PRODUCT: ACEITE FACIAL OLLETO OIL

REFERENCE: INZOF1021

BATCH: OFA1021

Madrid, March 4th, 2022

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Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
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1. SYNOPSIS

SPONSOR	CHAMORRO BENAVIDES SAS BIC CARRERA 8 5 71, VALLE DEL GUAMUEZ, PUTUMAYO
Tested product:	ACEITE FACIAL OLLETO OIL
Date of order:	26.08.2021
Testing Facility:	ZURKO RESEARCH S.L. Osa Mayor 4. 28023, Madrid (Spain). Tel: (+34) 91.521.15.88
Supervisor of Study:	Lorena Bellas Domínguez, Biologist
Study code:	VV_ET-4/20DXT2(D)-A_703_21_001, VV_ET-SC/20DXT2(D)-B_703_21_001,
Subjects:	Number of subjects enrolled: 23 Gender: female and male Age range: 18 - 70 years old Number of subjects completed: 22
Experimental area:	Face and neck
Application:	Duration: 28 days Frequency: twice a day, in the mornings and at nights
Test period:	20/01/2022 to 18/02/2022
Test parameters:	Evaluation of luminosity efficacy with Colorimeter CL 400. Dermatological assessment by clinical grading: reduction of the size and color of the spots. Dermatologist assessment of tolerance. Subjective questionnaire
Design of study:	<u>DOT0 (before product application)</u> : Measurements of luminosity efficacy, clinical grading of the color and size of the spots and dermatological assessment of tolerance <u>D28 (after 28 days of continuous use of the product)</u> : Measurements of luminosity efficacy, clinical grading of the color and size of the spots, dermatological assessment of tolerance and subjective questionnaire
Evaluation:	Descriptive statistics (average, standard deviation, variation percentages) and importance: Mixed Linear - Effects Models and Wilcoxon Signed - Rank Test Graphical evaluation and percentage summary.

Results

All the results detailed below are statistically significant with a p-value lower than 0,05.

- **Dermatological assessment of efficacy**
 - After 28 days of continuous use of the product, color of the skin spots decreases an average of 26 % in relation to the baseline.

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

- After 28 days of continuous use of the product, the size of the skin spots decreases an average of 18 % in relation to the baseline.

- **Subjective efficacy**

After 28 days of continuous use of the product, most of the panelists had a positive opinion about the organoleptic characteristics, where 86% of the panelists were satisfied with the general opinion of the product.

According to the subjective efficacy after 28 days of continuous use of the product, 82% of the panelists were satisfied with the result on the skin and 82% of the panelists would buy the product.

- **Dermatological assessment of tolerance**

According to the clinical examination performed by the dermatologist, none of the panelists showed any skin alteration after 28 days of continuous use of the product.

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

2. IDENTIFICATION OF THE STUDY

Name of the study: Evaluation of the efficacy of a cosmetic product under dermatological control. Subjective appreciation of organoleptic characteristics and efficacy.

Director of the Laboratory: María Barbero Calderón.

Head of Efficacy Department: Lorena Bellas Domínguez.

Sponsor: CHAMORRO BENAVIDES SAS BIC.

Sponsor address: CARRERA 8 5 71, VALLE DEL GUAMUEZ, PUTUMAYO.

Tested element: ACEITE FACIAL OLLETO OIL, reference: INZOF1021, batch: OFA1021.

3. OBJECTIVE AND PRINCIPLE OF THE STUDY

The objective of this study is to evaluate the instrumental and dermatological efficacy and the acceptability, subjective efficacy and tolerance of the product, **ACEITE FACIAL OLLETO OIL**, reference: **INZOF1021**, batch: **OFA1021**, in 20 panelists for a period of 28 days using the product according to the conditions stipulated by the customer.

To evaluate the product efficacy, the following biometric measurements were carried out:

- **Evaluation of the luminosity** by means of the evaluation with **Colorimeter® CL 400** device (Courage & Khazaka electronic), the first day before the application of the product (baseline) and 28 days after the continuous use of the product.

In addition, a dermatological evaluation of efficacy by clinical grading was carried out to evaluate the efficacy of the product:

- **Clinical grading**: evaluating the reduction of the size and color of the spots effect the first day before the application of the product (baseline) and 28 days after the continuous use of the product.

Additionally, the acceptability of the product was measured by means of a subjective evaluation of the efficacy and by the evaluation of organoleptic properties. Other characteristics of the product were also assessed by means of subjective evaluation.

Therefore, this study has as objective to evaluate the acceptability, subjective efficacy and tolerance of the panelists that participated in the study, and to perform the dermatological following-up of the possible adverse symptoms that could appear with the use of the product.

The study will be carried out in accordance with ethical principles registered in the latest version of the Declaration of Helsinki.

4. TYPE OF STUDY

This test was performed under dermatological control in the Experimental Centre.

The study was carried out following general conditions in Zurko Research, established for the execution of study projects on humans (Structure and Content of Clinical Study Reports from ICH Harmonized Tripartite Guideline; Guideline for good clinical practice E6 (R2) of June 14th, 2017, EMA/CHMP/ICH/135/1995 of May 1st, 1996, European Parliament and Council Guideline 2001/20/CE – May 1st, 2001).

Previously, Zurko Research assessed the suitability of the product for the type of study and the methodology to be employed.

5. RESEARCH CENTER

5.1. Research Centre

ZURKO RESEARCH, S.L.

Osa Mayor 4

28023 Madrid (Spain)

Tel: (+34) 915 211 588

5.2. Research team

Director of the Laboratory: María Barbero Calderón, Pharmacist.

Head of Efficacy Department: Lorena Bellas Domínguez, Biologist.

Dermatologist: Javier Pedraz Muñoz. Medical license number: 283706434.

Technicians: Lorena González Flores, Magdalena González Rodríguez, Sara Ruiz Mayorga, Delia Urbina García.

Statistician: Raquel Chica Martínez.

6. STUDY SCHEDULE

Beginning of the experimental phase: January 20th, 2022.

End of the experimental phase: February 18th, 2022. *

*Due to different recruitment phases

7. PANELISTS

7.1. Ethical aspects

Each panelist participating in the study was previously informed about the type and the procedures of the study and signed an informed consent before the beginning of the study. The original informed consents were archived in Zurko Research.

7.2. Number of panelists

23 panelists were included in the study. The number of panelists required at the end of the study 20.

One of the panelists (V18) left the study at D28 for reasons unrelated to it. None of the panelists were excluded by the researcher due to not fulfilling the inclusion criteria.

Therefore, the efficacy was verified in 22 at the end of the study.

The participants in the study complied with the following criteria of inclusion and exclusion, checked through the recruitment questionnaire (Annex I).

7.3. Specific inclusion criteria

The specific inclusion criteria, defined in the protocol, were as follow:

- Age: 18 - 70 years old,
- Gender: female and male,
- Skin type: all skin types (sensitive skin and resistant skin),
- Presence of spots,
- Good health,
- Availability for the length of the study,
- Understanding the information about the objective and development of the study,
- Signing of the informed consent.

7.4. Specific exclusion criteria

The specific exclusion criteria, defined in the protocol, were as follow:

- Presence of pathologies in the experimental area,
- Presence of pathologies that may interfere with the study,
- Presence of relevant dermatological pathologies (atopic dermatitis, psoriasis, lupus rosacea, ringworm...),
- Panelists who have been subjected to an extraction or transplantation of organs; panelists who have suffered a cranial trauma with lengthy loss of consciousness in the last five years, or subjects with cranial trauma with current sequelae,

*Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,*

- To present cardiovascular, digestive, neurological, psychiatric, genital, urinary, hematological or endocrine progressive alteration,
- To present immunodeficiency,
- Previous history of medicinal, cosmetics, healthcare, household, industrial products (especially latex, aluminum or nickel) intolerance,
- Previous history of allergies, photosensitivity or phototoxicity,
- Progressive cutaneous alteration,
- Progressive febrile process,
- Metabolic photodermatitis: porphyria, tryptophan metabolism disorders,
- Panelists under treatment with antibiotics, antihistaminics, corticosteroids, beta blockers, retinoids, azelaic acid, anti-acne treatments or with a treatment completed during the 15 days prior to the study,
- Panelists who have taken treatment with topical or oral anti-inflammatory in the week before the study,
- Application of other similar topical products in the experimental area during the study,
- Application of other cosmetic types not usually used in the experimental area,
- Being pregnant or breastfeeding,
- Presence of allergies to this type of cosmetic products,
- Participation in any other study that would interfere with the current study,
- Refusal to sign the informed consent form.

The panelists were warned about the possible adverse or disgusting reactions of the product and its reversibility. In case of any adverse reaction or doubt of it, the panelists were advised to suspend immediately the application of the product, and to contact the center that would inform the specialists responsible for the clinical evaluation.

The complete availability of the panelists was also confirmed so as not to compromise the clinical and subjective evaluation at the end of the study.

8. METHODOLOGY

8.1. Criteria for application of the product

Product type: Leave on.

Experimental area: Face and neck.

Recommended amount: 3 drops (0,21 grams).

Frequency of use: Twice a day, in the mornings and at nights.

Duration of the study: 28 days.

Preliminary action: The experimental area must be clean.

Application instructions: Circular massages until completely absorbed.

Precautions: Do not ingest.

8.2. Experimental procedure

Summary of the experimental procedure:

D0	23 panelists signed the informed consent and filled in a recruitment questionnaire	
	Verification of the inclusion criteria	The researcher verified the specific inclusion and exclusion criteria of panelists
	Evaluation of luminosity efficacy	Colorimeter® CL 400
	Clinical grading	Reduction of the size and color of the spots
	Tolerance	Dermatological assessment of tolerance
D28	Evaluation of luminosity efficacy	Colorimeter® CL 400
	Clinical grading	Reduction of the size and color of the spots
	Subjective efficacy	Subjective questionnaire after 28 days of use of the product
	Tolerance	Dermatological assessment of tolerance
	22 panelists filled in the subjective product questionnaire	

8.3. Biometric measurements

Environmental conditions:

On the days of measurement, the panelists participating in the study remained in an acclimatized room for 20 – 30 minutes, with the following conditions:

Temperature $20^{\circ}\pm 2^{\circ}\text{C}$ and relative humidity 40-60%.

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

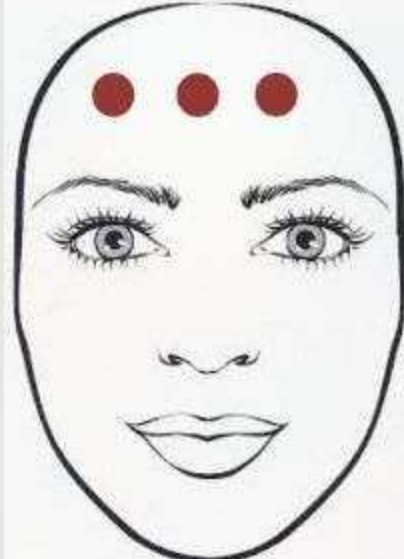
Device Colorimeter® CL 400: Measurement of luminosity efficacy

The skin color efficacy on the skin was evaluated by the **Colorimeter® CL 400** (Courage + Khazaka electronic GmbH, Germany) before the product application (baseline) and after 28 days of continuous use of the product.

The measurement principle is based on the ability of the probe to emit a white LED light, to uniformly illuminate the skin. The light reflected by the skin is measured on the probe. The data obtained is corrected by a color matrix so that they are as close as possible to normalized values.

The value to be evaluated is:

- L*: that measures the skin brightness. The higher the value, the lighter the skin.

Colorimeter® CL 400		
Panelist	Age Gender Number of panelists	18 - 70 years old Female and male D0 (n=23) D28 (n=22)
Test site	Anatomical location	Forehead 
Environmental conditions	Room temperature Ambient air relative humidity	20°C 40-60%
Experimental times	General Duration of the study	Baseline: D0 D28
Measurement	Number of consecutive measurements	3
Statistical study	Distribution: Normal distribution P-value	T test on the linear mixed-effect model parameters P<0,05 (confidence interval 95%).

8.4. Dermatological tolerance assessment

On the first day of attendance at the center, the dermatologist, together with the researcher, verified the inclusion and exclusion criteria defined for the study. In case of non-compliance with any criteria, the panelist involved would be excluded before starting the study. At the same time, a visual evaluation of the skin of the panelist in the experimental area was carried out, evaluating the type of skin and possible alterations that could be present before the use of the product.

At the end of the study, the dermatologist and the researcher in charge of the study performed the same evaluation as at the beginning.

The alterations evaluated will be desquamation, dryness, acne prone skin, redness, spots, oedema, vesicles and others on a five-point scale (0: absence, 1: very slight, 2: slight, 3: moderate, 4: intense). In those cases where the panelists would show a different skin alteration, the dermatologist would also take a note of it. It will be also indicated if the observed alterations could be related to the use of the product, according to the scale Not related, Improbable, Possible, Probable, Sure or Not Valuable.

The interpretation of the results of the dermatological examination was collected in individual evaluation sheets.

8.5. Dermatological evaluation of efficacy: clinical grading

The first day before the product application, and 28 days after the continuous use of the product, the dermatologist evaluates the intensity of:

- Color of the skin spots
- Size of the skin spots

For the evaluation of color of the skin spots, a 5-point scale is used. The scale runs from grade 0 to grade 4. Grade 0 represents absence of the parameter and grade 4 represents a higher intensity of the parameter evaluated

For the evaluation of the size of the skin spots, a 5-point scale is used. The scale runs from grade 0 to grade 4. Grade 0 represents the absence of spot and 4 represents a severe presence of spot.

8.6. Subjective evaluation

At D0 and D28, panelists completed a questionnaire answering questions concerning the acceptability, efficacy and tolerance of the product.

For the global appreciation and organoleptic characteristics of the product and global appreciation and characteristics of the packaging, a hedonic scale of five points is used:

- 5: I like it very much,
- 4: I like it slightly,
- 3: I neither like it nor dislike it,
- 2: I dislike it slightly,
- 1: I dislike it very much.

For evaluate the absorption of the product on the skin after the application, a scale of 5 points was used:

- Very quick
- Quick
- Intermediate
- Slow
- Very slow

For evaluate the greasy feeling during the application and the greasy residue after the absorption, a scale of 4 points was used:

- Nothing
- Little
- Quite a lot
- A lot

For the efficacy of the product a hedonic scale of five points is used:

- 5: Completely agree,
- 4: Agree,
- 3: Neither agree nor disagree,
- 2: Disagree,
- 1: Completely disagree.

Panelists with opinions between 4 and 5 are considered satisfied.

*Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,*

In the questionnaire of subjective evaluation that the panelists completed at the end, also questions relative to the tolerance were included after the continued use of the product. In case the panelist detected unpleasant symptoms, they would fill a questionnaire of Notification Form of Unwanted Effects with the help of the researcher and specialists.

8.7. Statistical study of the results

Descriptive statistics of results from biometric parameters were reported for each experimental time, including average, standard deviation and plots of results.

Individual data were reported as individual values for each experimental time (Annex II).

Multiple biometric measurements along time (consecutive measurement within panelist, panelists assessed on several days), and subsequently correlated observations, were considered by including random effects at test subject level and by allowing the intercept to vary randomly among subjects.

Linear Mixed-Effect Models (LMM) were fitted to evaluate the efficacy of the treatment along times for luminosity efficacy. The effect of the treatment on the biometric measurements was interpreted comparing each evaluation time with respect to the baseline.

Wilcoxon Signed- Rank Test was used to evaluate the dermatological assessment of efficacy: clinical grading (color of the skin spots and size of the skin spots). The effect of the treatment on the biometric measurements was interpreted comparing each evaluation time with respect to the baseline time.

A significance value of 0,05 was established (95% confidence interval).

9 RESULTS

9.1. Dermatological assessment of tolerance

Evaluation of alterations associated with the use of the product

The dermatologist evaluated the changes present in the panelists and indicated those related to the use of the product.

No panelists showed any skin alterations after 28 days of continuous use of the product.

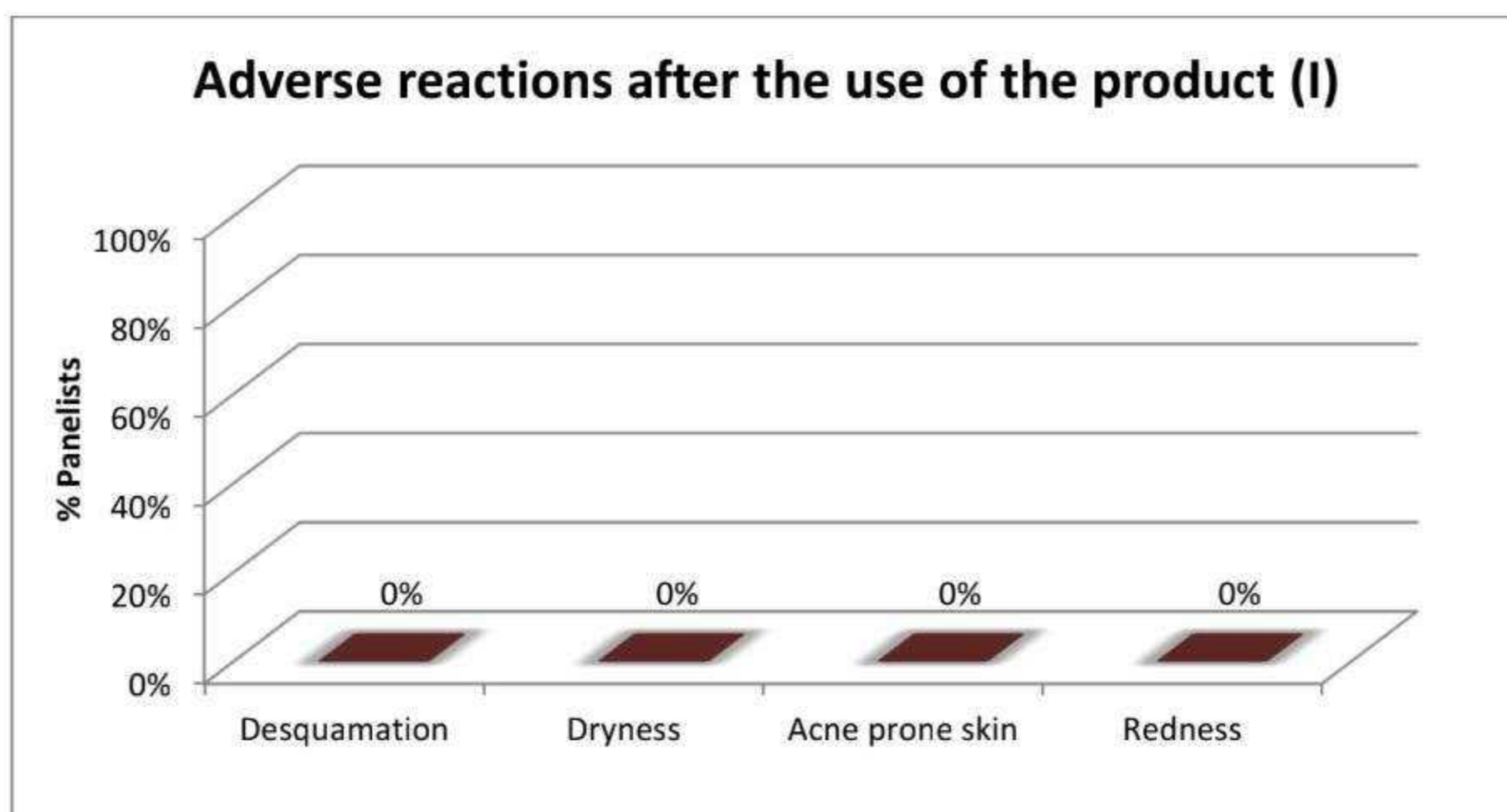


Figure 1. Percentage of alterations on the skin after the use of the product (n=22).

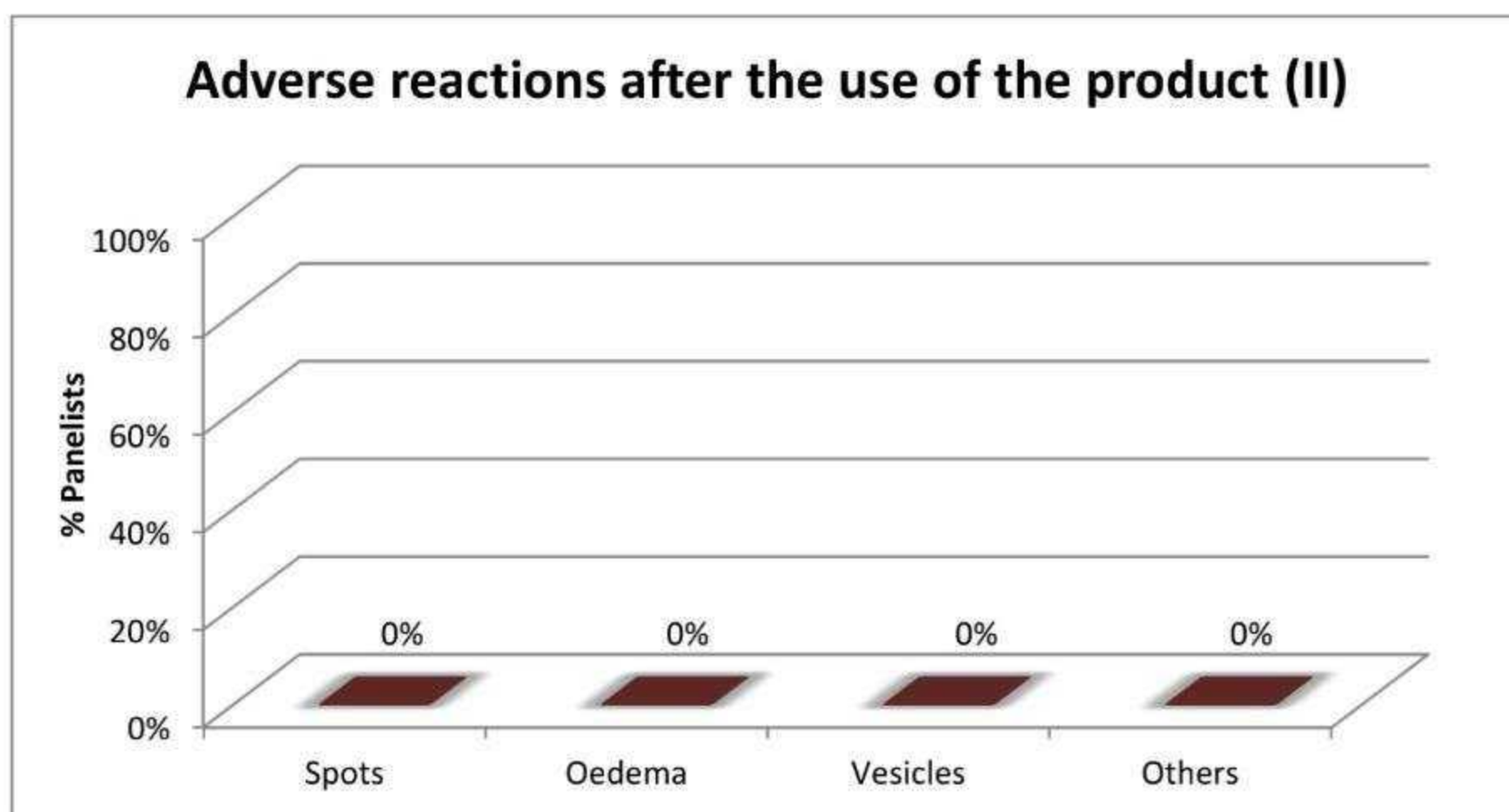


Figure 2. Percentage of alterations on the skin after the use of the product (n=22).

9.2. Instrumental efficacy

9.2.1. Evaluation of luminosity efficacy

The individual data (absolute values for each measurement) at different times are included in Annex II.

The following table shows the descriptive statistics of the skin luminosity value (L^* value), the average, the standard deviation, the percentage of absolute variation with respect to baseline and the percentage of panelists with improvement. The second part of the table shows the results of the statistical analysis that evaluates the differences in relation to baseline. The table shows the predicted average, the standard error, the t-test, the p-value and the significance.

Luminosity efficacy		
	D0	D28
Average	58,64	58,31
Standard deviation	3,63	4,79
% of absolute variation with respect to D0	-	-1%
% of panelists with improvement	-	45%
LINEAR MIXED-EFFECTS MODELS (D28 Vs. D0)		
Predicted average	58,64	58,51
Standard error	0,84	0,32
t test	-	-0,41
p value	-	0,68
Significance	-	NS

Table 1. Descriptive analysis (D0: n=23 and D28: n=22) and significance for luminosity efficacy.

- After 28 days of continuous use of the product, luminosity decreases an average of 1% in relation to the baseline. This difference is not statistically significant with a p-value higher than 0,05.

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

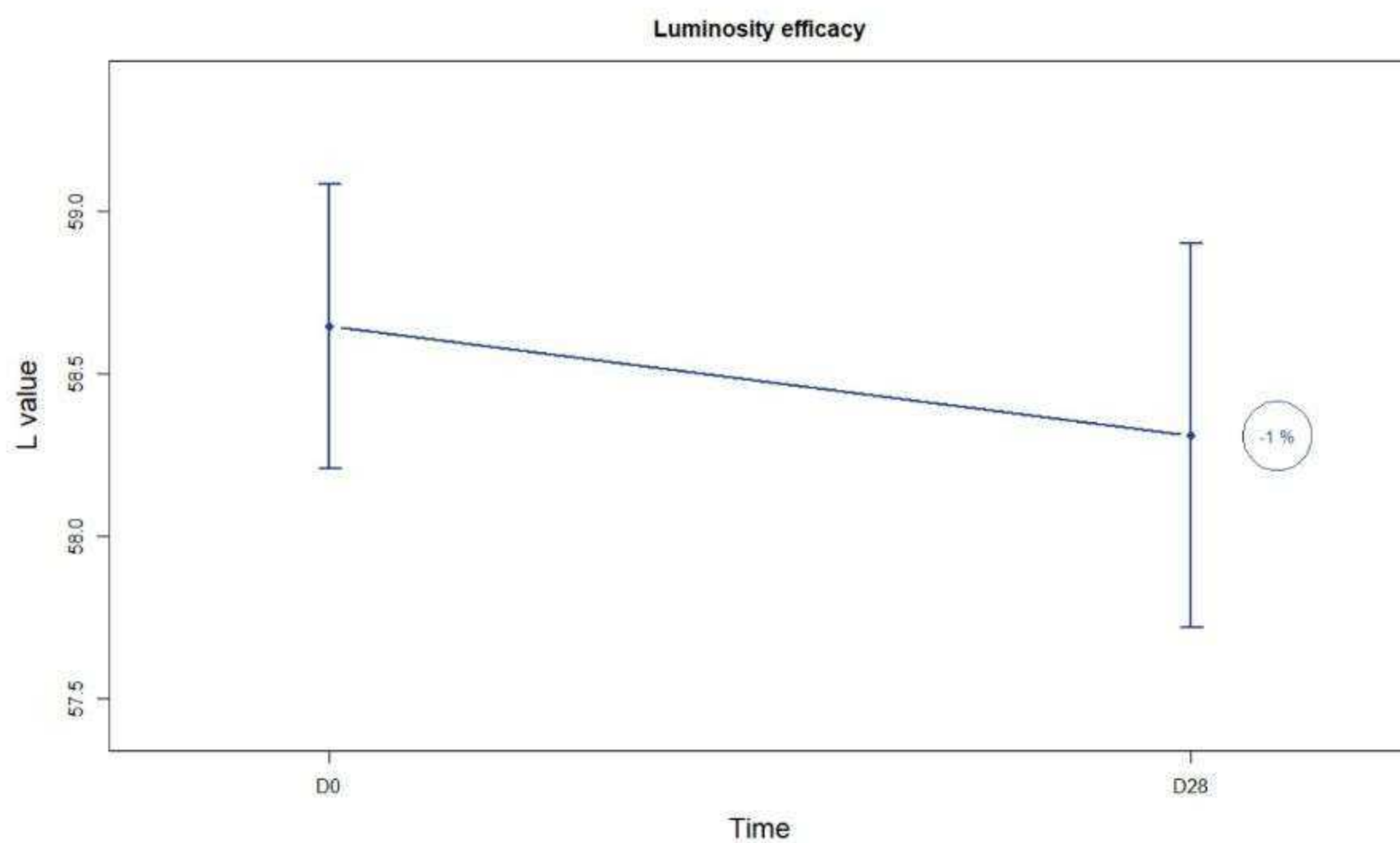


Figure 3. L value average $\pm$ SD over time (D0 and D28).

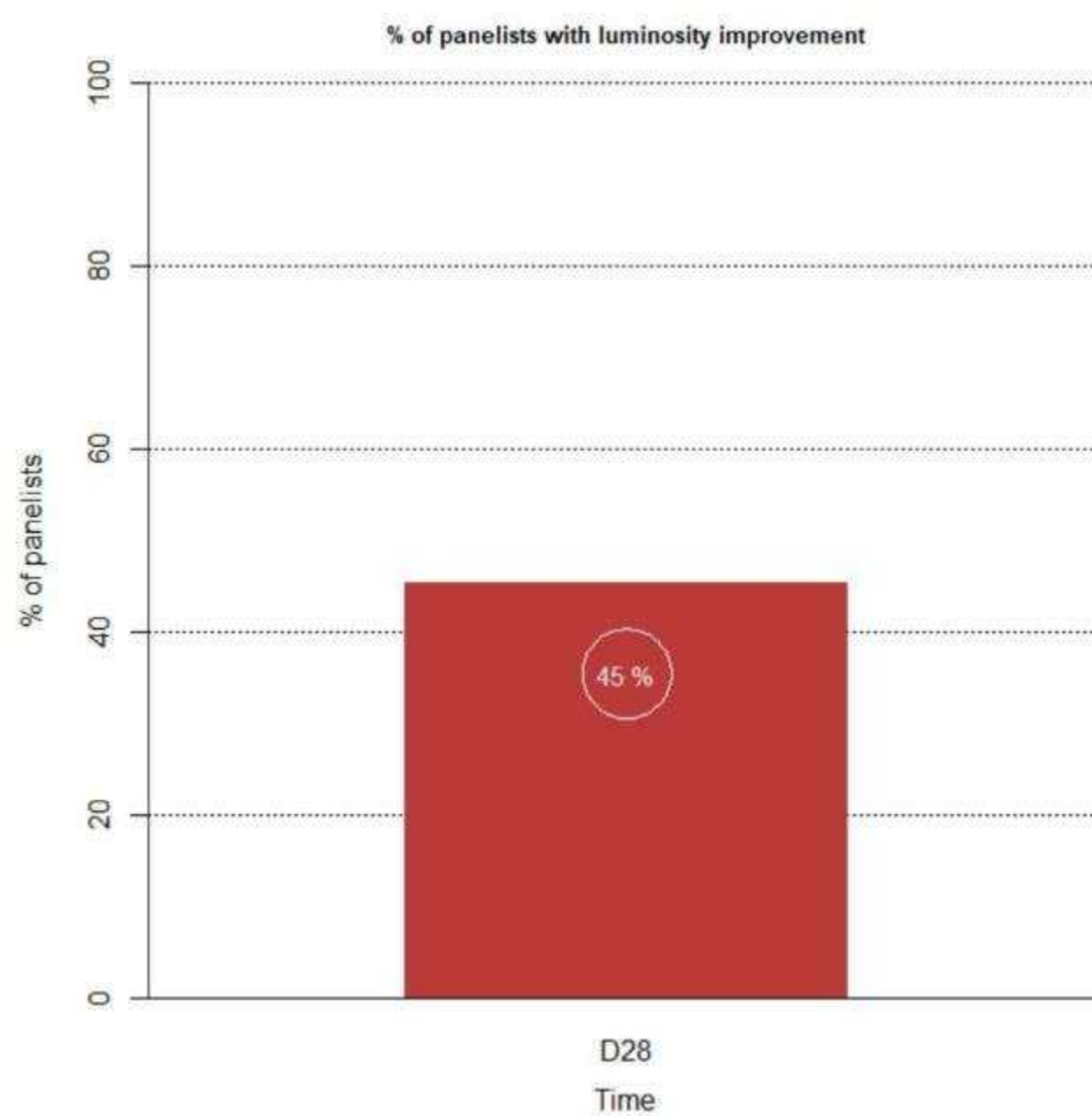


Figure 4. % of panelists with luminosity improvement (D28).

9.3. Dermatological assessment of efficacy: clinical grading

9.3.1. Color of the skin spots

The individual data (absolute values for each measurement) at different times are included in Annex II.

The following table shows the descriptive statistics of the color of the skin spots after 28 days of continuous use of the product, the average, the standard deviation, the percentage of absolute variation with respect to baseline and the percentage of panelists with improvement. The second part of the table shows the results of the statistical analysis that evaluates the differences at different times. The table shows the V-value, the p-value and the significance.

Dermatological evaluation: Color of the skin spots		
	D0	D28
Average	3,09	2,27
Standard deviation	0,68	1,03
% of absolute variation with respect to D0	-	-26%
% of panelists with improvement	-	77%
WILCOXON SIGNED-RANK TEST (D28 Vs. D0)		
V-value	-	153,00
p value	-	6,37E-05
Significance	-	S

Table 2. Descriptive analysis and significance for color of the skin spots (n=22).

- After 28 days of continuous use of the product, color of the skin spots decreases an average of 26 % in relation to the baseline. This difference is statistically significant with a p-value lower than 0,05.

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

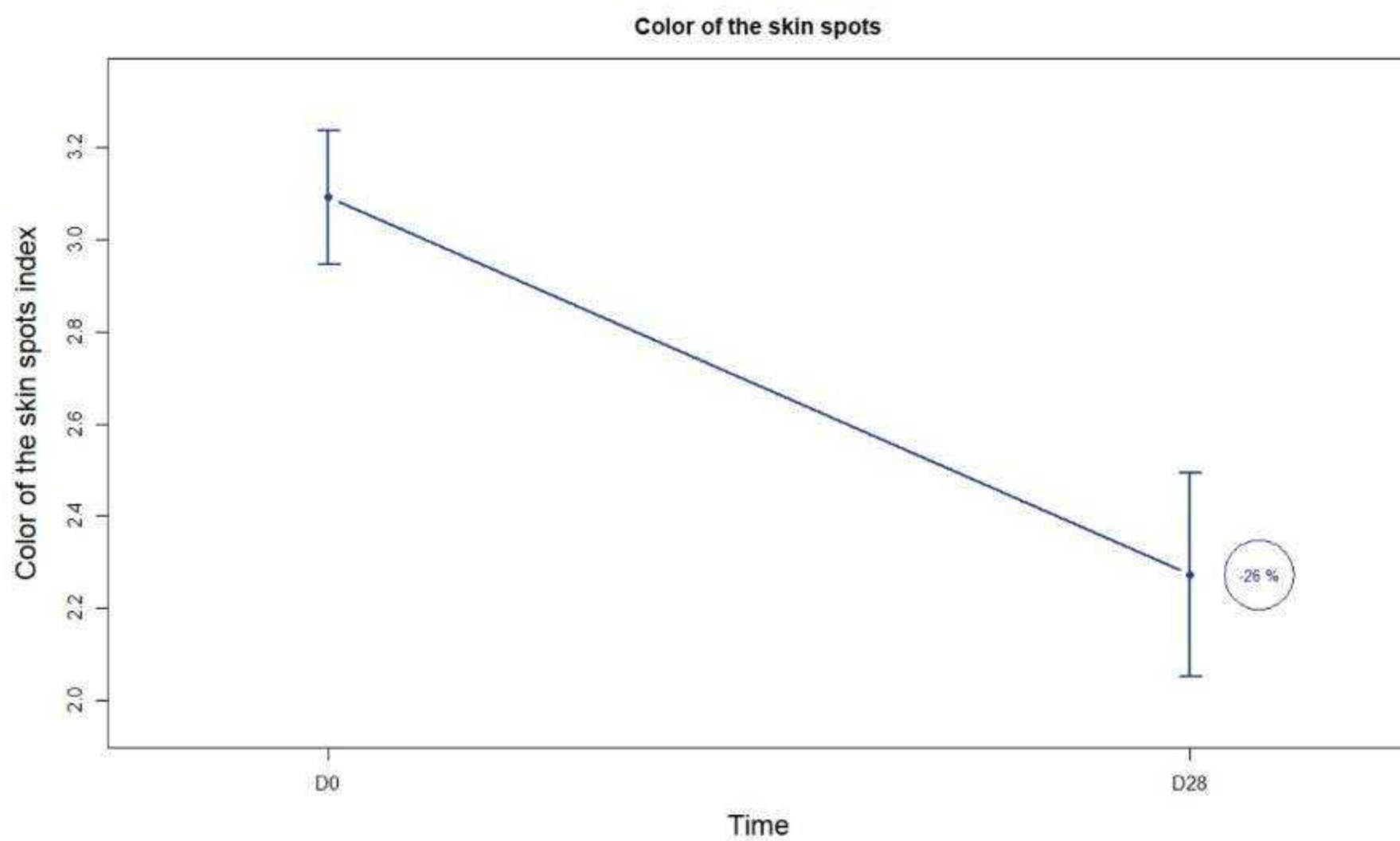


Figure 5. Color of the skin spots index $\pm$ SD over time (D0 and D28).

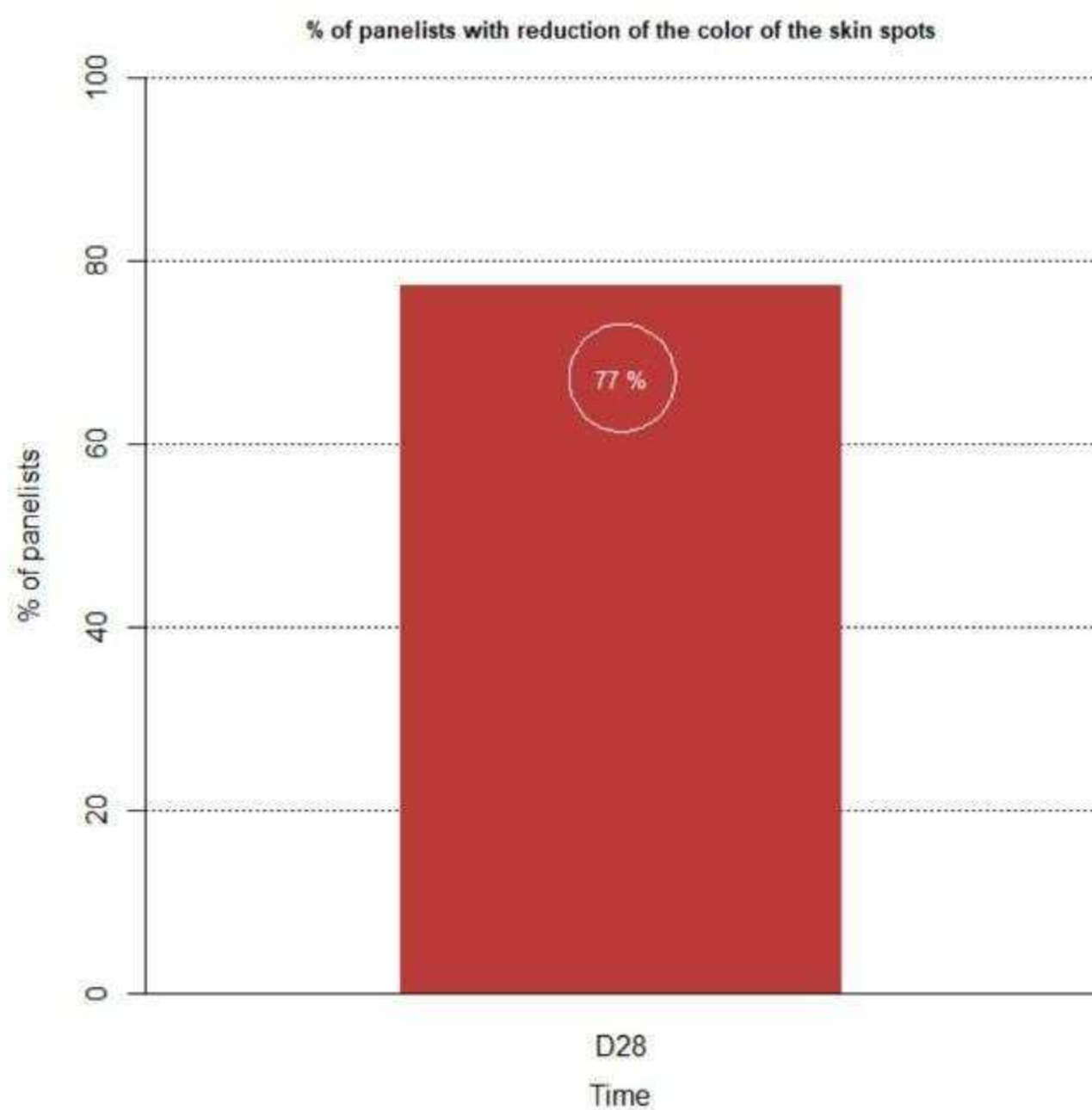


Figure 6. % of panelists with reduction of the color of the spots (D28).

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

9.3.2. Size of the skin spots

The individual data (absolute values for each measurement) at different times are included in Annex II.

The following table shows the descriptive statistics of the size of the skin spots after 28 days of continuous use of the product, the average, the standard deviation, the percentage of absolute variation with respect to baseline and the percentage of panelists with improvement. The second part of the table shows the results of the statistical analysis that evaluates the differences at different times. The table shows the V-value, the p-value and the significance.

Dermatological evaluation: Size of the skin spots		
	D0	D28
Average	2,95	2,41
Standard deviation	0,84	0,96
% of absolute variation with respect to D0	-	-18%
% of panelists with improvement	-	50%
WILCOXON SIGNED-RANK TEST (D28 Vs. D0)		
V-value	-	66,00
p value	-	1,59E-03
Significance	-	S

Table 3. Descriptive analysis and significance for size of the skin spots (n=22).

- After 28 days of continuous use of the product, the size of the skin spots decreases an average of 18 % in relation to the baseline. This difference is statistically significant with a p-value lower than 0,05.

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

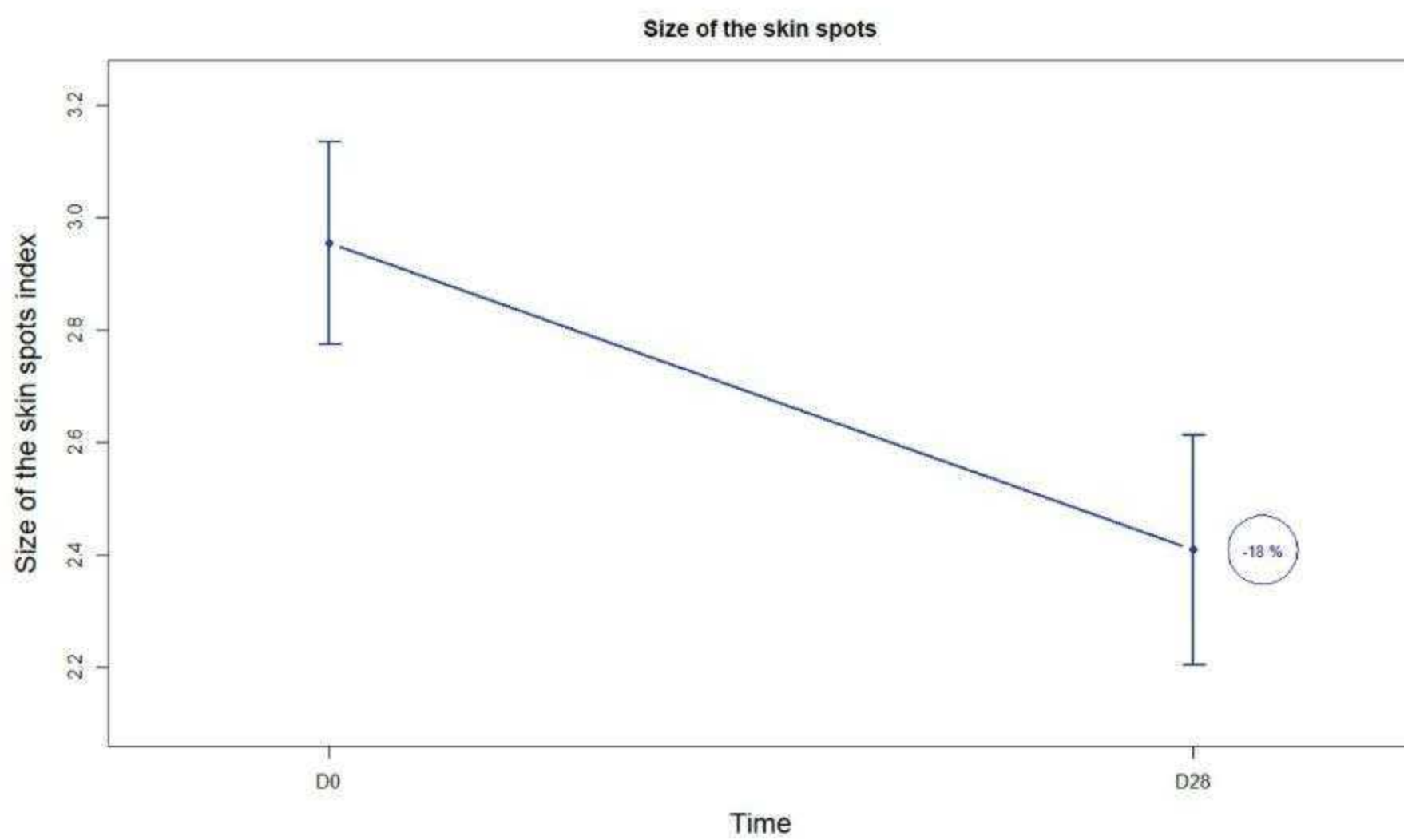


Figure 7. Size of the skin spots index $\pm$ SD over time (D0 and D28).

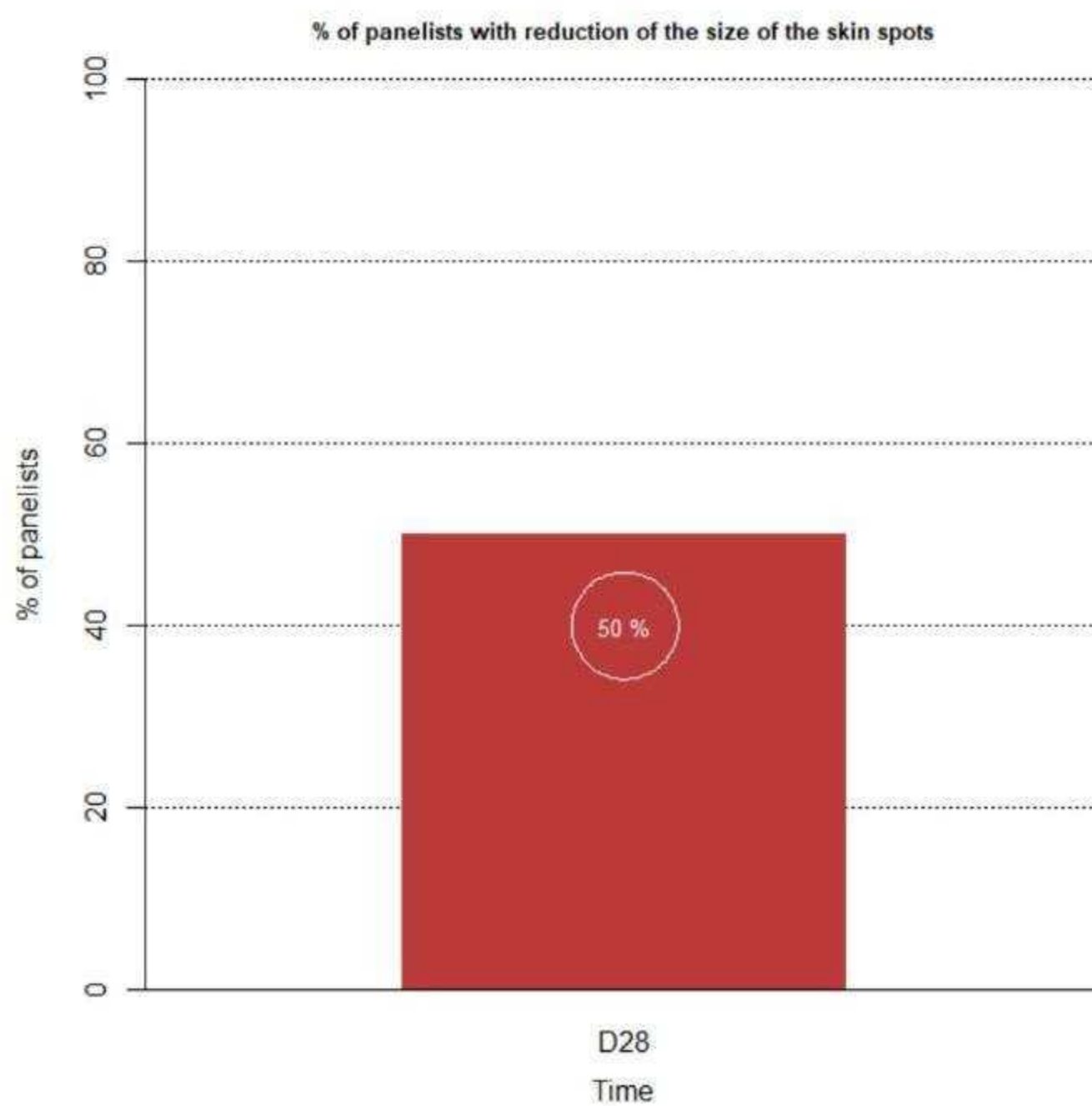


Figure 8. % of panelists with reduction of the size of the skin spots (D28).

9.4. Subjective evaluation of the product by the panelists

The following figures show the percentage of panelists satisfied with the global appreciation and efficacy of the product after 28 days of continuous use of the product

- **Global appreciation and characteristics**

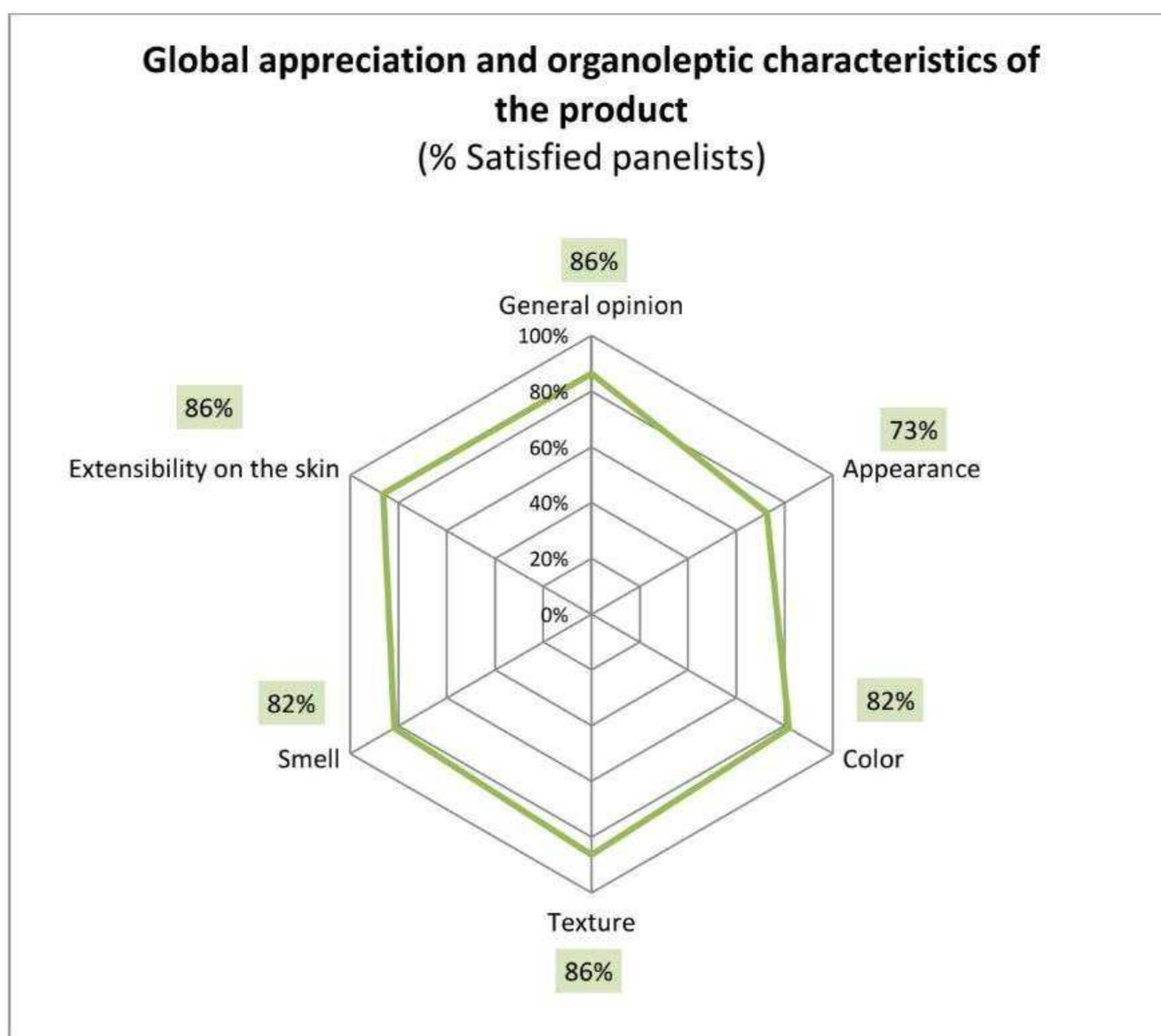


Figure 9. Percentage of panelists satisfied with the general and organoleptic characteristics of the product (n=22).

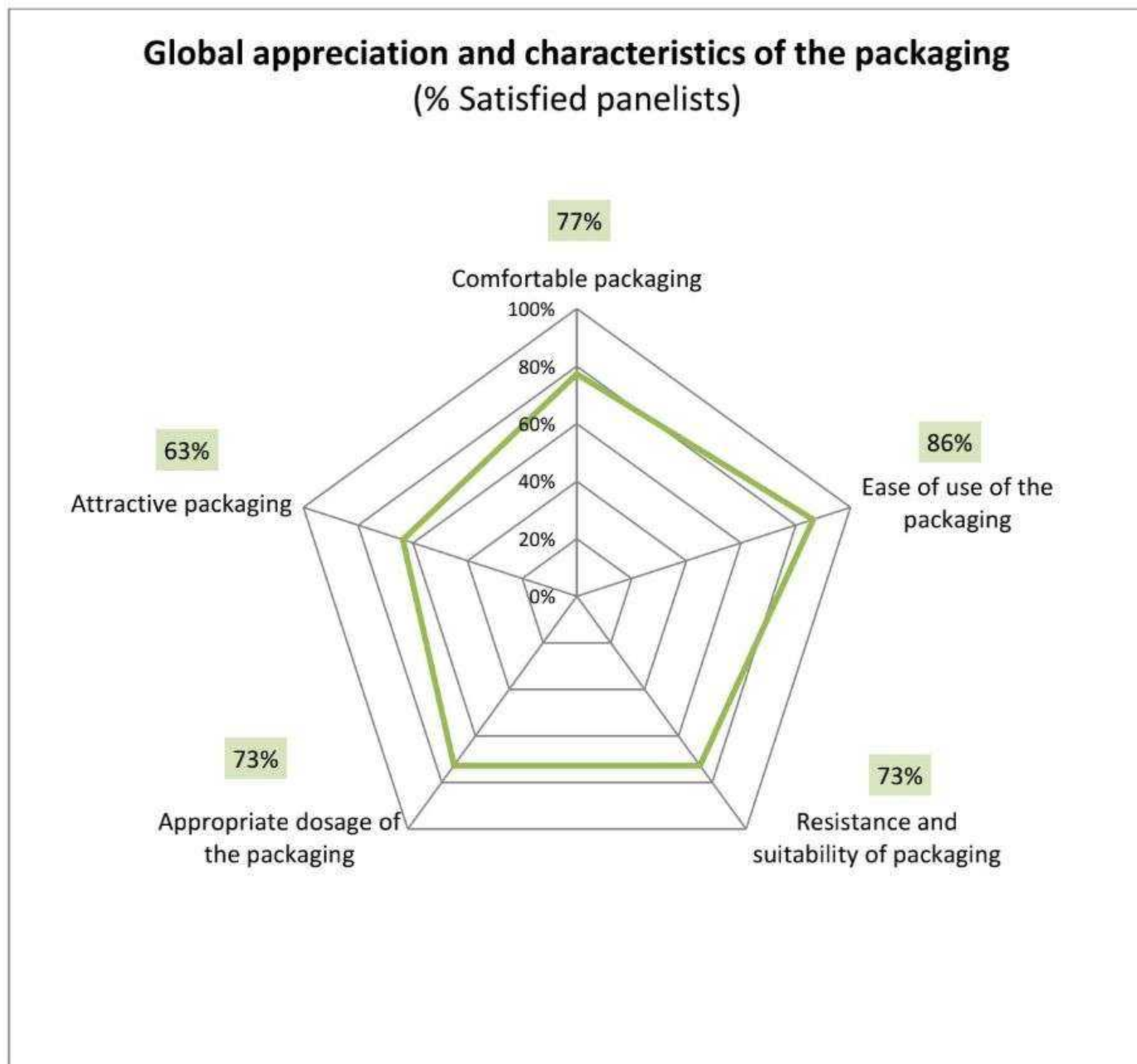


Figure 10. Percentage of panelists satisfied with the general and characteristics of the packaging (n=22).

- **Absorption of the product after the application**

Panelists were asked about the absorption of the product after the application, after 28 days of continuous use of the product.

9% of panelists answered that the absorption was very quick, 63% of panelists answered that the absorption was quick, 14% of panelists answered that the absorption was intermediate, 14% of panelists answered that the absorption was slow, 0% of panelists answered that the absorption was very slow.

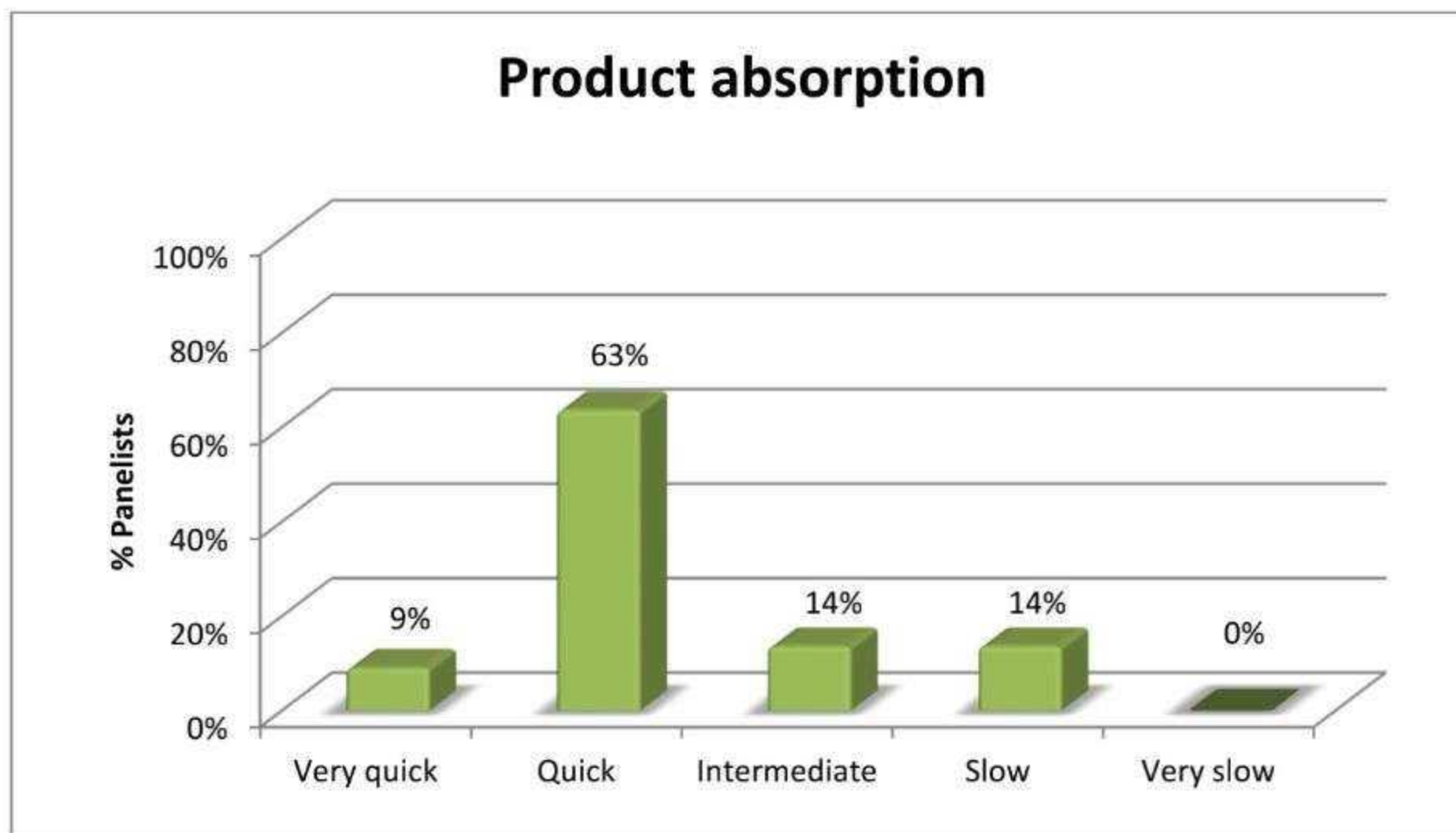


Figure 11. Absorption of the product after the application (n=22).

- **Greasy feeling during the application**

Panelists were asked if there was a greasy feeling during the application, after 28 days of continuous use of the product.

14% of panelists answered that there was none greasy feeling, 50% of panelists answered that there was some greasy feeling, 23% of panelist answered that there was quite a lot greasy feeling and 13% of panelists answered that there was a lot of greasy feeling.

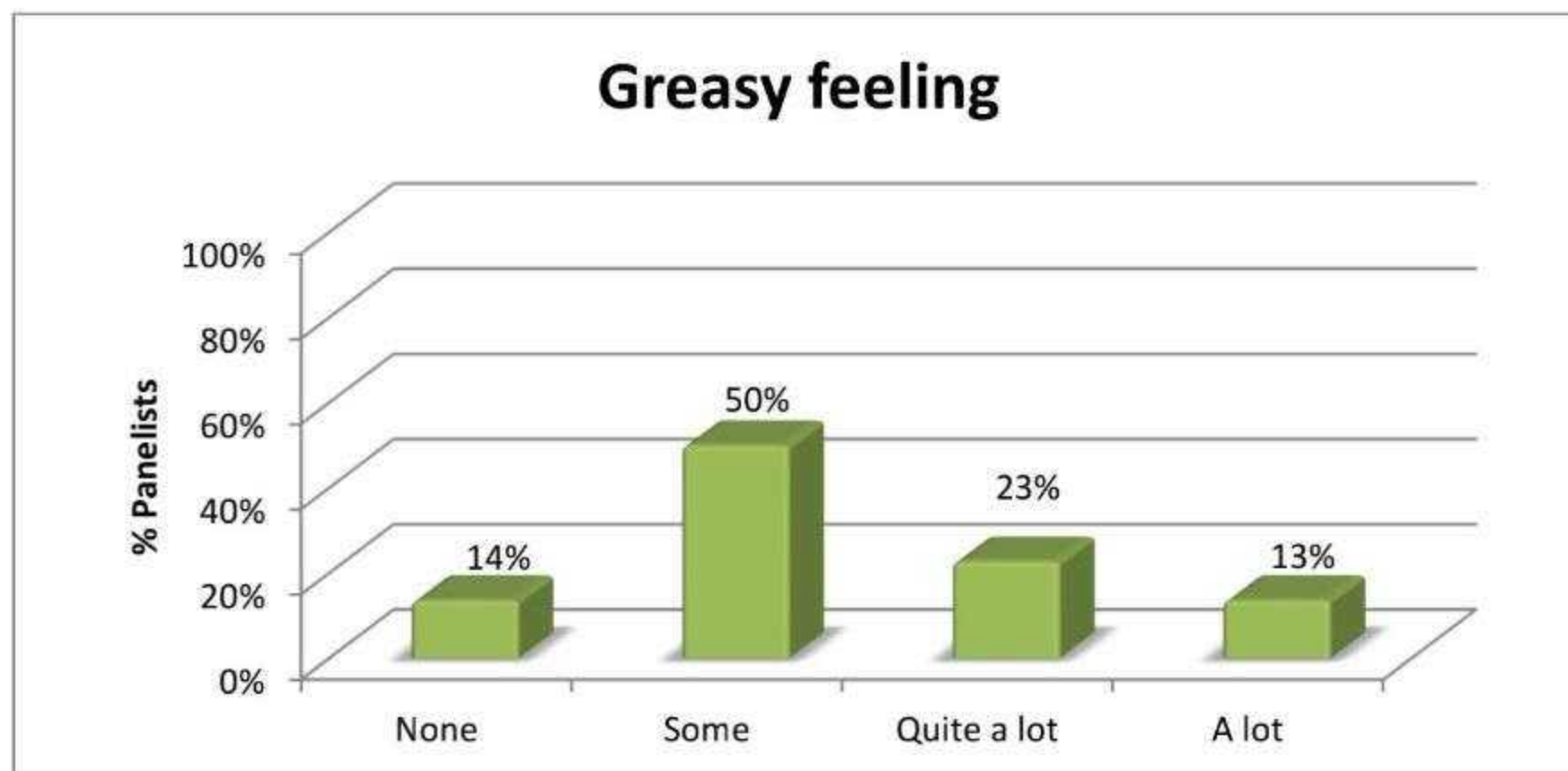


Figure 12. Greasy feeling during the application (n=22).

- **Greasy residue after absorption**

Panelists were asked if there was a greasy residue after absorption, after 28 days of continuous use of the product.

41% of panelists answered that there was none greasy residue, 36% of panelists answered that there was some greasy residue, 14% of panelists answered that there was quite a lot of greasy residues and 9% of panelists answered that there was a lot of greasy residues.

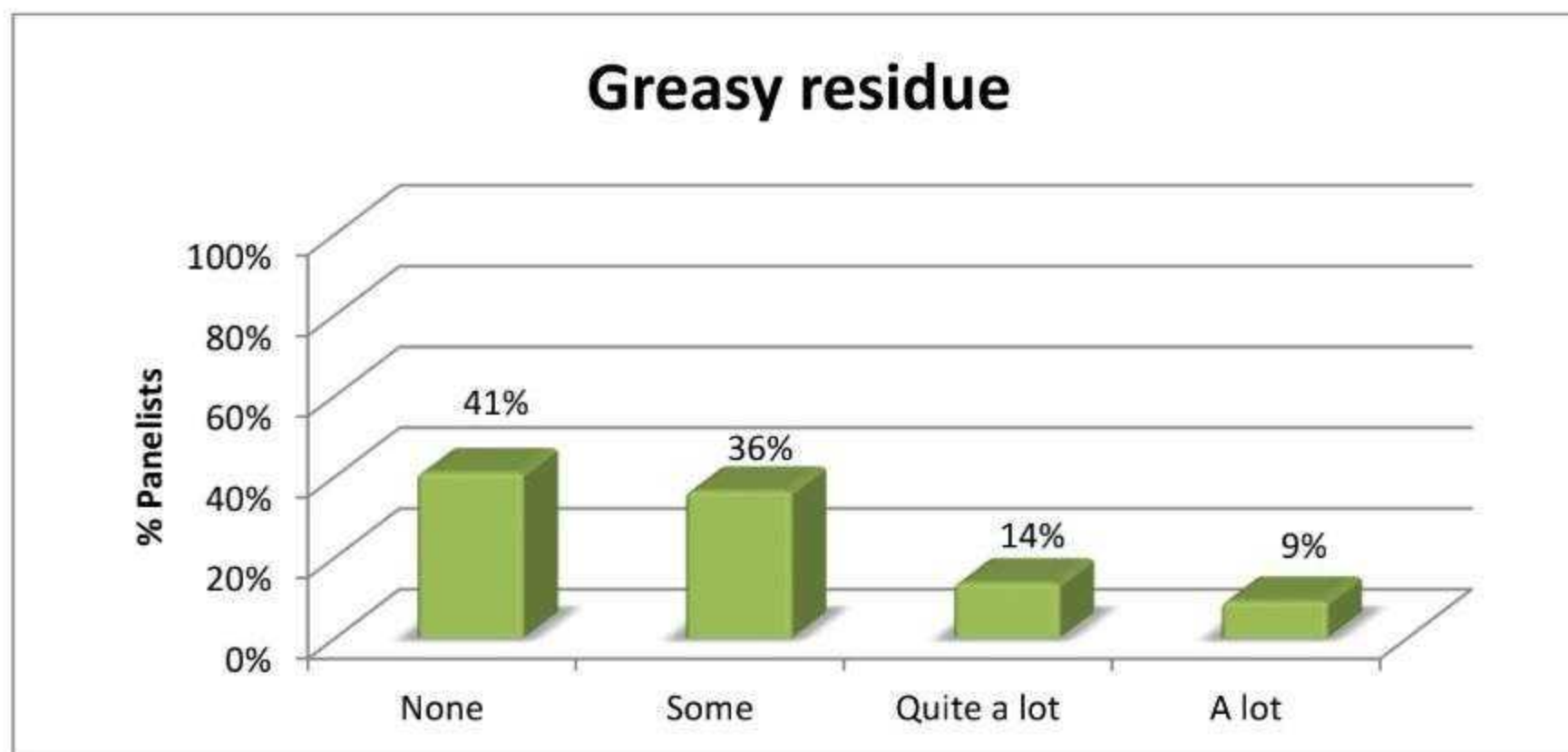


Figure 13. Greasy residue after absorption (n=22).

- **Efficacy**

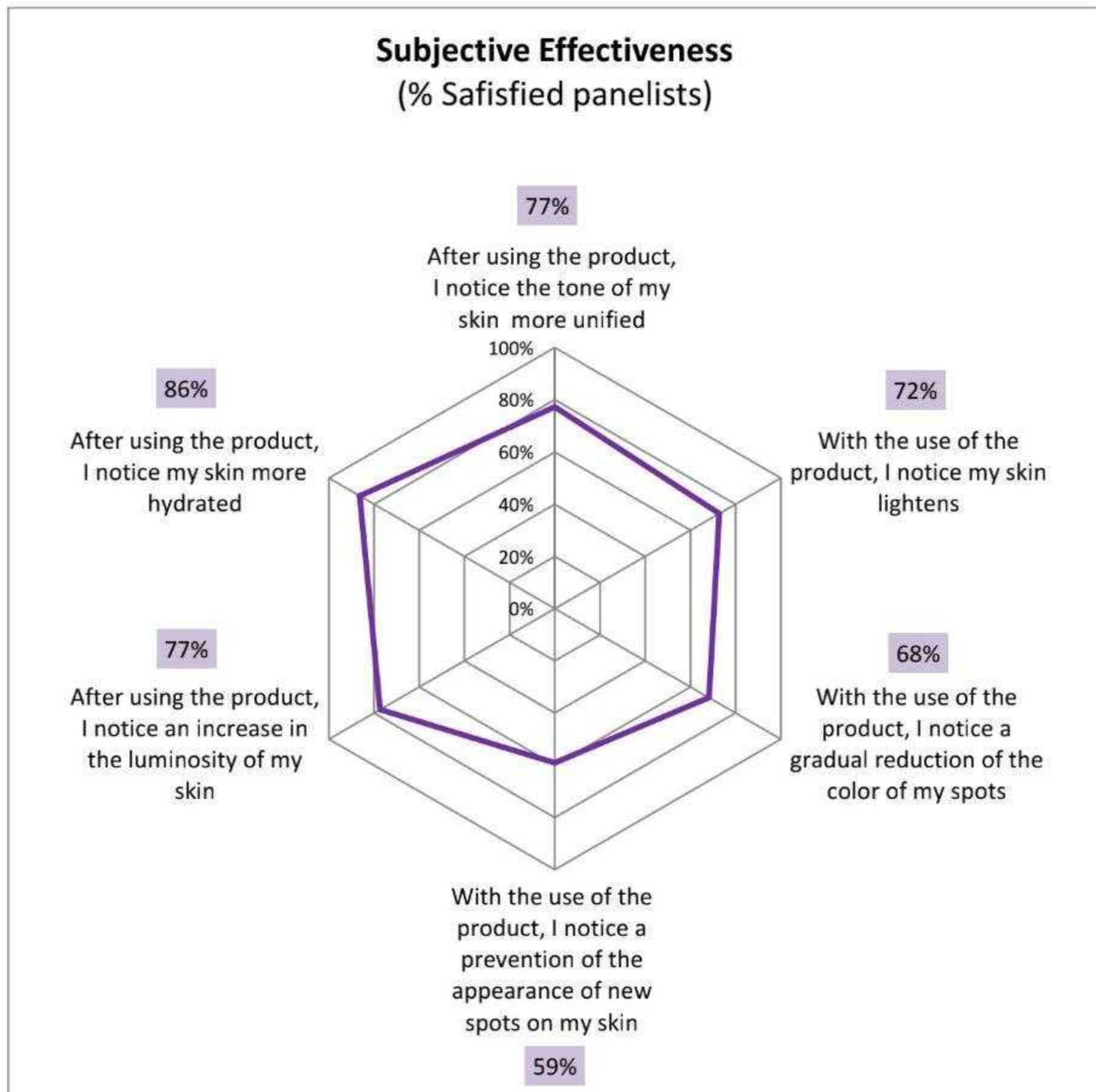


Figure 14. Percentage of panelists satisfied with efficacy of the product (n=22).

- **Result on the skin**

Panelists were asked about their grade of satisfaction with the result of the product on the skin, after 28 days of continuous use of the product.

32% of panelists were very satisfied, 50% of the panelists were satisfied and 18% of the panelists were indifferent with the result of the product on the skin.

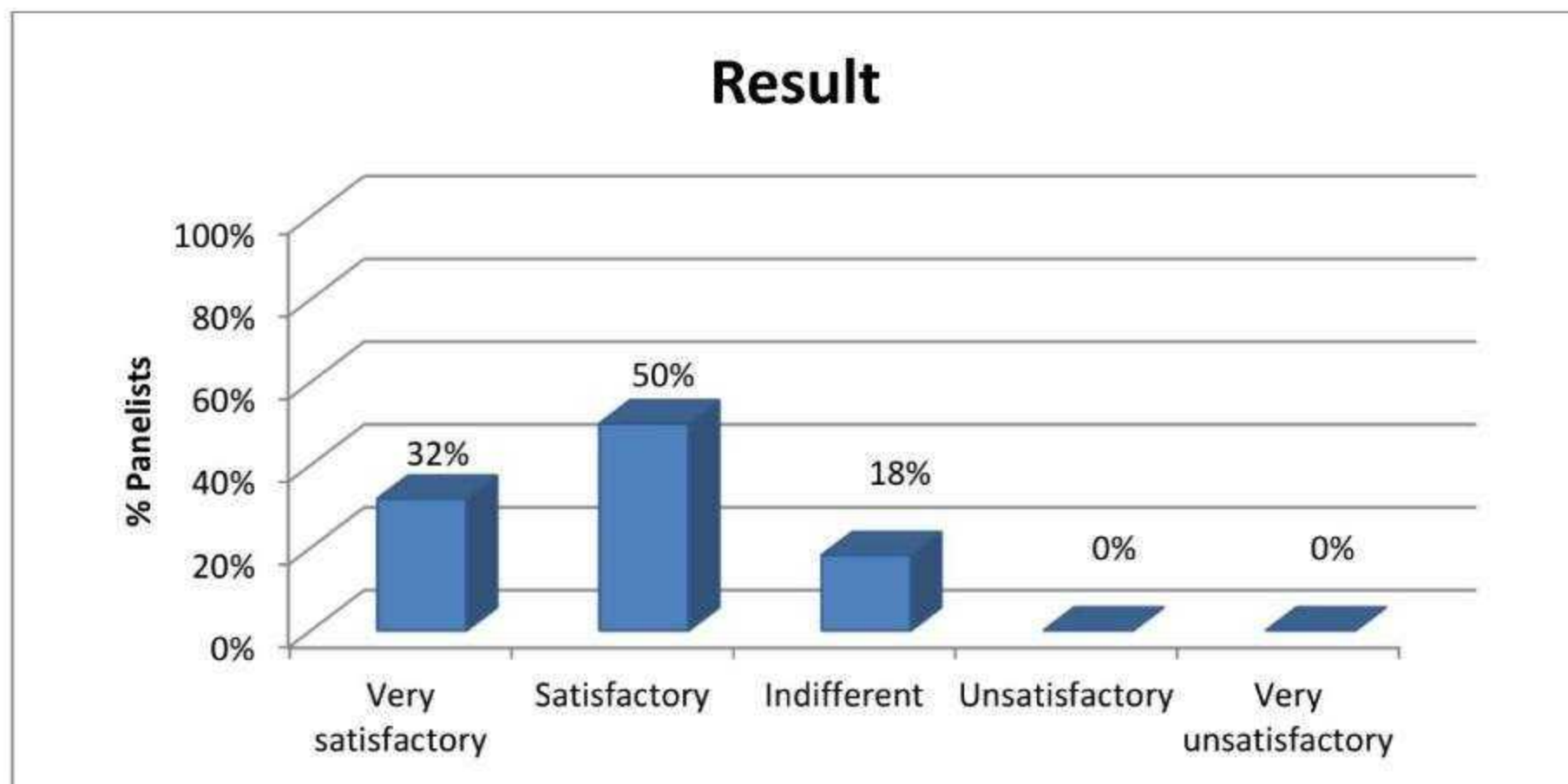


Figure 15. Subjective evaluation about the result of the product on the skin by the panelists (n=22).

- **Compliance with expectations**

The panelists were asked if they considered that the product had fulfilled their expectations, after 28 days of continuous use of the product.

82% of the panelists answered that the product had fulfilled their expectations; whereas 18% of the panelists answered that the product hadn't fulfilled their expectations.



Figure 16. Subjective evaluation on the fulfillment of the expectations by the panelists after the use of the product (n=22).

Among the reasons of the fulfillment of the expectations expressed by panelists, were included:

- "My skin feels softer and improves the color of my spots".
- "The smell of the product was really good".
- "My skin feels more hydrated"

Among the reasons of not fulfillment of the expectations expressed by the panelists for the product, are:

- "The product is too much greasy."
- "The product leaves greasy residue after the application, I don't like feeling it leaves on my skin."

- **Purchase intention**

The panelists were asked if they would buy this product compared to what they usually use, in case the price was suitable, after 28 days of continuous use of the product.

55% of the panelists answered that, surely, they would buy it, 27% of the panelists answered that, probably, they would buy it, 9% of the panelists answered that they didn't know, 9% of the panelists answered that, probably, they would not buy it and none of the panelists answered that, surely, they would not buy it.

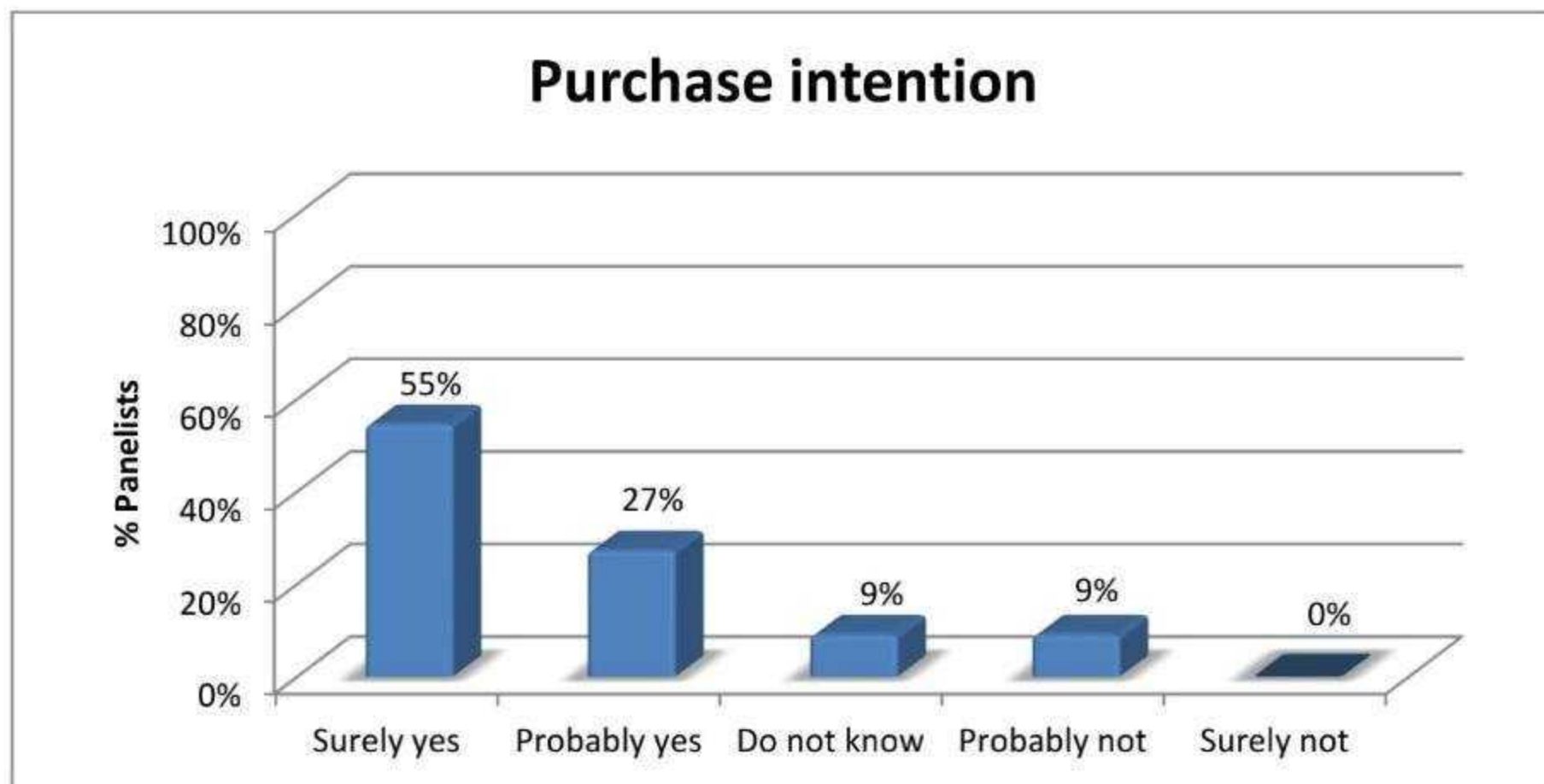


Figure 17. Purchase intention by the panelists after the use of the product (n=22).

10. CONCLUSION

The objective of this study was to evaluate the instrumental and dermatological efficacy and the acceptability, subjective efficacy and tolerance of the product, **ACEITE FACIAL OLLETO OIL**, reference: **INZOF1021**, batch: **OFA1021**, in 20 panelists for a period of 28 days using the product according to the conditions stipulated by the customer.

Under the adopted experimental conditions and considering the defined instrumental parameters, it can be concluded:

Results

All the results detailed below are statistically significant with a p-value lower than 0,05.

- Dermatological assessment of efficacy
 - After 28 days of continuous use of the product, color of the skin spots decreases an average of 26 % in relation to the baseline.
 - After 28 days of continuous use of the product, the size of the skin spots decreases an average of 18 % in relation to the baseline.
- Subjective efficacy

After 28 days of continuous use of the product, most of the panelists had a positive opinion about the organoleptic characteristics, where 86% of the panelists were satisfied with the general opinion of the product.

According to the subjective efficacy after 28 days of continuous use of the product, 82% of the panelists were satisfied with the result on the skin and 82% of the panelists would buy the product.

- Dermatological assessment of tolerance

According to the clinical examination performed by the dermatologist, none of the panelists showed any skin alteration after 28 days of continuous use of the product.

*Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,*

11. DOCUMENT CONSERVATION AND SAMPLES

The following documentation relating to the study will be stored in the facilities of Zurko Research following the provisions of ISO 9001:2015:

- Study protocol and its modifications (signed).
- Primary data.
- Final report.
- Documents of the sponsor.

The documentation will be stored for 5 years. At 5 years the possibility of an extension due to the commercialization of the test product will be consulted with the promoter. In case of no response, it will be destroyed.

A sample of the evaluated product (enough for the execution of the study) will be stored in Zurko Research's library for 1 year from the date of receipt.

12. BIBLIOGRAPHICAL REFERENCES

1. The SCCS'S Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation 9th Revision.
2. www.cosmeticsinfo.org

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

SIGNATURES

The undersigned declare that this study has been carried out in the essence of the Clinical Good Practices (Guideline for good clinical practice E6 (R2) of June 14th, 2017, EMA/CHMP/ICH/135/1995 of May 1st, 1996, European Parliament and Council Guideline 2001/20/CE – May 1st, 2001).

The results here presented reflect accurately and completely the raw data of the study.

Researcher: I, the undersigned, Laura Mato Castro, declare that this study has been carried out under my responsibility.

Signature:

	Laura Mato Castro
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Dermatology Team: Zurko's dermatology team, led by the dermatologist Javier Pedraz (medical license number: 283706434), and Natalia Zawierta, as adjunct dermatologist, declare that this study has been reviewed under their responsibility. In representation,

Signature:

	ZAWIERTA NATALIA MARIA - Y3942816D
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*Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,*

ANNEXES

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

Annex I: Information about the panelists

Panelists		Age (Years)	Gender F= female M=male	Skin type (R/S)	Habitual use	Brand
Ref.	Acronym					
1	V01	57	F	S	No	-
2	V02	56	M	R	No	-
3	V03	59	F	R	No	-
4	V04	22	M	S	No	-
5	V05	69	F	S	No	-
6	V06	65	M	R	No	-
7	V07	32	F	S	No	-
8	V08	64	F	R	No	-
9	V09	40	F	R	No	-
10	V10	59	F	R	No	-
11	V11	30	M	R	No	-
12	V12	52	F	S	No	-
13	V13	61	F	S	No	-
14	V14	55	F	S	No	-
15	V15	65	F	S	No	-
16	V16	43	M	R	No	-
17	V17	44	F	S	Yes	Babaria
18	V18	20	F	S	No	-
19	V19	53	F	S	No	-
20	V20	37	F	S	Yes	Pond's
21	V21	58	F	S	No	-
22	V22	64	F	S	No	-
23	V23	64	F	S	No	-

R= Non- sensitive

S= Sensitive

Annex II: Results of instrumental efficacy and clinical grading

Instrumental efficacy

- Evaluation of luminosity efficacy

Acronym	L Value	
	D0	D28
V01	58,70	58,13
V02	55,97	53,67
V03	55,66	54,21
V04	53,99	55,41
V05	64,55	57,60
V06	57,19	56,67
V07	61,61	68,53
V08	55,15	55,55
V09	59,57	61,02
V10	61,38	62,36
V11	54,39	53,82
V12	56,04	55,60
V13	62,57	63,83
V14	64,76	64,67
V15	52,89	53,01
V16	55,22	49,38
V17	59,17	61,98
V18	63,44	-
V19	59,64	60,41
V20	60,34	59,25
V21	62,01	64,69
V22	55,05	53,79
V23	59,50	59,25

“-”: withdrawal

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

Clinical grading

- Color of the skin spot

Acronym	Color of the skin spots index	
	D0	D28
V01	3	2
V02	4	4
V03	4	4
V04	2	1
V05	3	3
V06	4	3
V07	2	1
V08	3	2
V09	3	2
V10	3	2
V11	2	1
V12	3	1
V13	3	2
V14	3	2
V15	4	4
V16	3	2
V17	3	2
V19	3	2
V20	3	2
V21	2	1
V22	4	3
V23	4	4

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

- Size of the skin spot

Acronym	Size of the skin spots index	
	D0	D28
V01	3	2
V02	3	3
V03	4	4
V04	2	1
V05	3	3
V06	4	3
V07	2	1
V08	4	3
V09	1	1
V10	3	3
V11	2	1
V12	3	2
V13	3	3
V14	3	2
V15	4	2
V16	3	3
V17	3	2
V19	2	2
V20	3	2
V21	2	2
V22	4	4
V23	4	4

Annex III: Subjective questionnaire results

- After 28 days using the product

Topic	General opinion					Appearance				
Opinion	5	4	3	2	1	5	4	3	2	1
Number of panelists	17	2	3	0	0	13	3	5	1	0
% of panelists	77%	9%	14%	0%	0%	59%	14%	22%	5%	0%
Topic	Color					Texture				
Opinion	5	4	3	2	1	5	4	3	2	1
Number of panelists	13	5	4	0	0	11	8	2	1	0
% of panelists	59%	23%	18%	0%	0%	50%	36%	9%	5%	0%
Topic	Smell					Extensibility on the skin				
Opinion	5	4	3	2	1	5	4	3	2	1
Number of panelists	16	2	1	3	0	14	5	1	2	0
% of panelists	73%	9%	5%	13%	0%	64%	22%	5%	9%	0%

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

Topic	Comfortable packaging					Ease of use				
Opinion	5	4	3	2	1	5	4	3	2	1
Number of panelists	14	3	4	1	0	16	3	2	1	0
% of panelists	64%	13%	18%	5%	0%	73%	13%	9%	5%	0%
Topic	Resistance and suitability of packaging					Appropriate dosage				
Opinion	5	4	3	2	1	5	4	3	2	1
Number of panelists	14	2	4	2	0	11	5	6	0	0
% of panelists	64%	9%	18%	9%	0%	50%	23%	27%	0%	0%
Topic	Attractive packaging									
Opinion	5	4	3	2	1					
Number of panelists	6	8	5	1	2					
% of panelists	27%	36%	23%	5%	9%					

Study references: VV_ET-4/20DXT2(D)-A_703_21_001,
VV_ET-SC/20DXT2(D)-B_703_21_001,

Topic	After using the product, I notice the tone of my skin more unified					With the use of the product, I notice my skin lightens				
Opinion	5	4	3	2	1	5	4	3	2	1
Number of panelists	6	11	4	1	0	5	11	3	3	0
% of panelists	27%	50%	18%	5%	0%	23%	49%	14%	14%	0%
Topic	With the use of the product, I notice a gradual reduction of the color of my spots					With the use of the product, I notice a prevention of the appearance of new spots on my skin				
Opinion	5	4	3	2	1	5	4	3	2	1
Number of panelists	6	9	5	2	0	4	9	6	1	2
% of panelists	27%	41%	23%	9%	0%	18%	41%	27%	5%	9%
Topic	After using the product, I notice an increase in the luminosity of my skin					After using the product, I notice my skin more hydrated				
Opinion	5	4	3	2	1	5	4	3	2	1
Number of panelists	8	9	5	0	0	11	8	2	1	0
% of panelists	36%	41%	23%	0%	0%	50%	36%	9%	5%	0%

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