

Assessment of the efficacy of an anti-aging product on a panel of 20 volunteers

STUDY 17E3961

Quote D17-656-2

Study performed on:

+ 20 Caucasian women

+ Reference :

Rivoli Crème de jour jeunesse II

Torstone

Lab-01095.4

14.12.17

+ Over 28 days

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STUDY 17E3961	
QUOTE D17-656-2	
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Summary of the study

▪ **TITLE:**

Assessment of the efficacy of an anti-aging product on a panel of 20 volunteers

▪ **AIM OF THE STUDY:**

The aim of the study is to assess on a panel of 20 volunteers aged between 40 and 50 years old, the efficacy of an anti-aging product on wrinkles.

This efficacy will be measured through:

- Underneath eye wrinkles assessment by Aeva He®
- Dermatological control
- Self-assessment questionnaire

The various measurements were recorded during a first visit at T0, immediately after application of the product at Timm and at T+28 days after applying the product only in the morning.

▪ **PROGRESS OF THE STUDY:**

20 women, aged between 40 and 50 years old, meeting the inclusion and non-inclusion criteria defined by the promoter were included in the study.

▪ **RESULTS AND CONCLUSION:**

The aim of the study was to assess on a panel of 20 volunteers during 28 days, the efficacy of an anti-aging product on anti-wrinkle effect.

❖ **Immediately after application, we can conclude that the product:**

- **tends to improve the depth average of the underneath eye wrinkles**
- **decreases the underneath eye wrinkles volume**

Furthermore,

- **90% of volunteers included in the study found that their skin looks more hydrated**
- **75% of volunteers included in the study found that their skin seems more flexible and more soothed**

❖ **After 28 days of application, we can conclude that the product :**

- **tends to decrease the underneath eye wrinkles volume**

Furthermore,

- **70% of volunteers included in the study found that their skin looks more hydrated**
- **75% of volunteers included in the study found that their skin seems firmer and smoother**
- **65% of volunteers included in the study found that their fine lines and their dull complexion seem reduced faced with daily agressions**

→ Under the conditions of the study, the dermatologist concludes to a very good cutaneous tolerance of the product tested.

1 AIM OF THE STUDY

The aim of the study is to assess on a panel of 20 volunteers aged over 40 years old, the efficacy of an anti-aging product on wrinkles.

This efficacy will be measured through:

- Underneath eye wrinkles assessment by Aeva He®
- Dermatological control
- Self assessment questionnaire

The various measurements were recorded during a first visit at T0, immediately after application of the product at Timm and at T+28 days after applying the product only in the morning.

2 EXPERIMENTAL DESIGN

2.1 Study design

The efficacy of the product was assessed on 20 women meeting the inclusion and non-inclusion criteria previously defined by the promoter.

Several measurements were recorded on the volunteers.

The volunteers applied the product only in the morning from T0 to T+28 days, according to promoter's recommendations.

Each volunteer was asked to notify Laboratory BIO-EC of any discomfort or undesirable event that would occur. They did not stop or change the frequency of application without prior notice.

During each visit, assessments were done using the same method.

2.2 Volunteers selection and method

- **Recruitment** (Week 02): Women aged between 40 and 50 years old with wrinkles and living in polluted environment.

- **First visit at T0** : (Week 03), the technician in charge of the study:
 - Checks out of the criteria of inclusion and non-inclusion,
 - Checks out of the well understanding of the study,
 - Signing of the agreement by the volunteers,
 - Makes initial biometrical measurements on underneath eyes:
 - AevaHe®

The dermatologist makes a control of the skin on face.

- **At Timm (after application)** : (Week 03), the technician in charge of the study:
 - Makes biometrical measurements on underneath eyes :
 - AevaHe®
 - Gives to volunteers the test product and self-assessment questionnaire
- The dermatologist makes a control of the skin on face.

From T0 to T+28 days: Volunteers apply the product on morning and evening on the face

- **Final visit at T+28 days** : (Week 07), the technician in charge of the study:
 - Records adverse events,
 - The dermatologist makes a control of the skin on face.
 - Makes biometrical measurements on underneath eyes:
 - AevaHe®
 - Retrieves test product and self-assessment questionnaire.
 - Gives compensation to volunteer.
- The dermatologist makes a control of the skin on face.

3 VOLUNTEERS

3.1 Inclusion and non-inclusion criteria

3.1.1 Inclusion criteria

- Caucasian women
- Aged between 40 and 50 years old,
- With wrinkles
- Living in a polluted environment

The volunteers should commit themselves to:

- Use the product in conformity with the recommendation use
- Not using any other product on the studied zone

3.1.2 Non-inclusion criteria

- Pregnancy or breast feeding women,
- Persons having dermatological problems and/or know allergy to cosmetic products.
- Persons under medical treatment potentially capable of influencing the measured parameters

3.2 Volunteers included in the study

Overall, 20 Caucasians women meeting the inclusion and non-inclusion criteria defined in the protocol were included in the study. They were informed of the possible adverse effects from using the product and the technical conditions in which the assessment is performed. They willingly signed the consent form which was written in compliance with the Declaration of Helsinki and the December 20th, 1988 act of the Code de la Santé Publique.

3.2.1 Demographic characteristics

The demographic characteristics of the volunteer group (mean \pm SD) are as follows:

Rivoli Creme de jour Jeunesse Torstone Lab-01095.4 14.12.17	N = 20 women
	Age : 46 \pm 3 years old

3.2.2 Schedule compliance

No volunteer left the study prematurely. All volunteers returned for their appointments.

3.2.3 Concomitant treatments

The volunteers included in the study did not take any concurrent treatment likely to induce a modification of the cutaneous state.

4 PRODUCTS

4.1 Study product

The products were identified as follow :

Rivoli crème de jour Jeunesse II

Torstone

Lab-01095.4

14.12.17

These test products have been stored at room temperature and were both white cream packed by the promoter in vials.

4.2 Product use

Products were dispatched to volunteers at T0. Volunteers apply the product on morning and evening on the whole face. The amount of product to be applied was left to the volunteers by their cosmetic habits. Any remarks were noted during the final appointment.

5 METHODS

5.1 Assessment of skin relief and mechanical properties using AEVA_HE®

Based on a patented fringe projection unit combined with stereo imaging techniques, the AEVA-HE system offers best performances and flexibility to address different studies/measurements from wrinkles reduction to body reshaping. It is designed to quantify efficacy assessment for cosmetics, aesthetical and dermatology products and treatments.

It is dedicated to the following applications:

- Face (wrinkles, fine lines and pores, glabella, eyebags, nasogenian fold, lips, sagging)
- Part of Body reshaping, firmness (circumference of waist, legs, and breast)
- Automatic or interactive areas extraction
- Amplitude, roughness, volume, areas, circumference evaluation

Measurements were done at T0 and T+28 days.

5.2 Dermatological control

The product has been tested under dermatological control at T0 and T+28days.

5.3 Self-assessment questionnaire

Assessment of the sensation felt, efficacy and cosmetic quality of the product was performed through a self-assessment questionnaire completed on Eval&Go by volunteers after the first application and after 28 days of product application.

Eval & GO is a SaaS application of feedback management. It permits to create On-line surveys, to publish them by link or by email, to collect the answers and analyze the results in real time. Access to the service is via an internet connection and a recent web browser (Internet Explorer 9+, Chrome, Safari, Firefox). It is on the basis of subscriptions without no installation on computers. Any use of Eval & GO software or services is subject to the terms and conditions.

6 RESULTS

6.1 Atmospheric conditions around Paris

Maximal and minimal temperatures around Paris during the study were:

- January (T0 and Timm): 1.8 °C to 14.7°C
- February (T+28 days): -4°C to 11.1°C

6.2 Statistical method

The basic statistical parameters (mean and standard deviation) were calculated for each data point and recorded. Then, the assessment of the overall effect of the test product was made by calculating the variation of percentage compared to the initial measurement.

In order to determine whether the identified changes were significant or not, a Student's t-test was performed. The statistical analysis (through Prism v5.04 software by GraphPad) was made with Student's t-test on paired samples. The assumptions were the randomness and normal distribution of the samples.

6.3 Protocol deviation

All inclusion and evaluation criterion were respected.

6.4 Undesirable events

No adverse effects occurred during the study.

6.5 Results of underneath eye wrinkles by AEVA-HE

Means of anti-aging parameters for the global population are gathered in the table below. Individual values for each volunteer are presented in the appendixes.

The data below were not analyzed due to artefacts measurements :

- Volunteers 9 and 10 at Timm
- Volunteers 8, 9 and 11 at T28days

6.5.1 Depth average

Means of depth average deviation parameter are gathered in the table below.

	Values			Delta of variation		% of variation	
	T0	Timm	T+28 days	Timm	T+28 days	Timm	T+28 days
Product	-0,042 ± 0,017	-0,043 ± 0,013	-0,046 ± 0,016	0,002 ± 0,009	0,000 ± 0,012	-5,01% ns	0,05% ns
	# Significant p<0.1		* Significant p<0.05		**Significant p<0.01		

Immediately after application of the product, we can observe :

- A non significant decrease of depth average of **5,01% (p>0,1)** of the underneath eye wrinkles

After 28 days of application of the product, we can observe :

- A non significant increase of depth average of **0,05% (p>0,1)** of the underneath eye wrinkles

➔ **We can conclude that the product tends to improve the depth average of the underneath eye wrinkles immediately after application.**

6.5.2 Wrinkles Volume

Means of negative volume deviation parameter are gathered in the table below.

	Values			Delta of variation		% of variation	
	T0	Timm	T+28 days	Timm	T+28 days	Timm	T+28 days
Product	0,755 ± 0,506	0,583 ± 0,362	0,864 ± 0,622	-0,248 ± 0,341	-0,001 ± 0,541	-32,86% **	-0,17% ns

Immediately after application of the product, we can observe :

- A significant decrease of the underneath eye wrinkles volume of **32,86% (p<0,01)**
-

After 28 days of application of the product, we can observe :

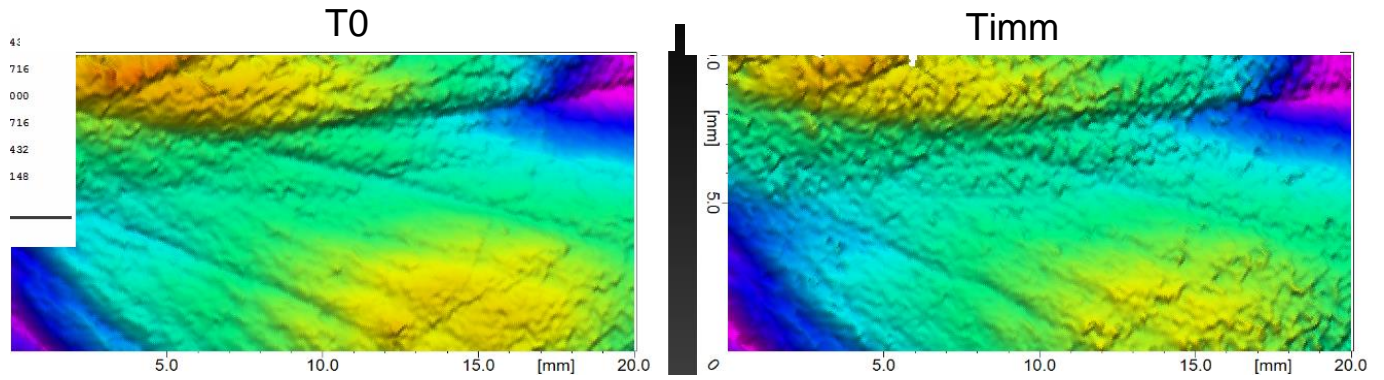
- A non significant decrease of the underneath eye wrinkles volume of **0,17% (p>0,1)**

→ **We can conclude that the product :**

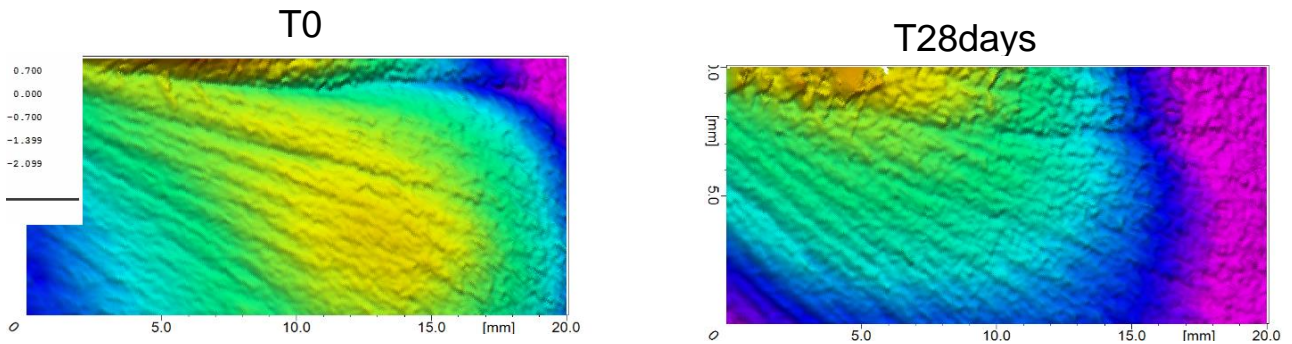
- **decreases the underneath eye wrinkles volume immediately after application**
- **tends to decrease the underneath eye wrinkles volume after 28 days of application**

Illustration of wrinkles with Aeva

Volontaire 15 :



Volontaire 18 :



6.6 Dermatological control

The product has been tested under dermatological control at T0 and T+28days.
No intolerance reaction has been detected by the dermatologist.

➔ **Under the conditions of the study, the dermatologist concludes to a very good cutaneous tolerance of the product tested.**

6.7 Self-assessment questionnaire (Percentage result)

6.7.1 After the 1st application

❖ *Global evaluation of the product*

	Very pleasant	Pleasant	Nor pleasant, Neither unpleasant	Unpleasant	Very unpleasant
GLOBAL APPRECIATION	25	70	5	0	0
Aspect	45	50	5	0	0
Texture	55	35	10	0	0
Fragrance	55	25	20	0	0

After the 1st application :

- **95 %** of volunteers found that the product was very pleasant or pleasant.
- **95%** of volunteers thought that the aspect of the product was very pleasant or pleasant.
- **90 %** of volunteers thought that the texture of the product was very pleasant or pleasant.
- **80 %** of volunteers thought that the fragrance of the product was very pleasant or pleasant.

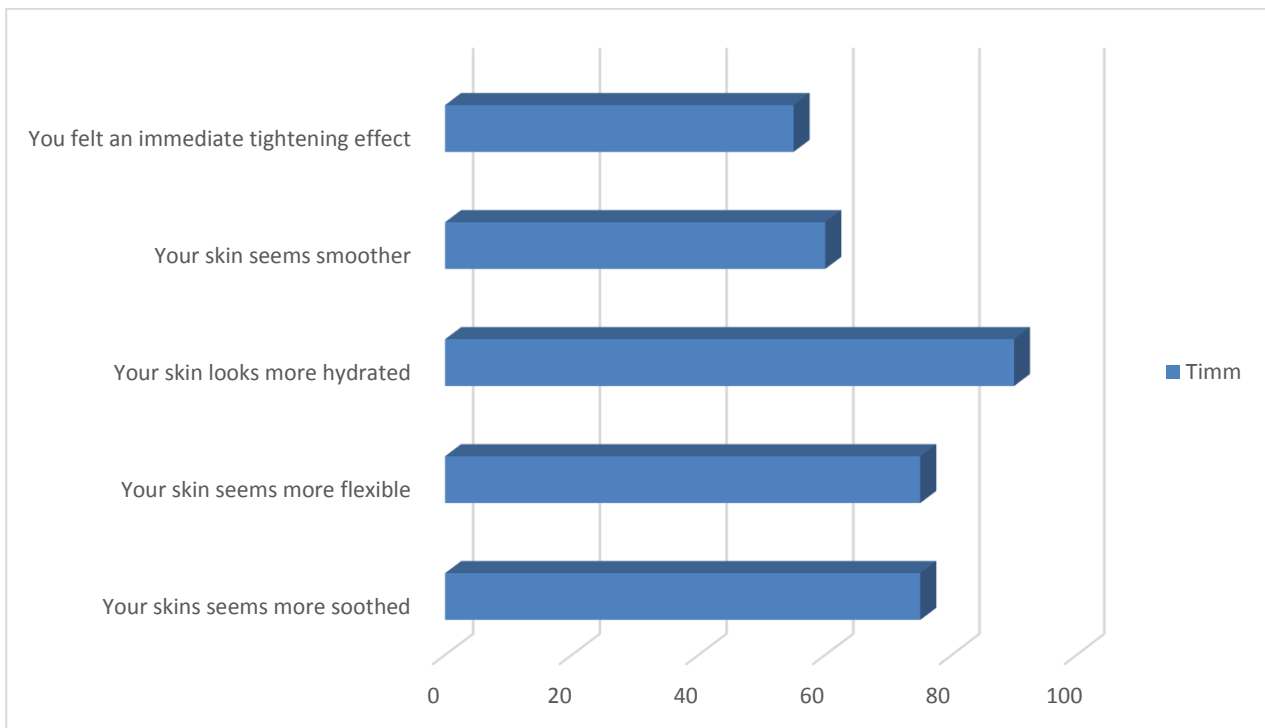
- **100 %** of volunteers included in the study found that the product was easy to apply.
- **95 %** of volunteers included in the study found that the product penetrates easily.
- **65 %** of volunteers included in the study found that the product doesn't leave an oily film
- **55 %** of volunteers included in the study found that the product doesn't leave a sticky film
- **70%** of volunteers included in the study found that the product leaves a soft finish
- **55 %** of volunteers included in the study found that the product leaves a silky finish

❖ *Assessment of the efficacy of the product*

- **50 %** of volunteers noticed an intense or moderate improvement of their skin smoothness
- **40 %** of volunteers noticed an intense or moderate improvement of their skin firmness

After the 1 st application :	Agree	Quite agree	Not so much agree	Disagree
Your skins seems more soothed	20	55	25	0
Your skin seems more flexible	25	50	20	5
Your skin looks more hydrated	45	45	10	0
Your skin seems smoother	25	35	40	0
You felt an immediate tightening effect	10	45	35	10

Graphical representation of the questionnaire's results:



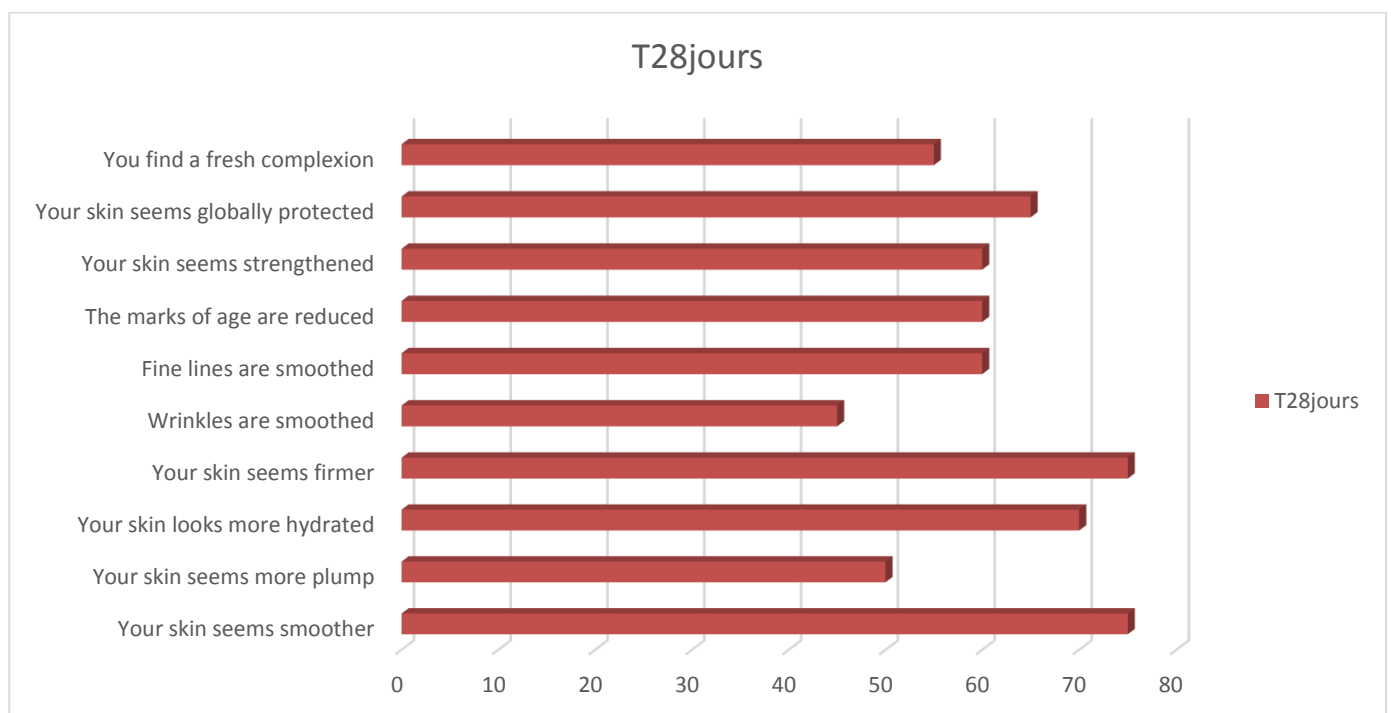
➡ Immediately after application of the product :

- **90%** of volunteers included in the study found that their skin looks more hydrated
- **75%** of volunteers included in the study found that their skin seems more flexible and more soothed

6.7.2 After 3 weeks

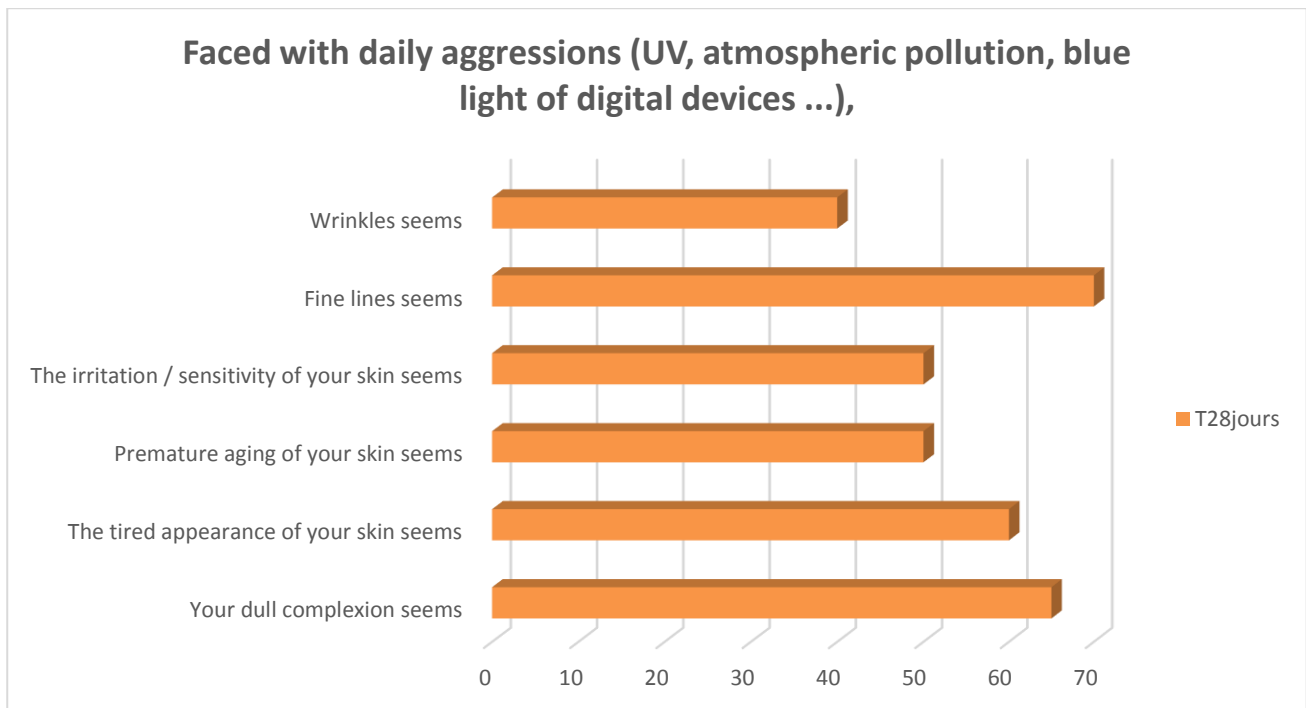
	Agree	Quite agree	Not so much agree	Disagree
Your skin seems smoother	15	60	20	5
Your skin seems more plump	15	35	40	10
Your skin looks more hydrated	25	45	30	0
Your skin seems firmer	25	50	20	5
Wrinkles are smoothed	10	35	50	5
Fine lines are smoothed	10	50	30	10
The marks of age are reduced	10	50	30	10
Your skin seems strengthened	20	40	35	5
Your skin seems globally protected	10	55	35	0
You find a fresh complexion	20	35	35	10

Graphical representation of the questionnaire's results:



Faced with daily aggressions (UV, atmospheric pollution, blue light of digital devices ...),	Greatly reduced	Reduced	Unchanged	Worse
Your dull complexion seems	10	55	35	0
The tired appearance of your skin seems	5	55	40	0
Premature aging of your skin seems	0	50	50	0
The irritation / sensitivity of your skin seems	15	35	50	0
Fine lines seems	10	55	35	0
Wrinkles seems	10	30	60	0

Graphical representation of the questionnaire's results:



➡ 28 days after application of the product :

- **70%** of volunteers included in the study found that their skin looks more hydrated
- **75%** of volunteers included in the study found that their skin seems firmer and smoother
- **65%** of volunteers included in the study found that their fine lines and their dull complexion seem reduced faced with daily aggressions

❖ *In conclusion*

- **0%** of volunteers included in the study felt an unpleasant sensation or incomfort.
- No volunteers interrupted the treatment.
- After 28 days of use, **75%** of volunteers are satisfied with this product and **70%** would like to continue to use this product.
- Regardless of price, **65%** of volunteers would buy this product
- **20%** of volunteers think that the product is a luxury product, **55%** think that the product is a drugstore product and **30%** think that the product is a cheap product

7 CONCLUSION

The aim of the study was to assess on a panel of 20 volunteers during 28 days, the efficacy of an anti-aging product on anti-wrinkle effect.

- ❖ Immediately after application, we can conclude that the product:
 - tends to improve the depth average of the underneath eye wrinkles
 - decreases the underneath eye wrinkles volume

Furthermore,

- 90% of volunteers included in the study found that their skin looks more hydrated
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→ Under the conditions of the study, the dermatologist concludes to a very good cutaneous tolerance of the product tested.

8 STUDY REPORT ARCHIVING

+ Raw data filing

The raw data consists of:

- Image analysis results
- Assays results
- Biometrological results using devices

All the raw data is kept in a paper file and a backup is saved when it is possible (depending on the used device).

+ Products ; samples ; blocks and blades filing

The products entrusted to BIO-EC are preserved one year after using the tested product.

The blocs, the stained and immunostained slides revealed by alkaline phosphatase and peroxidase are kept at BIO-EC's for fifteen years.

The frozen blocs will stay in possession of BIO-EC for two years at minus 80°C. If the culture media are harvested during the study, they will be stored for two years at minus 80°C.

After that, and without any other instructions from the client, they will all be destroyed.

+ Final report filing

The paper file is archived and kept for 20 years

The study report (raw data, images, preliminary reports, final report) and all the computer data are saved thanks to a double internal backup (KERTEL BOX2CLOUD, RAID 1) and by an automated and daily external system, Backupia (KERTEL Group).

Our computer system is protected by the anti-viruses Microsoft Security Essential, F-Secure and McAfee Saas.



Appendixes

Characteristics of volunteers

Volunteer	Age
1	46
2	50
3	45
4	49
5	45
6	47
7	45
8	48
9	50
10	47
11	48
12	46
13	46
14	41
15	41
16	47
17	41
18	44
19	44
20	43
Moyenne	45,7
Ecart type	2,8

Results of AEVA : Depth

Product							
Volunteers	Mean depth (µm)			Deviation		Variation	
	T0	Timm	T28	Timm-T0	T28-T0	%Timm	%T28
1	-0,046	-0,052	-0,036	-0,006	0,010	13,23%	-21,09%
2	-0,031	-0,034	-0,045	-0,004	-0,014	11,38%	45,63%
3	-0,037	-0,043	-0,053	-0,006	-0,016	14,97%	43,00%
4	-0,066	-0,059	-0,071	0,007	-0,006	-10,66%	8,96%
5	-0,043	-0,044	-0,038	-0,001	0,005	1,89%	-12,50%
6	-0,053	-0,066	-0,048	-0,013	0,005	25,46%	-9,35%
7	-0,044	-0,040	-0,048	0,005	-0,003	-10,53%	7,37%
8	-0,024	-0,026	-0,032	-0,002	-0,008	9,18%	33,36%
9	-0,013	-0,017	-0,016	-0,004	-0,003	27,96%	20,08%
10	-0,026	-0,029	-0,019	-0,003	0,007	11,96%	-27,35%
11	-0,019	-0,024	-0,027	-0,004	-0,008	23,18%	40,77%
12	-0,024	-0,022	-0,024	0,002	0,000	-6,86%	-1,40%
13	-0,047	-0,033	-0,040	0,014	0,007	-29,85%	-15,59%
14	-0,059	-0,058	-0,064	0,001	-0,004	-1,88%	7,47%
15	-0,056	-0,048	-0,077	0,007	-0,021	-13,19%	38,47%
16	-0,042	-0,047	-0,043	-0,004	-0,001	10,10%	1,34%
17	-0,041	-0,039	-0,048	0,002	-0,007	-4,78%	18,35%
18	-0,060	-0,039	-0,030	0,021	0,030	-34,78%	-49,74%
19	-0,078	-0,061	-0,069	0,018	0,009	-22,83%	-11,66%
20	-0,038	-0,036	-0,039	0,002	-0,001	-5,42%	1,69%
MEAN	-0,042	-0,043	-0,046	0,002	0,000	-5,01%	0,05%
SD	0,017	0,013	0,016	0,009	0,012		

Results of AEVA : Volume

Product							
Volunteers	Volume sum(mm3)			Deviation		Variation	
	T0	Timm	T28	Timm-T0	T28-T0	%Timm	%T28
1	0,522	0,594	0,265	0,073	-0,257	13,95%	-49,25%
2	0,385	0,658	1,364	0,273	0,979	71,00%	254,63%
3	1,407	1,192	1,587	-0,215	0,181	-15,29%	12,84%
4	1,237	0,744	1,695	-0,493	0,458	-39,85%	37,01%
5	0,637	0,512	0,495	-0,125	-0,142	-19,58%	-22,32%
6	0,923	0,779	0,905	-0,144	-0,018	-15,61%	-1,90%
7	0,998	0,508	1,885	-0,490	0,888	-49,10%	88,99%
8	0,200	0,055	0,547	-0,145	0,347	-72,37%	173,37%
9	0,042	0,079	0,147	0,037	0,105	89,18%	252,28%
10	0,094	0,027	0,021	-0,067	-0,073	-71,18%	-77,57%
11	0,145	0,110	0,380	-0,036	0,235	-24,53%	161,92%
12	0,136	0,069	0,170	-0,067	0,034	-49,10%	25,05%
13	1,127	0,818	0,478	-0,310	-0,649	-27,46%	-57,55%
14	1,141	0,564	1,002	-0,577	-0,139	-50,54%	-12,14%
15	1,300	0,941	1,679	-0,359	0,379	-27,64%	29,13%
16	0,512	0,548	0,414	0,035	-0,099	6,91%	-19,28%
17	0,896	0,566	1,011	-0,329	0,115	-36,77%	12,86%
18	1,479	0,174	0,097	-1,305	-1,382	-88,23%	-93,46%
19	1,524	1,345	1,221	-0,179	-0,303	-11,75%	-19,90%
20	0,387	0,315	0,393	-0,072	0,006	-18,67%	1,52%
MEAN	0,755	0,583	0,864	-0,248	-0,001	-32,86%	-0,17%
SD	0,506	0,362	0,622	0,341	0,541		