FINAL REPORT

CLINICAL DERMATOLOGY STUDY
WITH INSTRUMENTAL EFFICACY
FOR THE EVALUATION OF THE COSMETIC DEVICE
GLAMOUR NEW YORK MULTIWAVE

SPONSOR	GLAMOUR - NYC INC
Address	5151 Procyon Street, Suite 103, Las Vegas, Nevada 89118
Protocol code	2022-MTHBEA0422
Research Center	METHODEX SL – Barcelona – Spain
Investigator	Jessica Zumaquero – Dermocosmetics Dr. David Roche – Statistics
Experimental Dates	September 01, 2022 – October 28,2022
Report Final	November 02nd 2022

RESEARCH TEAM

The research team states that this study has been carried out under the principles of Good Clinical Practice (International Recommendations ICH Topic E6, CPMP/ICH/135/95 of May 1st 1996, European Parliament and Council Guideline 2001/20/EC-DOCE of May 1st 2001).

The results presented in this report reflect the test data of the volunteers.

INDEX

1. SUMMARY

Title of the study:	Study of skin acceptability and efficacy of the cosmetic device **GLAMOUR NEW YORK MULTIWAVE** after treatment for 4 weeks (2 times a week).
Objective:	Determining the improvement in skin after treatment with **GLAMOUR NEW YORK MULTIWAVE.** Evaluation of the safety and efficacy of the equipment during its use two times a week for 1 month in consultation for 15 minutes each led (30 minutes or 1 hour/45 min each session)
Design:	Single study centre
Sample of the study:	20 volunteers (15 facial and 5 body)
Treatment:	Treatment with the device for 4 weeks (2 times a week) in consultation. Volunteers are divided into 2 groups: 15 facial and 5 body. In the facial group the skin of the visage is evaluated and in the body group the skin of the neck/neckline and cellulitis on the legs are evaluated. The device was used with a different LED light mode each week to assess its effectiveness and each volunteer was treated with the most appropriate light mode for their skin type.

Study Schedule and scheme:

Procedure	Selection Visit VS (Day -14)	Initial Visit (Day 1) – Session 1	Intermediate visits – Sessions 1 to 7	Final Visit (T28 days / 4 weeks) – Session 8
Recruitment / Selection	X			
Inclusion / exclusion criteria. Visual skin assessment of the experimental areas by the specialist technician	X			
Informed Consent Signature and Subject Information Sheet		X		
Treatment with the device		X		
Questionnaire completion (every week)		X		
Measurements with the instrumental equipment: SoftPlus®, Cell-meter® and Visioface®		X		X
Photographs with SoftPlus®, Visioface® and photographic camera		X		X
Visual cutaneous assessment of the experimental areas by the specialist technician		X	X	X
Adverse events		X		

Study variables:

Main variable:

- Reactions considered as undesirable effects related to the research device.
- Evaluation of Adverse Events (safety).
- Efficacy of the device by assessing, for the facial group, wrinkles and elasticity/firmness on the eye contour and melanin (if they had sunspots) with SoftPlus® and pores, luminosity with Visioface®. For the body group, the elasticity/firmness, melanin ((if they had sunspots) of the neckline and cellulite on the legs, elasticity/firmness were also evaluated.

	Secondary variables: • Questionnaire completed by the volunteers each week. The subjective efficacy data was subjected to statistical calculation. • Reactions observed by the volunteers.
Statistic analysis:	The characteristics of the device were evaluated through a subjective questionnaire, specifically designed for this study, completed by the volunteers every week until the end of the study. A descriptive analysis was also carried out comparing subjective questions about the condition of the skin made before starting the study and at the end. Qualitative variables are presented using a frequency table and quantitative variables using mean and standard deviation. Statistical significance is analysed by means of t-student or Wilcoxon test, of the parameters measured with the instrumental equipment and of the questions of the subjective questionnaires carried out throughout the study. The results of the assessments are grouped according to the characteristics presented on the skin and the group to which the volunteer belongs (facial or body). It is detailed on the pages 11-12. Graphs are attached for the correct visualization of the results.

2. GENERAL INFORMATION

2.1. Protocol title

Clinical Dermatology study with instrumental efficacy for the evaluation of the cosmetic device **GLAMOUR NEW YORK MULTIWAVE.**

2.2. Product (device) under investigation

Application

Cosmetic

Device usage

Functions/claims and times for the Led lights of GLAMOUR NEW YORK MULTIWAVE

On Visage:

-RED LIGHT: Antiaging - Reduces the appearance of wrinkles – Improves texture – Helps the production of collagen and elastin in the skin
-GREEN LIGHT: Sunspot reduction – Radiance/brightening – Improves skin texture
-BLUE LIGHT: Antibacterial – Minimize pores –Cleans impurities from the skin
-YELLOW LIGHT: Reduces deep of the wrinkles – Improves skin flaccidity – Promotes collagen production – Stimulates tissue regeneration, freckles and redness – Cicatrizing – Improves skin circulation (couperosis)
-WHITE LIGHT (FLASH): Stabilizes treatment – Relaxes the skin – Provides a healthier effect to the skin
-CYCLE (MULTIFUNCTION): Combine all the lights to treat more aspects of the skin at the same time.
The lights are determined according to the skin of the volunteer, and can be combined with each other. The time of each light is 15 minutes and the total duration of the session is 30 minutes per volunteer/session.
For "CYCLE" mode the set time is 30 minutes.

On Neck and Neckline:

-RED LIGHT: Antiaging - Reduces the appearance of wrinkles – Improves texture – Helps the production of collagen and elastin in the skin
-GREEN LIGHT: Sunspot reduction – Radiance/brightening – Improves skin texture
-BLUE LIGHT: Antibacterial – Minimize pores – Cleans impurities from the skin
-YELLOW LIGHT: Reduces deep of the wrinkles – Improves skin flaccidity – Promotes collagen production – Stimulates tissue regeneration, freckles and redness – Cicatrizing – Improves skin circulation (couperosis)
-WHITE LIGHT (FLASH): Stabilizes treatment – Relaxes the skin – Provides a healthier effect to the skin

On Legs:

-GREEN LIGHT: Cellulite reduction + Elasticity and Firmness (Tensor effect)
-YELLOW LIGHT: Boosts circulation – Drains toxins – Soothing skin

In both groups (facial and body) the lights used are combined with the WHITE LIGHT (FLASH) at the same time, thus activating and preparing the skin tissue so that the light can penetrate much deeper.

2.3. Device handling

The study device was delivered by the sponsor to Methodex, who was in charge of performing the treatment to the participants.

Methodex complied with the device storage conditions:

- Protected from sunlight
- Preserved avoiding direct contact with the ground
- Keep the device clean
- Do not allow water or any type of liquid to enter the device

3. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

N	Number (volunteers/subjects)
T	Time
IC	Informed Consent
CVQ	Subjective Volunteer Questionnaire
CRF	Case Report Form
SIS	Subject Information Sheet
GCP	Good Clinical Practices

4. ETHICS

4.1. Ethical aspects in the conduct of the study

The reference study was carried out in accordance with the ethical principles governed by the Declaration of Helsinki and the guidelines established by Good Clinical Practices, including the preservation of the documentation generated during the execution of the study.

4.2. Information regarding the subject and informed consent

Volunteers were informed about the characteristics of the study, its possible risks and benefits, and all questions raised by the volunteers were answered. They were also explained that their participation was voluntary, being able to withdraw from the study at any time without having to give explanations and that both access to their medical history and the data collected during the reference study would be treated as established in the Regulation General Data Protection ("GDPR") of the EU20.

During the selection phase, the volunteer was explained, in an exhaustive manner, what the study consisted of, it's possible benefits and risks, their right not to participate or the resignation from the study once their participation in the study began, without that this would undermine their attention for the moment of the study or for possible future participation in any other clinical study.

The volunteers were provided with the SIS to review and to ensure their understanding and to confirm their participation in the study. The IC was subsequently provided for signature to have in a written format the volunteer's confirmation and acceptance in the study in order to comply with the guidelines established by Good Clinical Practices.

5. STUDY POPULATION

Selection of volunteers

20 volunteers over 25 years of age were selected, who met the following inclusion criteria. None were excluded.

5.1. Inclusion criteria

- Female volunteers over 25 years old with signs of ageing/redness/acne-prone skin/sunspots. All skin types.
- Apparent good health.
- Adequate cultural level and understanding of the study.
- Agree to voluntarily participate in the study and give their informed consent in writing.
- Volunteers with no acute illness during the study and in the week prior to the start of the study.
- No skin pathologies in the week prior to the start of the trial.
- Volunteers who are not undergoing pharmacological treatment.
- Volunteers will not apply other cosmetic products to the areas to be treated during treatment with the device.

5.2. Exclusion criteria

- Reactivity to cosmetic devices of the same category as the test device.
- Previous involvement in other skin treatment studies.
- Apply medical or cosmetic products that can worsen hyperpigmentation due to light (such as topical corticosteroids or topical vitamin C).
- Evidence of any current viral, fungal, or bacterial infection.
- Present any metallic object in the body (prosthesis, pacemaker, piercings...)
- Taking medications that can cause photosensitivity (oral isotretinoin, oral acitretin, oral tetracycline such as minocycline or doxycycline).
- Receiving radiation or chemotherapy treatments.
- Dermatological Pathology such as Rosacea, Urticaria or angioedema crises, Psoriasis, Dermatitis A., Vitiligo or any other skin disorder.

- Cutaneous hyperreactivity.
- General pathology such as: Asthma under treatment (even discontinuous), Heart problems, Kidney problems, Cancer (even old), Infections such as Tuberculosis, Hepatitis, Arthritis.
- Treatments: Topical or oral corticosteroids for sustained use, Topical or oral anti-inflammatories for sustained use, Insulin, Anxiolytics, antidepressants, treatments for insomnia, Antiepileptic, Cardiology (beta-blockers), Hypotensive agents, Anticoagulants.
- Carry out a treatment containing topical corticosteroids in the experimental area during the 8 days prior to the start of the study.
- Volunteers should not be pregnant or breastfeeding.

5.3. Information to the participant

All volunteers were informed of the characteristics of the study verbally and in writing through the Subject Information Sheet, which included information on the following aspects:

- Rights of the person participating in the study
- Objective
- Methodology used
- Treatment of the device
- Discomforts and risks arising from the study
- Possible adverse events
- Access to data and confidentiality
- Researcher responsible for the study

Finally, after the explanation of the study, the volunteers were asked to provide the Informed Consent in writing. By signing and dating the consent form, the volunteer confirmed their participation.

Throughout the study, the volunteers kept the SIS, with all the relevant study information and their copy of the Informed Consent. The investigator retained the volunteers' Informed Consent in the study file.

6. OBJECTIVES

6.1. Main objective

To assess the effectiveness and acceptability of the treatment with the **GLAMOUR NEW YORK MULTIWAVE** for 4 weeks (2 times a week) in healthy volunteers and assess safety and adverse events. In the facial group, Softplus® was used to assess wrinkles and the elasticity/firmness of the eye contour and melanin on sunspots. Visioface® was used to evaluate luminosity and pores of the visage. In the body group, Softplus® was used to assess elasticity/firmness and melanin on sunspots of the neckline. The cellulitis on legs was assessed through the Cell-meter® equipment and elasticity/firmness on legs was evaluated with Softplus®. The subjective efficacy of the treatment with the device was evaluated at the final of each week through a questionnaire for all the volunteers.

7. ENVIRONMENTAL CONDITIONS

All measurements are performed in a room with controlled temperature (21°C -/+ 1) and relative humidity (50% +/- 10%). Participants spend 10-20 minutes acclimatising before measurements are taken.

8. EVALUATION METHODS – INSTRUMENTAL EQUIPMENT

8.1. SOFTPLUS® wrinkles

The measurement of wrinkles with the Soft Plus® equipment allows evaluating the dimensions of the wrinkles present in the skin in terms of their length, width and depth.
The image is captured using the capture button on the microcamera. Next, the dimensions of the wrinkles to be evaluated are analysed, using the rule that the program has.
The units of the parameters of wrinkles are measured in mm.

8.2. SOFTPLUS® elasticity and Firmness (tensor effect)

Measurements of elasticity and firmness together are used to assess the tensor effect.
SOFT PLUS® is a device used to measure the elasticity and firmness of the most superficial layer of the skin by exerting a suction probe.
The skin spontaneously returns to its normal position through the opening of the probe when the time set by the device elapses (approximately 5 seconds).

The measuring principle of the SOFT PLUS® equipment is mechanical suction through stress and deformation of the skin. The skin is suctioned through a small opening in the tube after depressing the plunger by reaching a stable position and applying constant pressure.

The data obtained from the equipment will be analyzed to determine the tightening effect with conventional units (c.u.) that have values between 0 and 50.
The improvement in terms of elasticity and joint firmness (tensor effect) occurs the higher the number (closer to the value of 50).

8.3. SOFTPLUS® melanin

The melanin probe is a simple and quick tool to measure the main component responsible for skin color. Numerous international scientific studies have demonstrated its benefits in the dermatological and cosmetological field. The measurement principle is reflection photometric at 2 wavelengths (λ=875nm and λ=660nm) through a sensor at the tip.
Melanin is measured using specific wavelengths chosen to correspond to different absorption rates of pigments. In this way the spots on the skin can be measured.

The result of the melanin value is displayed on a scale of 0 - 100 c.u.

8.4. VISIOFACE®

Visioface® is an ideal device for documentation of treatments and for carrying out dermatological studies:

- Pores: count according to size, total area, comparisons and evolution. Measurements are expressed in pixels (px).
- Spots of colour and luminosity of the skin (px).
- Wrinkles: analyses their volume (px^3), area (px^2) and depth (px), and shows the evolution of the treatment.
- Recommendation of product and treatments based on the analysis. Visioface® provides a stable and homogeneous illumination of the visage with its 210 white light LEDs.

It integrates a high-resolution reflex camera (18 Mpx) with a special lens with which high-resolution front and side images are obtained. The procedure for taking images consists of resting the forehead and chin on the positioners and the reflex camera is triggered. This allows the improvement of the skin to be measured.

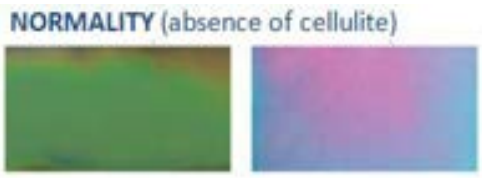
8.5. CELL-METER®

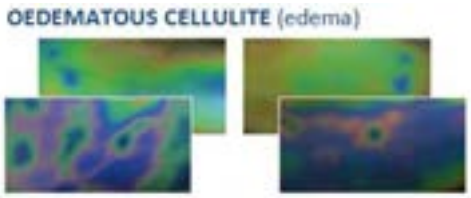
Beyond the aesthetic problem, cellulite itself represents connective tissue pathology. A local disorder that causes the accumulation of fat, and causes a change in the appearance of the skin.

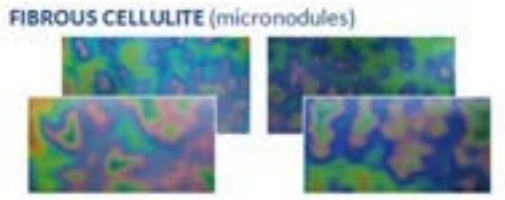
This chemical and structural modification of the tissue leads to: Deficient arterial, venous and lymphatic micro-circulation. Retention of water and toxins derived from a malfunction of cell drainage.

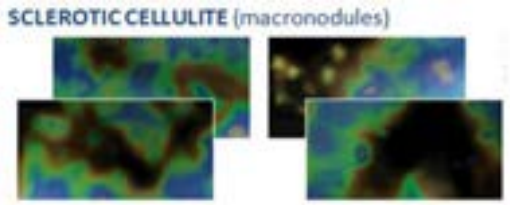
Contact thermography with microencapsulated liquid crystals is a simple and very effective technology that solves the detection of cellulite from its early stages, when visual examination is not enough.

These allow to visualize, with colour images, the temperature of the areas under examination to show the alterations in skin temperature caused by cellulite in its different stages:









9. STUDY DESIGN

This study lasts 4 weeks in which each volunteer was treated with the most appropriate light mode for their skin type and answered some questionnaires as shown below:

WEEK 1	WEEK 2	WEEK 3	WEEK 4
Treatment with GLAMOUR NEW YORK MULTIWAVE	**Treatment with GLAMOUR NEW YORK MULTIWAVE**	**Treatment with GLAMOUR NEW YORK MULTIWAVE**	**Treatment with GLAMOUR NEW YORK MULTIWAVE**
Initial questionnaire T0 on the skin condition (before starting the study) + First week skin improvement questionnaire at the end of the week	**Second week skin improvement questionnaire at the end of the week**	**Third week skin improvement questionnaire at the end of the week**	**Fourth and final week skin improvement/condition and recommendation of treatment questionnaire at the end of the week**

The study is comprised of 20 women using the GLAMOUR NEW YORK MULTIWAVE for 4 weeks (treatment 2 times a week) – total of 8 sessions.
Volunteers are divided into 2 groups: 15 facial and 5 body. In the facial group, the skin of the visage was evaluated and in the body group, the skin of the neck/neckline and cellulitis on the legs, elasticity/firmness was evaluated.

SELECTION:

Two weeks prior to the start of the experimental phase, potential volunteers already included in the Methodex database were selected and the inclusion / exclusion criteria were verified.
Volunteers made the following visits:

Initial visit – T0 (day 1-Session 1)

- It was assessed that it meets the inclusion criteria.
- The subject's information sheet was given to the volunteer and once she had understood everything related to the study and signed the informed consent, the study began.
- The volunteer completed an initial subjective questionnaire on the perception of its current skin condition.
- Demographic and skin type data were collected and included in the data collection. In addition, measurements and photographs were taken with the corresponding instrumental equipment according to the group described above.
- The volunteers remained on a stretcher for the time established per session according to the corresponding group, applying a mask and a different light mode to the skin with the device provided by the promoter.

Each volunteer was visited twice a week to carry out the corresponding treatment until completing the 4 weeks.

Note: For both groups, at the end of each week, a cosmetic efficacy questionnaire was carried out (D7 + D14 + D21 + D28).

Intermediate visits (Sessions 2, 3, 4, 5, 6, 7)

- The safety of the device and adverse events was evaluated.
- The volunteers remained on a stretcher for the time established per session according to the corresponding group, applying a mask and a different light mode to the skin with the device provided by the promoter.

Final visit – T4 weeks (day 28-Session 8)

- The safety of the device and adverse events was evaluated.
- The volunteers remained on a stretcher for the time established per session according to the corresponding group, applying a mask and a different light mode to the skin with the device provided by the promoter.
- Measurements and photographs were made with the corresponding instrumental equipment according to the group described above.
- Volunteers completed a final questionnaire on the effectiveness of treatment with the device and their current skin condition.

10. DERMATOLOGICAL TOLERANCE AND SAFETY ASSESSMENT

The safety profile was evaluated by recording adverse events and evaluating the results. Any type of adverse event was collected in the CRF and communicated by the participant spontaneously or at the direction of the investigation team, and was described in the corresponding record to document the tolerability to it.

At the end of the study, the corresponding skin evaluation was carried out and the volunteers filled out a questionnaire about the possible alterations that could appear after treatment with the device.

10.1. Parameters studied

Main variables:

- Reactions considered as undesirable effects related to the research device.
- Evaluation of Adverse Events (safety).
- Efficacy of the device by assessing, for the facial group, wrinkles and elasticity/firmness on the eye contour and melanin (if they had sunspots) with SoftPlus® and pores, luminosity with Visioface®. For the body group, the elasticity/firmness, melanin ((if they had sunspots) of the neckline and cellulite on the legs, elasticity/firmness were also evaluated.

Secondary variables:

- Subjective assessment of the efficacy of the device, through a questionnaire to all the volunteers: the satisfaction of the volunteers in relation to the device studied was assessed through their responses to the questionnaire (each week) by statistically analysing the results from the graphs and the subjective questionnaire.
- Assessment of reactions observed by the volunteers.

11. PUBLICATION POLICY

The personal data issued in the report, as well as any reference to Methodex or / and the researchers may not be used for advertising without prior consent.

12. STATISTIC ANALYSIS

The characteristics of the device were evaluated through a subjective questionnaire, elaborated expressly for this study, completed by the volunteer at the final of each week and compared with some questions made in the initial visit respect to the final visit. Data from measurements at T4 weeks were compared with those at T0 for further analysis.

The treatment data was analysed according to the characteristics of the skin and the group of volunteers (facial or body) before and after (T0-T28 days → Sessions 1-8):

FACIAL GROUP (N=15)

On visage

N=5 Redness – Photographs with VISIOFACE®
N=10 Sunspots – Melanin assessment before and after with SOFTPLUS®. Photographs with VISIOFACE®
N=5 Acne-prone skin – Pores assessment with VISIOFACE®. Photographs with VISIOFACE®
N=15 Brightness/ luminosity + Elasticity and firmness assessment with SOFTPLUS®. Photographs with VISIOFACE®
N=10 Antiaging – Wrinkles assessment with SOFTPLUS®. Improves texture (subjective). Photographs with SOFTPLUS®

BODY GROUP (N=5)

On neck and neckline

N=5 Melanin (sunspots) + Elasticity and firmness assessment with SOFTPLUS®. Improves brightness/luminosity (subjective). Photographs with a camera

On legs

N=5 Cellulitis – Thermographic plates with CELL-METER® + thigh perimeter with a tape measure. Elasticity and firmness assessment with SOFTPLUS®. Photographs with a camera

12.1. Data processing

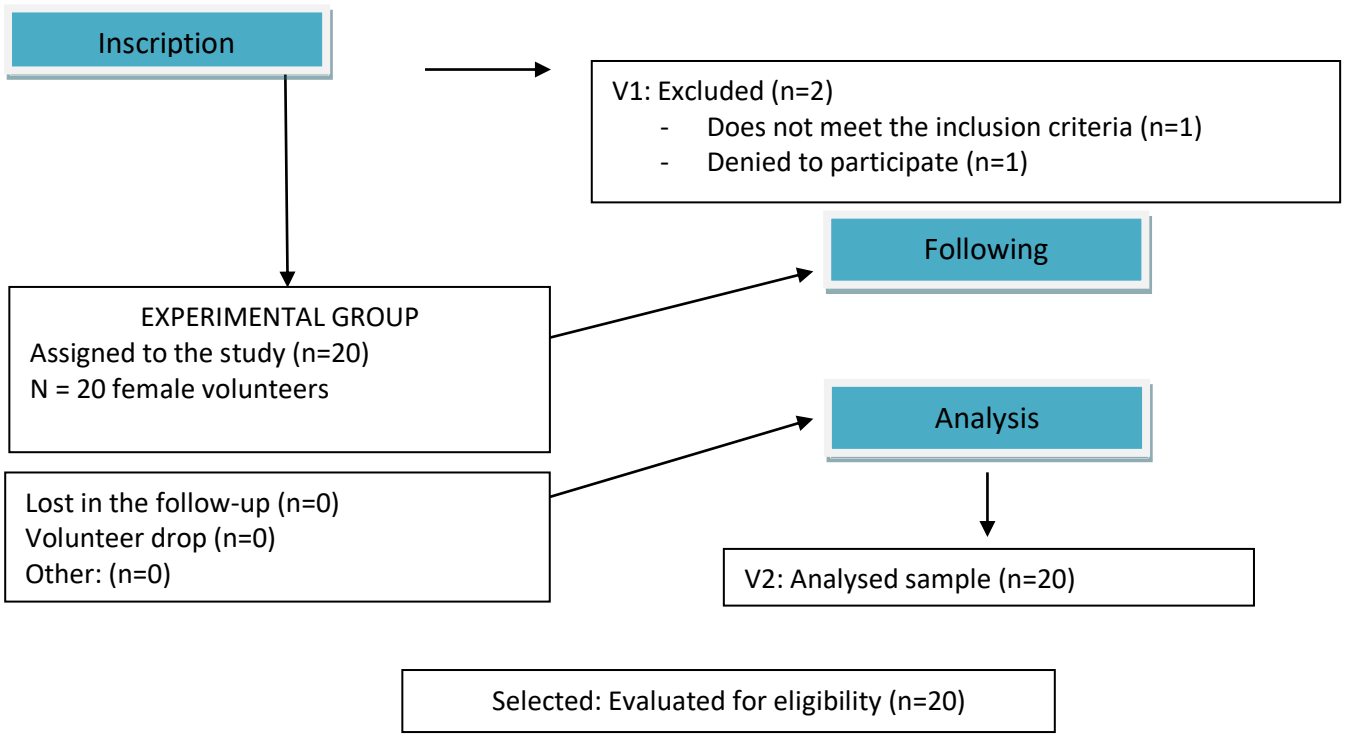
The study data was treated according to the reference standards of confidentiality and quality criteria.
The information was validated through internal consistency controls, studying the missing values. The data was verified and corrected when it was fully validated.

12.2. Descriptive statistics

The analysis of the results began with the description of the characteristics of the people included in the study. This description includes information regarding continuous variables (N, mean, standard deviation, minimums and maximums) and regarding discrete variables (relative and absolute frequencies).

12.3. Statistical tests

To study statistical significance, a normality test (Shapiro Wilks) is used and, according to its result, the mean difference test is performed: t-student (when normality is fulfilled) or the Wilcoxon test (when normality is not fulfilled), both paired.



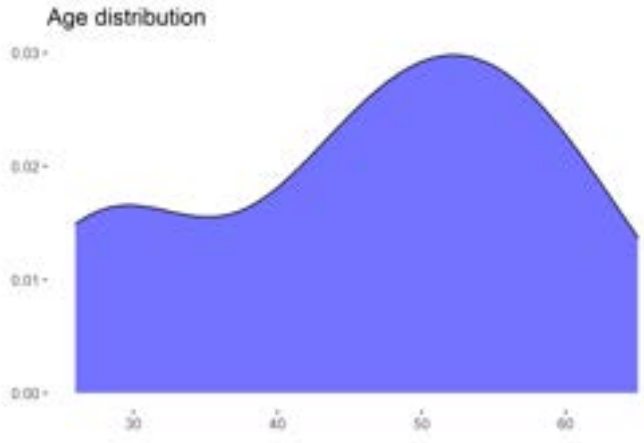
13.RESULTS

13.1. Demographic data

GENDER: The sample is made up of 20 women.

AGE: The following table and graph show the age distribution.

	N	Minimum	Q1	Median	Mean	Q3	Maximum	Standard Deviation
Age	20	26.00	37.75	48.50	46.20	55.50	65.00	12.48



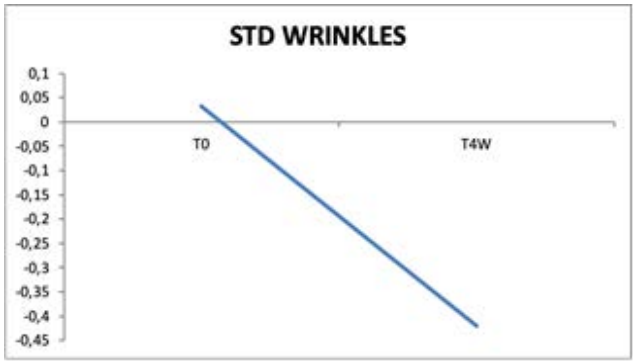
13.2. Phototype and type of skin

DEFINITION	Phototype
LIGHT SKIN, UNTANNED, VERY SENSITIVE TO SUNBURN	I
SKIN A LITTLE DARKER, UNTANNED. ALSO SENSITIVE TO SUNBURN	II
LIGHT SKIN OR SLIGHTLY BROWN, TANNED, RESISTANT TO INSOLATION	III
BROWN SKIN, VERY INSOLATION RESISTANT AND VERY FAST TANNING	IV
ASIAN SKIN	V
BLACK SKIN	VI

13.3. Assessment of the winkles of the eye contour

Wrinkles (Decrease implies improvement)

The wrinkles parameter provided by the Softplus® equipment in the eye contour randomly. The following graph shows the evolution of the wrinkles with the mean values for T0 (before session 1) and T4 weeks (after session 8) for 10 volunteers (N=10). The table shows the descriptive statistics regarding wrinkle, the difference with respect to T0 and p-value, with the mean values for the 2 times in the measurement area.



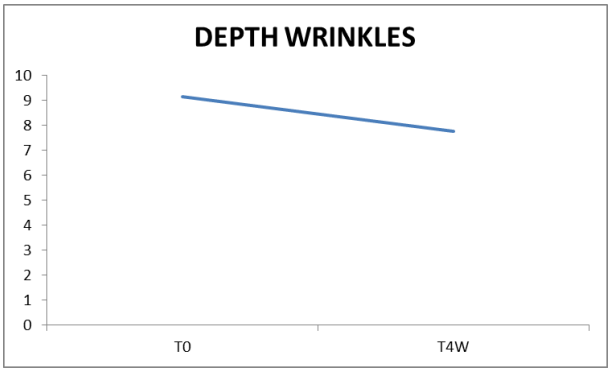
MEASUREMENT	Mean T0 ± SD	Mean T4 weeks ± SD
Wrinkles (*)	0.03[1]± 0.66	-0.41[1]± 0.78
Differences with T0		-0.45
p-value	0.002**	

* (*) Wilcoxon test, according to the normality of the distribution of the difference, checked by Shapiro-Wilk test, at 1% risk
** Statistically significant variation: $p < 0.05$ / Non-significant variation: $p \geq 0.1$.

[1] All variables have been standardized by centering the mean and dividing by the standard deviation.

According to the data obtained, we can observe the decrease in the mean wrinkles in the eye contour to T4 weeks. The result obtained is statistically significant.

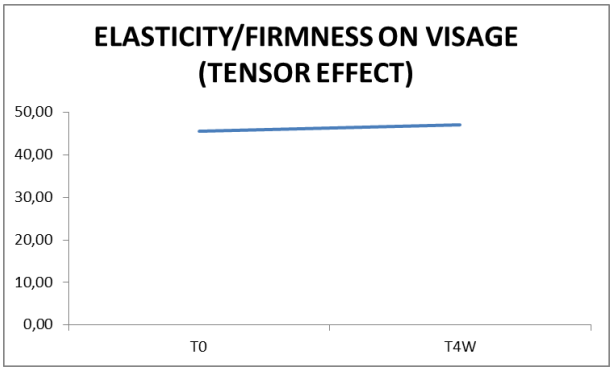
The parameters related to wrinkles in terms of length, width and depth are shown in more detail below.



13.4. Assessment of the elasticity/firmness of the eye contour

Elasticity/firmness (Increase implies improvement)

The elasticity/firmness parameter provided by the Softplus® equipment in the eye contour randomly has been evaluated. The following graph shows the evolution of the elasticity/firmness with the mean values for T0 (before session 1) and T4 weeks (after session 8) for 15 volunteers (N=15). The table shows the descriptive statistics regarding elasticity/firmness, the % difference with respect to T0 and p-value, with the mean values for the 2 times in the measurement area.



MEASUREMENT	Mean T0 ± SD	Mean T4 weeks ± SD
Elasticity/firmness (*)	45.53[2]± 1.41	47.00[2]± 0.85
% Differences with T0		3.22%
p-value	0.0021**	

(*) Wilcoxon test, according to the normality of the distribution of the difference, checked by Shapiro-Wilk test, at 1% risk
** Statistically significant variation: $p < 0.05$ / Non-significant variation: $p \geq 0.1$.

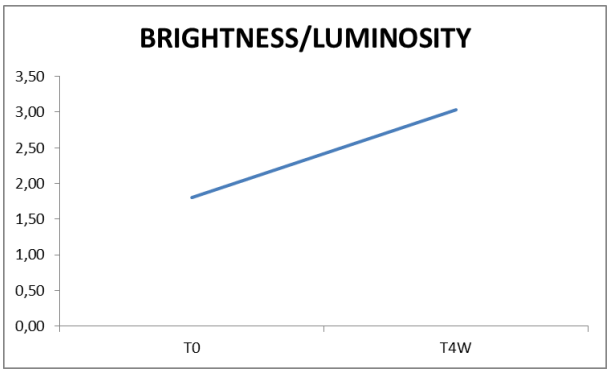
[2]The data obtained from the equipment was analysed to determine the tightening effect with conventional units (c.u.) that have values between 0 and 50.
The improvement in terms of elasticity and joint firmness (tensor effect) occurs the higher the number (closer to the value of 50).

According to the data obtained, we can observe an improvement in the elasticity and firmness of the eye contour at T4 weeks. The result obtained is statistically significant.

13.5. Assessment of the brightness/luminosity on the visage VISIOFACE®

Brightness/luminosity (Increase implies improvement)

The luminosity parameter provided by the Visioface® equipment on the overall visage has been evaluated. The following graph shows the evolution of Brightness/luminosity with the mean values for T0 (before session 1) and T4 weeks (after session 8) for 15 volunteers (N=15). The table shows the descriptive statistics regarding brightness/luminosity, the % difference with respect to T0 and p-value, with the mean values for the 2 times in the measurement area.



MEASUREMENT	Mean T0 ± SD	Mean T4 weeks ± SD
Brightness/luminosity (*)	1.81[3] ± 0.81	3.03[3] ± 1.04
% Differences with T0		67.87%
p-value	≅0**	

(*) Wilcoxon test, according to the normality of the distribution of the difference, checked by Shapiro-Wilk test, at 1% risk
** Statistically significant variation: $p < 0.05$ / Non-significant variation: $p \geq 0.1$.

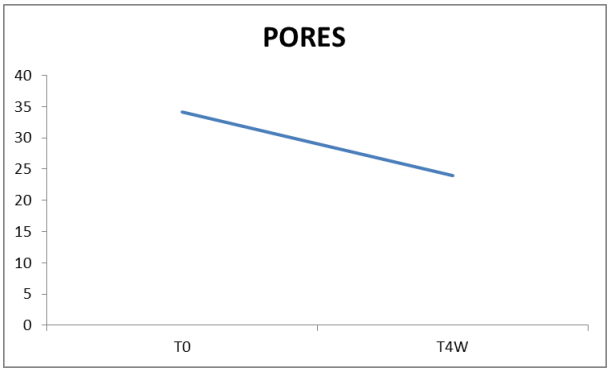
[3]Brightness/luminosity of the skin (px)

According to the data obtained, we can observe the increase in the mean Brightness/luminosity on visage to T4 weeks. The result obtained is statistically significant.

13.6. Assessment of the pores on the visage VISIOFACE®

PORES (Decrease implies improvement)

The pores parameter provided by the Visioface® equipment on the overall visage has been evaluated on volunteers with acne-prone skin. The following graph shows the evolution of pores with the mean values for T0 (before session 1) and T4 weeks (after session 8) for 5 volunteers (N=5). The table shows the descriptive statistics regarding pores, the % difference with respect to T0 and p-value, with the mean values for the 2 times in the measurement area.



MEASUREMENT	Mean T0 ± SD	Mean T4 weeks ± SD
Pores (*)	34.10[4] ± 12.60	24.00[4] ± 11.23
% Differences with T0		-29.62%
p-value	0.0313*	

(*) Wilcoxon test, according to the normality of the distribution of the difference, checked by Shapiro-Wilk test, at 1% risk
** Statistically significant variation: $p < 0.05$ / Non-significant variation: $p \geq 0.1$.

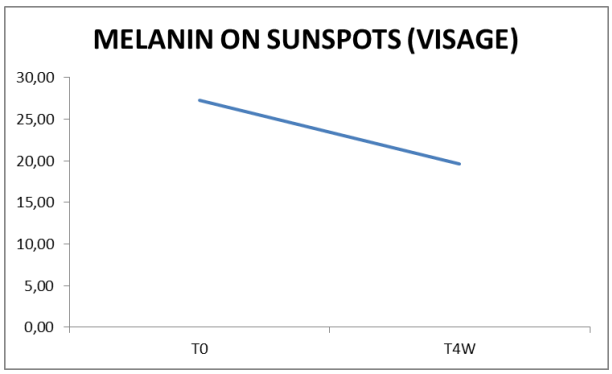
[4]Pores of the skin (px)

According to the data obtained, we can observe the decrease in the mean pores on the visage to T4 weeks. The result obtained is statistically significant.

13.7. Assessment of the melanin of sunspots on the visage SOFTPLUS®

MELANIN (Decrease implies improvement)

The melanin parameter provided by the Softplus® equipment on the sunspots of the visage has been evaluated. The following graph shows the evolution of melanin with the mean values for T0 (before session 1) and T4 weeks (after session 8) for 10 volunteers (N=10). The table shows the descriptive statistics regarding melanin, the % difference with respect to T0 and p-value, with the mean values for the 2 times in the measurement area.



MEASUREMENT	Mean T0 ± SD	Mean T4 weeks ± SD
Melanin (*)	27.28[5]±8.48	19.66[5]±5.35
% Differences with T0		-27.93%
p-value	0.0039**	

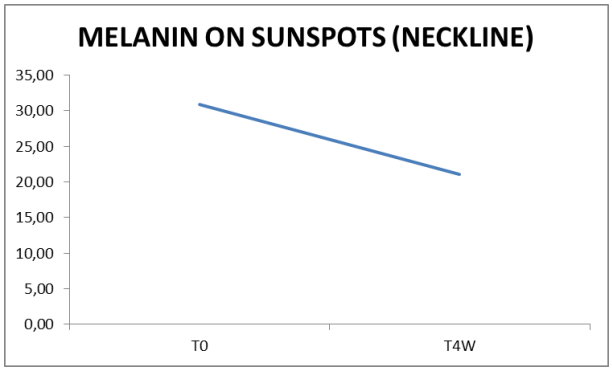
(*) Wilcoxon test, according to the normality of the distribution of the difference, checked by Shapiro-Wilk test, at 1% risk
** Statistically significant variation: $p < 0.05$ / Non-significant variation: $p \geq 0.1$.

[5]The data obtained from the equipment was analysed to determine the melanin with conventional units (c.u.) that have values between 0 and 100.
The improvement in terms of melanin of sun spots occurs the lower the number (closer to the value of 0).
According to the data obtained, we can observe an improvement in the sunspots of the visage at T4 weeks. The result obtained is statistically significant.

13.8. Assessment of the melanin of sunspots on the neckline SOFTPLUS®

MELANIN (Decrease implies improvement)

The melanin parameter provided by the Softplus® equipment on the sunspots of the neckline has been evaluated. The following graph shows the evolution of melanin with the mean values for T0 (before session 1) and T4 weeks (after session 8) for 5 volunteers (N=5). The table shows the descriptive statistics regarding melanin, the % difference with respect to T0 and p-value, with the mean values for the 2 times in the measurement area.



MEASUREMENT	Mean T0 ± SD	Mean T4 weeks ± SD
Melanin (*)	30.93[5]±11.70	21.10[5]±7.94
% Differences with T0		-31.79%
p-value	0.0313*	

(*) Wilcoxon test, according to the normality of the distribution of the difference, checked by Shapiro-Wilk test, at 1% risk
** Statistically significant variation: $p < 0.05$ / Non-significant variation: $p \geq 0.1$.

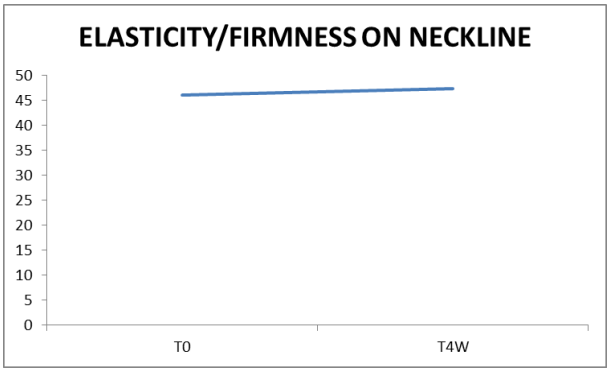
[5]The data obtained from the equipment was analysed to determine the melanin with conventional units (c.u.) that have values between 0 and 100.
The improvement in terms of melanin of sunspots occurs the lower the number (closer to the value of 0).

According to the data obtained, we can observe an improvement in the sunspots of the neckline at T4 weeks. The result obtained is statistically significant.

13.9. Assessment of the elasticity/firmness of the neckline SOFTPLUS®

Elasticity/firmness (Increase implies improvement)

The elasticity/firmness parameter provided by the Softplus® equipment in the neckline has been evaluated. The following graph shows the evolution of the elasticity/firmness with the mean values for T0 (before session 1) and T4 weeks (after session 8) for 5 volunteers (N=5). The table shows the descriptive statistics regarding elasticity/firmness, the % difference with respect to T0 and p-value, with the mean values for the 2 times in the measurement area.



MEASUREMENT	Mean T0 ± SD	Mean T4 weeks ± SD
Elasticity/firmness (*)	46.00[6]± 0.71	47.40[6]± 0.89
% Differences with T0		3.04%
p-value	0.0488*	

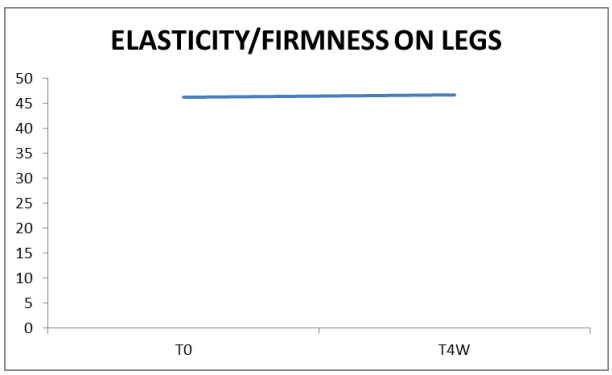
(*) Wilcoxon test, according to the normality of the distribution of the difference, checked by Shapiro-Wilk test, at 1% risk
** Statistically significant variation: $p < 0.05$ / Non-significant variation: $p \geq 0.1$.

[6]The data obtained from the equipment was analysed to determine the tightening effect with conventional units (c.u.) that have values between 0 and 50.
The improvement in terms of elasticity and joint firmness (tensor effect) occurs the higher the number (closer to the value of 50).

According to the data obtained, we can observe an improvement in the elasticity and firmness of the neckline at T4 weeks. The result obtained is statistically significant.

13.10. Assessment of the elasticity/firmness of the legs SOFTPLUS®

The elasticity/firmness parameter provided by the Softplus® equipment in the legs has been evaluated. The following graph shows the evolution of the elasticity/firmness with the mean values for T0 (before session 1) and T4 weeks (after session 8) for 5 volunteers (N=5). The table shows the descriptive statistics regarding elasticity/firmness, the % difference with respect to T0 and p-value, with the mean values for the 2 times in the measurement area.



MEASUREMENT	Mean T0 ± SD	Mean T4 weeks ± SD
Elasticity/firmness (*)	46.20[7]± 0.84	46.80[7]± 0.45
% Differences with T0		1.30%
p-value	0.0745	

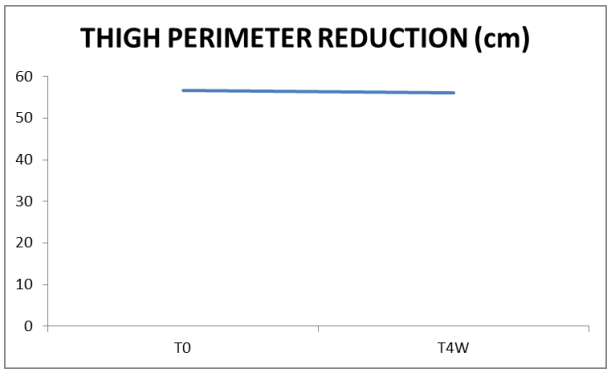
(*) Wilcoxon test, according to the normality of the distribution of the difference, checked by Shapiro-Wilk test, at 1% risk
** Statistically significant variation: $p < 0.05$ / Non-significant variation: $p \geq 0.1$.

[7]The data obtained from the equipment was analysed to determine the tightening effect with conventional units (c.u.) that have values between 0 and 50.

The improvement in terms of elasticity and joint firmness (tensor effect) occurs the higher the number (closer to the value of 50).
A trend can be observed in the improvement of elasticity and firmness (tensor effect) in the thighs of the legs at T4 weeks. The result obtained is not statistically significant.

13.11. Assessment of the perimeter of the thigh SOFTPLUS®

The thigh perimeter on the legs has been evaluated through a tape measure. The following graph shows the evolution of the thigh perimeter with the mean values for T0 (before session 1) and T4 weeks (after session 8) for 5 volunteers (N=5). The table shows the descriptive statistics regarding thigh perimeter, the % difference with respect to T0 and p-value, with the mean values for the 2 times in the measurement area.



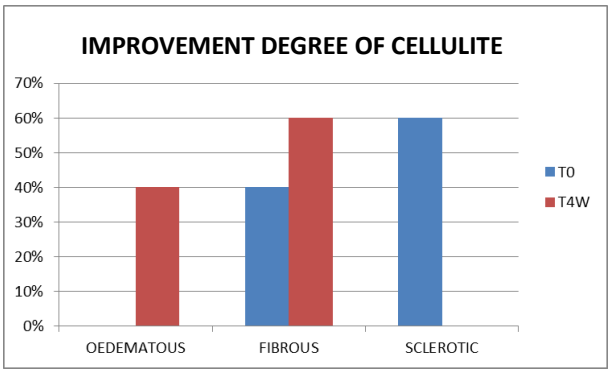
MEASUREMENT	Mean T0 ± SD	Mean T4 weeks ± SD
Elasticity/firmness (*)	56.70[8]± 3.63	56.10[8]± 3.44
% Differences with T0		-1.06%
p-value	0.0473*	

(*) Wilcoxon test, according to the normality of the distribution of the difference, checked by Shapiro-Wilk test, at 1% risk
** Statistically significant variation: $p < 0.05$ / Non-significant variation: $p \geq 0.1$.

[8]The data obtained was analysed to determine the perimeter of the thigh on the legs with values expressed in cm.
The improvement occurs when the final value with respect to the initial decreases.
According to the data obtained, we can observe an improvement in the thigh perimeter of the legs at T4 weeks. The result obtained is statistically significant.

13.12. Assessment of the cellulite of the legs CELL-METER®

The cellulite degree provided by the Cell-meter® equipment in the legs has been evaluated. The following graph shows the evolution of the cellulite degree with the mean values for T0 (before session 1) and T4 weeks (after session 8) for 5 volunteers (N=5).



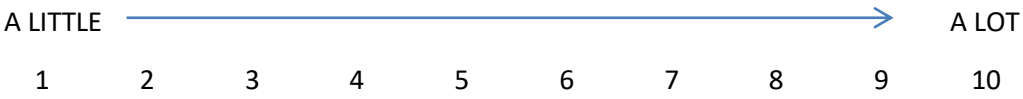
The following table shows the descriptive statistics regarding cellulite degree, the % of each degree of cellulite for the 2 times in the measurement area.

	T0		T4 WEEKS	
CELLULITE DEGREE	NUMBER OF VOLUNTEERS	% OF VOLUNTEERS	NUMBER OF VOLUNTEERS	% OF VOLUNTEERS
OEDEMATOUS	0	0%	2	40%
FIBROUS	2	40%	3	60%
SCLEROTIC	3	60%	0	0%
TOTAL	5	100%	5	100%

It can be seen how the degree of cellulite decreases, showing a higher degree of cellulite at T0 (a higher % of sclerotic and fibrous) and a lower degree of cellulite at T4 weeks (the sclerotic cellulite disappears and the fibrous becomes oedematous).

13.13. Response Analysis

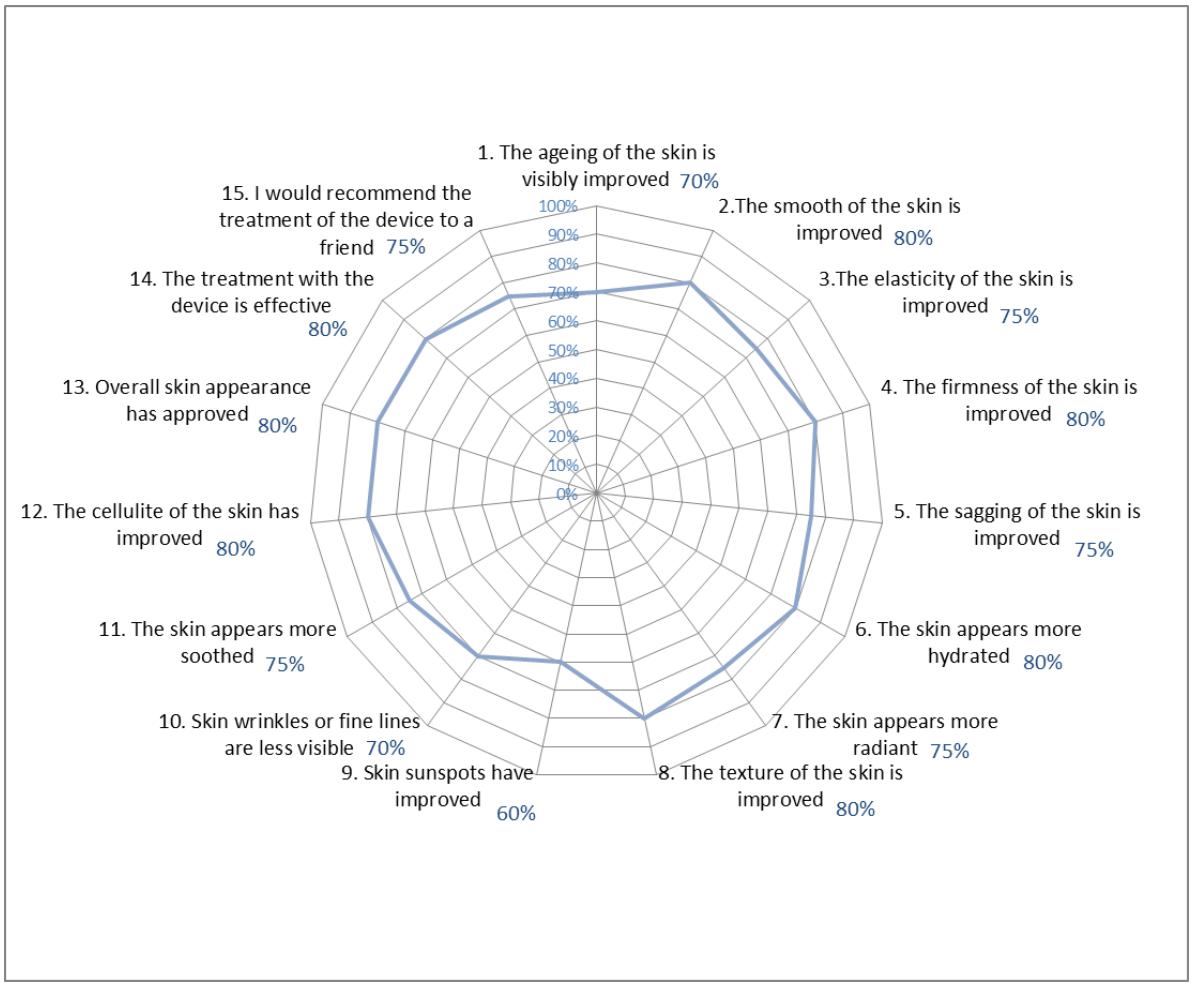
The answers to the subjective questionnaire were obtained from a scale of 1 to 10, where 1 is that there is practically no improvement ("a little") and 10 is a lot of improvement ("a lot").



The answers were later adapted as categorical answers to be better statistically interpreted, as shown in the table:

Scale answers (1 to 10)	Categorical answers
1,2	Nothing/ Strongly disagree
3,4,5	A little/ Disagree
6,7,8	Enough/ Agree
9, 10	A lot/ Strongly agree

NOTE: The below web chart has been calculated by adding up the positive responses for each question (sum of "% A lot/Strongly agree" + "% Enough/Agree").



For the following table, please find the relevant definitions below:

a. The % of positive evaluations, is defined as, the % of answers of the positive categories together.

b. The p-value of the test that contrasts whether the previous proportion of positive evaluations is greater than 50% and consequently greater than the proportion of negative evaluations. This p-value indicates the probability of being wrong when affirming that the positive evaluations would be greater than the negative ones extrapolating to the entire population (regardless of what was obtained in this sample).

c. All the questions were asked for an N of 20 volunteers, except the question about cellulite (question 12), which was about an N of 5 volunteers.

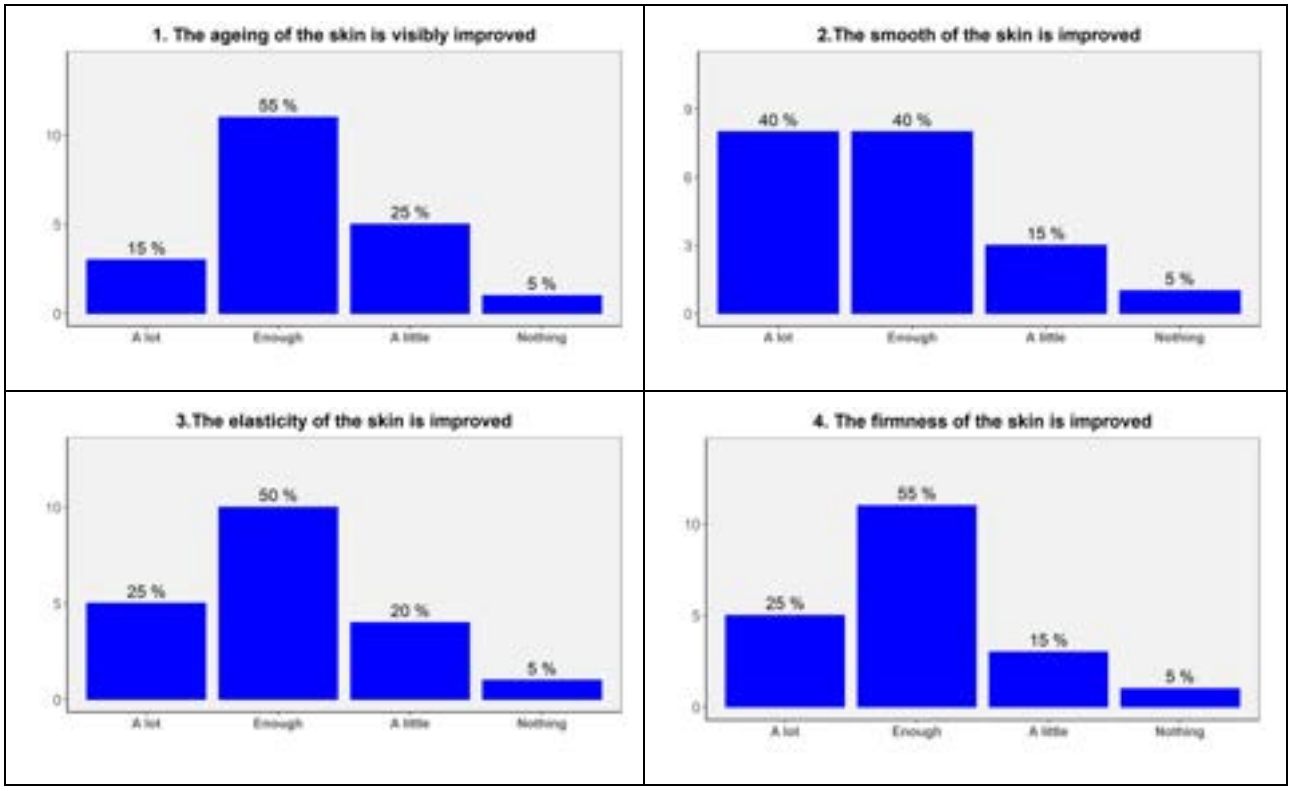
QUESTIONS	PERCENTAGE	P_VALUE
1. THE AGEING OF THE SKIN IS VISIBLY IMPROVED	70%	0.0588
2.THE SMOOTH OF THE SKIN IS IMPROVED	80%	0.007**
3.THE ELASTICITY OF THE SKIN IS IMPROVED	75%	0.0221*
4. THE FIRMNESS OF THE SKIN IS IMPROVED	80%	0.007**
5. THE SAGGING OF THE SKIN IS IMPROVED	75%	0.0221*

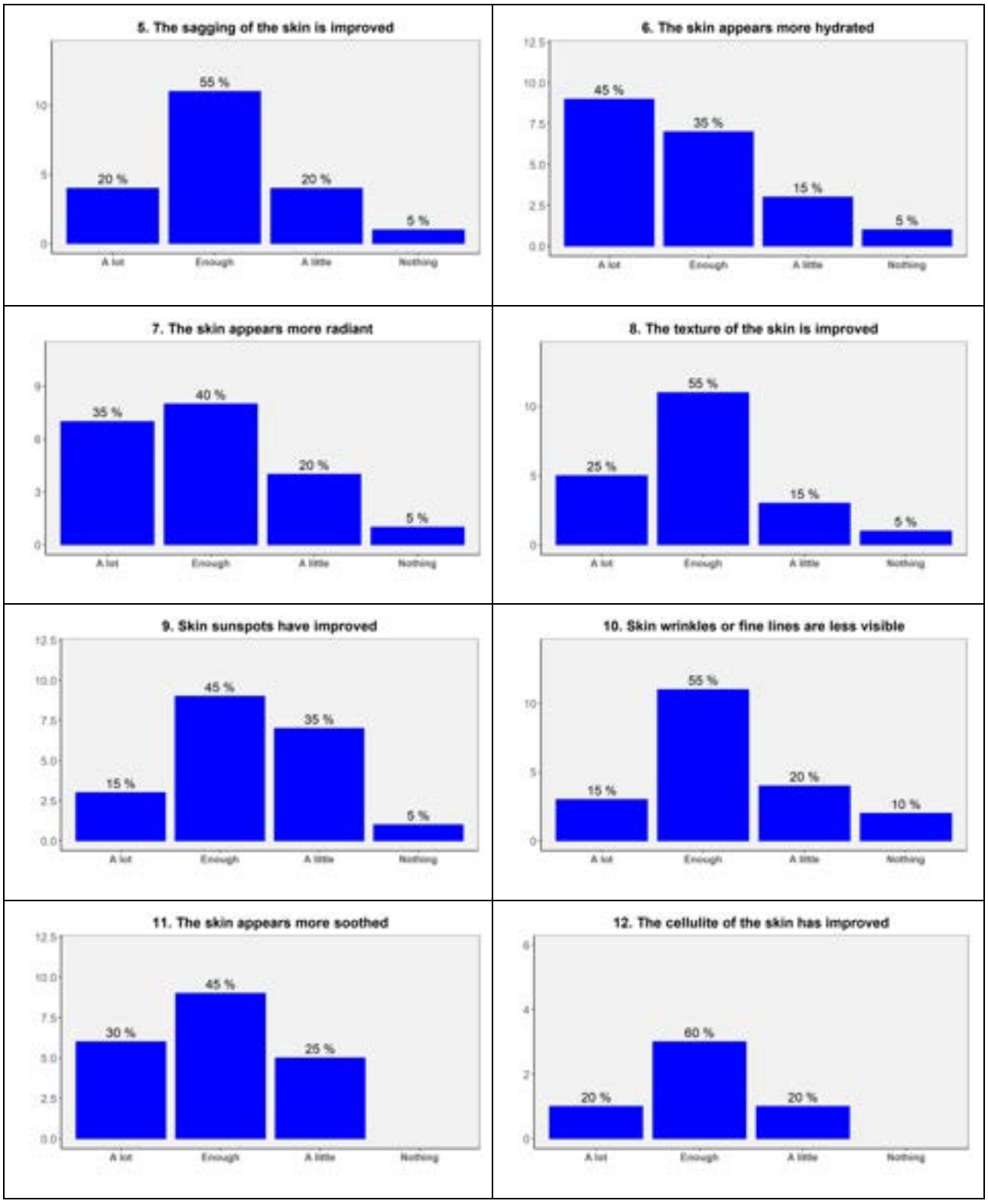
6. THE SKIN APPEARS MORE HYDRATED	80%	0.007**
7. THE SKIN APPEARS MORE RADIANT	75%	0.0221*
8. THE TEXTURE OF THE SKIN IS IMPROVED	80%	0.007**
9. SKIN SUNSPOTS HAVE IMPROVED	60%	0.2512
10. SKIN WRINKLES OR FINE LINES ARE LESS VISIBLE	70%	0.0588
11. THE SKIN APPEARS MORE SOOTHED	75%	0.0221*
12. THE CELLULITE OF THE SKIN HAS IMPROVED	80%	0.1138
13. OVERALL SKIN APPEARANCE HAS APPROVED	80%	0.007**
14. THE TREATMENT WITH THE DEVICE IS EFFECTIVE	80%	0.007**
15. I WOULD RECOMMEND THE TREATMENT OF THE DEVICE TO A FRIEND	75%	0.0221*

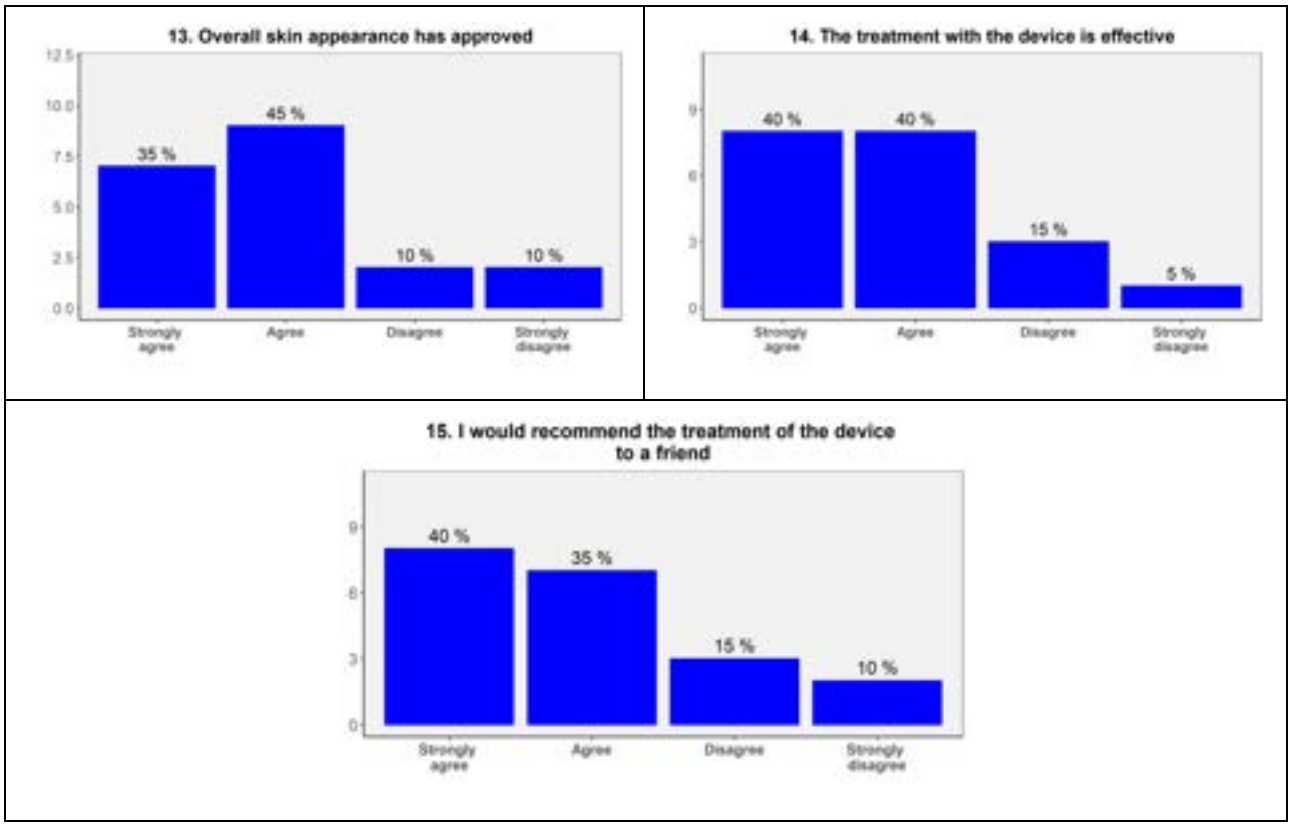
** 5% significance ** 1% significance*

13.14. Individual graphs demonstrating the subjective questionnaire

Final questions about the general opinion of the treatment with the device




5. The sagging of the skin is improved
20 %
55 %
20 %
5 %
A lot
Enough
A little
Nothing
6. The skin appears more hydrated
45 %
35 %
15 %
5 %
A lot
Enough
A little
Nothing
7. The skin appears more radiant
35 %
40 %
20 %
5 %
A lot
Enough
A little
Nothing
8. The texture of the skin is improved
25 %
55 %
15 %
5 %
A lot
Enough
A little
Nothing
9. Skin sunspots have improved
15 %
45 %
35 %
5 %
A lot
Enough
A little
Nothing
10. Skin wrinkles or fine lines are less visible
15 %
55 %
20 %
10 %
A lot
Enough
A little
Nothing
11. The skin appears more soothed
30 %
45 %
25 %
A lot
Enough
A little
Nothing
12. The cellulite of the skin has improved
20 %
60 %
20 %
A lot
Enough
A little
Nothing



13.15. Subjective skin evaluation before and after

The volunteers answered subjective questions about the appearance of their skin before starting the clinical trial (T0) and after finishing treatment with the **GLAMOUR NEW YORK MULTIWAVE** device (T4 weeks).

	Aged skin	Smooth skin	Elastic skin	Skin firmness	Sagging skin	Skin hydration	Radiant skin	Skin texture	Skin sunspots	Wrinkles or fine lines	Soothed skin	Cellulite of the skin
T0	5,8	5,6	5,6	5,3	5,6	5,3	5,1	5,4	6,7	5,8	5,6	8,4
T4 WEEKS	5,0	7,1	6,6	6,4	5,5	7,3	6,8	6,8	6,1	5,1	6,9	7,6

SKIN APPEARANCE

It can be seen how the skin appearance is improved in all of the aspects after carrying out the treatment with the GLAMOUR NEW YORK MULTIWAVE for 4 weeks.
The condition on the skin is improved in all the aspects.
The most noticeable improvements on the skin have been in the smooth, firmness, hydration, radiant, texture, soothed and cellulite compared to T0.

13.16. Tolerance: detection of adverse effects

THERE WERE NO UNPLEASANT SYMPTOMS DURING THE STUDY

14. ASSESSMENTS AND CONCLUSIONS

After 4 weeks of the treatment with the device:
GLAMOUR NEW YORK MULTIWAVE reduces wrinkles on the eye contour.
GLAMOUR NEW YORK MULTIWAVE improves the elasticity/firmness (tensor effect) on the eye contour, neckline and legs.
GLAMOUR NEW YORK MULTIWAVE has improved the luminosity and pores on the visage.
GLAMOUR NEW YORK MULTIWAVE reduces the melanin of sunspots on the visage and neckline.

GLAMOUR NEW YORK MULTIWAVE reduces the thigh perimeter and improves the cellulite on the legs.

Safety and tolerance

In relation to the subjective and dermatological evaluation of tolerance carried out in the study, no volunteer has shown any type of alteration or has presented unwanted symptoms due to the treatment of the device **GLAMOUR NEW YORK MULTIWAVE** for 4 weeks.

Acceptability

The **GLAMOUR NEW YORK MULTIWAVE** device has been favourably evaluated by the volunteers who participated in this study.