

# GREDECO

Research and Evaluation Group in Dermatology and Cosmetology

Ove LED MASK – Lucibelle Paris  
September -December 2021

**Protocol No. 79.6.21**

## **CLINICAL EVALUATION OF THE ANTI-AGING EFFICACY OF THE MASK LED Ove by Lucibelle Paris ON 20 HEALTHY VOLUNTEERS**

**Product under study:**

**Ove LED MASK -Lucibelle Paris**

**Report J84: December 16, 2021**

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## 1) OBJECTIVE OF THE STUDY

Lucibelle Paris offers red LED photomodulation devices aimed at stimulating cellular regeneration and thus reducing the signs of skin aging (wrinkles, lack of tone, roughness of the skin). Aclinal study was conducted on 20 healthy volunteers (women and men aged 45 to 70) using the Ove LED mask for 3 months on the entire face.

The anti-aging efficacy of the device was analyzed using the following parameters:

- anti- wrinkle effect with measurement of the depth of the crow's feet wrinkle,
- sagging of the facial oval by clinical scoring,
- firmness and elasticity of the skin with measurement by cutometer,
- density of the dermis by ultrasound analysis,
- smoothing of the skin with measurement of roughness at the cheek,
- pore diameter measured on macrophotographs with Proscope x30,
- homogeneity of the complexion by chromametric measurement of the internal and external part of the face.
- seborrhea-regulating effect with measurement of the sebum rate and quantification of the number of pores containing porphyrin on subjects with combination to oily skin.

Volunteer satisfaction was assessed at the end of the study via a self-administered questionnaire.

The study is taking place under the dermatological supervision of Dr Sylvie Boissic.

**Efficacy assessments are carried out after 1, 2 and 3 months of use and also 2, 4 and 6 weeks after stopping the sessions:**

	<b>J0</b>	<b>J28</b>
<b>Checking inclusion/non-inclusion criteria</b>	<b>X</b>	
<b>Informed consent</b>	<b>X</b>	
<b>Photographs</b>	<b>X</b>	<b>X</b>
<ul style="list-style-type: none"> <li>• Evaluation of the anti-wrinkle effect by measuring the depth of the crow's feet wrinkle</li> <li>• Clinical evaluation of sagging facial contours</li> <li>• Measurement of skin firmness and elasticity by the cutometer</li> <li>• Measurement of dermis density by ultrasound analysis</li> <li>• Evaluation of skin smoothness by measuring roughness at the of the cheek</li> <li>• Measurement of pore diameter by analysis of macrophotographs at Proscope x30</li> <li>• Analysis of skin tone homogeneity by chromametric measurements</li> <li>• Sebum level measurement using the Skin Diagnostic® SD 207 sebumeter (Monaderm)</li> <li>• Quantification of the number of pores containing porphyrin (Visiopor®)</li> </ul>	<b>X</b>	<b>X</b>
<b>Control of dermatological tolerance</b>	<b>X</b>	<b>X</b>
<b>Satisfaction self-questionnaire</b>	<b>X</b>	<b>X</b>
<b>Report</b>	<b>X</b>	<b>X</b>

## 2) PRODUCT UNDER STUDY

### 2.1) Product identification

#### Ove LED Beauty Mask –Lucibelle Paris



### 2.2) Conditions of use of the product

The OVE LED mask is given to the subjects on D0 with the following instructions:

- Carrying out pre-programmed 12-minute LED sessions on the face, twice a week and spaced 72 hours apart, over a period of 3months.
- During the sessions, volunteers must wear the protective glasses provided and keep their face clean and free of make-up within the field of action of the LED light.

Throughout the study, subjects kept their usual day and night creams, cleansers and makeup products.

## 3) METHODOLOGY

### 3.1) Study Timeline

- Open-label study
- Evaluations compared to initial values
- Subjects are their own references
- Under dermatological control

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### **3.3) Investigators**

**Investigator: Dr Sylvie Boisnic, Dermatologist**

**Clinical research assistants: Angela Rodrigues and Juliet Jesunayagam**

## **4) DATES OF THE STUDY**

**Inclusion dates (D0): September 7 to 15, 2021**

## **5) SUBJECTS OF THE STUDY**

### **5.1) Number of subjects**

- Pre-selection visit: recruitment of 20 healthy volunteers (women and men) aged between 45 and 70 years showing signs of skin aging.

### **5.2) Inclusion criteria**

#### **General criteria**

- Volunteer able to follow the terms of the trial in their entirety; •Volunteer having given, after oral and written information on the trial, his/her free, informed and written consent;
- Subject benefiting from a social security system.

#### **Specific criteria**

- 15 women and 5 men of Caucasian type,
- Age: 45 to 70 years,
- Presence of signs of skin aging (wrinkles, lack of tone, roughness of the skin).

#### **Specific criteria for women:**

- 5 subjects with combination to oily skin,
- 10 subjects with normal to dry skin.

#### **Specific criteria for men:**

- Sensitive skin with irritation from repeated shaving,
- Seborrhic skin (combination to oily) with dilated pores,
- Sagging around the eyes.

### **5.3) Exclusion criteria**

- Persons suffering from epilepsy,



- Women who are pregnant or wish to become pregnant during the study or breastfeeding,
- Participants in any other clinical study evaluating cosmetics, medicines or medical devices,
- Subjects having had an injection / facial implantation of any agent of non-absorbable filling,
- Subjects under concomitant treatment (or not stopped for at least 3months) with anti-inflammatories, oral or injectable corticosteroids (inhaled corticosteroids are authorized as well as topical corticosteroid therapy not involving the head or neck),
- Subjects having concomitant treatment with immunosuppressant or chemotherapy or radiotherapy,
- Subjects presenting an acute inflammatory reaction or abacterial or viral infection on the face or seen less than 2 months after the end of such an episode;
- Subjects having a history or an associated pathology of the autoimmune type or of the connective tissue type.

### 5.4) Study constraints

For the study to run smoothly, volunteers are asked:

- to maintain their habits of care products (face cream) / cleansers and makeup (same products and same frequencies of use), which they will have had for at least 2 weeks before the start of the study and which they will continue until the end of the study,
- to avoid any facial hair removal in the 2days preceding each visit,
- to maintain their lifestyle habits / diet, weight,
- to avoid if possible any other local treatment without prior authorization from the person in charge of the study,
- to declare all drug treatments,
- to report any undesirable events / complications

For each visit to GREDECO, do not apply anything to the face (neither cream nor makeup).

### 5.5) Early termination of the study

The subject may stop the study for the following reasons:

- voluntary withdrawal;
- medical reason (medical treatment that could interfere with the results of the current test, COVID-19);
- adverse event with decision to stop in agreement with the dermatologist responsible;
- severe adverse event (death, hospitalization, etc.);
- meeting an exclusion criterion.

### 5.6) Collection of adverse events

Adverse events are collected with the date of the event, the location and duration of the event, the measure taken (stopping applications, drug treatments, etc.), the severity (very mild, mild, moderate, serious) and an assessment of the imputability to the tested product (very likely, likely, possible, doubtful, excluded).

In the event of an adverse event related to the use of the product tested, a clinical investigation is carried out by the dermatologist, possibly with photographs taken. If necessary, atypical treatment is prescribed by the doctor. If these effects persist, the dermatologist remains in contact with the subject until the symptoms have completely resolved. In the event of a significant adverse effect related to the product tested, withdrawal from the study may be considered.

### 5.7) Reporting of adverse events

Each adverse event must be reported to the study sponsor within 48 hours and must be included in the study report.

### 5.8) Subjects lost to follow-up

When a subject does not show up for the visit, the persons responsible for the GREDECO laboratory must contact him several times before considering him lost to follow-up.

Each study exit must be justified and reported in the final report.

### 5.9) Exclusion period

At the end of the study, subjects have a minimum exclusion period of 14 days before being able to participate in a new study.

## 6) REGULATORY PROVISIONS

### 6.1) Regulatory procedures

This study is carried out in accordance with:

- good clinical practices (CPMP, July 1996)
- to the law of December 20, 1988 (n° 2004-806 of August 9, 2004)
- the Helsinki declaration (1964)

### 6.2) Independent of the ethics committee

The study was carried out independently of any ethics committee, as stipulated by applicable guidelines.

### 6.3) Recruitment of subjects

Recruitment of subjects is carried out from the GREDECO panel of volunteers.

The identity of each subject participating in the study remains confidential through the use of an identification number.

### 6.4) Consent

The consent to participate must be dated and signed by the subject and the investigator in duplicate. A copy is kept by the subject.

### 6.5) Compliance with the protocol

The investigator undertakes to comply with the protocol. Any modification must be discussed in advance between the investigator and the sponsor.

### 6.6) Insurance

The GREDECO laboratory is insured by MACSF (premises and civil liability) whose contract number is 6096750-79B.

### 6.7) Subject compensation

An allowance is given to each volunteer at the end of the study.

### 6.8) Archives

All original study data are kept for 10 years by the company GREDECO.

### 6.9) Contractual obligations

A financial contract is established between the GREDECO laboratory and the sponsor before the start of the study. Payment is made by the sponsor of the study after presentation of invoices.

## 7) EVALUATION OF EFFECTIVENESS

### 7.1) Photographs

Photographs taken using the LifeViz mini device allow us to visualize the modulation of the different parameters studied (2D and 3D face, depth of wrinkles).

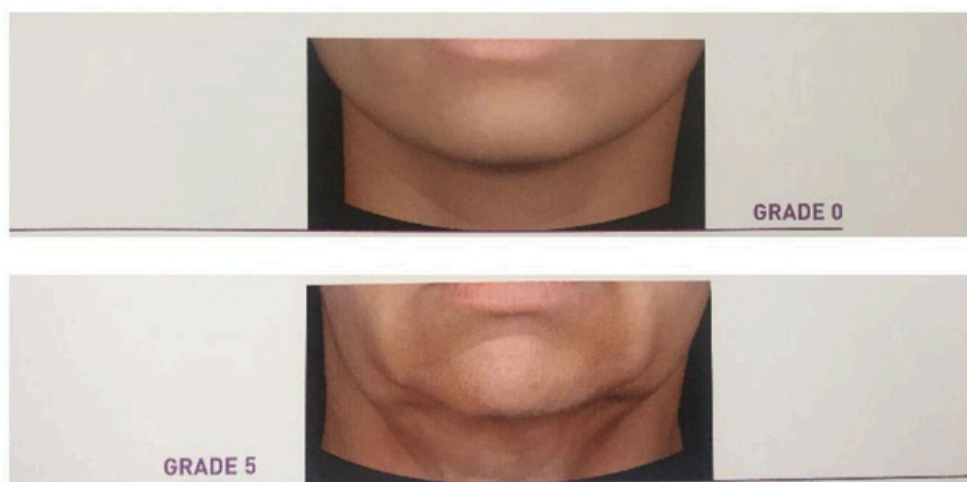
### 7.2) Evaluation of the anti-wrinkle effect by measuring the **depth of the wrinkle crow's feet** from LifeViz micro® photographs

The analysis is carried out on the deepest crow's feet wrinkle. The average depth expressed in mm is equal to the total volume (= positive volume – negative volume), divided by the surface area of the wrinkle contour. The contour of the deepest wrinkle is taken at visit D0 and transposed to the following visits.

### 7.3) Clinical evaluation of **facial oval sagging** using Roland BAZIN score

The clinical assessment of sagging facial contours is carried out by the dermatologist using the ROLAND BAZIN scale.

For women, this scale has 6 grades (0 being the absence of sagging). This sagging corresponds to the sagging of the lower part of the face on each side of the chin which makes the oval of the face irregular. This scoring does not take into account the double chin.



### 7.4) Measurement of skin **firmness** and **elasticity** by the cutometer

The Cutomètre® is intended to measure the biomechanical properties of the upper layers of the epidermis by applying negative pressure (suction) that deforms the skin. The measurement principle is based on the suction method. A negative pressure is created in the device and the skin is sucked into the measuring cup of the probe. After a defined time, the skin is released inside the probe.

This measuring principle provides information on the firmness and elasticity and mechanical properties of the skin surface and allows the objective quantification of skin age. The decrease in the suction depth (R0) of the skin indicates a firming/tightening effect (increase in firmness).

The relaxation phase will allow us to observe the elastic properties of the skin. Skin elasticity is indicated by the parameter R5 (net elasticity) which is increased in case of increase in skin elasticity (R5=1 corresponding to 100% elasticity).

### 7.5) Measurement of **dermal density** by ultrasound analysis

The ultrasound is performed at the level of the right cheek with the 2D 20MHz probe of 12.1 mm of narrow focus exploration. The image capture as well as the analysis of the dermal density is done by the Advanced Control software. The dermal density is expressed in %.

### 7.6) Evaluation of skin smoothness by measuring roughness **at** the cheek level from LifeViz micro® photographs

Skin texture assessment is performed by analyzing the roughness at the upper right or left cheek using the LifeVizMicro® device analysis software .

Roughness is calculated by adding the positive and negative volumes in absolute value and dividing it by the closing surface of the area considered. This parameter reflects the regularity or lack of regularity of the skin surface. Roughness is unitless.

### 7.7) Measuring **pore diameter** from Proscope x30 macrophotographs

Macrophotographs taken using the PROSCOPE® (x30) allow visualizing the modulation of pore diameter. Pore diameter measurements will be taken: 6 to 10 measurements in order to obtain an average diameter in  $\mu\text{m}$ . This measurement of pore size is carried out at the level of the cheek in contact with the wings of the nose.

### 7.8) Chromametric analysis of **skin tone homogeneity**

Colorimeters express colors through digital data that conform to international standards by the CR400® chromameter (Minolta, Osaka, Japan). The  $L^*a^*b^*$  color space (also called CIELAB) is currently one of the most widely used to measure the color of objects in virtually all fields. The measurement is based on light reflected perpendicular to the skin surface and the data collected allow atrichromatic analysis  $L^*$ ,  $a^*$ ,  $b^*$  at 450, 560 and 600 nm, respectively.

The  $L^*$  parameter corresponds to the skin's brightness and is expressed as a percentage, between the brightness of black (0) and white (100). The  $a^*$  parameter represents the color and saturation on an axis from red (+299 positive value) to green (-300 negative value). The  $b^*$  parameter, on the other hand, defines the color and saturation on an axis from yellow (+299 positive value) to blue (-300 negative value).

As part of the assessment of skin tone homogeneity, two measurements of the  $L$  parameter will be taken (inner and outer part of the right or left cheek) using the Konica Minolta CR/DP-400® Chromameter. A calculation of the difference of the

two measurements are then taken. The decrease in the gap between the two measurements indicates an increase in the homogeneity of the skin. The increase in the homogeneity of the complexion can also be visualized in 3D.

### 7.9) **Sebum level** measurement using the Skin Diagnostic® SD 207 sebumeter (Monaderm)

Measurement carried out only on 10 subjects with combination to oily skin.

The sebum measurement performed by the Skin Diagnostic® SM 815 sebumeter from Monaderm (Courage & Khazaka, Cologne, Germany) is a direct measurement of sebaceous secretion, using a photometric method. A 64 mm<sup>2</sup> frosted film with a thickness of 100 µm is applied to the skin surface on the right cheek in contact with the wing of the nose. The amount of sebum is expressed in µg/ cm<sup>2</sup> of skin.

### 7.10) Quantification of the **number of pores containing porphyrin** (Visiopor® )

Measurement carried out only on the 10 subjects with combination to oily skin.

Macrophotography using the VISIOPOR® PP 34 using ultraviolet light allows visualizing and quantifying the porphyrins contained in the pores over an 8x10 mm region. Orange-red fluorescence indicates the presence of porphyrins (correlated with the presence of certain bacteria such as P. acnes) through non-obvious clinical lesions (follicular impacts and comedones) and obvious ones (comedones, papules and pustules). Macrophotography is performed on the left cheek in contact with the wing of the nose and image analysis allows quantifying the number of pores containing porphyrins.

### 7.9) **Self-assessment questionnaire**

The self- assessment questionnaire is provided by the company Line 5. Volunteers answer the self-assessment questions during the visit D28, D56 and D84.

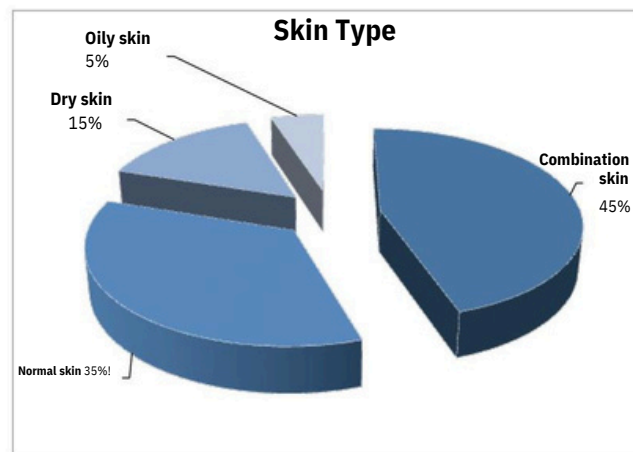
### 7.10) Evaluation of **tolerance** by the dermatologist

### 7.11) Statistical analysis

The results are presented in the form of tables (mean ±SD over the 20 subjects). The two- tailed Student's statistical test for paired data is performed in the case where the data follow a normal distribution (verified by the Shapiro Wilk test). Otherwise, the non- parametric Wilcoxon test is performed. For all statistical tests, an alpha risk of 5% is used (significance at p<0.05).

## 8) RESULTS

A total of 15 women and 5 men were included in this study with a mean age of  $55.6 \pm 7.39$  years. The distribution of skin type of the volunteers is shown in the graph below:



Dermatological tolerance was excellent for all subjects who used the Lucibelle Paris Ove LED mask on their face for 56 days.

### 8.1) Measurement of **crow's feet wrinkle** depth from LifeViz micro photographs

#### 8.1.a) Group 1: 20 volunteers

Ove LED Mask -Lucibelle Paris				
Depth of the goose wrinkle paw (LifeViz Micro) -mm	J0	J28	J56	J84
Mean $\pm$ SD (n=20 volunteers)	0.077 $\pm$ 0.03	0.065 $\pm$ 0.02	0.050 $\pm$ 0.02	0.050 $\pm$ 0.03

Crow's Feet Wrinkle Depth (LifeViz Micro) -mm				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.001	S	-15.6%
J56/ J0	Student	7.81x10 <sup>-7</sup>	S	-34.7%
J84/ J0	Student	6.55x10 <sup>-7</sup>	S	-38.3%

On average across 20 subjects, a significant reduction of 15.6% in the depth of the crow's feet wrinkle, measured by image analysis, was observed at D28 and of **38.3%** after 84 days of use of the Ove LED mask.

#### 8.1.b) Group 2: 15 women

Ove LED Mask -Lucibelle Paris				
Depth of the goose wrinkle paw (LifeViz Micro) -mm	J0	J28	J56	J84
Mean $\pm$ SD (n=15 women)	0.072 $\pm$ 0.02	0.063 $\pm$ 0.02	0.045 $\pm$ 0.02	0.040 $\pm$ 0.02

Crow's foot depth (LifeViz Micro) of the wrinkle of the -mm				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.026	S	-12.5%
J56/ J0	Student	5.88x10 <sup>-5</sup>	S	-37.9%
J84/ J0	Student	2.73x10 <sup>-5</sup>	S	-43.5%



### 8.1.c) Group 3: 5men

Ove LED Mask -Lucibelle Paris				
Depth of the goose wrinkle paw (LifeViz Micro) -mm	J0	J28	J56	J84
Mean $\pm$ SD (n=5 men)	0.090 $\pm$ 0.03	0.069 $\pm$ 0.02	0.066 $\pm$ 0.03	0.07 $\pm$ 0.03

Crow's Feet Wrinkle Depth (LifeViz Micro) -mm				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.013	S	-23.1%
J56/ J0	Student	0.003	S	-27.1%
J84/ J0	Student	0.005	NS	-26.0%

On average across 5 men, a significant reduction of 23.1% in the depth of the crow's feet wrinkle was also observed at D28 and 27.1% after 56 days of use of the Ove LED mask.

### 8.2) Clinical evaluation of facial oval sagging using R. BAZIN score

#### 8.2.a) Group 1: 20 volunteers

Ove LED Mask -Lucibelle Paris				
Relaxation of the facial oval -Rscore. BAZIN	J0	J28	J56	J84
Mean $\pm$ SD (n=20 volunteers)	3.23 $\pm$ 0.73	3.05 $\pm$ 0.69	2.75 $\pm$ 0.62	2.43 $\pm$ 0.61

Sagging of the facial oval - score by R. BAZIN				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Wilcoxon	0.011	S	-5.4%
J56/ J0	Wilcoxon	1.94x10 <sup>-4</sup>	S	-14.7%
J84/ J0	Wilcoxon	1.65x10 <sup>-4</sup>	S	-24.8%

On average across 20 subjects, a significant reduction of 5.4% in the sagging of the facial oval, clinically assessed by the Roland BAZIN score, was observed at D28 and of 24.8% after 84 days of use of the Ove LED mask.

### 8.2.b) Group 2: 15 women

Ove LED Mask -Lucibelle Paris				
Relaxation of the facial oval -Rscore. BAZIN	J0	J28	J56	J84
Mean $\pm$ SD (n=15 women)	3.30 $\pm$ 0.77	3.10 $\pm$ 0.71	2.80 $\pm$ 0.62	2.50 $\pm$ 0.68

Sagging of the facial oval - score by R. BAZIN				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Wilcoxon	0.020	S	-6.1%
J56/ J0	Wilcoxon	7.22x10 <sup>-4</sup>	S	-15.2%
J84/ J0	Student	7.46x10 <sup>-5</sup>	S	-24.2%

On average, in 15 women, a significant reduction of 6.1% in the sagging of the facial oval, clinically assessed by the Roland BAZIN score, was observed at D28 and of **24.1%** after 84 days of use of the Ove LED mask.

### 8.2.c) Group 3: 5men

Ove LED Mask -Lucibelle Paris				
Relaxation of the facial oval -Rscore. BAZIN	J0	J28	J56	J84
Mean $\pm$ SD (n=5 men)	3.00 $\pm$ 0.61	2.90 $\pm$ 0.65	2.60 $\pm$ 0.65	2.50 $\pm$ 0.61

Sagging of the facial oval - score by R. BAZIN				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Wilcoxon	1	NS	-3.3%
J56/ J0	Student	0.099	NS	-13.3%
J84/ J0	Student	0.034	S	-16.7%

On average across 5 men, the modulation of the sagging of the facial oval, clinically assessed by the Roland BAZIN score, is significantly reduced by **16.7%** after 84 days of use of the Ove LED mask.

### 8.3) Measurement of skin firmness by the cutometer (R0 value)

#### 8.3.a) Group 1: 20 volunteers

Ove LED Mask -Lucibelle Paris				
Firmness of the skin (cutometer) -ValuRe0	J0	J28	J56	J84
Mean $\pm$ SD (n=20 volunteers)	0.3969 $\pm$ 0.07	0.3429 $\pm$ 0.07	0.3187 $\pm$ 0.05	0.30 $\pm$ 0.06

Skin firmness (cutometer)			- Value	R0
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	1.83x10-4	S	-13.6%
J56/ J0	Student	7.10x10-6	S	-19.7%
J84/ J0	Student	4.91x10-6	S	-23.6%

On average across 20 subjects, the significant decrease of 13.6% in the R0 value measured by the cutometer reflects an increase in skin firmness after 28 days of using the Ove LED mask. After 84 days, this improvement is **23.6%**.

#### 8.3.b) Group 2: 15 women

Ove LED Mask -Lucibelle Paris				
Firmness of the skin (cutometer) -ValuRe0	J0	J28	J56	J84
Mean $\pm$ SD (n=15 women)	0.3742 $\pm$ 0.07	0.3263 $\pm$ 0.07	0.3183 $\pm$ 0.06	0.30 $\pm$ 0.06

Skin firmness (cutometer) - Value R0				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.002	S	-12.8%
J56/ J0	Student	7.40x10-5	S	-14.9%
J84/ J0	Student	3.19x10-4	S	-20.7%

On average across 15 women, the significant decrease of 12.8% in the R0 value measured by the cutometer reflects an increase in skin firmness after 28 days of using the Ove LED mask. After 84 days, this improvement is **20.7%**.

### 8.3.c) Group 3: 5 men

<i>Ove LED Mask -Lucibelle Paris</i>				
Firmness of the skin (cutometer) -Value R0	J0	J28	J56	<b>J84</b>
Mean $\pm$ SD (n=5 men)	0.4650 $\pm$ 0.03	0.3926 $\pm$ 0.06	0.3198 $\pm$ 0.03	0.32 $\pm$ 0.05

Skin firmness (cutometer)			- Value	R0
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.059	NS	-15.6%
J56/ J0	Student	3.39x10 <sup>-3</sup>	S	-31.2%
<b>J84/ J0</b>	Student	4.12x10 <sup>-3</sup>	S	<b>-31.3%</b>

On average across 5 men, a significant decrease of **31.3%** in the R0 value reflecting an increase in skin firmness was observed after 84 days of using the Ove LED mask.

### 8.4) Measurement of skin elasticity by the cutometer (R5 value)

#### 8.4.a) Group 1: 20 volunteers

Ove LED Mask -Lucibelle Paris				
Skin elasticity (cutometer) - Value R5	J0	J28	J56	J84
Mean $\pm$ SD (n=20 volunteers)	0.5412 $\pm$ 0.11	0.5417 $\pm$ 0.10	0.6091 $\pm$ 0.11	0.6121 $\pm$ 0.11

Skin elasticity (cutometer) - Value R5				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.979	NS	+0.1%
J56/ J0	Wilcoxon	4.49x10 <sup>-4</sup>	S	+12.5%
J84/ J0	Student	7.72x10 <sup>-4</sup>	S	+13.1%

On average across 20 subjects, a significant increase of **13.1%** in the R5 value measured by the cutometer, reflecting an increase in skin elasticity, was observed after 84 days of use of the Ove LED mask.

#### 8.4.b) Group 2: 15 women

Ove LED Mask -Lucibelle Paris				
Elasticity of skin (cutometer) -Value R5	J0	J28	J56	J84
Mean $\pm$ SD (n=15 women)	0.5030 $\pm$ 0.10	0.5198 $\pm$ 0.09	0.5889 $\pm$ 0.09	0.60 $\pm$ 0.11

Skin elasticity (cutometer) - Value R5				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.450	NS	+3.3%
J56/ J0	Student	9.23x10 <sup>-4</sup>	S	+17.1%
J84/ J0	Student	3.73x10 <sup>-4</sup>	S	+18.7%

On average across 15 women, a significant increase of **18.7%** in the R5 value measured by the cutometer, reflecting an increase in skin elasticity, was observed after 84 days of using the Ove LED mask.

### 8.4.c) Group 3: 5men

<i>Ove LED Mask -Lucibelle Paris</i>				
Elasticity of <sup>there</sup> skin (cutometer) -ValuRe5	J0	J28	J56	<b>J84</b>
Mean ±SD (n=5 men)	0.6557 ±0.09	0.6076 ±0.09	0.6695 ± 0.08	0.6600 ± 0.10

Skin elasticity (cutometer) of the - Value R5				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.230	NS	-7.3%
J56/ J0	Student	0.397	NS	+2.1%
<b>J84/ J0</b>	Student	0.900	NS	+0.1%

On average, over 5men, anon-significant increase in the R5 value reflecting an increase in skin elasticity was observed after 84 days of using the Ove LED mask.

### 8.5) Measurement of dermis density by ultrasound analysis

#### 8.5.a) Group 1: 20 volunteers

Ove LED Mask -Lucibelle Paris				
Density of dermis (ultrasound)	J0	J28	J56	J84
Mean $\pm$ SD (n=20 volunteers)	36.33 $\pm$ 8.71	45.91 $\pm$ 5.87	51.23 $\pm$ 9.54	53.66 $\pm$ 7.60

Dermis density( u ltrasound)				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Wilcoxon	0.201	S	+26.4%
J56/ J0	Wilcoxon	3.81x10 <sup>-6</sup>	S	+41%
J84/ J0	Student	1.10x10 <sup>-7</sup>	S	+47.7%

On average across 20 subjects, a significant increase of 26.4% in dermal density measured by ultrasound was observed at D28 and **47.7%** after 84 days of use of the Ove LED mask.

#### 8.5.b) Group 2: 15 women

Ove LED Mask -Lucibelle Paris				
Density of dermis (ultrasound)	J0	J28	J56	J84
Mean $\pm$ SD (n=15 women)	36.55 $\pm$ 8.08	45.47 $\pm$ 4.80	50.36 $\pm$ 10.19	52.27 $\pm$ 7.89

Dermis density( u ltrasound)				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	3.38x10 <sup>-3</sup>	S	+24.4%
J56/ J0	Wilcoxon	1.22x10 <sup>-4</sup>	S	+37.8%
J84/ J0	Student	3.26x10 <sup>-7</sup>	S	+43%

On average for 15 women, a significant increase of 24.4% in dermal density measured by ultrasound was observed at D28 and **43%** after 84 days of using the Ove LED mask.

### 8.5.c) Group 3: 5men

Ove LED Mask -Lucibelle Paris				
Density of the dermis (ultrasound)	J0	J28	J56	J84
Mean $\pm$ SD (n=5 men)	35.68 $\pm$ 11.43	47.23 $\pm$ 8.95	53.84 $\pm$ 7.6	57.83 $\pm$ 5.27

Dermis density (ultrasound)				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.72	NS	+32.4%
J56/ J0	Student	0.36	S	+50.9%
J84/ J0	Student	0.03	S	+62.1%

On average for 5men, a significant increase of **62.1%** in dermal density measured by ultrasound is observed after 84 days of using the Ove LED mask.



### 8.6) Evaluation of skin smoothness by measuring roughness at the cheek level from LifeViz micro photographs

#### 8.6.a) Group 1: 20 volunteers

Ove LED Mask -Lucibelle Paris				
Cheek roughness (image analysis)	J0	J28	J56	J84
Mean $\pm$ SD (n=20 volunteers)	0.825 $\pm$ 0.30	0.769 $\pm$ 0.33	0.675 $\pm$ 0.32	0.628 $\pm$ 0.26

Cheek roughness (image analysis)				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Wilcoxon	0.008	S	-6.8%
J56/ J0	Wilcoxon	5.72x10 <sup>-6</sup>	S	-18.2%
J84/ J0	Student	1.51x10 <sup>-4</sup>	S	-23.8%

On average across 20 subjects, a significant reduction of 6.8% in cheek roughness measured by image analysis, indicating smoothing of the skin, was observed at D28 and of **23.8%** after 84 days of use of the Ove LED mask.

#### 8.6.b) Group 2: 15 women

Ove LED Mask -Lucibelle Paris				
Cheek roughness (image analysis)	J0	J28	J56	J84
Mean $\pm$ SD (n=15 women)	0.831 $\pm$ 0.32	0.771 $\pm$ 0.34	0.701 $\pm$ 0.30	0.636 $\pm$ 0.27

Cheek roughness (image analysis)				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Wilcoxon	0.026	S	-7.3%
J56/ J0	Wilcoxon	1.83x10 <sup>-4</sup>	S	-15.7%
J84/ J0	Student	7.57x10 <sup>-4</sup>	S	-23.5%

On average for 15 women, a significant reduction of 7.3% in cheek roughness measured by image analysis, indicating smoothing of the skin, was observed at D28 and **23.5%** after 84 days of use of the Ove LED mask.

### 8.6.c) Group 3: 5 men

<i>Ove LED Mask -Lucibelle Paris</i>				
Cheek roughness (image analysis)	J0	J28	J56	<b>J84</b>
Mean $\pm$ SD (n=5 men)	0.806 $\pm$ 0.26	0.763 $\pm$ 0.31	0.598 $\pm$ 0.40	0.605 $\pm$ 0.24

Cheek roughness (image analysis)				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.166	NS	-5.3%
J56/ J0	Student	0.077	NS	-25.9%
<b>J84/ J0</b>	Student	0.131	NS	-25.0%

On average for 5 men, skin roughness measured by image analysis indicating skin smoothing is not significantly reduced after 28 and 84 days of using the Ove LED mask.

### 8.7) Measuring pore diameter from Proscope x30 macrophotographs

#### 8.7.a) Group 1: 20 volunteers

<i>Ove LED Mask -Lucibelle Paris</i>				
Pore diameter ( $\mu$ m)	J0	J28	J56	<b>J84</b>
Mean $\pm$ SD (n=20 volunteers)	116.51 $\pm$ 33.96	83.33 $\pm$ 35.94	80.73 $\pm$ 30.10	78.28 $\pm$ 25.16

Diameter of the (pores) $\mu$ m)				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	3.46x10 <sup>-5</sup>	S	-28.5%
J56/ J0	Student	3.86x10 <sup>-5</sup>	S	-30.7%
<b>J84/ J0</b>	Student	1.05x10 <sup>-5</sup>	S	<b>-32.8%</b>

On average across 20 subjects, a significant decrease of 28.5% in pore diameter was observed at D28 and **32.8%** after 84 days of use of the Ove LED mask.

### 8.7.b) Group 2: 15 women

<i>Ove LED Mask -Lucibelle Paris</i>				
Pore diameter ( $\mu\text{m}$ )	J0	J28	J56	<b>J84</b>
Mean $\pm$ SD (n=15 women)	122.38 $\pm$ 33.68	88.01 $\pm$ 35.48	84.18 $\pm$ 30.62	80.66 $\pm$ 24.55

Diameter of the (pores) $\mu\text{m}$				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	4.88x10 <sup>-4</sup>	S	-28.1%
J56/ J0	Student	5.76x10 <sup>-4</sup>	S	-31.2%
<b>J84/ J0</b>	Student	1.53x10 <sup>-4</sup>	S	<b>-34.1%</b>

On average for 15 women, asinificant reduction of 28.1% in pore diameter was observed at D28 and 34.1% after 84 days of use of the Ove LED mask.

### 8.7.c) Group 3: 5 men

<i>Ove LED Mask -Lucibelle Paris</i>				
Pore diameter ( $\mu\text{m}$ )	J0	J28	J56	<b>J84</b>
Mean $\pm$ SD (n=5 men)	98.90 $\pm$ 31.50	69.28 $\pm$ 37.40	70.38 $\pm$ 29.05	71.14 $\pm$ 28.52

Diameter of the (pores) $\mu\text{m}$				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.048	S	-29.9%
J56/ J0	Student	0.020	S	-28.8%
<b>J84/ J0</b>	Student	0.023	S	<b>-28.1%</b>

On average for 5men, asinificant decrease of 29.9% in pore diameter was observed at D28 and **28.1%** after 84 days of use of the Ove LED mask.

### 8.8) Chromametric analysis of skin tone homogeneity

#### 8.8.a) Group 1: 20 volunteers

Ove LED Mask -Lucibelle Paris				
Variation of the setting L(*inner part and cheek) external	J0	J28	J56	J84
Mean $\pm$ SD (n=20 volunteers)	1.70 $\pm$ 1.23	1.57 $\pm$ 1.12	1.15 $\pm$ 0.97	1.11 $\pm$ 0.99

Parameter variation L* (inner and outer part of the cheek)				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.560	NS	-7.7%
J56/ J0	Wilcoxon	0.002	S	-32.7%
J84/ J0	Wilcoxon	1.07x10 <sup>-2</sup>	S	-34.9%

On average over 20 subjects, a significant increase in skin homogeneity is observed with a decrease in the variation of the Lparameter of 34.9% after 84 days of use of the Ove LED mask.

#### 8.8.b) Group 2: 15 women

Ove LED Mask -Lucibelle Paris				
Variation of the setting L(*inner part and cheek) external	J0	J28	J56	J84
Mean $\pm$ SD (n=15 women)	1.78 $\pm$ 1.30	1.60 $\pm$ 1.29	1.11 $\pm$ 1.09	1.13 $\pm$ 1.02

Variation of the parameter (internal part of the cheek)				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.510	NS	-10%
J56/ J0	Wilcoxon	0.002	S	-37.3%
J84/ J0	Wilcoxon	0.016	S	-30.9%

On average for 15 women, a significant increase in skin homogeneity is observed with a decrease in the variation of the Lparameter of **30.9%** after 84 days of using the Ove LED mask.

### 8.8.c) Group 3: 5men

Ove LED Mask -Lucibelle Paris				
Variation of the parameter (Extinction coefficient)	J0	J28	J56	J84
Mean $\pm$ SD (n=5 men)	1.49 $\pm$ 1.07	1.50 $\pm$ 0.36	1.25 $\pm$ 0.58	0.76 $\pm$ 0.88

Parameter variation L* (inner and outer part of the cheek)				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.990	NS	+0.4%
J56/ J0	Student	0.478	NS	-16.1%
J84/ J0	Student	0.113	NS	-48.9%

On average for 5men, skin homogeneity is not significantly improved after 84 days of using the Ove LED mask.

### 8.9) Measurement of **sebum level** using the Skin Diagnostic® SD 207 sebumeter (Monaderm) for 10 subjects with combination to oily skin

#### 8.9.a) Group 1: 10 volunteers

Ove LED Mask -Lucibelle Paris				
Rate of forehead sebum (µg/cm2)	J0	J28	J56	J84
Mean ± SD (n=10 volunteers)	285.60 ± 114.30	185.90 ±104.55	103.20 ±42.64	84.80 ±37.96

Rate of ( sebum µg/cm2 )				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.025	S	-34.9%
J56/ J0	Student	2.89x10-4	S	-63.9%
J84/ J0	Student	1.68x10-4	S	-70.3%

On average, on 10 subjects with combination to oily skin, a significant reduction of 34.9% in the quantity of sebum on D28 and **70.3%** after 84 days of use of the Ove LED mask was observed.

#### 8.9.b) Group 2: 5women

Ove LED Mask -Lucibelle Paris				
Rate of ( sebum µg/cm2 )	J0	J28	J56	J84
Mean ± SD (n=5 women)	294.80 ± 108.93	168.80 ±102.81	83.30 ±22.02	66.20 ±12.91

Rate of sebum ( µg/cm2 )				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.130	NS	-42.7%
J56/ J0	Student	0.014	S	-71.6%
J84/ J0	Student	0.008	S	-77.5%

On average for 5women with combination to oily skin, a significant reduction of 77.5% in the amount of sebum after 84 days of using the Ove LED mask is observed.

### 8.9.c) Group 3: 5men

<i>Ove LED Mask -Lucibelle Paris</i>				
Rate of ( sebum µg/cm2 )	J0	J28	J56	<b>J84</b>
Mean ± SD (n=5 men)	276.40 ± 131.61	203.00 ±115.31	122.60 ±51.63	103.40 ±47.01

Rate of ( sebum µg/cm2 )				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.129	NS	-26.6%
J56/ J0	Student	0.019	S	-55.6%
<b>J84/ J0</b>	Student	0.022	S	<b>-62.6%</b>

On average for 5men with combination to oily skin, asignificant decrease of **62.6%** in the amount of sebum after 84 days of using the Ove LED mask is observed.

### 8.10) Quantification of the number of pores containing porphyrin (Visiopor®) for 10 subjects with combination to oily skin

#### 8.10.a) Group 1: 10 volunteers

Ove LED Mask -Lucibelle Paris				
Number of pores containing porphyrins	J0	J28	J56	J84
Mean $\pm$ SD (n=10 volunteers)	31.40 $\pm$ 11.23	32.50 $\pm$ 15.26	25.90 $\pm$ 14.49	24.10 $\pm$ 10.07

number of pores containing porphyrins				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.587	NS	+3.5%
J56/ J0	Student	0.090	NS	-17.5%
J84/ J0	Wilcoxon	0.006	S	-23.2%

On average, in 10 subjects with combination to oily skin, a significant decrease in the number of pores containing porphyrins of 23.2% was observed after 84 days of using the Ove LED mask.

#### 8.10.b) Group 2: 5 women

Ove LED Mask -Lucibelle Paris				
number of pores containing porphyrins	J0	J28	J56	J84
Mean $\pm$ SD (n=5 women)	37.0 $\pm$ 4.0	37.60 $\pm$ 8.20	38 $\pm$ 8.25	32 $\pm$ 6.44

number of pores containing porphyrins				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.812	NS	+1.6%
J56/ J0	Student	0.655	NS	+2.7%
J84/ J0	Student	0.051	NS	-13.5%



On average, in 5women with combination to oily skin, anon-significant decrease in the number of pores containing porphyrins is observed after 84 days of using the Ove LED mask.

### 8.10.c) Group 3: 5men

Ove LED Mask -Lucibelle Paris				
Numberof pores containing porphyrins	J0	J28	J56	J84
Mean $\pm$ SD (n=5 men)	25.80 $\pm$ 13.75	27.40 $\pm$ 19.78	13.80 $\pm$ 6.18	16.20 $\pm$ 5.54

Number of pores containing porphyrins				
Comparison	Test	p-value	Significance	% variation
D28/ D0	Student	0.661	NS	+6.2%
J56/ J0	Student	0.027	S	-46.5%
J84/ J0	Student	0.070	NS	-32.7%

On average for 5men with combination to oily skin, asignificant decrease of 46.5% in the number of pores containing porphyrins is observed after 56 days of using the Ove LED mask.

### 8.11) Summary of efficacy results across the entire panel

20 volunteers n=	J28	J56	J84
Crow's foot wrinkle depth	-15.6%	-34.7%	-38.3%
Oval release score	-5.4%	-14.7%	-24.8%
Firmness (R0)	-13.6%	-19.7%	-23.6%
Elasticity (R5)	NS	+12.5%	+13.1%
Dermis density	+26.4%	+41.0%	+47.7%
Roughness of the cheek	-6.8%	-18.2%	-23.8%
Pore diameter	-28.5%	-30.7%	-32.8%
Evenness of complexion	NS	-32.7%	-34.9%
Sebum level (n=10)	-34.9%	-63.9%	-70.3%
Number of pores with porphyrin (n=10)	NS	NS	-23.2%

## 9) CONCLUSION

**This clinical study conducted on 20 healthy volunteers (15 women and 5 men) highlights the excellent dermatological tolerance and anti-aging efficacy on the face of the Lucibelle Paris Ove LED Mask after 1, 2 and 3 months of use.**

**From the first month of use (D28), a significant improvement in the following parameters was observed:**

- **15.6% reduction in the depth of the crow's feet wrinkle,**
- **5.4% decrease in the clinical score of sagging of the facial oval and 13.6% decrease in the R0 value, measured by the cutometer, reflecting a firming effect,**
- **26.4% increase in dermal density measured by ultrasound,**
- **6.8% reduction in cheek roughness and 28.5% reduction in pore diameter, demonstrating a smoothing effect,**
- **34.9% decrease in the amount of sebum.**

**After 2 months of use (D56), a further improvement of the previous parameters was observed. A significant increase of 12.5% skin elasticity measured by R5 value and 32.7% skin tone uniformity measured by chromametry were also observed.**

**After 3 months of use (D84), all analyzed parameters are improved compared to the values obtained at D56.**

**At D84, statistical analysis of the group of 5men highlights asignificant improvement in the following parameters:**

- **a significant decrease of 16.7% in the relaxation of the oval of the face**
- **a significant decrease of 31.3% in the R0 value reflecting an increase in skin firmness**
- **a significant increase of 62.1% in dermis density measured by ultrasound**
- **a significant decrease of 28.1% in pore diameter**
- **a significant decrease of 62.6% in the quantity of sebum**

**100% of subjects noticed an improvement in the condition of their skin after 84 days of using the Lucibelle Ove LED Mask.**

**Done in Paris, December 16, 2021**

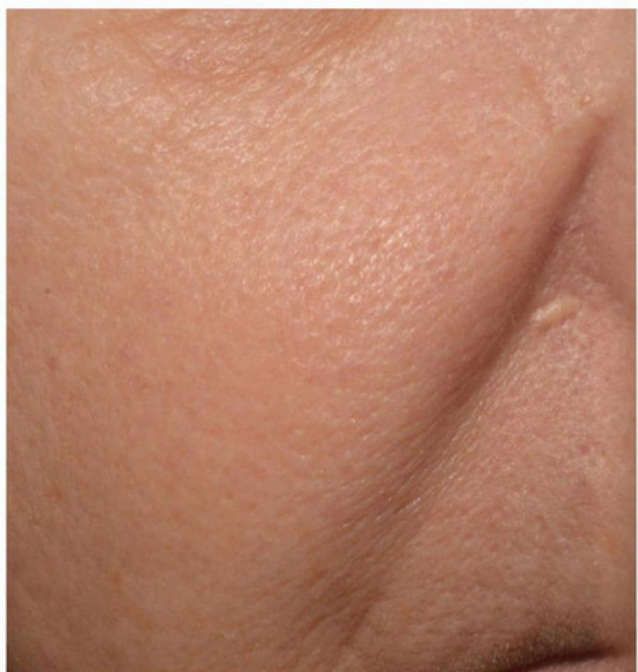
**Dr. S Boisnic,  
Dermatologist  
Research Director, GREDECO**



## **SUBJECT #4: J0/J28 RIGHT PLAY**

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### **Reduction in pore size**



## **SUBJECT #4: J0/J56 RIGHT PLAY**

**Decrease pores of the size of the**





## **SUBJECT #9: J0/J56 Right Cheek**

**Decrease pores of the size of the**



**SUBJECT #11: J0/J84**

**Decrease pawfrom the depth of the goose wrinkle**



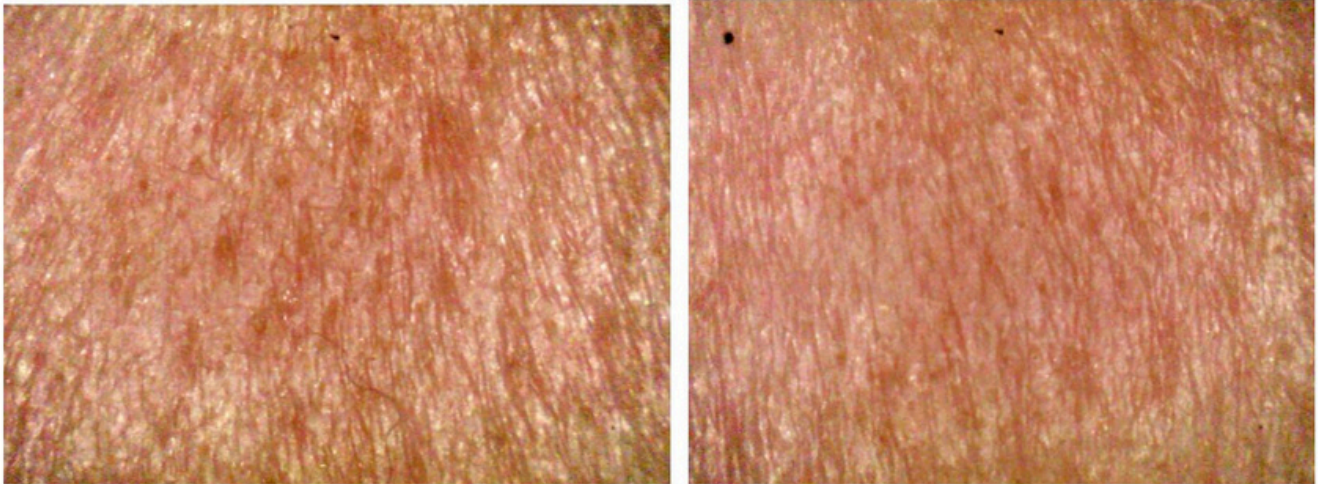


# GREDECO

Research and Evaluation Group in Dermatology and Cosmetology

Ove LED MASK – Lucibelle Paris

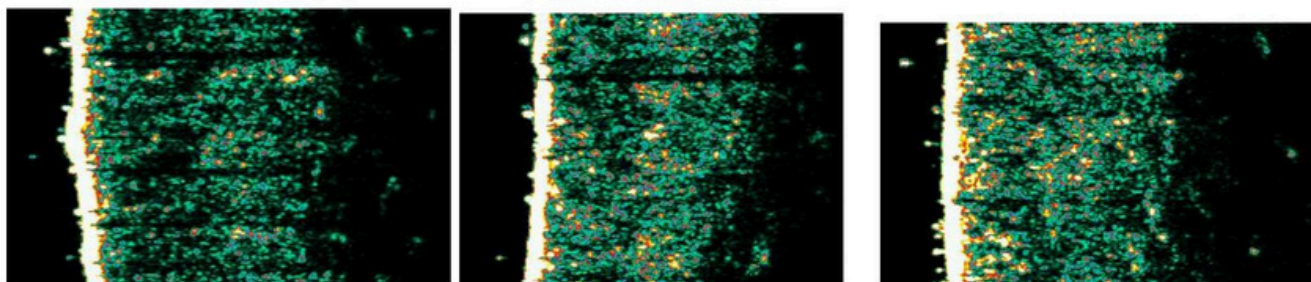
September -December 2021



## **SUBJECT #19: J0/J84 2D and 3D Face**

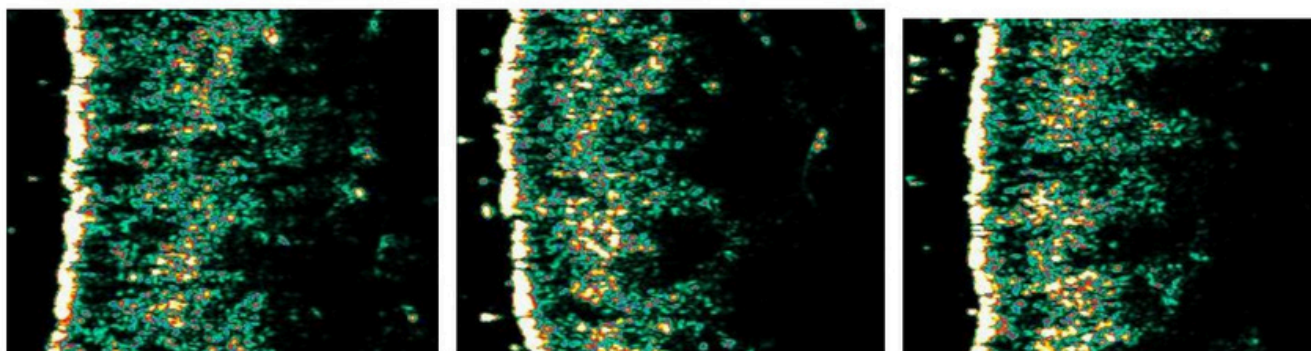
Global facial rejuvenation with smoothing of the forehead and eye area

peri region



**SUBJECT No. 10: ultrasound D0/D28/D56**

Increased skin density



**SUBJECT No. 20: ultrasound D0/D28/D56**

Increased skin density

