

**REPORT ON THE CLINICAL EVALUATION OF THE 89FA9C  
D@89J79 IN DERMATOLOGY AND COSMETOLOGY  
REALISED ON VOLUNTARY SUBJECTS RECRUITED AT THE  
PITIÉ-SALPÊTRIÈRE HOSPITAL IN PARIS**

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## Abstract

In the modern era of the 21st century, image and physical aesthetics have become integral parts of our lives. Dermatological and cosmetic treatments are experiencing a huge increase in development thanks to new technologies such as intense pulsed light. These clinical innovative procedures open new horizons for the treatment of inflammatory acne, solar and senile lentigos, flat angioma, rosacea, telangiectasia, stretched melasmas and generally speaking all types of treatments aimed at vascular and pigmentation problems as well as hair removal and skin rejuvenation.

An independent study was carried out by a group of researchers, doctors and dermatologists on each of the conditions on 24 patients of different skin types, notably using high skin types (VI), who volunteered within the public hospital in Paris, Pitié Salpêtrière.

Different objective criteria and scientific evaluations were taken to allow the study to score and measure the clinical effectiveness and the tolerance using the device for each situation. In addition, a paraclinical evaluation device was used to generate macrographs.

The DERMEO's medical light pulsed device that was tested, selects the spectral bands adapted to each destination of pathological or aesthetic treatment.

The results of these clinical evaluations have showed an excellent level of effectiveness while assuring the innocuousness of treatments.

A significant regression of acne based lesions accompanied by a good tolerance was observed after only 2 sessions.

Significant reduction in rosacea like vascular lesions, telangiectasias and rosacea acne were observed on different parts of the body. These reductions are due to a filtration which targets the absorption peak of oxyhaemoglobin along with a high level of fluence. The esthetic treatments such as the treatment of non pathological pigmented spots decreased the level of pigmentation substantially that had satisfying scores from the patient and the investigator. An increase in skin tone and radiance as well as a reduction in pore was observed for skin rejuvenation treatment for cellular stimulation.

Hair removal treatments were carried out on different parts of the body, on different phototypes, revealing an excellent tolerance on skin types II to V and a significant reduction in more than 80% of the number of hairs per cm<sup>2</sup> after only 2 sessions.

Thus, the clinical trials carried out on each of the medical and aesthetic situations have demonstrated the success of DERMEO's device for dermatological and cosmetic treatments.

The patients tested throughout the study were always comfortable.

The multi-pulsed flash mode that was programmed in line with a water-cooled handpiece with a Xenon lamp permitted the treatments to have assured innocuousness.

**Conforms with the MED DEV 2.7.1 guide. 3rd Revision**

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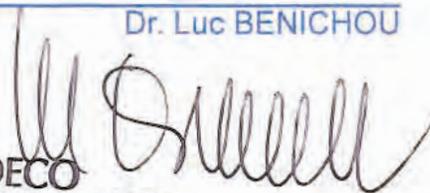
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## Introduction

The last fifteen years have seen the rapid development of the technology known as intense pulsed light. These IPL devices use flash lamps for skin rejuvenation<sup>1</sup>, hair removal<sup>1</sup> and in the treatment of certain dermatological diseases. Because of their efficiency, resulting from simplified use and much greater comfort for subjects, these technologies have taken a place once occupied by lasers.

The company DERMEO has developed a versatile pulsed light device due to their innovative modular solutions.

This device has a central unit and a unique hand piece equipped with two easily interchangeable elements:

- on one side, a block containing the flash lamp and the connection system to its cooling,
- on the other, various quartz filters, allowing the device to be used for all possible applications and phototypes clinically encountered. A graphical interface allows automatization of the settings if desired, depending on the characteristics of the skin to be treated.

This study was undertaken to assess the effectiveness and safety of different treatments that may be conducted with the F GTO GQ "RN" f g x leg.

## 1. Objective of study :

At the request of DERMEO company, the study clinically evaluated the efficiency and safety of the DERMEO IPL device on a total of 24 subjects, some with darker skin<sup>1</sup>, treated according to the indications (skin rejuvenation<sup>1</sup>, acne, rosacea and red spots, melasma and pigmented spots and hair removal<sup>1</sup>).

## 2. Duration of study :

9 months from June 2008 to March 2009

## 3. Tested Subjects and criteria for inclusion :

All subjects treated, completed a medical form to exclude contraindications against such treatment. They were also informed on the modalities and nature of the treatment proposed and signed a consent form for the treatment.

- For acne, two subjects were selected. They had long term, inflammatory acne at a moderate severity level on the dorsal region.

The subjects had stopped all anti-acne treatments: topical for 15 days, cyclins for 30 days and isotretinoin for 6 months.

- For skin rejuvenation<sup>1</sup>, three subjects were selected according to the following inclusion criteria:

Women aged between 48 and 70 with clinical signs of photo-aging (decrease of tonicity of the skin, decrease of complexion brightness and presence of wrinkles and 'crow's feet' around the eyes). They agreed not to use products aiming at moisturizing, topical or oral, around the eyes during the experiment period.

- For vascular lesions, subjects had to have on the face, both erythrosis areas and many vascular dilatations. They had to be between 35 and 65. Five subjects were selected, two suffering from rosacea and one with isolated vascular dilatations on the sides of the nose.

- For pigmented lesions, the subjects had either an extended melasma, vitiligo (two subjects).

- For brown age spots, 4 subjects were selected with areas of hyper-pigmentation, in dark aesthetic character only, on the hands or face and therefore were subjects to no pathology.

- For Hair Removal, seven subjects were selected, one with a high phototype (VI)<sup>1</sup>. The treated areas were: armpits (two subjects), bikini (one subject), lower limbs (one subject), upper lip (one subject with high phototype), arms (one male subject), face (one subject).

\* In the United States of America the authorized claims by the F.D.A. are: removal of unwanted hair from phototype skin I to V, treatment of benign cutaneous vascular lesions from phototype skin I to III, treatment of benign pigmented epidermal and cutaneous lesions from phototype skin I to III, treatment of inflammatory acne from phototype skin I to III.

## 4. Device tested

A pulsed light device with a spectrum range from 420 to 1200 nm with a power up to 40 J/cm<sup>2</sup> at crystal level.

The xenon lamp has a cooling system by using an internal water circuit.

The emission mode is multi-pulsed with 3 to 8 micro-pulses per flash, with a pulse duration from 2 to 5 ms and an interval from 5 to 60 ms.

A graphical interface allows to set the machine on manual or automatic mode.

The settings used for the study were on automatic mode.

Treatment programs configured by the device, allow the use of different sets of Quartz / filters available:

- AR (420-1200 nm) for acne treatments,
- VR filter for vascular treatments (515-1000 nm and 500-600nm and 670-1200nm),
- SR filter for skin rejuvenation (535-1200 nm)<sup>1</sup>,
- PL filter for pigmented lesion treatments (550-1200 nm),
- HR filter (620-1200 nm) for light skin hair removal,
- DS filter (750-1200 nm) for dark skin hair removal<sup>1</sup>.

## 5. Criteria for clinical evaluation

### For acne :

The clinical evaluation of acne was conducted under the ECIA scale (rating scale of acne lesions) with determination of three types of scores:

The IS score (0 to 5 depending on the number of papules and pustules)

The R score (0 to 5 depending on the number of open or closed comedos)

The Ip score (0 to 5 depending on the number of nodules and inflammatory cysts).

The score 1 corresponds to less than 5 elements,

The score 2, from 5 to 9 elements,

The score 3, intermediate from 10 to 19 elements,

The score 4, important from 20 to 40 elements,

The score 5, the highest, with more than 40 elements.

### Skin rejuvenation<sup>1</sup> :

#### a – Face skin tonicity (touch analysis) :

- |                                  |   |
|----------------------------------|---|
| - Tonic skin :                   | 0 |
| - Slight loss of tonicity :      | 1 |
| - Medium loss of tonicity :      | 2 |
| - Significant loss of tonicity : | 3 |

#### b – Complexion brightness :

- |             |   |
|-------------|---|
| - Radiant : | 0 |
| - Dull :    | 1 |

#### c- Cutaneous pores dilation (mid facial region) :

- |                       |   |
|-----------------------|---|
| - Small dilated:      | 0 |
| - Moderately dilated: | 1 |
| - Very dilated:       | 2 |

#### d – Shadows under the eyes :

- |              |   |   |
|--------------|---|---|
| - Presence : | 1 | 0 |
| - Absence:   |   | 0 |

#### e - Clinical Assessment of the wrinkles depth

- |                     |   |
|---------------------|---|
| - Shallow :         | 0 |
| - Slightly deep :   | 1 |
| - Moderately deep : | 2 |
| - Very deep :       | 3 |

### For rosacea and limited vascular blotches :

#### a - Clinical Assessment of the diameter of vessels:

- |          |   |
|----------|---|
| - Thin   | 0 |
| - Medium | 1 |
| - Thick  | 2 |

#### b - Clinical Assessment of the lesions extent:

- |                   |   |
|-------------------|---|
| - Small extent :  | 0 |
| - Medium extent : | 1 |
| - Strong extent : | 2 |

#### c - Assessment of red pigmentation intensity:

- |             |   |
|-------------|---|
| - Low :     | 0 |
| - Medium :  | 1 |
| - Intense : | 2 |

### For pigmented lesions and brown pigment spots :

#### a - Clinical assessment of the spots pigmentation:

- |                         |   |
|-------------------------|---|
| - Clear:                | 0 |
| - Moderately pigmented: | 1 |
| - Highly pigmented:     | 2 |

\* In the United States of America the authorized claims by the F.D.A. are: removal of unwanted hair from phototype skin I to V, treatment of benign cutaneous vascular lesions from phototype skin I to III, treatment of benign pigmented epidermal and cutaneous lesions from phototype skin I to III, treatment of inflammatory acne from phototype skin I to III.

b - Number of brown pigment spots on the treated area:

- Low: 0
- Medium number: 1
- Many: 2

#### For hair removal :

The criteria for clinical evaluation were counting the number of hair present on 1 cm<sup>2</sup> of the treated area.

### 6. Tolerance criteria

The evaluation of tolerance immediately after treatment was completed according to the following criteria:

- Presence of erythema
- Presence of edema
- Sensation of heat

For the treatment of brown pigmented spots, two other criteria were considered:

- Red blotches around the spots
- Spots hyperpigmentation

The evaluation of the delayed tolerance was done according to the existence of following criteria:

- Erythema
- Appearance of edema
- Phlyctena and crusts
- Hyperpigmentation
- Hypopigmentation
- Scar

### 7. Paraclinical assessment criteria (SkinStation, Proscope)

- The SkinStation is a device equipped with various probes to determine the volume, in mm<sup>3</sup>, occupied by a wrinkle around the eye.

Similarly, it allows for pigmented spots, to measure the intensity of pigmentation expressed relative to a calibration range from white to black.

- The Proscope is a device that allows you to make macro pictures.

## 8. Results of the treatments

### A - Treatments of pathological lesions:

1) Treatment of acne for 2 subjects.

AR filter 420-1200 nm with big surface crystal

Subject n°19 :

Aged 22. Treatment of back lesions.

Skin type setting: « Medium ».

Train of pulse: 5 pulses , the first one of 3ms duration, then the others 4ms, with intervals of 25ms.

At Day0:

IS score: 3

R score: 4

Ip score: 1

Power level: 8 J/cm<sup>2</sup>.

Very good immediate tolerance

At D8:

IS score: 1

R score: 3

Ip score: 0

Power level: 10 J/cm<sup>2</sup>.

Sunburn sensation for 24 h.

At D15 Result:

IS score: 1

R score: 3

Ip score: 0

Significant improvement of lesions after the first session, confirmed by the second session.

Correct tolerance throughout.

Doctor's grade: 7/10

Subject's grade: 7.5/10



Before



After 3 sessions



Before



After 3 sessions

### Subject n°01 :

Age: 45. Treatment of back lesions.

Skin type setting: «Light».

Train of pulse: 4 pulses the first one of 4ms duration, then the others 5ms with an interval of 15ms.

At D0:

IS score: 1

R score: 3

Ip score: 0

Power level: 8 J/cm<sup>2</sup>

Good tolerance, light burn sensation for 24 h.

At D8:

IS score: 1

R score: 3

Ip score: 0

Power level: 12 J/cm<sup>2</sup>

Good tolerance

At D15 Result:

IS score: 1

R score: 1

Ip score: 0

Significant improvement of lesions after the second session.

Note: Subject had holidays with sun exposure which could have improved acne.

Doctor's grade: 8/10

Subject's grade: 7/10

### Overall result for the two subjects:

A significant improvement of lesions was noted in both cases giving the subjects a significant aesthetic benefit. It may be noted, in general, as part of acne treatment with IPL alone, it would be interesting to evaluate the therapeutic benefit by remote monitoring of the recurrence of acne lesions.

### 2) Brown pigmented lesion treatments for 3 subjects

PL filter 550-1200 nm : with big surface crystal

#### Subject n°16 :

Aged 42 with melasma on both cheeks.

Skin type setting: « Medium ».

Train of pulses: 4 pulses, the first one of 4 ms duration, then the others 5ms, with an interval of 25ms

At D0 :

Spot pigmentation intensity clinical score of 1,5 on left cheek and of 1 on right cheek.

Power level : 15 J/cm<sup>2</sup>

Very good tolerance

At D10 :

Spot pigmentation intensity clinical score of 0,5 on right cheek. Left cheek was underway in desquamation.

Power level : 15 J/cm<sup>2</sup>

Very good tolerance

At D20 Result :

Spot pigmentation intensity clinical score of 0 on both cheeks.

Very good tolerance

Significant improvement

Doctor's grade : 8/10  
Subject's grade : 10/10



### Subject n°15 :

Aged 48 with diffuse vitiligo and significant residual pigmentation of the chin and neck. The only area treated was the chin.

Skin type setting : « White »  
Train of pulse : 4 X 4/15/5

#### At D0 :

Spot pigmentation intensity clinical score of 1,5 on the chin  
Power level : 15 J/cm<sup>2</sup>  
Good tolerance

#### At D10 :

Spot pigmentation intensity clinical score of 1,2 on the chin  
Power level : 15 J/cm<sup>2</sup>  
Good tolerance

#### At D20 :

Result : spot pigmentation intensity clinical score of 1,0 on the chin  
Good tolerance  
Poor result.

Doctor's grade : 4/10  
Subject's grade: 3/10



### Subject n°25

Aged 38, presenting with diffused pigmentation and melasma on the face.

Skin type setting: « Medium »

Train of pulse: 4 pulses, the first one of 4ms duration, then the others 5ms, with an interval of 25ms.

#### At D0:

The pigmentation was essentially on the cheeks with a clinical intensity score of 2  
Power level: 15 J/cm<sup>2</sup>  
Automatic mode  
Good tolerance

#### At D30:

Score: 1.5  
An improvement of the pigmentation was observed by the subject and the investigator.  
A second treatment was completed:  
Power level: 18 J/cm<sup>2</sup>  
Automatic mode  
Light erythema (duration 20 minutes) and pigmentation temporarily increased (3days)

#### At D60:

Large improvement.  
Score 1.2 and 0 in certain sections.  
Conclusion: Good tolerance and efficiency of treatment for the management of melasma.

Doctor's grade: 8/10  
Subject's grade: 8/10



### Overall results for the three subjects:

All cases could be considered difficult.

It should be noted, however, that a satisfactory result on a melasma (subjects 16 and 25), after only two sessions of pulsed light is very encouraging. For subject 25, after only 2 sessions, an improvement of the pigmentation was accompanied by good tolerance.

The second case, concerning the elimination of a residual pigmentation area on the face, persisting after the development of a large range of vitiligo, may be considered as a borderline case. The result after two sessions is small, but may suggest a further improvement if the treatment was to be continued.

### 3) Face rosacea treatment for 5 subjects

VR filter 515-1200 nm with big surface crystal.

Treatment of vascular dilations on the nose and erythrosis on the neck for one subject, treatment of telangiectasias on the neck and rosacea on the face for another subject and treatment of acne rosacea and telangiectasias on the face and neck for the third subject.

#### Subject n°13 :

Woman aged 54, with rosacea on face and neck.

Skin type setting: « Light »

Vessel type setting: « Medium »

Train of pulse: 5 pulses of 4ms with an interval of 20ms.

#### At D0:

Score 1.5 for vessel diameter

Score 2 for extent of lesions

Score 2 for red pigmentation intensity

Power level: 15 J/cm<sup>2</sup>

Poor tolerance: presence of a significant erythema on the face and neck for 8 days with visible crystal marks.

#### At D10:

Score 1 for vessels diameter

Score 1.5 for lesions extent

Score 1.5 for red pigmentation intensity

Strong improvement

Power level: 15 J/cm<sup>2</sup>

Once again, the subject poorly supported the treatment: after 4 days erythema was still present. A topical (Cicalfate) was required to relieve the subject and a cosmetic (Couvrance) was used to conceal redness.

#### At D20 Result:

Score 1 for vessels diameter

Score 1 for lesions extent

Score 0.5 for red pigmentation intensity

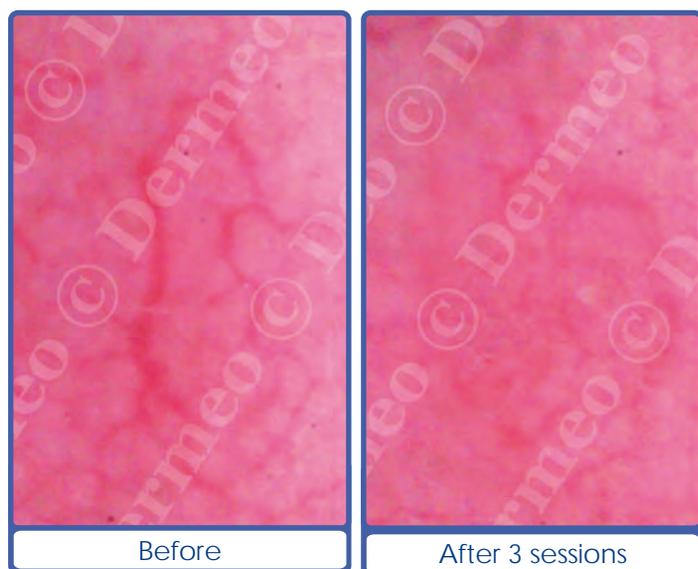
8 days of topical (Cicalfate) twice a day were necessary to remove redness.

On the neck, we noted the presence of hyper-pigmentation limited to the size of crystal.

In conclusion, the tolerance was reduced but the effectiveness was satisfactory.

Doctor's grade: 8/10

Subject's grade: 8/10



**Subject n°18:**

Woman aged 54, with rosacea on the face  
 Skin type setting: « Light »  
 Vessels type setting: « Medium »  
 Train of pulse: 5 pulses of 4ms with an interval of 20ms.

**At D0:**

Score 1.5 for vessels diameter  
 Score 2 for lesions extent  
 Score 1.5 for red pigmentation intensity

Power level: 12 J/cm<sup>2</sup>

The treatment has caused a 1st degree burn. Subject applied a topical (Cicalfate) on the erythema which persisted 9 days.

**At D10:**

Score 1.5 for vessels diameter  
 Score 1 for lesions extent  
 Score 0.5 for red pigmentation intensity  
 Important improvement.

Power level: 24 J/cm<sup>2</sup> with small surface crystal.

Correct tolerance, except for erythema which followed the session and the unpleasant sensation of heat during and after session.

**At D20 Result:**

Score 1 for vessels diameter  
 Score 1 for lesions extent  
 Score 0.5 for red pigmentation intensity

Average tolerance due to the presence of erythema post-treatment.  
 Efficacy has been very satisfactory.

Doctor's grade: 8/10

Subject's grade: 8/10



**Subject n°12 :**

The treatment did not carry out satisfactory results as the subject was too tanned.

**Subject N° 23 :**

VR filter 515-1200 nm with small surface crystal.

Woman aged 54, with vascular dilatations on sides of the nose and an erythrosis area on the neck.

Skin type setting: « White »

Vessel type setting: «Thin»

Train of pulses: 4 pulses, the first one of 5 ms duration, then the others 4ms with an interval of 15ms

Treatments were made with the small surface crystal.

**At D0:**

Score 1 for vessels diameter

Power level: 24 J/cm<sup>2</sup> on first pass then 28 J/cm<sup>2</sup> on the second  
 Good tolerance.

**At D10:**

Score 1 for vessels diameter

Medium tolerance with an intermittent pruritus sensation during the showers.

Power level: 1 pass only at 28 J/cm<sup>2</sup> and at 22 J/cm<sup>2</sup> on the neck

#### At D20 Result:

Score 0.5 for vessel diameter

Medium tolerance

Efficiency was assessed as moderate by the subject and the experimenter.

Doctor's grade: 5/10

Subject's grade: 7/10



Before



After 3 sessions



Before



After 3 sessions

#### Subject N° 26:

VR filter 500-600nm and 870-1200nm.

Woman aged 54 presenting with telangiectasias on the shoulders and lower neck and rosacea on the face.

Skin type setting: « White »

Vessel type setting: « Thin »

Train of pulses: 4 pulses, the first one of duration 5ms, then the others 4ms with an interval of 20ms

#### At D0:

Score 0.5 for the vessel diameter

Score 1 for the intensity of pigmentation

Score 2 for lesion assessment

The treatment was done with a hand piece having a filter of VR 500-600nm and 870-1200nm, with a power level of 15 J/cm<sup>2</sup> on the face and 12 J/cm<sup>2</sup> on the neck and décolleté. The machine was set on automatic mode.

#### At D10:

Score 0 for vessel diameter with an improvement clinically noted by both the investigator and the subject.

Score 0.5 for intensity of the pigmentation with a general improvement.

Score 1.8 for lesion assessment with again an improvement.

A second treatment was done with a hand piece with a filter of VR 500-600nm and 870-1200nm, at a fluence of 15 J/cm<sup>2</sup> on the face and 12 J/cm<sup>2</sup> on the neck and shoulders in automatic mode.

Skin type setting: « White »

Vessel type setting: « Thin »

Redness was observed immediately after the treatment.

#### At D30:

Score 0 for vessel diameter with an improvement.

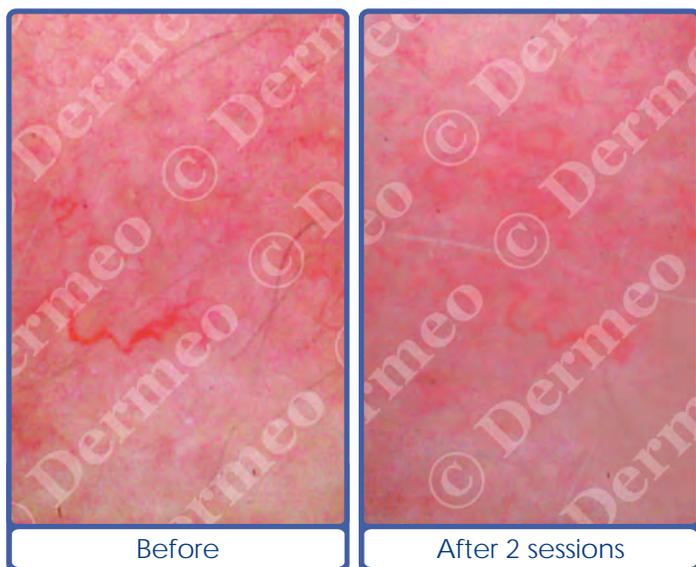
Score 0.2 for the pigmentation intensity with a general improvement.

Score 1 for the lesion assessment, again, with a general improvement.

In conclusion, an improvement of rosecea was observed by the investigator and the subject. The treatments were well tolerated. We can also note that there was an improvement in the tonicity of the skin.

Doctor's grade: 8/10

Subject's grade: 9/10



Score 0.5 for the pigmentation intensity.  
Score 1.2 for the lesion assessment.

In conclusion, the tolerance and efficiency for the rosacea treatment was good. We can note that for 2 subjects there was a marked improvement in general skin tone.

Doctor's grade: 9/10  
Subject's grade: 9/10



### Subject N° 27:

VR filter 500-600nm and 870-1200nm.

Woman aged 70 presenting a rosacea on the shoulders, lower neck and telangiectasias on the face.

Skin type setting: « Light »

Train of pulses: 4 pulses, the first one of 5ms duration, then the others 4ms with an interval of 20ms

#### At D0:

Score 1.5 for the vessel diameter

Score 1.8 for the intensity of pigmentation

Score 2 for lesion assessment

The treatment was done with a hand piece having a filter of VR 500-600nm and 870-1200nm, with a power level of 15 J/cm<sup>2</sup> in automatic mode.

Skin type setting: « Light »

Vessel type setting: « Thick »

#### At D15:

Improvement was noted by the investigator for the area of rosacea and a marked improvement on the general skin tone.

Score 1.5 for vessel diameter.

Score 1.5 for intensity of the pigmentation.

Score 1.5 for lesion assessment.

A second treatment was done with a hand piece with a filter of VR 500-600nm and 870-1200nm, at a fluence of 16 J/cm<sup>2</sup> in automatic mode.

Skin type setting: « Light »

Vessel type setting: « Thick »

#### At D30:

Improvement noted by the investigator for the area of rosacea and a marked improvement in general skin tone.

Score 1.5 for vessel diameter.

### Overall results for the five subjects:

These 5 cases were treated with success. However for 2 subjects there were immediate and delayed reduction in tolerance. It is apparent to us, in the process of this study that the best tolerance can be obtained by cooling the treatment zone before and after treatment and by using a crystal of small size, permitting the more precise targeting of the vascular lesions.

This was the case when using the small size crystal (15x15mm = 2.25cm<sup>2</sup>) which allowed a good level of tolerance to the treatment and an improvement of the rosacea, telangiectasias and acne while demonstrating equal efficacy on the lesions

## B – Aesthetic Treatments:

### 1) Treatment of brown pigmented spots for 4 subjects

PL filter 550-1200 nm using large surface crystal

#### Subject n°17:

Aged 41, subject with diffuse pigmentation on the face as well as isolated spots on the hands.

Skin type setting: «Medium»

Train of pulses: 4 pulses, the first one of 5ms duration, then the others 4ms with an interval of 25ms

#### At D0:

Clinical assessment score of pigmentation intensity (Proscope):

- 0.5 on right cheek
- 1.5 on left cheek
- 1 on right hand
- 1.5 on left hand

Power level: 15 J/cm<sup>2</sup>

Good immediate tolerance

#### At D20

Result: clinical assessment score of pigmentation intensity (Proscope):

- 0.1 on right cheek
- 0.8 on left cheek
- 0.4 on right hand
- 0.6 on left hand

Significant improvement in pigmentation intensity of the hands with best results seen on the left hand, slight decrease of the pigmentation of the face.

To be noted: increased sensitivity of the left hand to touch.

Doctor's grade: 5/10

Subject's grade: 5/10



#### Subject N° 10:

Aged 55, had two pigmented marks on cheeks.

Skin type setting: «Brown»

Train of pulses: 4 pulses, the first one of 5 ms duration, then the others 4ms with an interval of 30ms

#### At D0:

Clinical assessment score of pigmentation intensity:

- 2 for mark n°1 and 0,180 (measurement with SkinStation)
- 1 for mark n°2 and 0,110 (measurement with SkinStation)

Power level: 18 and 20 J/cm<sup>2</sup>

Good tolerance

#### At D20 Result:

Clinical assessment score of pigmentation intensity:

- 0.2 for mark n°1 and 0.020 (measurement with SkinStation)
- 0.4 for mark n°2 and 0.060 (measurement with SkinStation)

Significant improvement.

Tolerance was excellent.

Doctor's grade: 8/10

Subject's grade: 8/10

**Subject N° 11:**

Aged 43 had two pigmented marks on cheekbones.

Skin type setting: «Medium»

Train of pulses: 4 pulses, the first one of 5ms duration, then the others 4ms with an interval of 25ms

**At D0:**

clinical assessment score of pigmentation intensity (Proscope):

- 1.5 for mark n°1 and 0.120 (measurement with SkinStation)
- 0.5 for mark n°2 and 0.06 (measurement with SkinStation)
- 0.5 for mark n°3 and 0.07 (measurement with SkinStation)

Power level: 16 and 18 J/cm<sup>2</sup>

The subject felt a burning sensation on the day of treatment until the evening.

**At D20**

Result: clinical assessment score of pigmentation intensity (Proscope):

- 0 for mark n°1 and 0.01 (measurement with SkinStation)
- 0.5 for mark n°2 and 0.06 (measurement with SkinStation)
- 0.2 for mark n°3 and 0.04 (measurement with SkinStation)

The improvement was significant for mark n°1 but only slight for the other marks. A test was done with the small surface crystal after the two sessions. However, we did not observe any decrease of pigmentation.

Tolerance was satisfactory.

Doctor's grade: 8/10

Subject's grade: 8/10

**Subject N° 24:**

Male aged 68 presented with lentigo spots of hands and face.

Skin type setting: «Medium»

Train of pulses: 4 pulses, the first one of 4ms duration, then the others 6ms with an interval of 25ms

**At D0:**

Lentigo of the hand: Score 1.2 for the assessment of the pigmentation

Lentigo under the eye: Score 2

The treatment was done with a hand piece, a large size filter, PL 550-1200nm, and a power level of 15J/cm<sup>2</sup> in automatic mode.

**At D30:**

Improvement only seen for the under eye lentigo

Lentigo of the hand: Score 1.2 for assessment of pigmentation

Lentigo under the eye: Score 1

A second treatment was done with a hand piece, a large size filter, PL 550-1200nm, and a power level of 15 J/cm<sup>2</sup> in automatic mode.

Skin type setting: «Medium»

**At D60 Result:**

Lentigo of the hand: Score 1 for assessment of pigmentation

Lentigo under eye: Score 1

Very good tolerance.

In conclusion, a small decrease of the pigmentation of the lentigo on the back of the hand was seen while the spot under the eye was greatly improved.

Doctor's grade: 7/10

Subject's grade: 7/10

The fourth case did benefit from a second session. This confirms the necessity of a second session to obtain an improvement of the brown spots, and could have gone on to completely disappear.



**Overall result for the four subjects:**

In 3 out of 4 cases, we have only performed a single session. The results obtained were scientifically measured and, according to our experience, were completely satisfactory. The results would very likely be further improved with a second session.

## 2) Skin rejuvenation<sup>1</sup> in cell stimulation treatment for 3 subjects

SR filter 535-1200 nm with large surface crystal  
Treatments were completed on the subjects' face.

### Subject N° 4 :

Woman aged 48  
Skin type setting: «Light»  
Treatment type setting: Tonic  
Train of pulses: 5 pulses, the first one of 3ms duration with an interval of 20ms

#### At W0:

Score 3 for face skin tonicity  
Score 0.5 for complexion brightness  
Score 1 for cutaneous pore dilatation  
Score 3 for clinical assessment of the wrinkles depth and volume measurement by SkinStation of 90 mm3  
Score 1 for shadows under the eyes

Power level: 14J/cm<sup>2</sup> on the face and 11 J/cm<sup>2</sup> on the forehead.  
Excellent tolerance.

#### At 2 weeks:

Score 0 for face skin tonicity  
Score 0 for cutaneous pore dilatation  
Score 2 for clinical assessment of wrinkle depth  
Observation:  
Slight increase in complexion brightness  
No variation for shadows under the eyes

Power level: 15 on the face and 12 J/cm<sup>2</sup> on the forehead  
Erythema localised on mandibular region  
Burning sensation on left peri-auricular region for 24 h after treatment.

#### At 4 weeks:

Score 1.5 for tonicity of the skin of the face  
Score 0 for cutaneous pore dilatation  
Score 1.5 for clinical assessment of wrinkle depth  
Observation:  
Increase in complexion brightness  
No variation for shadows under the eyes

Power level: 15 on the face and 12 J/cm<sup>2</sup> on the forehead  
Presence of erythema more significant than at the second session

#### At 6 weeks:

Score 1 for tonicity of the skin of the face  
Score 0 for cutaneous pore dilatation  
Score 1.5 for clinical assessment of wrinkle depth and volume measurement by SkinStation of 70 mm3

Observation:

Slight increase in complexion brightness  
No variation for shadows under the eyes  
Good tolerance  
Significant efficacy for complexion brightness and wrinkle depth.

Doctor's grade: 7/10

Subject's grade: 7/10



### Subject N° 5

Woman aged 45  
Skin type setting: «Light»  
Treatment type setting: Tonic  
Train of pulses: 5 pulses of 3ms with an interval of 20ms

#### At W0:

Score 1.5 for face skin tonicity  
Score 0.5 for complexion brightness  
Score 1 for cutaneous pore dilatation  
Score 1.5 for clinical assessment of wrinkle depth and volume measurement by SkinStation of 65 mm3  
Score 0 for shadows under the eyes

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Power level: 12 on the face and 10 J/cm<sup>2</sup> on the forehead  
Excellent tolerance.

**At 2 weeks:**

Score 0 for face skin tonicity  
Score 1 for cutaneous pore dilatation  
Score 1 for clinical assessment of wrinkle depth  
Observation:  
Slight increase in complexion brightness  
No variation for shadows under the eyes

Power level: 14 on the face and 11 J/cm<sup>2</sup> on the forehead  
Good tolerance

**At 4 weeks:**

Score 0 for face skin tonicity  
Score 1 for cutaneous pore dilatation  
Score 0.5 for clinical assessment of wrinkle depth  
Observation:  
Stabilised complexion brightness  
No variation for shadows under the eyes

Power level: 12 J/cm<sup>2</sup> on the forehead and the rest of the face  
The subject noticed skin hypersensitivity for 2-3 days after the session.

**At 6 weeks:**

Score 0 for face skin tonicity  
Score 1 for cutaneous pore dilatation  
Score 0.5 for clinical assessment of wrinkle depth and volume measurement by SkinStation of 50 mm<sup>3</sup>

Observation:  
Stabilised complexion brightness  
No variation for shadows under the eyes  
Excellent tolerance.  
Very good efficacy for face skin tonicity and complexion brightness.

Doctor's grade: 8/10  
Subject's grade: 8/10



**Subject N° 6:**

Woman aged 54  
Skin type setting: « Medium »  
Treatment type setting: Tonic  
Train of pulses: 5 pulses of 3ms with an interval of 25ms

**W0:**

Score 2 for face skin tonicity  
Score 0.5 for complexion brightness  
Score 2 for cutaneous pore dilatation  
Score 3 for clinical assessment of the wrinkles depth and volume measurement by SkinStation of 80 mm<sup>3</sup>  
Score 1 for shadows under the eyes

Power level: 14 on the face and 11 J/cm<sup>2</sup> on the forehead  
Excellent tolerance.

**At 2 weeks:**

Score 1 for face skin tonicity  
Score 1 for cutaneous pore dilatation  
Score 2 for clinical assessment of wrinkle depth  
Observation:  
Slight increase in complexion brightness  
No variation for shadows under the eyes

Power level: 15 on the face and 12 J/cm<sup>2</sup> on the forehead and upper lip  
Good tolerance

**At 4 weeks:**

Score 1 for face skin tonicity  
Score 1 for cutaneous pore dilatation  
Score 2 for clinical assessment of wrinkle depth  
Observation:  
Slight increase in complexion brightness  
No variation for shadows under the eyes

Power level: 15 on the face and 12 J/cm<sup>2</sup> on the forehead and upper lip  
Good tolerance

**At 6 weeks:**

Score 0 for face skin tonicity  
Score 1 for cutaneous pore dilatation  
Score 2 for clinical assessment of wrinkle depth and volume measurement by SkinStation of 72 mm<sup>3</sup>

**Observation:**

Significant increase in complexion brightness  
No variation for shadows under the eyes  
Excellent tolerance.  
Very good efficacy for face skin tonicity and complexion brightness and moderate efficacy on the crow's-feet around the eyes.

Doctor's grade: 7/10  
Subject's grade: 6.5/10



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## C – Hair removal treatments

Hair removal face and body for 6 subjects

### Subject N°1 :

Woman aged 40.  
Armpit hair removal.  
Skin type setting: « Medium »  
Train of pulses: 6 pulses, the first one of 3ms duration, then the others 4ms with an interval of 25ms  
HR filter 620-1200 nm, large surface crystal

#### W0:

Number of hairs: 25/cm<sup>2</sup>

Power level: 15 J/ cm<sup>2</sup>  
Type of hair: « Thick »  
Excellent tolerance

#### At 6 weeks:

Re-growth was slower than usual.  
Number of hair: 6/cm<sup>2</sup>

Power level: 15 J/ cm<sup>2</sup>  
Type of hair: « Thick »  
Excellent tolerance

#### At 12 weeks:

Re-growth still very slow.  
Number of hairs: 8/cm<sup>2</sup>

Power level: 15 J/ cm<sup>2</sup>  
Type of hair: « Medium »  
Excellent tolerance

#### At 16 weeks -Observation:

Excellent results and tolerance, there are only 6 hair/cm<sup>2</sup> left. A 78% reduction in pilosity on the area treated after 2 sessions only. The subject has an impression of slow re-growth with finer hair. Total satisfaction for the subject.

Doctor's grade: 8/10  
Subject's grade: 8/10



Subject N°2:

Woman aged 45  
Armpit hair removal.  
Skin type setting: « Light »  
Train of pulses: 6 pulses, the first one of 3 ms duration, then the others 4ms with an interval of 20ms  
HR filter 620-1200 nm large surface crystal

#### W0:

Number of hairs: 28/cm<sup>2</sup>

Power level: 15 J/ cm<sup>2</sup>  
Type of hair: « Thick »  
Excellent tolerance

#### At 6 weeks:

Re-growth was slower than usual.  
Number of hair: 9/cm<sup>2</sup>

Power level: 15 J/ cm<sup>2</sup>  
Type of hair: « Thick »  
Excellent tolerance

#### At 12 weeks:

Re-growth still very slow.  
Number of hair: 7/cm<sup>2</sup>

Power level: 15 J/ cm<sup>2</sup>  
Type of hair: «Medium»  
Excellent tolerance

#### At 16 weeks:

##### Observation:

We have achieved excellent results: there are only 4 hairs/cm<sup>2</sup> remaining, this is a decrease of more than 85% of hair over 12 weeks and after only 2 sessions. Re-growth was visibly slower with finer hair.

In addition, the tolerance is absolutely satisfactory.

Doctor's grade: 8/10  
Subject's grade: 8/10



**Subject N°3:**

Woman aged 48  
Bikini hair removal  
Skin type setting: «Light»  
Type of hair: «Thick»  
Train of pulses: 6 pulses, the first one of 3 ms duration, then the others 4ms with an interval of 20ms  
HR filter 620-1200 nm with large surface crystal

**W0:**

Number of hairs: 8/cm<sup>2</sup>

Power level: 15 J/ cm<sup>2</sup>  
Pruritus without inflammation was observed during the two days following the session.

**At 6 weeks:**

Re-growth was slower than usual.  
Number of hairs: 4/cm<sup>2</sup>  
Power level: 18 J/ cm<sup>2</sup>  
During the session an engine failure occurred. The session had to be interrupted.  
Only the left side of the bikini has been treated.  
Good tolerance.

**At 12 weeks:**

Re-growth still very slow.  
Number of hairs: 4/cm<sup>2</sup>

Power level: 15 J/cm<sup>2</sup>  
Excellent tolerance

**At 16 weeks:**

Observation:  
We have achieved excellent results: there are only 3 hairs/cm<sup>2</sup> remaining  
Re-growth was visibly slower with finer hair.  
In addition, tolerance was excellent.  
The subject was completely satisfied.

Doctor's grade: 8/10  
Subject's grade: 10/10

**Subject N°7:**



Woman aged 36  
Leg hair removal  
Skin type setting: « White »  
Type of hair: « Medium »  
Train of pulses: 6 pulses, the first one of duration 3ms, then the others 4ms with an interval of 20ms  
HR filter 620-1200nm with large surface crystal

**W0:**

Number of hairs: 13/cm<sup>2</sup>

Power level: 20 J/ cm<sup>2</sup>  
Excellent tolerance

**At 6 weeks:**

Number of hairs: 6/cm<sup>2</sup>

Power level: 20 J/ cm<sup>2</sup>  
Good tolerance

**At 12 weeks:**

Number of hairs: 6/cm<sup>2</sup>

Power level: 20 J/ cm<sup>2</sup>

Excellent tolerance

#### At 16 weeks - Observation:

We have obtained excellent results, there are only 4 hairs/cm<sup>2</sup> remaining. This represents a decrease in hair density of 75% after 3 sessions.

Hair re-growth was thinner over the sessions.

The subject has an impression of more supple skin.

In addition, the tolerance was excellent.

Doctor's grade: 8/10

Subject's grade: 8/10



#### Subject N°21:

Woman aged 38

Facial contour hair removal

HR filter 620-1200 nm with large surface crystal

Skin type setting: « Brown »

Type of hair: « Thin »

Train of pulses: 6 pulses, the first one of 3ms duration, then the others 4ms with an interval of 20ms

W0:

Number of hairs: 17/cm<sup>2</sup>

Power level: 13 then 15 J/ cm<sup>2</sup>

A slight erythema appeared after the session as well as pimples. They lasted for 3 days.

At 3 weeks:

Re-growth has been slow, number of hairs: 2/cm<sup>2</sup>

Power level: 15 J/ cm<sup>2</sup>

Good tolerance

At 6 weeks:

Number of hairs: 3/cm<sup>2</sup>

Power level: 15 J/ cm<sup>2</sup>

Excellent tolerance

At 9 weeks - Observation:

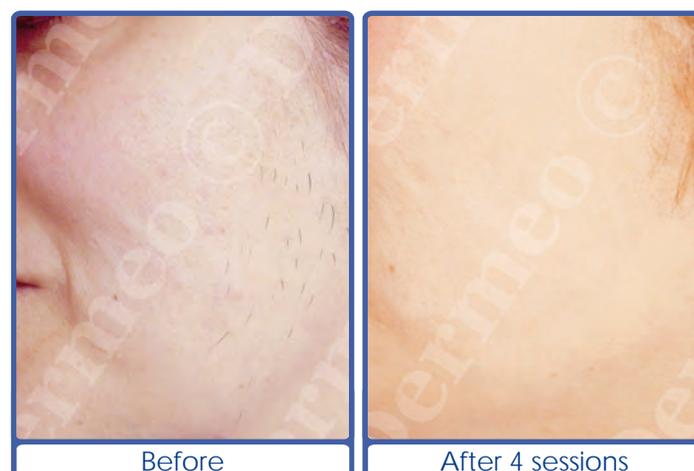
Number of hairs: 3/cm<sup>2</sup>

Good tolerance

The achieved results are very satisfying. 82% of hair has not re-grown after 9 weeks and 3 sessions of treatment. The number of hairs on the treated area has decreased and the re-growth is slower.

Doctor's grade: 8/10

Subject's grade: 8/10



#### Subject N°22:

Man aged 21

Right arm hair removal

Skin type setting: « Light »

Type of hair: « Medium »

Train of pulses: 6 pulses, the first one of 3ms duration, then the others 4ms with an interval of 20ms

HR filter 620-1200 nm with large surface crystal

**W0:**

Number of hairs: 6/cm<sup>2</sup>

Power level: 18 J/cm<sup>2</sup> for inner arm, 20 J/cm<sup>2</sup> for outer arm  
The subject had a pruritus sensation for 2 to 3 days.

**At 6 weeks:**

Number of hairs: 3/cm<sup>2</sup>

Power level: 18 J/cm<sup>2</sup> for inner arm, 20 J/cm<sup>2</sup> for outer arm  
Excellent tolerance

**At 12 weeks:**

Number of hairs: 3/cm<sup>2</sup>

Power level: 18 J/cm<sup>2</sup> for inner arm, 20 J/cm<sup>2</sup> for outer arm  
Excellent tolerance

**At 16 weeks**

Observation:

Number of hairs: 2/cm<sup>2</sup>

The result is very satisfying.

Hair removal on the arm will allow the subject to get a tattoo on the treated area.

Doctor's grade: 8/10

Subject's grade: 8/10

**Subject N°9:**

Subject with high phototype: VI<sup>1</sup>

Woman aged 41

Upper lip hair removal.

Skin type setting: « Dark »

Type of hair: « Thin »

Train of pulses: 6 pulses, the first one of 4ms duration, then the others 5ms with an interval of 40ms

DS filter 750-1200 nm with large surface crystal

**W0:**

Number of hairs: not able to count because the down hair was thin and dense.

Power level: 15 J/cm<sup>2</sup>

Excellent tolerance

**At 3 weeks:**

Number of hairs: not able to count

Power level: 15 J/cm<sup>2</sup>

Excellent tolerance

**At 6 weeks:**

Number of hairs: 10/cm<sup>2</sup>

Power level: 15 J/cm<sup>2</sup>

Unlike the excellent tolerance observed in the two previous sessions, the third session resulted in a heat sensation followed by the appearance during the following days of two small areas of de-pigmentation followed by a slight hyper-pigmentation and then a return to normal.

Regarding hair removal, the result is very satisfactory.

Doctor's grade: 8/10

Subject's grade: 8/10



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Before



After 3 sessions



Before



After 3 sessions

### Overall result for the seven subjects :

The results are excellent and guarantee our grade of 8/10 in each of the 7 cases. This is in addition to having very good immediate and delayed tolerance and the unanimous satisfaction of the subjects.

On average, 80% of the hair had disappeared after 2 or 3 sessions; this shows a definitive elimination of the hair in anagen phase at the time of the treatment and the significant slowdown of the re-growth of the hairs which were not completely destroyed. The subjects had a high level of satisfaction and comfort from the treatments.

In each case, a significant decrease in hair density was observed with only a small number of sessions.

## DISCUSSION AND CONCLUSION

The study that has been entrusted by DERMEO company allowed us, under normal consultation conditions, to assess the performance of the pulsed light device on 24 subjects.

The cases covered all indications of IPL and included difficult cases considering various types of skin and phototypes<sup>1</sup>. The cases enabled us to determine the performance of this device which is made under French design and manufacture.

Regarding effectiveness, we have obtained in almost all configurations and time limits results which are very satisfying (Acne) or even excellent (rosacea, brown pigmented lesions, hair removal<sup>1</sup>, skin rejuvenation<sup>1</sup>). Only certain pigmented lesion spots and isolated vascular dilations need to be reassessed using higher power level.

The subjects treated in this study presented with pathologies such as rosacea, retentional and inflammatory acne, general redness (blotchiness), telangiectasia, vitiligo and melasma.

All of the therapeutic treatments have shown satisfaction. As for the purely aesthetic treatments provided, such as stimulating cellular rejuvenation<sup>1</sup>, treatment of brown spots and hair removal on light and dark skins<sup>1</sup>, the history of care demonstrates a high level of safety and efficacy.

Regarding the tolerance, it was excellent, apart from the brief sensation of heat felt at the time of the flash, especially in depilation. Only two treatments (rosacea) were followed by an erythema which persisted for several days before disappearing. Hair removal treatments on the very high phototype VI<sup>1</sup> demonstrated efficiency with, during the last session only, a reversible hyperpigmentation.

Finally, the handling of the device has given us complete satisfaction. The graphical interface allows quick and simple settings according to the indication and choice of skin phototype to treat. The adoption of a modular filter system with a very simple change instead of having to change the hand piece seemed to us very convenient.

The addition of the LAMP CARTRIDGE directly interchangeable by the operator, without the requirement of a technician, optimised the treatments and made the machine more usable than others.

The dermatologic and aesthetic treatments with DERMEO's IPL device present a high level of effectiveness and safety.

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## Annexe : Board benefice / Side effects

Situations	Benefits	Side effects
<b>Acne</b>	<p>Significant regression of acne lesions accompanied by a good tolerance at the second session. Significant aesthetic benefit.</p> <p><b>Average mark:</b> <b>Doctors : 7.5/10</b> <b>Patients : 7.25/10</b></p>	No severe side effect was observed secondary.
<b>Hair Removal</b>	<p>A reduction of more than 80% of the hairs per cm<sup>2</sup> on the zone treated after just two sessions. A beneficial effect on the skin appears more toned and flexible.</p> <p><b>Phototypes Light</b></p> <p><b>Average mark:</b> <b>Doctors : 8/10</b> <b>Patients : 8.33/10</b></p>	No severe side effect was observed secondary.
	<p>The results were very satisfactory as evidenced by ratings by patients and doctors.</p> <p><b>Phototypes Dark</b></p> <p><b>Average mark:</b> <b>Doctors : 8/10</b> <b>Patients : 8/10</b></p>	Sensation of heat. Hyperpigmentation followed by small area of discoloration at the end of the fourth session and then a quick return to normal.
<b>Skin rejuvenation</b>	<p>Increased radiance and efficiency noted to the depth of wrinkles. Improved skin tone. The pores are tightened.</p> <p><b>Average mark:</b> <b>Doctors : 7.33/10</b> <b>Patients : 7.16/10</b></p>	No severe side effect was observed secondary.
<b>Vascular lesions</b>	<p>Results were very effective. An improvement in skin tone.</p> <p><b>Rosacea</b> <b>Acne Rosacea</b> <b>Telangiectasia</b></p> <p><b>Average mark:</b> <b>Doctors : 7.6/10</b> <b>Patients : 8.2/10</b></p>	A bad immediate tolerance was observed in 2 subjects with the appearance of first degree burns and erythema of the neck and face. These effects are reversible, in fact after 8 days the subjects had no further sequelae. No severe side effect was observed secondary.
<b>Pigmented lesions (pathological nature)</b>	<p>Significant improvement of melasma in the second session until the disappearance of the task at the last session. Improvement in pigmentation.</p> <p><b>Mélasma</b> <b>Pigmentation diffuse</b></p> <p><b>Average mark:</b> <b>Doctors : 8/10</b> <b>Patients : 8/10</b></p>	Erythema appeared 20 minutes and then disappeared immediately. No severe side effect was observed secondary.
<b>Brown pigmented spots (aesthetic nature)</b>	<p>Significant improvement, reduction of pigmentation.</p> <p><b>Lentigo</b> <b>Pigmentation diffuse</b></p> <p><b>Average mark:</b> <b>Doctors : 7/10</b> <b>Patients : 7/10</b></p>	Burning sensation until evening time No severe side effect was observed secondary.