SCITON

PROFILE™ BBL™ PULSED LIGHT MODULE: NON-ABLATIVE PIGMENTED LESION/SKIN TREATMENT

Introduction

Pigmented lesions can be treated with the selective absorption of light in melanin. This process was described as early as 1968 using ruby (694 nm) and Nd:YAG (1064 nm) lasers (Solomon et al., J Inv Derm, 1968, 50:141-146). The absorption converts light into heat energy, which raises the temperature of the target. With appropriate selection of fluence and pulse width the temperature will be high enough to alter and damage the target resulting in its elimination.

Pigmented lesions are treated by selective destruction of melanin or melanocytes with short high intensity light pulses.

The theory of Selective Photothermolysis explains how wavelength, energy, pulse width and thermal relaxation time all play a part in the destruction of a target and the preservation of surrounding tissue. Because of the large surface area-to-volume ratio, melanin and microvessels rapidly lose absorbed energy (heat) into the surrounding tissue. The thermal relaxation time of very small vessels is less than 1 millisecond, while that of larger vessels and hair can be 20 -100 milliseconds (ms) depending on size, and the thermal relaxation time of the epidermis is 3 -10 ms.

The PROFILE BBL can deliver enough energy or fluence to effectively target melanin and surface vessels, and has variable pulse widths for treating a range of target sizes. When the BBL is used to treat pigmented lesions there is heat build-up in tissue from the absorption of light energy in melanin and surrounding melanocytes. The heat dissipates into surrounding tissue. Absorption of the BBL light in melanin can be substantial, and a longer pulse width and lower fluence are recommended for darker skin.

Surface Cooling

Although absorption of the BBL light in melanin may be desirable, some epidermal cooling may be beneficial to protect the skin. The amount of cooling required will vary with the depth of the lesion. Lighter skin types require less cooling and darker skin types require more cooling for deep lesions. The BBL contact cooling plate insures that the epidermis is adequately protected from overheating regardless of skin type. When the BBL is used to treat pigmented lesions in dark skin, there is heat build-up in tissue from the absorption of light energy in normal melanin. Surface cooling can do little to differentiate between normal melanin and the lesion if they are at the same depth in skin, however lengthening the pulse width can provide some selectivity,

Pulse Width

Pigmented lesions are darker than normal melanin in skin. The melanin in the lesion occurs at a higher density giving the lesion a darker appearance. The principal of selective

photothermolysis can be used to preferentially treat the darker lesions. Since the epidermis normally has a thermal relaxation time of 3-10 milliseconds, using pulse widths of 20 ms or longer can avoid damage to normal melanin during treatment.

Fluence

The amount of energy per unit area applied to skin during the treatment pulse is the fluence. The heat build up in skin is directly proportional to the fluence. Darker targets absorb more energy and will reach higher temperatures. Therefore darker lesions require less fluence than lighter colored lesions to reach the same therapeutic level. An important consideration is skin type since pigmented lesions in light skinned individuals can be lighter than normal skin color in dark skinned individuals.

Classification of Skin Types

The following table offers a broad guidance to identifying skin types based on hair, skin and eye color as well as sun reaction.

Fitzpatrick Scale

Type	Hair Color	Skin Color	Eye Color	Sun Reaction
I	Red	Light	Blue-green	Burn, never tan
II	Blonde	Light	Blue	Burn, may tan
III	Brown	Medium	Brown	Burn, then tan
IV	Brown-black	Moderate brown	Brown-black	Tan
V	Black	Dark brown	Dark	Tan
VI	Black	Black (African)	Dark	Tan

Consultation / Treatment

The consultation or initial visit allows an exchange of views between case provider and patient in an attempt to reach a decision regarding treatment. The patient must understand the procedure, pre and post care instructions, and expectations before the procedure is performed.

Patient Education (Expectations)

The BBL is used to reduce flushing, telangiectasia, redness, dyspigmentation, and improve skin tone. Patients must understand that results vary with each individual. Multiple treatments may be necessary over a time span (2-4 week intervals) to reduce pigmented lesions in most areas. Results should be evaluated several weeks post treatment.

The BBL light pulse is often described as a wave of heat with the sensation of a pinprick. A topical anesthetic may be necessary.

Patient Documentation Forms

- Consent: the process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during consultation. It acknowledges that the patient understands the procedure and that all questions have been answered.

- Review post care instructions and confirm that the patient will adhere to such instructions throughout the course of their treatment.

- Post-treatment appointments are scheduled for: treatment assessment, patient evaluation and routine therapy.

Photographs

Before and after photographs should be taken throughout the course of the treatment to monitor patient response to therapy. Photographs should be taken prior to treatment, immediately after treatment and during follow-up visits. Camera settings should be the same to maintain photographs of similar quality. Photographs are useful in demonstrating efficacy of treatment to the patient.

Pre Treatment Procedure

- For better results, patients should avoid sun exposure, tanning beds and tanning creams for 2-3 weeks prior to treatment and throughout the course of their BBL treatment. Sunless tanning lotions must also be avoided for 2-3 weeks prior to treatment. However, if sun exposure is not avoidable treatment sessions need to be increased since treatments on sun-exposed skin will require lower fluence settings to protect the epidermis.

- Instruct the patient that recent sun exposure may result in cancellation of the treatment.

Post Testing Evaluation

- If a test area was done than an evaluation of the tested area usually occurs 1-2 weeks post treatment.

- Verify that any hypo/hyperpigmentation has been transient (to date). If the patient is concerned about the pigmentary changes, further treatments may be delayed. Once the area returns to normal skin tone, treatments may be resumed.

- Further testing may be indicated depending on the results seen from the first tested area(s).

Determination of Clinical Endpoint

Caution: Treating with excess energy levels can result in adverse effects

such as abnormal pigmentation, blistering and scarring.

- Darkening of the pigmented lesion and mild erythema should be noted in the skin. If the treatment area has even the slightest tan, the erythema response may be greater. If blistering occurs, treatment should be stopped immediately. Treatment can resume when the tan has faded.

Treatment Procedures

- The highest energy density determined through test spots should be utilized. An increase in fluence should be tolerated after 2-3 consecutive treatments.

- Double treatment of the same area is not recommended and can increase the chances of post treatment complications.

- Treatments are scheduled at 2 to 4 week intervals for most areas, 6 to 8 weeks for hair removal.

Sun Protection

- A broad spectrum (UVA/UVB) sun block with an SPF of 30 must be applied 15 minutes prior to casual sun exposure.

- Prolonged sun exposure requires repeated applications of sun block every 2 hours (e.g. yard work, beach activities, etc.).

- Sun block must be reapplied after swimming.

- Sun exposure to the treatment area should be avoided at least 2-3 weeks prior to treatment.

Adverse Effects

Complications, though rare, can occur and should be discussed and understood. The patient must understand the importance of the post-care instructions, and that failure to comply may increase the probability of complications.

- Scarring, though rare can occur following any intense light procedure.

- Histamine/Hives: some patients develop raised papules similar to hives. This irritation usually subsides in a few hours.

- Pigmentary changes: hyperpigmentation or hypopigmentation may occur. There is a higher risk in darker skin types.

Post Treatment Skin Care

Patients should receive post skin care instruction following each laser treatment.

Application of an ointment or aloe vera:

I. Ointment may be applied to the area to prevent drying. Ointment applied following the laser treatment can have a soothing effect.

II. An antibiotic ointment should be utilized if there is any blistering or break in the skin, and the patient should be instructed to contact the office.

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The following protocol is a safe start guide based upon the clinical observations of experienced physicians.

IMPORTANT: **Treating with too high of a fluence or overlapping pulses may lead to undesirable outcomes, including blisters, depressions and transient hyperpigmentation, all due to overheating of tissue. Attention to technique, and conservative treatments are recommended. This guide is not intended as a replacement for clinical training, preceptorship or supervised experience. Please follow the instructions in the Operator's Manual for the system you will be using.**

1. PRE-TREATMENT CONSIDERATIONS

1.1. CLEAN SKIN

Use a mild cleanser to remove any dirt, makeup, or moisture from the treatment area. Follow with an alcohol wipe. Allow alcohol to evaporate before treatment. Use special care around the eyes.

1.2. PATIENT EXAMINATION

Shave the area to be treated. Lesion type, size , and color; veins and telangiectasias; wrinkles; and skin tone should be classified prior to treatment according to size and depth. A pre-treatment photo will help to assist in evaluating the effectiveness of the treatment.

1.3. ANESTHESIA

Use a topical preparation, as needed, to alleviate discomfort for sensitive patients or sensitive areas prior to treatment. Remove before treatment with mild soap and water or an alcohol swab, then plain water. Dry the area thoroughly before treatment.

1.4. EYEBROWS AND BEARDED AREAS

Use caution when treating over beards – fluence should be lowered, and there is a small possibility of alopecia. A small test area is recommended.

Eyebrows should be protected as there is a small possibility of alopecia.

1.5. EYE PROTECTION

Always use eye protection for the patient, the operator, and anyone in the treatment room during the treatment.

1.6. TREATMENT OF AREAS WITH ARTIFICAL MAKE-UP, TATTOOS AND DARKENED MOLES.

Areas tattooed with designs or artificial make-up should be avoided. Not only do they create an additional and unwanted target for deposition of heat, but those targets with red or frosty white appearance commonly have iron or titanium in their composition. The red or white pigment will often oxidize and turn black from exposure to high intensity light. If you must treat those areas, a test spot with close monitoring for one to four days is recommended.

CAUTION: Tattooed areas should not be treated. Tattoo ink may absorb energy resulting in a color change in tattoo ink or a risk of epidermal damage. Darkened moles should not be treated. Moles may absorb energy resulting in a color change creating a risk of epidermal damage and the inability to monitor the lesion under ABCD guidelines.

2. SETTING TREATMENT PARAMETERS

2.1 FLUENCE

Starting fluence will be will depend on the condition and the skin type. The parameters in Table 1 are safe start parameters. Patient response can vary, so fluence setting should begin low and be increased gradually after assessing the individual patient response. The desired response is spontaneous erythema at the sight of the lesion. Fluence and pulse widths may change for a patient during the series of treatments. Be sure to properly evaluate the treatment parameters before each treatment based on previous successes, or complications, and the response of the patient to questions about the first 24 hours after the previous treatment. Those who respond with no irritation, and without prolonged erythema for the first 24 hours after treatment are within a safe, and possibly low, fluence range.

Note: Increase fluence in 1-J/cm^2 increments.
Excessive fluence or pulse stacking can lead to dermal injury or blisters.

2.2 COOLING

Cooling is recommended for patient comfort and for protecting the surface of dark skin with deeper lesions. Treating with lower COOLING temperatures will require treating with higher FLUENCE settings. The inverse also applies. Most treatment can be performed at the 25°C setting. A thin coating of colorless gel, KY, or

surgilube should be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin.

Note: Treating with cooler temperatures requires good contact with the skin surface. Changing cooling temperature by as little as 4°C will influence immediate clinical results.

2.3 PULSE WIDTH

Select the starting pulse width from the table. It may be necessary to change the pulse width and fluence to achieve the desired amount of erythema. Shorter pulse width and higher fluence settings are more aggressive. Longer pulse width and lower fluence settings are less aggressive.

2.4 FILTER SELECTION

The 515-nm filter is used for treating pigmented lesions. If a 420-nm filter is available it can be used to treat superficial pigmented lesions in light skin at lower fluence levels.

Table 1. Treatment starting parameters.

Skin Type	Fluence ($J/cm^{2)}$	Pulse Width (ms)	Filter (nm)	Cooling (°C)
I – II	4	10	420	15
I – II with light solar damage	12	10	515	25
I - II with heavy solar damage	9	20	515	10 - 25
III – IV	9	20	515	10 - 25
V	7	30	515	10 - 25
VI	n/a	n/a	n/a	n/a

3. TECHNIQUE

3.1. PATIENT POSITION

Position is based on the area to be treated. Patient should be in a comfortable position. The treatment area should be presented to the BBL user at a convenient height and position.

3.2. TEST AREA

Treating a test area before a patient's first treatment can establish their response threshold and help establish safe starting parameters. The test area should be monitored for response for a period of five to ten minutes. Blistering or the immediate grey or white presentation of the skin is the immediate concern.

TEST AREA should reach the desired response of lesion darkening and mild overall erythema within a few minutes. Increase fluence in small increments until the desired response is achieved.

CAUTION: Use only enough fluence to achieve the desired endpoint of lesion darkening and mild erythema. Keep fluence conservative for the first treatment session, and monitor the patient for any evidence of prolonged erythema, swelling, urticaria or blistering.

3.3. HANDPIECE POSITION

Position the patient so the BBL can be held perpendicular to the skin surface. Move the patient if necessary so that the treatment area is easy to reach.

Position the BBL so the cooling plate is in full contact with the skin. For highly curved regions, use the edge of the cooling plate while pushing the skin upward with your other hand to insure proper cooling.

The BBL must remain in contact with skin long enough before and after the light pulse to cool the surface of the skin and reduce the heat sensation. It will take several seconds for the deeper heat to propagate to the surface after the light pulse. A coating of colorless gel, KY, or surgilube should be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin.

3.4. TREATMENT METHOD

Match the “trailing edge” of the next treatment area to the “leading edge” of the previous treatment. The BBL will give a uniform treatment with uniform fluence within the treatment area.

Make certain to maintain complete skin contact with the treatment area before, during and after the treatment pulse. A coating of colorless gel, KY, or surgilube should be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin.

Do not overlap or immediately repeat BBL pulses.

For small isolated pigmented lesions a mask can be used to protect surrounding skin. Use a white card and cut out an area corresponding to the size of the lesion. Place the card over the lesion exposing such that only it is exposed to direct light from the BBL. Higher fluences can be used since the surrounding skin is shielded from intense light.

CAUTION: Do not stack pulses or overlap consecutive BBL treatment areas. Repeated pulses in the same location may lead to a build up of subsurface heat and a subsequent blister or burn. Blistering is an indication of over treatment due to excessive temperatures, which can be caused by improper cooling plate placement, overlapping pulses, repeated pulses, improper cooling temperatures, or excessive fluence.

4. TREATMENT GOALS

The immediate goal is lesion darkening and light erythema a few minutes after treatment. Patients will typically report feeling tighter skin or the sensation of mild sunburn following treatment.

CAUTION: Presentation of a blister or immediate graying or whitening of tissue indicates immediate complication. Treatment methods and parameters should immediately be reevaluated. The blisters or skin discoloration will commonly resolve without complication.

5. POST-TREATMENT CONSIDERATIONS

5.1. OBSERVATIONS

Erythema or a mild sunburn sensation should be noticed in the treatment area for up to two hours after treatment. Patients should not feel any significant discomfort after treatment.

5.2. INTERVENTION

While not often used, cold compresses can provide some comfort after treatment. If blistering occurs, aggressive wound treatment should be administered, i.e. Vigilon, Second Skin, silastic sheeting or other intervention.

5.3. INTERVAL

Recommended time interval between treatments is 2-4 weeks. 3 to 5 treatments may be necessary.

6. CONCURRENT PROCEDURES

COMBINATIONS –treatments may be given in combination with other minimally invasive therapies. If a patient is to receive another treatment (Botox, collagen injection) in conjunction with the PROFILE, it is advisable to perform the PROFILE treatment first. There may be increased sensitivity in the treated areas for an hour or two.

7. CONCLUSIONS

Do not be overly aggressive. Begin conservatively and be patient. Results are determined by the physiology of the patient's skin. Patients will usually notice a change in their darker pigmented lesions after the second treatment It will take longer for lighter pigmentation to resolve.

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1. Pre-Treatment:

- Clean area to be treated
- Clean hand piece prior to each treatment
- Eye Protection - Always use eye protection for the patient, the operator and anyone in the laser treatment room
- Hair should be shaved at the treatment site

2. Treatment:

- Apply a thin layer of colorless gel.
- Set Cooling Temperature; more cooling for darker skin types.
- Set pulse width.
- Set Fluence for TEST AREA, according to table or previous experience
- Adjust Fluence - to achieve desired response.

Table 1. Treatment starting parameters.

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I – II with light solar damage	12	10	515	25
I - II with heavy solar damage	9	20	515	10 - 25
III – IV	9	20	515	10 - 25
V	7	30	515	10 - 25
VI	n/a	n/a	n/a	n/a

- Treat with non-overlapping areas; use mask if necessary for small lesions.
- POSITION BBL COOLING PLATE in full contact with treated area.
- Use colorless gel, KY, or surgilube for better heat removal, improved optical coupling, and lubrication for floating the plate over skin without pressure.

3. Post-Treatment:

- OBSERVATIONS - Erythema for several hours after treatment.
- INTERVENTION - Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound treatment should be administered.
- INTERVAL - between PROFILE treatments is approximately 2- 4 weeks.

4. Perform treatment before Concurrent Procedures

CAUTION

Tattooed areas should not be treated. Tattoo ink may absorb laser energy resulting in a color change in tattoo ink or a risk of epidermal damage.

Overlapping pulses may lead to excessive temperature resulting in blisters or denatured collagen.

Do not stack pulses or overlap pulses. Repeated pulses in the same location may lead to a build up of heat and a subsequent blister or burn.