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Treatment Guidelines for the PicoWay® Laser System in Skin of Color

Picosecond laser therapy for benign pigmented lesions

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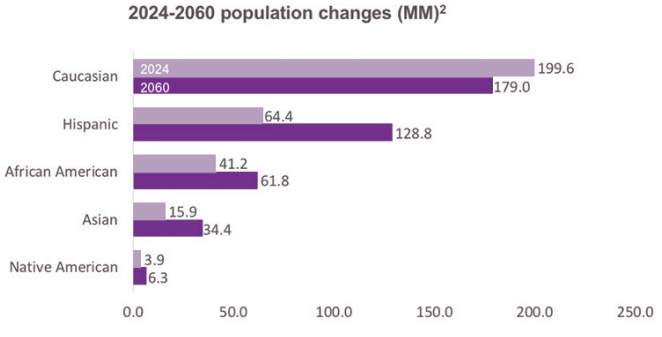
PicoWay picosecond laser system: A primarily photoacoustic, subsurface remodeling therapy that treats pigment-based dermatological disorders and lesions, clears tattoos, and improves skin appearance across Fitzpatrick skin types by handpiece, as outlined below.

FITZPATRICK SKIN TYPES CLEARED BY PICOWAY DEVICE HANDPIECES[1]

Indication	Handpiece Name and Wavelength	Fitzpatrick Skin Type
Tattoo removal	Zoom 532 nm	I-III
	785 nm	II-IV
	Zoom 1064 nm	I-VI
Benign pigmented lesions	Zoom 532 nm	I-IV
	Zoom 1064 nm	I-IV
Acne scars	Resolve 1064 nm	II-V
Wrinkles	Resolve 532 nm & 1064 nm	I-IV

INCREASING DEMAND FOR SKIN OF COLOR DERMATOLOGICAL TREATMENTS

By 2060, nearly 60% of the US population will comprise people with skin of color,[2] demonstrating the need for dermatological interventions that can meet the unique treatment needs and considerations of this growing patient demographic.



DIFFERENTIATING CHARACTERISTICS OF SKIN OF COLOR

Skin of color has key biological, structural, and functional differences, as compared to lightly pigmented skin[4]:

- Increased epidermal melanin content offers protection against harmful UV radiation, but also adds risk for hypopigmentation/hyperpigmentation and scarring[5]
- Singly dispersed larger melanosomes are widely distributed within epidermal keratinocytes[5]
- Increased prevalence of pigmentary disorders resulting from labile melanocyte responses[5]
- Tendency toward injury and inflammation from procedures is associated with hyper- and hypopigmentation[5]
- Darker skin has higher prevalence of keloids, which with increased fibroblast reactivity could lead to hypertrophic scarring.[5]

COMMON DERMATOLOGICAL DISORDERS

Due to specific biological characteristics of skin of color, these patients are more prone to certain dermatological conditions, such as melasma; café au lait marks (CALMs); Hori's nevus (also known as acquired bilateral nevus of Ota-like macules); lentigines; and post-inflammatory hyperpigmentation (PIH).

Melasma is increased pigmentation related to hormones (often known to patients as the "mask of pregnancy"), genetics, UV exposure,[6] and medications like birth control. Areas of the face typically affected include the upper lip, upper cheeks, and chin.

CALMs are pigmented lesions often referred to as "coffee with milk" because of their light brown coloration. These pigmented lesions are present at birth, and are more commonly called birthmarks, and remain throughout life. At birth, a single CALM is observed in only 5% of Caucasians and up to 15% of Americans of African descent,[7] further illustrating the biological differences and instances of dermatological conditions in patients with lighter versus darker skin of color.

Hori's nevus represents a pigmented skin lesion also referred to as acquired bilateral nevus of Ota-like macules (ABNOM). It's a relatively common skin disorder that is often misdiagnosed as melasma, among with other conditions. The cause of ABNOM may be due to inflammation, hormonal disruption, and UV exposure.[8]

Lentigines are benign lesions that occur on areas of the body that have frequent sun exposure, especially the face and on the backs of hands. Typically increasing with age, lentigines are more commonly found in middle-aged and older populations.[9]

PIH is increased pigmentation or dark spots at sites of inflammation.[10] PIH occurs when inflammation to the skin resulting from skin disorders and trauma such as acne, eczema, lichen planus, allergic reactions, surgery, and in some instances, even trivial injury, as with microdermabrasion, activates the release of inflammatory cells that trigger melanocytes (pigment cells) to produce more pigment within the skin. The result is increased pigmentation that varies in color (eg, tan to black) and size, and can occur anywhere on the body.[11]

SPECIAL LASER TREATMENT CONSIDERATIONS FOR SKIN OF COLOR

Outside of the advancements in laser therapies, one constant remains: treating benign pigmented lesions and tattoos on patients with skin of color (i.e. Fitzpatrick skin types IV-VI) requires a gentle yet powerful approach to accurately target the melanin or ink, while minimizing adverse side effects such as blistering or scarring that are more common to this patient group in comparison to lighter skin types (ie, Fitzpatrick skin types I-III).

When treating patients with skin of color, several considerations must be weighed to provide laser treatments that accurately target the chromophore, a molecular area that provides pigment/coloration, and not the surrounding melanin found in deeper skin tones.

Laser treatment considerations include[4,5]:

- a wavelength that is specific to and well absorbed by the chromophore being treated, good skin penetration, and preferential absorption of melanin;
- a laser that doesn't overheat surrounding tissues;
- a laser that offers highly customizable treatment parameters (eg, adjustable power, spot size and fluence, no compromise of spot size for fluence);
- and ideally a laser treatment that requires a small or reduced number of treatment sessions, relative to other laser treatment options, with minimal treatment time and low fluence.

THE PICOWAY SYSTEM: A REVOLUTIONARY LASER TREATMENT SOLUTION OR SKIN OF COLOR

The introduction of picosecond lasers has revolutionized dermatological treatments, providing the ideal characteristics and parameters required for treating patients of all Fitzpatrick skin types, including patients with skin of color, and raising the bar in the treatment of benign pigmented lesions and tattoos by achieving improved clearance of targeted lesions in fewer sessions when compared to Q-switched (QS) lasers,[12-14] without compromising tolerability. While nanosecond pulse durations found in QS lasers are measured in billionths of a second, the picosecond technology of the PicoWay laser system uses pulses that are measured in trillionths of a second, proving to be more efficient in breaking down melanin in benign pigmented lesions and particles of tattoo ink, so the body can easily rid itself of the debris as part of its natural biological elimination processes.[12-14]

Nanosecond lasers have restrictive use in skin of color due to the significant risk of PIH. With QS lasers, skin of color has a 25% risk of developing PIH.[15] Risk is reported to increase to 47% when the treatment is specific for lentigines, possibly due to the melanocytic hyperplasia noted histologically in a lentigo.[15]

Picosecond lasers can be used in a broader range of skin types than nanosecond lasers due to reduced risk of hyper- or hypopigmentation and scarring with picosecond photoacoustic versus photothermal effect. Shorter pulses and enhanced photoacoustic effect avoids overheating of skin and decreases risk of PIH. In skin of color, a clinical study with the picosecond laser demonstrated a low rate of PIH, at only 4.65% of the lesions.[16]

The innovative PicoWay picosecond laser system includes multiple wavelengths on one platform: 532nm, 785nm, and 1064nm. When treating pigmented lesions, the 1064nm and 532nm wavelengths are employed to target and clear chromophores. In tattoo removal treatments, all 3 wavelengths (1064nm, 532nm, and 785nm) may be employed to fraction and help clear away various ink colors. The 532nm wavelength is generally used to address superficial lesions, while the 1064nm wavelength allows for deeper epidermal penetration and can be used on all Fitzpatrick skin types (I-VI). The 1064nm enables users to target deeper lesions and severely photodamaged skin because it penetrates more deeply and initiates a wound response in the dermis. Additionally, the PicoWay Resolve handpieces at 1064nm treats acne scars, and at 1064nm and 532nm, treats wrinkles. The system's picosecond pulses can be administered with adjustable spot sizes with the 532nm Zoom, 785nm, and 1064nm Zoom handpiece (range from 2mm to 10mm) or with the Resolve handpiece (1064nm and 532nm) with identical split-beams in a 6mm x 6mm profile.

Compared to nanosecond lasers, with picosecond lasers, there can be:

- Better results (faster clearance, more efficient clearance, and fewer treatment sessions in tattoo removal)[17,18]
- Reduced hyper/hypopigmentation and scarring risk[17,18]
- Less pain[17]

With the PicoWay system, you also get:

- The shortest pulse durations of any aesthetic laser[19,20] for a photoacoustic effect that doesn't overheat surrounding tissue
- Resolve handpiece for treatment of acne scarring and wrinkles[1,21]

The treatment capabilities of the PicoWay laser system, and the results as seen in the following case studies, are both impressive and promising for treating skin of color.

TREATMENT OF CALMs

Over the years, clinical response and recurrence rates to QS laser therapy have demonstrated inconsistent results. Additionally, QS lasers carry the potential of causing substantial, lasting side effects, including scar formation and dyspigmentation.[10] While known to be used in treatment of CALMs, a QS 755nm laser is also known to have a high incidence of adverse side effects, providing serious concerns for darker skin types.[16]

In comparing treatment success rates of the QS Nd:YAG laser vs the PicoWay 532nm laser, the latter demonstrated greater success in clearing CALMs in patients with Fitzpatrick skin types II, III, and IV,[17] and minimizing side effects. In a retrospective case series analysis, the PicoWay 532nm laser delivered a higher clearance rate, a lower recurrence rate, and fewer and less severe side effects than the previously reported QS Nd:YAG laser modalities in the literature noted in the figure and table below.[17]

TREATMENT OF LENTIGINES[16]

In a clinical study, Asian patients with Fitzpatrick skin types III and IV were treated with the picosecond laser for solar lentigines. Researchers concluded there were "obvious differences" in epidermal and tissue damage when comparing sites treated using a QS laser with those sites treated with a picosecond laser, by way of histological evaluations. Electron microscopy showed destruction of melanosomes with surrounding tissue damage with the QS laser and without particular damage with the picosecond laser.

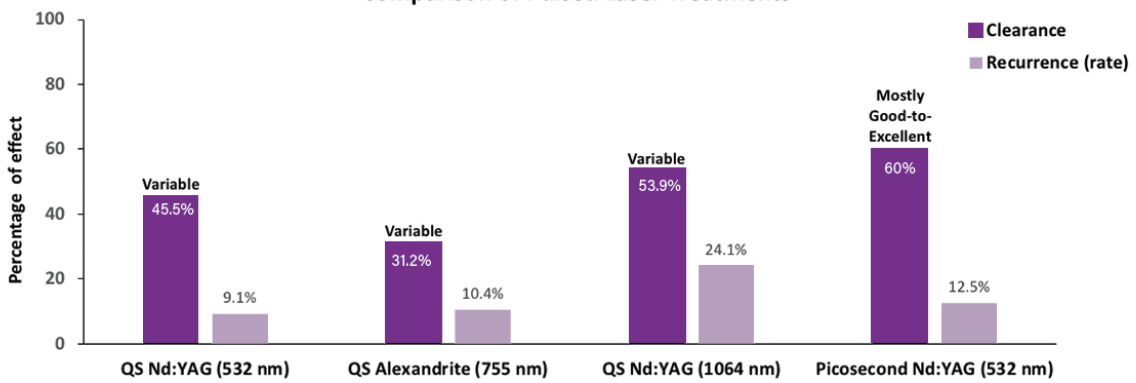
EXPERTS SHARE FIRSTHAND EXPERIENCE USING THE PICOWAY LASER ON SKIN OF COLOR

In September 2018, an expert-user panel of 15 physicians gathered to discuss their experiences treating multiple skin conditions in patients with skin of color using the PicoWay laser system. The panel agreed that in order to provide an optimal laser treatment for patients, multiple factors need to be balanced, including patient factors such as skin type and condition; and laser treatment factors such as fluence, diameter, pulse durations, treatment density, and output power. Multiple patient factors play a role in selecting a treatment parameter for each individual patient, thus the settings should be adjusted and customized to individual patient needs.

SHARED CASE STUDIES: KEY FINDINGS FOR THE PHYSICIAN COMMUNITY IN TREATING BENIGN PIGMENTED LESIONS

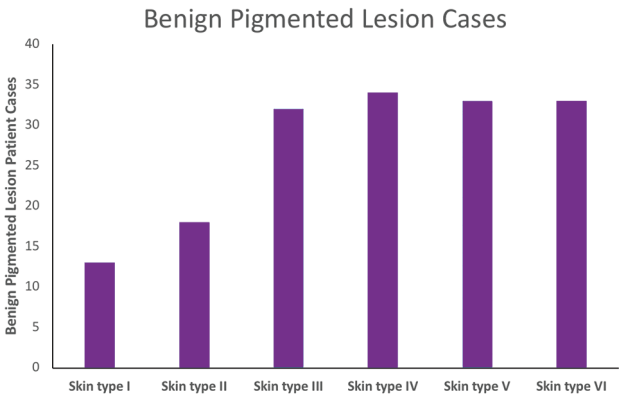
The majority of the cases presented by the expert-user panel focused on the treatment of benign pigmented lesions across Fitzpatrick skin types III-VI.

Comparison of Pulsed Laser Treatments



	QS Nd:YAG (532 nm)	QS Alexandrite (755 nm)	QS Nd:YAG (1064 nm)	Picosecond Nd:YAG (532 nm)
	N=22	N=48	N=32	N=16
# of treatments:	1-4	1-10	6	1-4
Adverse reactions[a]:	Hyperpigmentation	Hypopigmentation	Hypopigmentation	None

[a]All transient



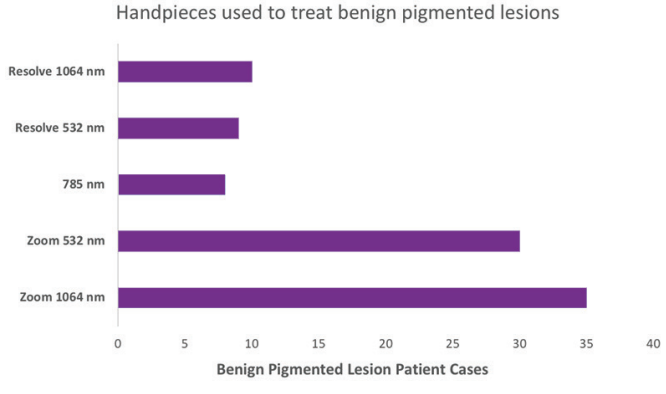
TREATMENTS BY PATIENT SKIN TYPE

Benign pigmented lesions treated included the following:

- Benign pigmented lesions
- Chicken pox scars
- Dermal pigment lesion
- Epidermal pigment lesion
- Labial melanotic macules
- Lentigines
- Lichen planus pigmentosus
- Localized argyria
- Ochronosis
- Melasma
- Nevus Fusco-caeruleus zygomaticus
- PIH (including acne; skin rejuvenation)
- Riehl's melanosis with and without melasma
- Seborrheic melanosis
- Solar lentigo
- Tear trough hyperpigmentation
- Underarm pigmentation

TREATMENT METHODOLOGY: HANDPIECES UTILIZED[b]

Zoom handpieces were primarily used to treat benign pigmented lesions in patients with skin of color. The Zoom 1064 handpiece, which allows for deeper epidermal penetration and adjustable spot sizes, was used most often.



b. The 785 nm handpiece is cleared by the FDA for blue/green tattoo removal, not for treatment of benign pigmented lesions.

TREATMENT PARAMETERS: MAXIMUM SPOT SIZE BY PATIENT SKIN TYPE

With the 1064nm Zoom handpiece, the 6mm spot size was the most commonly used for skin of color in the presented cases.

TREATMENT PARAMETERS: RANGE OF MAXIMUM FLUENCE

The fluence range used in treatment of benign pigmented lesions by the expert panel was wide, but average was within a tight range:

- Fluence ranged from 0.18 to 6 in treatment of benign pigmented lesions, with an average minimum fluence of 1.2 and average maximum fluence of 1.78 J/cm^2.

COMMON TREATMENT PARAMETERS IN SKIN OF COLOR

Clinical indication	Most often used wavelength/ handpiece	Spot size (mm)	Fluence range (J/cm^2)	Passes (median #)	Repetition rate (Hz)
Acne scars	Resolve 1064 nm	6x6 mm	0.16-2.9	3	Up to 8
Skin Rejuvenation					
Skin texture, tone, and color	Zoom 1064 nm	6-8 mm	0.16-1.2	2	2
Wrinkles	Resolve 1064 nm	6x6 mm	0.3-2.9	3	4-8
Benign Pigmented Lesions					
Lentigines	Zoom 532 nm	2-5 mm	0.4-3.25	1	1-2
CALMs	Zoom 532 nm	3-5 mm	0.5-1.4	1-2	NR
PIH	Zoom 1064 nm	6 mm	0.16-1.2	2	2
Nevus of Ota	Zoom 1064 nm	3-5 mm	0.2-3.7	2	7
Hori macules	Zoom 1064 nm	3-5 mm	1.4-3.7	1	NR
Other					
Tattoo	Zoom 1064 nm	3-5 mm	0.3-4.0	2	2
NR=not reported.					

GENERAL PICOWAY TREATMENT RECOMMENDATIONS FOR SKIN OF COLOR

Based on their collective experience and administered case studies that ranged in dermatological conditions, the expert-user panel determined general recommendations when treating benign pigmented lesions in patients with skin of color

using the PicoWay laser system, including the following:

- Utilize the 1064nm wavelength with the Zoom handpiece for most patients, treating 1 to 2 times to address skin conditions such as CALMs and PIH.
- In some patients, a 532nm or 785nm wavelength or handpiece may be more appropriate.[b]
- A skin care regimen consisting of sunscreen and/or isotretinoin and/or azelaic acid and/or hydroquinone, in the appropriate clinical context, is recommended post treatment.
- Utilize appropriate cooling techniques with either lower repetition rate or pausing between passes to reduce heating, making treatments more comfortable for patients. A skin cooling system can also be used to prevent overheating of the skin during treatment.

PANEL CONCLUSIONS

Overall, a picosecond laser with the shortest pulses and low repetition rate was found to be ideal for the treatment of skin of color. The expert-user panel noted several advantages with the PicoWay system, including improved skin texture, low patient downtime, and high patient satisfaction.

FEATURED CASE STUDY, RENITA LOURDHURAJAN, MD, DNB: SIGNIFICANT RESULTS AFTER 1 TREATMENT FOR SOLAR LENTIGO

Patient with Fitzpatrick skin type V treated for solar lentigo using PicoWay 532nm and 1064nm Zoom handpiece with a 1 Hz repetition rate. Using the 532nm wavelength (5mm spot size; 0.6 fluence rate), 4 pulses were administered to treatment site A (left solar lentigo), resulting in total clearance with 1 pass. Using the 1064nm wavelength (6mm spot size; 1 fluence rate), 14 pulses were administered to treatment site B (right solar lentigo), resulting in partial clearance with 2 passes. Adjuvant therapy was azelaic acid 20% and sunscreen.



Baseline **Results with 532 nm and 1064 nm wavelengths**

FEATURED CASE STUDY, RENITA LOURDHURAJAN, MD, DNB: LASTING RESULTS AFTER 1 TREATMENT FOR PIH

Patient treated for PIH post laser hair removal/chemical peel using PicoWay 1064nm Zoom handpiece with a 6mm spot size, 1.2 fluence rate, and 2 Hz repetition rate. A total of 467 pulses were administered over 2 passes.



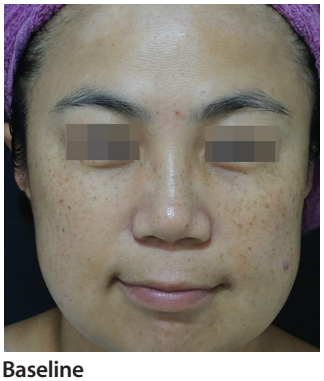
Baseline



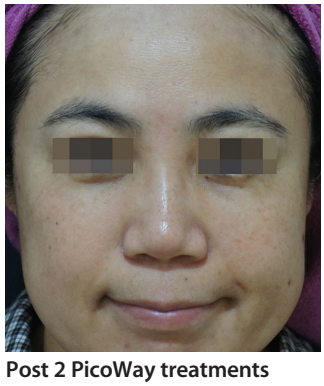
18 weeks post 1 PicoWay treatment

FEATURED CASE STUDY, CHAO-CHIN WANG, MD: SUBSTANTIAL IMPROVEMENT AFTER 2 TREATMENTS FOR LENTIGINES

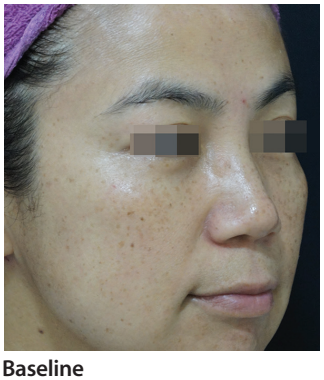
Patient treated in Taiwan for lentigines (freckles) using 2 treatments with PicoWay 785nm[b] and Resolve handpieces. The first session was conducted using the 785nm wavelength (2-3mm spot size, 1.6-3.25 fluence rate, 1-5 Hz repetition rate) and the Resolve 1064nm handpiece (6mm spot size, 1.3-2.3 fluence rate, 5 Hz repetition rate). The second session was conducted using the 785nm wavelength (2-3mm spot size, 1.8-2.75 fluence rate, 1-5 Hz repetition rate), the Resolve 532nm handpiece (6mm spot size, 0.83 fluence rate, 5 Hz repetition rate), and the Resolve 1064nm handpiece (6mm spot size, 0.19 fluence rate, 2 Hz repetition rate).



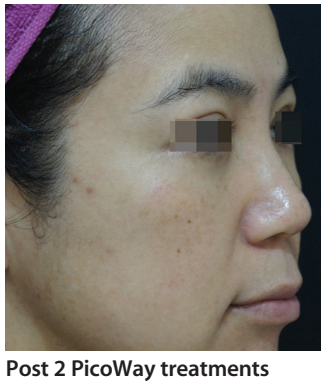
Baseline



Post 2 PicoWay treatments



Baseline



Post 2 PicoWay treatments

b. The 785 nm handpiece is cleared by the FDA for blue/green tattoo removal, not for treatment of benign pigmented lesions.

EXCELLENT TREATMENT POTENTIAL FOR SKIN OF COLOR

From research to patient application, the PicoWay system is a proven laser therapy with excellent implications for patients of darker skin types. The customizable treatment settings coupled with the dynamic Resolve and Zoom handpieces make for a truly personalized patient experience, tailoring each laser treatment to every patient's unique dermatological needs. PicoWay technology disrupts the status quo in laser treatments. Now, more than ever, physicians can "remove boldly, treat lightly" across patient skin types, including skin of color.

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- Douglas Wu, MD, PhD, Cosmetic Laser Dermatology, San Diego, CA, USA
- Konika Patel Schallen, MD, CMA Medicine, Jacksonville, FL, USA and Medical Director, Candela, Wayland, MA, USA

Disclaimer: The PicoWay system is available for use internationally. Approved indications may vary by country. In the United States, the PicoWay system is cleared for the following indications: tattoo removal, benign pigmented lesion removal, and the treatment of acne scars and wrinkles.[1]

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