

PicoWay® Resolve Fusion™ 532 nm and PicoWay® 730 nm picosecond laser handpieces for treating benign pigmented lesions

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Introduction

While Q-switched (QS) nanosecond laser technologies have been used for decades to treat benign epidermal and dermal pigmented lesions, picosecond lasers have changed the landscape, improving the side effect profile by reducing risk of epidermal injury and dyspigmentation.¹ The higher melanin content in individuals with skin of color can absorb the laser energy targeted at pigmented lesions, increasing the risks of unwanted side effects such as post inflammatory hyperpigmentation (PIH) and scarring.¹ A high PIH rate (28%) was reported previously, when using a QS alexandrite laser to treat freckles and lentigines in Asian skin.²

Picosecond lasers deliver high energy sub-nanosecond pulses that utilize a photomechanical effect to selectively destroy melanocytes in the targeted tissue, with reduced risk of unwanted thermal heating to surrounding tissue even in darker skin.³ A picosecond laser, using 532 nm and 1064 nm wavelengths for the treatment of benign pigmented lesions in Asians, including solar lentigines, freckles, café au lait macules, melasma, and Hori's Macules, showed a lower rate of PIH than that associated with Q-switched lasers.^{1,2} In another study, subjects with Fitzpatrick Skin Types II-IV were treated with a 532 nm picosecond laser for café-au-lait macules.⁴ Patients demonstrated good to excellent improvement, and post-treatment side effects were transient with no residual adverse effects or scarring at the last follow-up visit. Fractionated picosecond lasers produce microscopic lesions in the epidermis and dermis resulting in skin-remodeling effects.⁵ Asian ex-vivo skin samples, treated with a Nd:YAG laser system fitted with a beam-splitting optic, showed superficial, intra-epidermal

lesions and deep, intradermal lesions with no significant damage to the stratum corneum, epidermis, or overlying dermis.⁶ An increase of dermal collagen and elastin with improvement in appearance and texture of skin was observed in patients, who underwent picosecond laser treatment for acne scars.⁷

The PicoWay Laser System is a solid-state laser capable of delivering energy at wavelengths of 1064 nm, 532 nm, 730 nm or 785 nm at extremely short pulse durations, as low as 240 picoseconds with the new 730 nm handpiece.* The PicoWay System utilizes seven customized treatment handpieces that users can select for tattoo removal and treatment/removal of benign pigmented lesions, as well as treatment of acne scars and wrinkles.* The new Resolve Fusion handpiece (532 nm) is indicated for the treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV.*

The PicoWay Resolve 532 nm and 1064 nm lasers, with a 10x10 beam-splitting handpiece, improved photoaged skin and significantly decreased elastosis scores in subjects with Fitzpatrick Skin Types I-IV treated for facial wrinkles.^{5,8} The Resolve 1064 nm laser significantly decreased facial acne scars in subjects with Fitzpatrick Skin Types II-V with little to no downtime.⁹ A single treatment with the new PicoWay 730 nm laser resulted in significant pigmentary reduction in two Korean patients with skin type III-IV and multiple pigmented lesions on the face.³ Under an IRB-approved study protocol**, we evaluated the new Resolve Fusion 532 nm and 730 nm handpieces for treating benign pigmented lesions in 84 subjects.

Methods

Healthy male and female subjects presenting with the presence of benign pigmented lesions, assessed at baseline with Pigment Severity Score (PSS) of “2” (mild pigmentation) to “4” (severe pigmentation) were eligible to participate in the study. Subjects underwent up to four picosecond treatments, at 6-week intervals, to the face and/or body (i.e. chest, arms, neck, etc.) with the Resolve Fusion 532 nm handpiece and/or the PicoWay 730 nm handpiece. The PicoWay 730 nm handpiece is available with 2-4 mm spot sizes. The treatment pattern of the Resolve Fusion 532 nm handpiece is a 6 x 6 mm pattern in a 10 x 10 element array with 100 focused dots and diffuse rings (Figure 1).



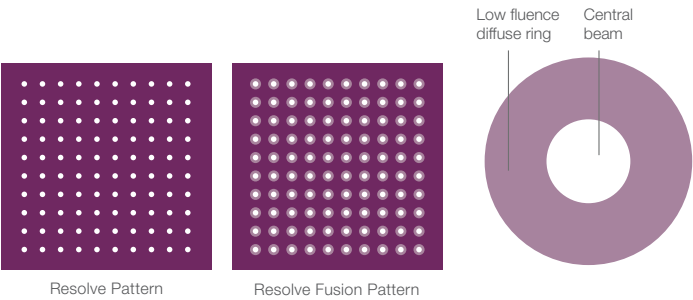
Figure 1. Resolve Fusion 532 nm Handpiece with Beam Profiles

Following treatments, discomfort associated with treatment was reported on a scale of 0=No pain to 10=Extreme pain. Digital clinical photography with standardized conditions was performed at all study visits. Blinded investigator assessment of pigment improvement was done at the 3-month follow-up after the final treatment, using a 5-Point Pigment Clearance Scale of 0=No improvement to 4=75-100% clearance. Subjects reported on their satisfaction with treatment outcome at the 3-month follow-up, using a 5-point Likert scale (2= Very satisfied to -2= Very dissatisfied).

Results

Subjects

A total of 84 participants (77 females, 7 males; mean age of 50±9 years, range 26-69) with Fitzpatrick skin type II (n=9), III (n=21), IV (n=53) and V (n=1) participated in the study. Many of the subjects (76%) had darker Asian or Mediterranean/Middle Eastern skin. Subjects underwent treatments to the face (n=68) and/or body (n=21) for pigmentation. Epidermal pigmentation (i.e. ephelides, solar lentigines, seborrheic keratosis, mixed dyschromia) was present in 69 subjects, dermal pigmentation (i.e. melasma) in two subjects and mixed epidermal pigmented lesions/ melasma in 15 subjects.



Treatments

A total of 315 treatments were performed. Full-face treatments were performed with the Resolve Fusion 532 nm handpiece (n=214 full face treatments), while the 730 nm handpiece was primarily used to treat focal areas of pigmentation on the face (n=38 treatments to the face) and body (n= 63 treatments). Treatment parameters were set according to physician discretion taking into consideration: location of treatment, skin type and handpiece wavelength. Treatment parameters are summarized in Table 1. Additional spot treatments or passes to focal areas were applied as needed.

Most of the treatments (79%, 248/315) were performed without topical anesthetic cream. In 37% of those treatments without topical anesthetic, Zimmer air cooling was used for patient comfort. Prior to the other treatments (21%, 67/315), topical anesthetic EMLA™ (Lidocaine/Prilocaine) or BLT (Benzocaine/Lidocaine/Tetracaine) cream was applied.

Treatment complications were minimal, and discomfort associated with treatment was generally mild (average score of 3.4) for treatments with the 730 nm laser to moderate (average score of 5.8) with the Resolve Fusion 532 nm handpiece. Darkening of pigment immediately following treatment is common and resolves within several days. There were three cases of trace to mild rebound melasma in Asian Fitzpatrick Skin Type III subjects with mixed epidermal pigmented lesions and melasma, who underwent 3-4 full-face treatments with the Resolve Fusion 532 nm laser. One case resolved spontaneously and the other two with application of 4% hydroquinone cream. There was one case of mild PIH and rebound melasma in an Asian Fitzpatrick Skin Type IV subject with solar lentigines and melasma treated with four full-face treatments with the Resolve Fusion 532 nm laser.

Resolve Fusion 532 nm (n=214)	Mean ± Standard Deviation (range)
Set Energy (mJ)	0.37±0.329 (0.2 - 2.9)
Spot Array (mm)	6x6
Rep Rate (Hz)	6±2 (1 - 9)
# of Full-Face Pulses/Tx 1	2,914±1,034 (715 – 5,079)
# of Passes	3±1 (1 - 7)
PicoWay 730 nm (n=101)	Mean ± Standard Deviation
Fluence (J/cm²)	2.3±0.9 (0.8 - 4)
Spot Size (mm)	2, 3 or 4
Rep Rate (Hz)	4±2 (0 - 10)
# of Passes	2 ±1 (1 - 8)

Table 1. Summary of Laser Treatment Parameters

PIH and melasma resolved with 4% hydroquinone cream. Whether melasma rebound was due to laser treatments or seasonal effects is unclear. Moderate PIH resolved spontaneously in an Asian Fitzpatrick Skin Type III subject who underwent four treatments with the PicoWay 730 nm laser for ephelides on the face. Overall rate for PIH was 2.4% (2/84) and 4.8% (4/84 subjects) for rebound melasma.

Blinded Investigator Assessment of Pigment Clearance at the 3-Month Follow-Up

Fifteen subjects were not available for assessment at the 3-month follow-up (i.e. moved out of state, scheduling, etc.). A total of 82 treated areas (58 face and 24 body) were assessed for pigment clearance at the 3-month follow-up. Of the 82 assessed areas, 47 had received three (9%) or four (91%) full-face Resolve Fusion 532 nm laser treatments, while the other 35 areas received 1-4 (mean 3.2±0.9) treatments with the PicoWay 730 nm laser to pigmented lesions on the face and body.

Most areas (83%, 68/82) responded to treatment with 77% of treated areas showing ‘Excellent’ or ‘Complete’ pigment improvement (Figure 2). There was no significant difference (p= 0.6985) in mean pigmentation scores between the two laser treatment cohorts. Visible reduction in pigmentation is shown in Figures 3 and 4.

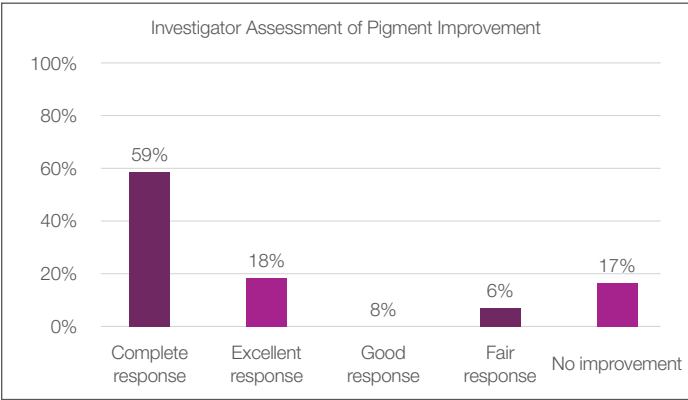


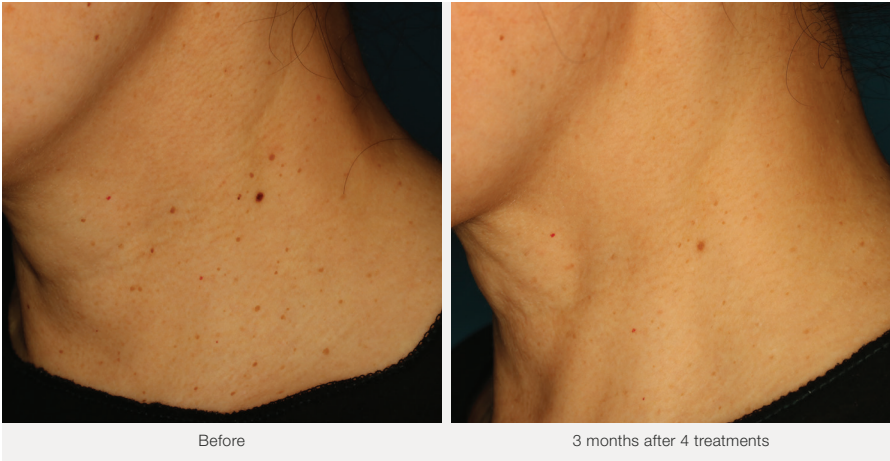
Figure 2. Investigator assessment of pigment improvement at the 3-month follow-up

Figure 3. A 46-year-old Asian female with Fitzpatrick Skin Type IV underwent 4 treatments with the Resolve Fusion 532 nm laser for mixed epidermal dyschromia. Pigment improvement was a 'Complete response' (75-100% clearance) at the 3-month follow-up.



Photos courtesy of K. Patel Schallen, MD, USA
All photos are unretouched. Individual results may vary.

Figure 4. A 56-year-old Asian female with Fitzpatrick Skin Type III underwent 4 treatments with the PicoWay 730 nm laser for epidermal ephelides. Pigment improvement was a 'Complete response' (75-100% clearance) at the 3-month follow-up.



Photos courtesy of K. Patel Schallen, MD, USA
All photos are unretouched. Individual results may vary.

**Subject Satisfaction
at the 3-Month Follow-Up**

Subjects reported on satisfaction with treatment outcome at the 3-month follow-up visit after the final treatment. Most of the assessments (94%) indicated satisfaction with treatment outcome, with 50% (41/82) of assessments reported as "Extremely satisfied" (Figure 5).

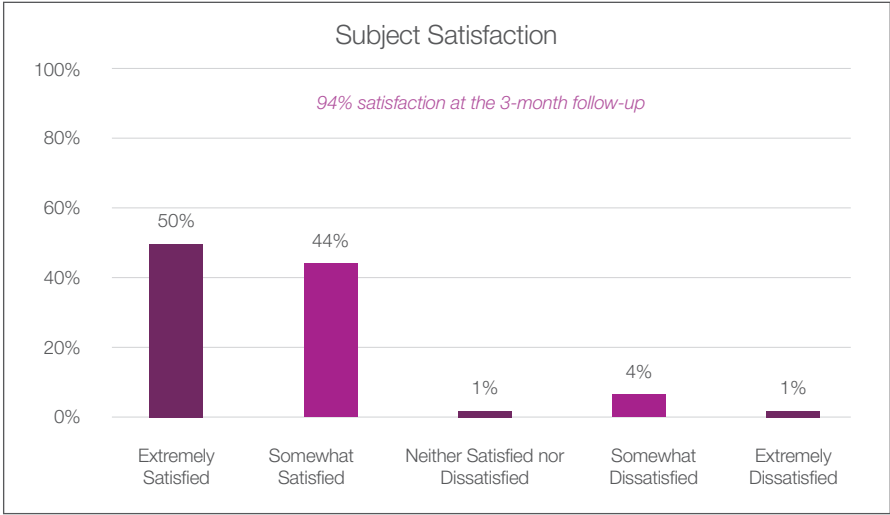


Figure 5. Subject satisfaction at the 3-month follow-up

Conclusion

In this study, a series of 3-4 full-face treatments with the Resolve Fusion 532 nm handpiece and focal treatments with the PicoWay 730 nm handpiece to the face and body resulted in >50% clearance of epidermal and dermal pigmented lesions for 77% of assessed areas. Subjects reported high satisfaction with treatment outcome. PIH rate was low in this population of darker-skinned subjects.

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- * PicoWay laser system 510(k) clearance [K191685], September 2019.
- ** Advarra IRB-approved protocol: "Candela - PWY18010, Evaluation of the PicoWay® Laser System with 730 nm and Resolve™ Fusion Handpieces for Treatment of Benign Pigmented Lesions and Wrinkles (Pro00030970)".

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