Efficacy of PICO Genesis[™] Procedure using 670 nm and 1064 nm of the enlighten [™] Laser on BPL and Dyschromia in Fitzpatrick Skin Phototypes II – IV

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Background

Substantial published evidence supports the safety and effectiveness of nanosecond lasers in the treatment of Benign Pigmented Lesions (BPLs), photo-aging, and photo-damage. These lasers operate at pulse durations much shorter than the thermal relaxation time of the intended target, melanosomes, and have been shown to resolve dyschromia. Based on the theory of selective photothermolysis, pulse widths shorter than those deployed by nanosecond lasers can confine the thermal dose to the target better and can also cause photomechanical disruption of the pigment to achieve the desired clinical effect.

The enlighten laser is an Nd:YAG picosecond laser system that treats pigmented lesions at wavelengths of 532 nm, 670 nm and 1064 nm. The 670 nm wavelength is indicated for treatment of Benign Pigmented Lesions (BPLs). The 532 nm wavelength is indicated for removal of Benign Pigmented Lesions (BPLs) and lighter colored tattoo inks. The 1064 nm wavelength is indicated for removal of BPL and darker colored tattoo inks.

Traditional Q-Switched Ruby (694 nm) lasers have been used extensively for laser toning and treatment of dyschromia. 1-3,5 The reason for the choice of this wavelength is its absorption by Melanin. Since 670 nm has similar Melanin absorption characteristics compared to the Ruby laser, 670 nm is thought to be it a more "favorable" wavelength for treating benign pigmented lesions on darker skin types with less side effects observed than with the 532 nm laser. The objective of this exploratory study was to evaluate the PICO Genesis procedure using the 670 nm and 1064 nm wavelengths of the enlighten laser on patients with FST II-IV desiring skin improvements through photo-rejuvenative techniques.

Materials and Methods

Ten female patients with FST II-IV who had visible evidence of BPLs, dyschromia, photo-damaged, or photo-aged skin were enrolled in the study. Eight were of Asian descent with FST IV, one was Caucasian with FST II, and one of Hispanic descent with FST III. Patients ranged in age from 40-61 (median of 47). All patients signed an informed consent prior to participating in the study. Patients

were not eligible if they had any type of cosmetic treatments or aesthetic injections within the previous six months, concurrent illness or infection, history of any type of abnormal wound healing, inflammatory or immune disorder, or pigmentary disorders.

Enrolled patients received up to three treatments at 4-6 week intervals with the PICO Genesis procedure using the enlighten laser (Cutera Inc.), specifically the 670 nm and 1064 nm wavelengths. PICO Genesis is a two part procedure: a. Treatment of individual lesions using 670 nm with no overlap to address dyschromia, BPLS and b. Global treatment of the face using 1064 nm with low fluence and multiple passes (4-5). Following this protocol on the study patients, areas showing BPLs were treated with the 670 nm laser at 660 picosecond pulse duration first, one lesion at a time. Subsequently, patients received a 1064 nm wavelength, 750 picosecond pulse duration treatment over the entire face with low fluence and high repetition rate. Typical shots administered during the 1064 nm part of PICO Genesis procedure range from 3000 to 5000 for the whole face. Fluence and spot size were selected based on the individual patient's skin type and pigmentation. Skin preparation, device usage, and patient follow-up procedures were conducted according to the manufacturer's instructions. Patients completed a 12-week follow-up after their final treatment and then exited the study.

Results

Of the ten patients enrolled in this study, results from three patients are presented. These patients tolerated the treatment well and had only minor, transient side effects and minimal downtime of 2-3 days. Table 1 presents the treatment settings for the three representative patients. Figures 1-3 show digital photos of the same three patients at baseline and following their treatment sessions.

Patient 1 is a 43 year old Caucasian woman with FST II and evidence of bilateral photo-damage and BPL (Figure 1). Individual lesions were treated with the 670 nm and global revitalization was achieved using 1064 nm. Significant reduction of pigmentation was seen following one treatment and overall improvement in overall dyschromia after the second treatment was observed. The patient

Table 1. enlighten Treatment Settings

Patient ID	Tx #	Wavelength (nm)	Treatment Area	Fluence (J/cm²)	Spot size (mm)
Patient 1	1	670	BPL	1	3
		1064	Full face	0.8	8
	2	670	BPL	1	3
		1064	Full face	0.8	8
Patient 2	1	670	L + R Cheek BPL	0.8	4
	2	670	L + R Cheek BPL	0.5 - 0.8	4
		1064	Full face	0.8	8
Patient 3	1	670	BPL	1	3
		1064	Full face	0.8	8
	2	670	BPL	1	3
		1064	Full face	0.8	8

reported a high level of satisfaction with the treatment.

Patient 2 (Figure 2) is a 61 year old Asian woman with FST IV and diagnosed with Hori's macules. With the 670 nm/1064 nm treatment, substantial pigment clearing was noted following the second treatment with moderate improvements to skin quality. By utilizing the 670 nm wavelength, which helps penetrate deeper and the shorter pulse durations which confine the thermal energy, no hyperpigmentation was observed post treatment. Further, this patient was not pretreated with topical medications to lighten the skin prior to initiation of treatments.

Patient 3, shown in **Figure 3**, is a 55 year old Asian female with FST IV. She had visible freckles and both superficial and deep BPL. Due to her darker skin and deeper lesions, the 532 nm wavelength was not optimal to use for her treatment. The deeper BPL were successfully removed using the 670 nm wavelength to treatment the individual lesions and her overall pigmentation improved markedly using the global treatment with the 1064 nm wavelength laser. Overall, the patient was satisfied with the treatment and reported that the skin quality had substantially improved, and that her friends and family could tell the difference.

Conclusions

In our study, the PICO Genesis procedure using 670 nm and 1064 nm wavelengths provided a significant therapeutic response for a range of patients with BPL and photo-damage indications. Minimal side effects were noted and no cases of hypo- or hyperpigmentation were noted as a result of the treatment. Patients reported improvement in both pigmentation and skin quality with minimal downtime.

Figure 1. Results for Patient 1



Baseline

Post Treatment 1

Post Treatment 2

Figure 2. Results for Patient 2



Baseline

Post Treatment 1

Post Treatment 2

Figure 3. Results for Patient 3



Baseline

Post Treatment 1

Post Treatment 2

Post Treatment 3

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