

# Split-Face Study with a New Picosecond Alexandrite Laser with Increased Output Energy, Independently Adjustable Fluence and Spotsize for Skin Rejuvenation, Skin Pigmentation, and Acne Scars with a Diffractive Lens Array

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*Doctors are paid consultants of Cynosure, LLC.*

## BACKGROUND:

The main application for the first picosecond device developed for use in a clinical setting was envisioned to be tattoos, and pigment was considered as a secondary application. The motivation for building and using a picosecond laser is that for tattoos, picosecond lasers offered better inertial confinement on thermo-mechanical stress in the tattoo particles and faster and better clearance, and for pigment, picosecond lasers offered the opportunity to target melanin with better thermal confinement of the heating within the melanosomes and the prevention of thermal damage to adjacent tissues and structures. The motivation for building and using a 755 nm picosecond laser over other wavelengths is that 755 nm offers a very high contrast between the absorption coefficient of melanin and blood – much higher than the contrast at 1064 nm and 532 nm. Additionally, nanosecond 755 nm lasers were established as the best for naevi in Asian skin. A recent adjustable fluence picosecond laser with

an increased energy output was created, and this allows for larger energy per pulse for larger treatment spot sizes and faster treatments. For tattoos, larger spots mean deeper, more efficient energy delivery, and for rejuvenation, larger spots with adjustable fluence provide fine tuning. The new picosecond Alexandrite laser used in this study allows for higher fluence output at a given spot size (50% more output energy). The adjustable fluence allows for flexibility and customization of treatment parameters and de-coupled adjustable fluence with adjustable spot size. The new 5 mm fixed handpiece allows for Focus treatments at a smaller spot size and increased fluence. Additionally, the new picosecond Alexandrite laser allows for a faster startup time <10 min vs. the current 15-20 min. The flat optic at relatively low energies can heat melanin in a manner which localizes the injury within the cells (thermal confinement) that appears to clear pigment without overheating and PIH. The fractional optic using the 755nm wavelength

generates an intra-epidermal injury which appears to mediate a dermal response with vascular dilatation and the generation of inflammatory factors which appears to be responsible for this temperature rise and clinical response which results in the generation of collagen, elastic tissue and mucin.

The picosecond Alexandrite with the flat optic and the diffractive lens array has become an important tool for skin rejuvenation, abnormal pigmentation, and treatment of tattoos. It is a particularly important device with the fractional optic in darker skin types. To address these demands, an adjustable fluence picosecond laser with an increased energy output was developed. This split-face study evaluated the use of a picosecond laser with independently adjustable fluence and spot size for skin rejuvenation and the treatment of pigmentation and acne scars.

## METHODS/DESIGN:

Twenty-three subjects were enrolled in this two-site study. Subjects had 2-4 treatments with diffractive lens array the original 200mJ/pulse picosecond device settings, as a baseline, on one half of their face with average fluence of 0.51 J/cm<sup>2</sup> and the new 300mJ/pulse picosecond alexandrite laser on the other half of their face with average fluence of 0.58 J/cm<sup>2</sup>. A subset of 3 subjects with melanin index (MI) between 21 and 36, Fitzpatrick skin type III to V, were treated with 8mm spot, 0.4J/cm<sup>2</sup> on one half of their face and with 10mm spot, 0.38J/cm<sup>2</sup> on the other half of the face. Evaluation for satisfaction (on a 6-point Likert scale) and improvement (graded with the GAIS Questionnaire) were evaluated by the subjects and the physicians. Subjects were also evaluated after each treatment, comparing the baseline vs the adjustable settings.

## RESULTS/ANALYSIS:

At the 30 day follow up, all subjects who attended were satisfied and noticed improvement; blinded graders rated 75% of the patients as 3- improved and 25% as 2- much improved on the GAIS scale. All subjects who filled questionnaires were also satisfied immediately after treatment on both sides of their faces. When asked about how the skin feels after

treatments, subjects responded "tighter" in 41%, "smoother" in 23% and "firmer" in 17%. Both sets of laser settings received similar responses from all subjects. Throughout this study, no serious adverse events occurred. There was no statistically significant difference in max pain scores, and average pain scores were 5.1/10 and 5.3/10 for the baseline and the adjustable settings, respectively. Split-face patients where the 8 and 10mm handpieces were compared at similar settings were treated on average with 12% smaller number of pulses on the 10mm side,  $p < 0.05$ . When all treatments for 8 and 10mm spot sizes were analyzed, the 10mm treatments were completed with 36% smaller number of pulses,  $p < 0.01$ .

## CONCLUSION:

In this split-face study, both the baseline and the adjustable laser settings were safe and tolerable with no analgesic and provided excellent efficacy results for the treatment of pigmentation, acne scars and skin rejuvenation. The increased energy output and the independently adjustable fluence and spotsize settings allowed these excellent results to be achieved with a statistically significant smaller number of pulses. Our experience and modeling data suggests that the treatment is safe for all skin types with appropriate cadence and avoidance of pulse stacking.

## KEY TAKE AWAYS:

- At 30 day follow up:
  - 100% of subjects were satisfied and noticed improvement
  - 100% of subjects were graded as improved by blinded evaluators
- Both sets of laser settings received similar responses from all subjects, but when all treatments for 8 and 10mm spot sizes were analyzed, the 10mm treatments (test device) uses 36% fewer pulses ( $p < 0.01$ ).
- No statistically significant difference in max pain score between the control device and test device. Average pain scores of all treatments were 5.1/10 and 5.3/10, respectively

BEFORE & AFTER #1:

	Left side	Right side
System	Control device	Test device
Spot size	8mm	10mm
Fluence	0.4	0.38
# pulses	1847	1471



Baseline



1 Month Post 3 Treatments

Right Side: Test Device Side



Baseline



1 Month Post 3 Treatments

Left Side: Control Device Side



Baseline



1 Month Post 3 Treatments

Before & After #2:

	Left side	Right side
System	Test device	Control device
Spot size	10mm	8mm
Fluence	0.38	0.4
# pulses	469	570



Baseline



3 Months Post 4 Treatments

Right Side: Control Device Side



Baseline



3 Months Post 4 Treatments

Left Side: Test Device Side



Baseline



3 Months Post 4 Treatments

Before & After #3:

	Left side	Right side
System	Test device	Control device
Spot size	8mm	8mm
Fluence	0.4 J/cm <sup>2</sup>	0.4 J/cm <sup>2</sup>
# pulses	2323	2365



Baseline



3 Months Post 4 Treatments

Right Side: Control Device



Baseline



3 Months Post 4 Treatments

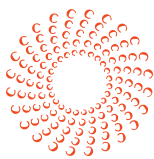
Left Side: Test Device Side



Baseline



3 Months Post 4 Treatments



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PicoSure Pro 755 with the Flat Lens is FDA cleared to treat pigmented lesions in skin types I-VI. PicoSure Pro 755 with the Platinum Focus Lens is FDA cleared to treat acne scars and wrinkles in skin types I-IV. Patient results will vary.

Like all medical procedures, not all patients are suitable for the treatment. A qualified practitioner is solely responsible for evaluating each subject's suitability to undergo treatment and for informing those being treated about any risks involved with the treatment, pre-and postoperative care, and any other relevant information. Individual results may vary and are not guaranteed. PRD-0841USA-EN