

A Split-Faced Study on Safety and Efficacy of a Novel Alexandrite Picosecond Laser Device with Higher and Adjustable Fluences

Authors: Sean Doherty, MD, Robert Murgia, MD

Doctors are paid consultants of Cynosure, LLC.

BACKGROUND:

Picosecond laser technology is a well-known and widely used option for non-ablative aesthetic treatments. Fractional 755nm picosecond lasers, specifically, have been widely embraced throughout the world over the last 9 years especially for skin rejuvenation, acne scars, and the treatment of abnormal pigmentation in darker skin types where post inflammatory hyperpigmentation is a constant worry. Although there are many devices currently on the market that use this type of technology, there is an increasing demand for new methods and novel laser technology to improve treatment outcomes. A novel

picosecond device, allowing 50% higher, adjustable fluences, was recently developed, allowing 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. This novel device's efficacy and safety were tested in this study.

MATERIALS AND METHODS:

15 subjects were enrolled and are scheduled to receive up to 4 split-faced treatments for pigmentary lesions and/or skin revitalization. Fitzpatrick Skin

Types II – IV, with a Melanin Index (MI) ranging from 15-29, were treated in the study. Each subject had one half of the face (fixed fluence side) treated with fixed parameters using standard recommended settings based on parameters available from a previously commercially available 755nm Alexandrite picosecond laser, while the other half (increased fluence side) was treated with same spot size but increased fluence (~13%) at each subsequent treatment, as tolerated. All subjects were treated with the 6mm diffractive lens array starting on both sides of the face at a fluence of 0.7 J/cm² at the first visit. This is the max

fluence available for diffractive optics in the previously commercially available 755nm picosecond laser. The novel 755nm picosecond laser provides 50% higher and adjustable fluence at the 6mm spot size. Each subsequent treatment increased the fluence on increased fluence side of the face by 0.1 J/cm², while the fluence on the other side of their face was held at 0.7 J/cm². At the 4th treatment visits, most subjects received the treatment fluence of 1.0J/cm² on the increased fluence side. The differences in fluence per treatment for this split-face study is outlined in the following table below:

	TREATMENT 1	TREATMENT 2	TREATMENT 3	TREATMENT 4
Fixed Fluence Side	0.7 J/cm ²	0.7 J/cm ²	0.7 J/cm ²	0.7 J/cm ²
Increased Fluence Side	0.7 J/cm ²	0.8 J/cm ²	0.9 J/cm ²	1.0 J/cm ²

Each subject was to return for 30 and 90 days post their last treatment to evaluate efficacy results through subject and physician questionnaires and photographic evidence.

RESULTS:

Overall, the treatment was well tolerated with pain scores averaging 3.4/10 on the fixed fluence side and 3.7/10 on the increased fluence side. There was no statistically significant difference in max pain experienced by subjects between both sides of face (p>0.05). Common side effects were erythema, edema, and pain/tenderness, all of which were mild and transient, resolving within days. Subjects experienced the same side effects on both sides of their faces. Additionally, both sides showed promising improvement in pigmentation and textures noticed by both patients and physicians, some as early as after their first treatment. At the 30 day follow up, subjects were satisfied 100% of the time with the fixed fluence side and the increased fluence side. According to the subject GAIS, subjects noticed improvement 93% of the time with the fixed fluence side, and 100% of the time with the increased fluence side. The physician was satisfied with the fixed fluence side 93% of the time and 100% of the time for the increased fluence side. According to the GAIS, the physician noticed improvement in 86% of the time for the fixed fluence side and 92% of the time with the increased fluence side.

CONCLUSION:

Given the increasing demand for adjustable treatment fluences to tailor to individual treatment

plans for potentially better efficacy, this study demonstrated that increased fluence available in this novel Alexandrite picosecond laser device can be used safely on skin types II-IV for the treatment of pigmentary lesions and/or skin revitalization. Similar patient treatment experience should be expected as well when the fluence is increased by up to 50%. Study results suggest that increasing fluence can result in safe treatments while allowing doctors to adjust fluence to maximize efficacy.

KEY TAKE AWAYS:

- Even though fluence increased, there was still a similar average pain and same sides effects reported on both sides of face
- 30 Day Follow Up:
- 100% satisfaction both sides
- Higher improvement/physician satisfaction on increased fluence side
 - SGAIS: fixed fluence- 93% improvement; increased fluence- 100% improvement
 - Physician Satisfaction: fixed fluence- 93% satisfied; increased fluence- 100% satisfied
 - PGAIS: fixed fluence- 86% improvement; increased fluence- 92% improvement
- Adjustable fluence provides ability to maximize efficacy

BEFORE & AFTER #1:



Pre 1 Treatment



1 Month Post 4 Treatments



Pre 1 Treatment



1 Month Post 4 Treatments

Right: Fixed Fluence

Tx 1-4: 0.7 J/cm²; 6mm,
755 nm, 10 Hz rep rate,
1405-1632 pulses,
avg. 1502 +/- 94 pulses



Pre 1 Treatment



1 Month Post 4 Treatments

Left: Increased Fluence

Tx 1-4: 0.7, 0.8, 0.9,
1.0 J/cm², 6mm,
755 nm, 10 Hz rep rate,
1398-1632 pulses,
avg. 1524 +/- 124 pulses

BEFORE & AFTER #2:



Pre 1 Treatment



1 Month Post 4 Treatments



Pre 1 Treatment



1 Month Post 4 Treatments

Right: Fixed Fluence

Tx 1-4: 0.7 J/cm²; 6mm,
755 nm, 10 Hz rep rate,
2438-2839 pulses,
avg. 2713 +/- 185 pulses



Pre 1 Treatment



1 Month Post 4 Treatments

Left: Increased Fluence

Tx 1-4: 0.7, 0.8, 0.9,
1.0 J/cm², 6mm,
755 nm, 10 Hz rep rate,
2649-3051 pulses,
avg. 2911 +/- 185 pulses

BEFORE & AFTER #3:



Pre 1 Treatment



1 Month Post 4 Treatments



Pre 1 Treatment



1 Month Post 4 Treatments

Right: Fixed Fluence

Tx 1-3: 0.7 J/cm²;
6mm, 755 nm, 10 Hz rep
rate, 579-2977 pulses,
avg. 2183 +/- 1116 pulses



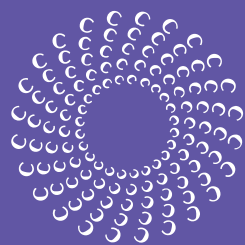
Pre 1 Treatment



1 Month Post 4 Treatments

Left: Increased Fluence

Tx 1-3: 0.7, 0.8, 0.9 J/cm²,
6mm, 755 nm, 10 Hz rep
rate, 608-2977 pulses,
avg. 2168 +/- 1075 pulses



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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. Talk to your medical provider about the risks and benefits of this procedure. 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-0842USA-EN