

Safety and Efficacy of Alexandrite Picosecond Device, Radiofrequency Microneedling Device, and Topicals in Complimentary Treatment on Patients with Darker Skin Types

Authors: Dr. Barry DiBernardo, Dr. David Turer

Drs. are paid consultants of Cynosure, LLC.

BACKGROUND:

Radiofrequency (RF) microneedling causes micro-injuries and delivers thermal energy, which triggers tissue contraction and an increase in the production of collagen and elastin. RF combined with microneedling has an advantage over traditional microneedling because it delivers RF energy deeply into the dermis. For treating skin conditions similar to what an RF microneedling device may be chosen to treat, an Alexandrite picosecond laser is also a viable and valuable option due to its photothermolysis and photomechanical impact on the skin. A third treatment option that has grown in popularity due to its non-invasive and affordable nature is treatment with topicals. This study investigates the usage of an RF microneedling device, an Alexandrite picosecond laser, and topicals as a treatment regimen for acne scars and facial aging. Specifically, this study seeks to treat these indications on a darker range of skin types to determine the safety and efficacy for what is commonly a more difficult demographic to treat.

METHODS/DESIGN:

Ten subjects with Fitzpatrick Skin Types ranging from III-V have been treated for a total of 37 treatments with the picosecond Alexandrite device and the RF microneedling device. All subjects were treated with an Alexandrite laser with a wavelength of 755nm, and the average fluence across treatments was 0.42 J/cm². The number of pulses for this device ranged from 260-6022, with an average of 1634 pulses. Subjects were treated with a repetition rate from 5 to 10 Hz and a spot size of 6, 8, or 10 mm. For the microneedling treatment, subjects received an average of 169 pulses, an average power of 18 W, an average depth of 1.9 mm, a repetition rate of 1 or 2 Hz, and 1-3 passes per treatment. Following each treatment, subjects were given a topical product regimen to apply to their face for the duration of the study. Additionally, subjects were given a hyaluronic acid mask post treatment. Subjects are in the process of returning for their 30 and 90 day follow ups, in which they are asked their satisfaction

(on a Likert scale of 1- extremely unsatisfied to 6-extremely satisfied) and their level of improvement on the Subject Global Aesthetic Improvement Scale (SGAIS) and Physician Global Aesthetic Improvement Scale (PGAIS) from 1-very much improved to 5-worsened.

ALEXANDRITE PICOSECOND LASER:

Parameters	
Wavelength	755nm
Lens Type	Diffraction Lens
Fluence	Avg. of 0.42 J/cm ²
Repetition Rate	5-10 Hz
Spot Size	6, 8, 10 mm

RF MICRONEEDLING:

Parameters	
Power	Avg. of 18 W
Pulse Width	10-65ms, avg. of 56.02 +/- 17.8
Depth	Avg. of 1.9 mm
Repetition Rate	1-2 Hz
# of Passes	1-3 per treatment

Demographics Information	
Sex	100% Female
Age (years)	39-67, avg. of 55.8 +/- 10.3
Weight (lbs)	129-175, avg. of 149.8 +/- 17.4
Ethnicity	Hispanic, Indian, Caucasian, Asian
Fitzpatrick Skin Type (FST)	III-V

RESULTS/ANALYSIS:

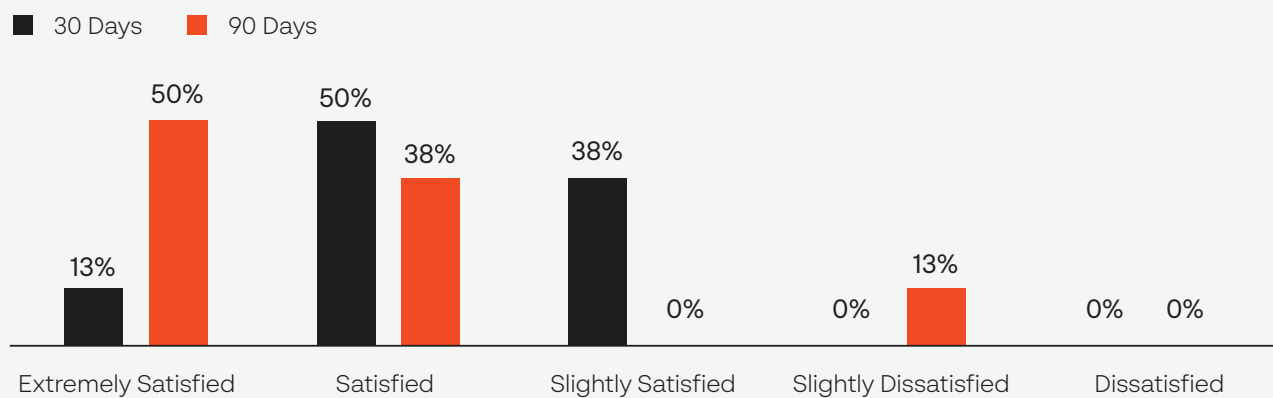
Typical post-treatment side effects were erythema, edema, and pin-point bleeding, and all side effects were transient. **There have been no reported instances of post-inflammatory hyperpigmentation.** Eight out of ten subjects have currently completed their 90 day follow up visit, and 67% of them were satisfied, 17% were slightly satisfied, and 17% were extremely satisfied. According to the SGAIS scores, 50% of subjects graded themselves as "Improved," 33% of subjects graded themselves as "Much Improved," and 17% of subjects graded themselves as "Very Much Improved." The physician graded 50% of subjects as "Much Improved," 33% of subjects as "Improved," and 17% of subjects as "No Change." The two subjects with Fitzpatrick Skin Types V were "Extremely Satisfied" and "Slightly Satisfied," graded themselves as "Much Improved" and "Improved," and were also graded as "Much Improved" and "Improved" by the Physician at the 30 day follow up.

KEY TAKEAWAYS:

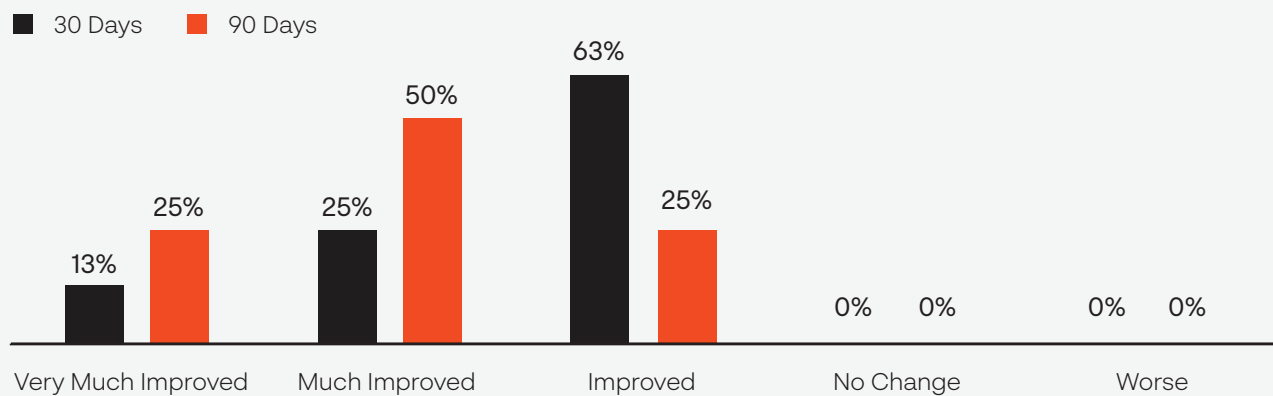
- 8/10 subjects have completed a 90 day follow up
- Continued improvement from 30 to 90 days
- At 90 days:
 1. Subject Satisfaction: 87% subject satisfaction
 2. SGAIS: 100% Improved
 3. PGAIS: 100% Improved
- There have been no reported instances of post-inflammatory hyperpigmentation in all subjects (FST III-V)



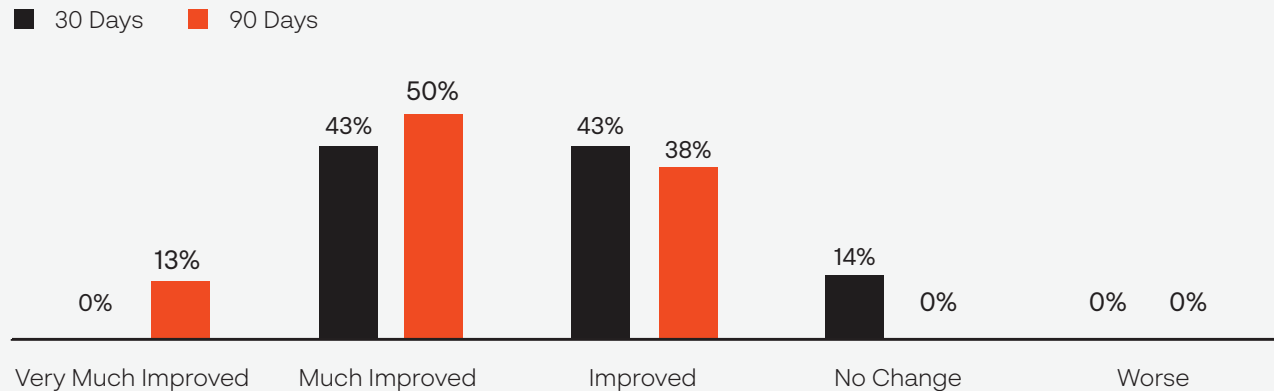
SUBJECT SATISFACTION



SGAIS

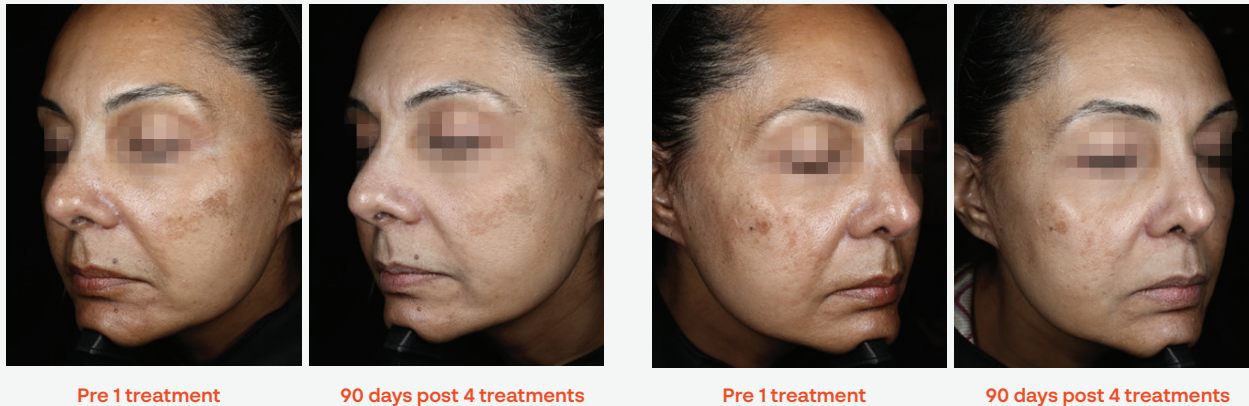


PGAIS



CONCLUSION:

The pain scores and lack of adverse events showcased in this study show that the complimentary treatment of the PicoSure Pro alexandrite picosecond laser, Potenza RF microneedling, and B.E. Beautiful Energy topicals prove to be a tolerable and safe treatment. The treatment results so far also indicate high levels of efficacy. The results also suggest that this treatment regimen may be suitable for individuals with higher Fitzpatrick Skin Types.



ALEXANDRITE PICOSECOND:

Fluence: 0.4 J/cm²; Rep Rate: 10 Hz, Spot size: 8 mm

RF MICRONEEDLING:

Power avg. 16.3W +/- 3.5; Pulse width: avg. 63ms +/- 5.3; Depth: 1.5-2.5 mm; Rep Rate: 1-2 Hz, # of Passes: 1-3



Pre 1 treatment



30 days post 4 treatments



Pre 1 treatment



30 days post 4 treatments

ALEXANDRITE PICOSECOND:

Fluence: 0.40 J/cm²; Rep Rate: 10 Hz; Spot size: 8 mm

RF MICRONEEDLING:

Power: avg 19.1 W +/- 4.9; Pulse Width: avg. of 57.5 +/- 8.2 ms; Depth: 1-2.5mm, Rep Rate: 1-2 Hz; Passes: 1-2 passes.



Pre 1 treatment



90 days post 4 treatments



Pre 1 treatment



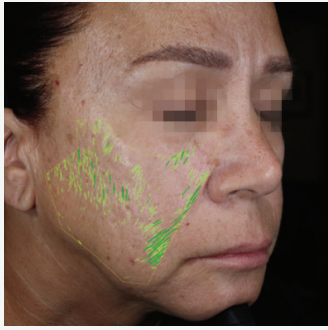
90 days post 4 treatments

ALEXANDRITE PICOSECOND:

Fluence: 0.40 J/cm²; Rep Rate: 10 Hz; Spot size: 8 mm

RF MICRONEEDLING:

Power: avg 15.4 W +/- 1.4; Pulse Width: avg. of 61.3 +/- 6.8 ms; Depth: 1-2mm, Rep Rate: 1-2 Hz; Passes: 1-2 passes.



Pre 1 treatment

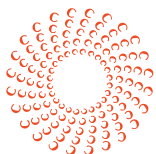


90 days post 4 treatments

Canfield Analysis Baseline vs. 90 days FU

Data Point Name	Description	Average Improvement	P-Value (Pair P-test)
Brightness	Mean brightness(L*) measured within the AOI	6%	0.0017
Color Evenness	Score characterizing color uniformity within the AOI. Score 0 non uniform. Score 1 most uniform.	14%	0.0052
Wrinkle Count	Count of wrinkles in AOI	-18%	0.0061

Significant improvement in brightness, skin color evenness and wrinkle counts at 90 days



CYNOSURE®
BEAUTIFUL ENERGY

© 2023 Cynosure, LLC. All rights reserved. Cynosure and PicoSure are registered trademarks of Cynosure, LLC. Potenza is a trademark of Jeisys Medical, Inc. The Potenza radiofrequency microneedling device is intended for electrocoagulation and hemostasis of soft tissue for dermatologic conditions. Potential side effects include temporary redness, temporary tingling, and burning sensation while receiving treatment. 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-0764