

## ABOUT DR. BARRY DiBERNARDO:

As one of the leading surgeons certified by the American Board of Plastic Surgeons; a certified instructor (for multiple laser, light-based, and skincare modalities in the field); and a published author named one of the "Top 24 Top Beauty Doctors" by **Harper's Bazaar Magazine** and "Top Plastic Surgeon, Eastern United States," in 2016 by **Aesthetic Everything**, Dr. DiBernardo is truly a world-leading expert. A 1984 graduate from Cornell University Medical College, for over 25 years, Dr. DiBernardo has continued research, teaching, and innovation in lasers, energy devices, skincare, injectables, hair transplant, and surgical aesthetics.

Important in clinical research applications, Dr. DiBernardo is also a master photographer. He is among the world leaders in clinical photography and imaging, contributing to patient health and the scientific community through photographic and imaging analysis.

*Dr. DiBernardo is a paid consultant of Cynosure.*



## INTRODUCTION:

Due to a variety of internal and external conditions, skin structure degrades over time. A major component of this syndrome involves enzymes that break down collagen and elastin, upon which the connective tissue, including skin, then loses its suppleness (and becomes loose). In addition to aging itself, UV exposure (i.e. photoaging), diet, and smoking all contribute to skin quality degradation (among other behaviors and environmental factors). In some areas of the body, unsightly changes in connective tissue can be concealed (although sometimes impractical during warmer months and times of intimacy). But in areas that are regularly in plain view (face, neck, décolleté), serious industry efforts must be executed to mitigate the ravages of aging and environmental factors.

According to a recent Aesthetic Lasers Market Analysis Report, the global aesthetic laser market size was estimated at \$969.5 million USD in 2021 and

is expected to expand at a growth rate of 16.6% from 2022 to 2030.<sup>1</sup> Thankfully, there is innovative, minimally invasive technology to improve treatment-outcomes and address industry demands.

The PicoSure<sup>®</sup>Pro, a picosecond Alexandrite laser, uses a very short pulse duration to create both photomechanical and photothermal effects on tissue (as seen with its use in tattoo/pigmentation removal) and interestingly produces greater tensile strength than when using a nanosecond lasers. This device, when combined with the Focus<sup>™</sup> Lens Array allows for an added degree of safety while still delivering high energy to affect the targeted tissue. The Focus<sup>™</sup> Lens Array is a specialized optical hand piece often described as a diffractive lens array in the medical literature; it distributes low energy density to the entire spot size, with increased density to approximately 5-10% of surface area in each spot. The PicoSure Pro device is cleared (FDA 510(k)140719) for use in wrinkles, acne scars, and benign pigmented lesions (both epidermal and dermal).

While the picosecond laser with diffractive lens array is widely used today in beautification, additional research studies like the latest study featured here today can supply important ongoing data on how the laser with diffractive lens array is used in the industry. Such research greatly benefits the dermatology community, plastic surgery community and patients alike, offering the opportunity to confirm, reinforce, and solidify the safety profile and better focuses the range of dermatological presentations in beautification that patients demand today.

## STUDY:

To assess the success of PicoSure Pro with diffractive lens array, ten healthy participants (adults between the ages of 18-65 years old) underwent treatment and were photographed and imaged using specialized imaging techniques throughout key stages of treatment and recovery. Following IRB approval and study participant qualification, patients were provided informed consent and enrolled according to International Council on Harmonisation and Good Clinical Practice standards (as well as applicable local regulations such as COVID-19 precautions).

Participants were provided up to four full-facial skin revitalization treatments (using 755 nm wavelength; 0.71 J/cm<sup>2</sup>; 10 Hz repetition rate; spot size of 6; individually customized pulses). Prior to treatment, participants were appraised of common side-effects, potential benefits, and the possibility of no benefit. Treatments occurred at approximately four-week intervals. At the start of the study, participants were offered the opportunity for continuation of treatments (where appropriate), should treatment benefits not yet have taken full effect by the end of the four study treatments. Participants were asked to refrain from sun exposure when possible (or wear sunblock) throughout the duration of the study.

At the conclusion of the treatment schedule, participants returned for 30-day and 90-day evaluations to capture potential treatment side effects and to undergo imaging/standardized photography. Imaging studies included standardized photographic analysis of 2D images, taken prior to each treatment (to compare to baseline photos). Three independent, blinded, expert physician-reviewers evaluated the images to see if they could correctly identify pre-treatment 2D images versus 2D images taken at 90-day follow-up (primary objective). Additional images were taken using VivoSight imaging at the 90-day follow up to compare to baseline imaging (secondary objectives).

Additional evaluations, in the form of questionnaires captured key safety and efficacy data. During each study treatment, both study participant and study clinician completed treatment questionnaires to capture key details. To capture a full spectrum of potential side-effects, participants were contacted by study staff approximately a week after each treatment (adverse events recorded on follow-up questionnaire). Other assessments included a standardized Treatment Discomfort/Pain Evaluation calculated using a grading scale (a scale of 0 [none] to 10 [maximum intolerable pain] using the universal pain assessment tool).

Both participant and treating-clinician completed satisfaction questionnaires as well. Participants used a 6-point Likert scale that ranges from "extremely satisfied" to "extremely unsatisfied." The Study Investigator used the Global Aesthetic Improvement Scale (GAIS) ranging from "worse" to "very much improved" to assess the improvement as seen.

Full statistical analysis was performed. Statistically-significant threshold for success was determined to be a minimum of  $\geq 80\%$  (correct identification of pre-treatment images when compared to post treatment [90-Day follow-up images]). Where the assessments evaluated participant improvement graded on a scale, such as the GAIS scale, the statistical significance was determined by comparing results against a hypothetical population that would have no change (average score of 4).

## RESULTS:

The treatment was well tolerated with a median pain score of 5/10, and no adjustments to treatment parameters were needed throughout the course of the study. No adverse events were reported by the subjects or physicians.

Study results were overall positive. At both the 30 and the 90 day follow up, all ten subjects reported that they were satisfied with the results. Additionally, the physician (using the GAIS scale), considered all subjects to have improved from the baseline at both the 30 and 90 day follow up.

The questionnaire information provided useful insight as to the device's capabilities, as it seemed to indicate that most subjects saw improvement in a large variety of their skin conditions, even when they initially did not have a concern with skin issues such as skin elasticity, skin texture, and pigmentation.

When identifying whether photographs were taken pre-treatment or post treatment (at the 90-day follow-up), the photographs were identified correctly most of the time, with a correct identification rate of 80%. Subject improvements from pre-treatment and post-treatment can be seen below, in figures 1-2.

FIGURE 1: (below) Photographs feature the results of Study Participant 02-ZR, which revealed at Day-30 an improvement in fine lines and rhytides (wrinkles), reduction/clearance of hyperpigmentation and uneven pigmentation, a remarkable reduction in infra-orbital dark circles, and minor tightening of lax tissue about the eye. While some positive results diminished over time, at the 90-day post-treatment mark, the participant still demonstrated some visible improvement.

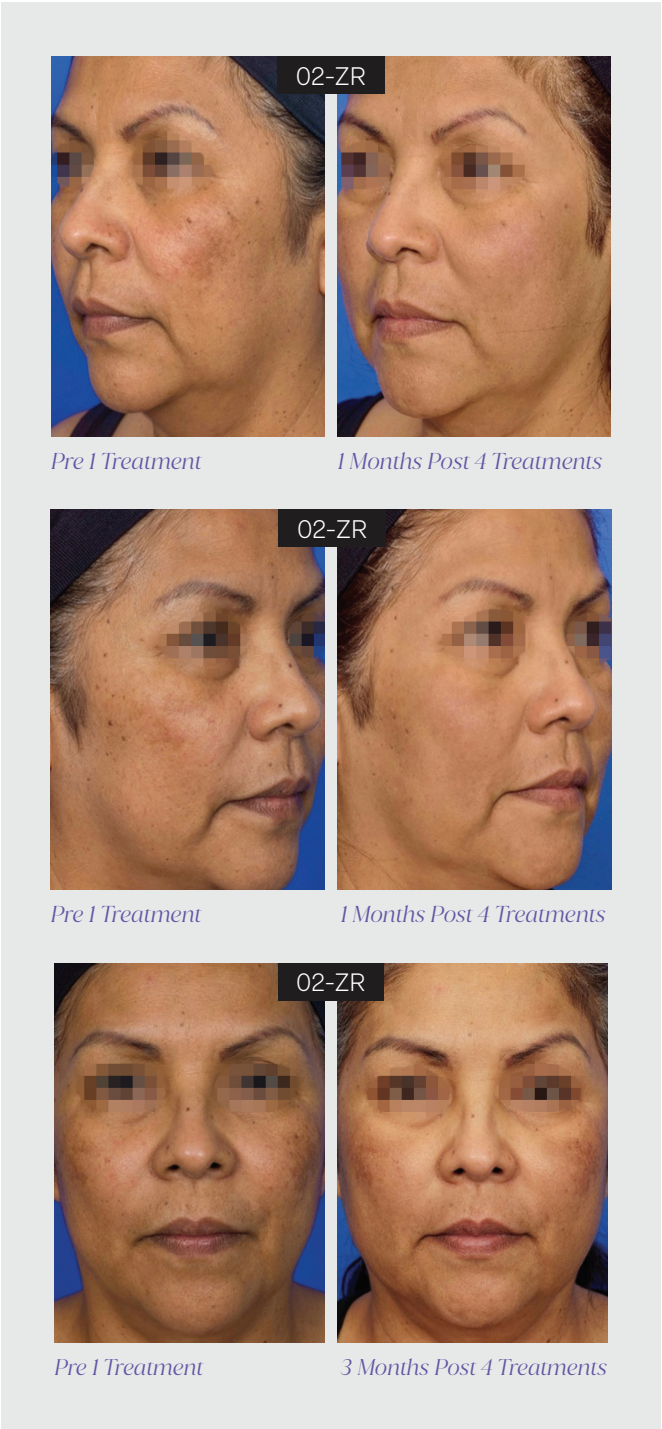


Figure 1: Study Participant 02-ZR photographs over time.

FIGURE 2: (below) Photographs feature the results of Study Participant 04-LL, which revealed at Day-30 an improvement in fine lines and rhytides (wrinkles), significant reduction/clearance of pigmentation (in particularly in the cheeks/forehead area), and a more even skin tone.



Figure 2: Study Participant 04-LL photographs over time.

## CONCLUSION:

Subjects present with a wide variety of skin conditions and needs when they elect to receive an aesthetic laser treatment. Understanding the skin care regimen subjects have already implemented can help the physician educate the patient to ensure success from their treatment by supplementing with a proper skin care regimen and daily lifestyle changes such as drinking more water and utilizing lotions daily. The questionnaires also revealed that patients expect treatment results to persist for at least 3 months.

In addition to this valuable information, this research also served to demonstrate the capabilities of the PicoSure Pro device utilizing the diffractive lens array. The reported pain scores during the treatment and lack of reported adverse events indicate that treatments with this device are safe and tolerable. The 100% subject satisfaction and improvement rates at all follow ups, in addition to the high rate of accurately identified pre vs. post treatment images, serve as testaments to the treatment results capable of being generated by PicoSure Pro.

## SOURCES:

1. <https://www.grandviewresearch.com/industry-analysis/aesthetic-lasers-market>



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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-0843USA-EN