PICOSURE® *pro*
by CYNOSURE®

Melasma Pigment: Addressing a Need for Innovative Individualized Care

Patients impacted by the skin pigmentation disorder called melasma often report dissatisfaction in day to day living with their skin condition, as well as dissatisfaction with the treatments that are commonly available in routine care[1-3] Typically occurring on areas of the body exposed to sunlight, particularly the face (forehead, cheeks, chin, bridge of nose, upper lips), melasma is characterized by irregular gray-brown patches of hyperpigmentation.[1-2] However, industry recommendations for topical application of sunscreen are often not enough to prevent the condition[1-2] By provoking melanocytes to over-produce the skin pigment melanin, or distribute melanin to skin cells in a non-uniform way, research also demonstrated that cosmetics, not just sun-exposure, may also act as a potential skin irritant that can activate or worsen melasma[1,4-5]

As a result, the medical literature describes melasma as both disfiguring and interrupting patient quality of life.[3]

WHO IS AT-RISK FOR MELASMA?

Although anyone can get melasma, various populations are naturally predisposed. For example, research revealed that ethnic groups with darker skin tones (Latin, Hispanic, Indian, Middle Eastern, African American, North African, Asian, and Mediterranean decent) naturally produce more melanin and this results in a predisposition to melasma[1,3] Interestingly, relatives of people with melasma were also at a higher risk for this skin pigmentation condition too.[1] While both men and women are affected by the condition, some research suggested that women are disproportionately impacted[1] (with hormones often implicated). Research has shown that pregnancy, representing a period of hormonal change, placed women at an increased risk for melasma.[1,4,6,] Similar risk-factors included birth control and hormone replacement therapy.[4]

Industry understanding of the mechanisms behind melasma has evolved, with more evidence of the role of photoaging, and perhaps, a closer distribution between the sexes (a condition that more closely corresponded to aging and sun exposure in the aforementioned predisposed populations).[5] These insights reinforced industry acceptance that people with medium skin color, not just darker tones, who live in areas of the world where the sun is intense, also are at an increased risk of melasma.

As a result of these complex factors, there is a high need for innovative, individualized treatment.[5,7] Fortunately, technology development in melasma treatment has evolved in exciting ways to provide individualized care.[8-12]

Photos courtesy of Emil Tanghetti, MD

These before and after photographs are of a patient treated with Cynosure's PicoSure device, not the PicoSure Pro device advertised herein. The PicoSure Pro device has the same parameters as the PicoSure device and so while individual results vary, similar results are expected.

CYNOSURE'S NOVEL PICOSECOND LASER TREATS MELASMA PIGMENT

As the first and only picosecond laser granted FDA-clearance for the treatment of melasma pigment, Cynosure's (Westford, MA) novel picosecond laser device, the PicoSure Pro laser, is leading the way. Previously cleared as a laser surgical instrument for use in general and plastic surgery and in dermatology in the United States, the U.S. Food and Drug Administration (FDA) recently granted additional clearance specifically to market for treatment of melasma pigment, Nevus of Ota and Hori's Macules pigment disorders. With proven clinical validation, there are over 83 publications in the medical literature[12] (and over 50 abstracts) to date that characterize or feature the PicoSure Pro laser technology in various models.

The PicoSure Pro laser operates by creating an intense photothermal impact in trillionths of a second through an ultra-quick picosecond pulse duration of light that spares the skin of high thermal damage (unlike other lasers and similar technology).[8-12] By primarily targeting the melanin chromophore, instead of water, the PicoSure Pro laser spares damage to surrounding tissues (and reduces side-effects).[8-12] In this larger process that researchers characterize as Laser-Induced Optical Breakdown (LIOB), epidermal repair mechanisms are stimulated and produce positive clinical findings.[9-12]

This photomechanical reaction stimulates the body's natural healing processes, including key components of youthful skin (with production of new collagen and elastin).[3, 8-12] The picosecond pulse duration's photo acoustic mechanisms also lighten (disperses) unwanted pigment.[9-12] As a result, the PicoSure Pro laser treats a range of pigmentary conditions with better clearance in fewer treatments.[8-12]

The PicoSure Pro laser offers versatility with three treatment wavelengths (532 nm, 755 nm, and 1064 nm), broad customizable pulse durations, spot sizes, fluency, and repetition rate. Treatments are customizable with 2-6mm, 5mm, 6mm, 8mm and 10mm spot sizes. The flat optic can address discrete targeted pigmented lesions. The photomechanical actions of the PicoSure Pro laser can even be enhanced.[9-12] The Focus lens and new Platinum Focus lens provide full-face treatments that improve texture and tone.

PUBLICATIONS ON THE USE OF INNOVATIVE PICOSURE TECHNOLOGY FOR MELASMA TREATMENT

Evaluation of the medical literature revealed 9 articles which discussed the use of the PicoSure Pro laser device for melasma pigment.[3,9-17] In total, 170 subjects were treated with the PicoSure Pro laser device using the 755 nm wavelength for melasma pigment.[3, 9-17] Treatment parameters described in the medical literature included the following dynamics:

- Number of treatments ranged from 1 to 14
- Treatment intervals ranged from 2-6 weeks
- Most common pulse duration was 750 ps
- Fluences ranged from 0.57-1.5 J/cm^2 flat optic, 0.4 J/cm^2 focus optic
- Spot sizes used were the 3.0-5.6 mm, 6 or 8mm
- Frequency of device was set to 2.5-10 Hz

HIGH EFFICACY FOR THE USE OF THE PICOSURE PRO LASER FOR MELASMA PIGMENT

The studies that directly characterized the use of PicoSure technology in patients with melasma were overwhelmingly positive.[3, 13-20] Targeting the mechanisms behind conditions like melasma, a confocal microscopy study performed by Jo et al. captured the noticeably decreased melanin-induced reflectance in the spinous and basal layers of treated skin.[13] Treatment also reduced melanocyte activation in the basal layers of the epidermis.[13] **Using confocal microscopy, the researchers also discovered that treated skin demonstrated a significant decrease in melanin index up to 24 hours post-treatment.[13]**

In a prospective study to evaluate the feasibility of reversing photoaging in melasma patients using the PicoSure Pro laser technology, Lin et al. demonstrated that participants (10) treated with the novel device sustained photoaging improvement and melasma clearance (quantified through standardized grading assessments).[3] **Melasma standardized industry grading scale (called MASI) reflected a 28% improvement at 12 weeks.**

At 20 weeks, a 39% improvement was reported. At 1 year, a 38% improvement (from baseline) was still observed.[9] Improvement in wrinkles could still be observed after 1-year follow-up when compared to baseline.[9]

Comparative research also demonstrated key benefits of picosecond laser technology over other pulse durations. Lee et al. demonstrated that the PicoSure Pro laser treatments produced a statistically significant improvement in melasma clearance over a Q-Switched Alexandrite Laser.[10-11]

LOW, TRANSIENT SIDE-EFFECTS OF THE PICOSURE PRO LASER

As with all pigmentary treatments with the Picosure Pro laser, there were no serious adverse events reported in any of the publications. Side-effects reported in the studies were primarily transient and included mild erythema, itching, desquamation, dryness, pruritis, scaling, hyperpigmentation, macular hypopigmentation, and very rare instances of melasma recurrence.[3, 13-20]

CONCLUSION

The medical literature supports the treatment of melasma pigment with the novel PicoSure Pro device, demonstrating novel customization and cutting-edge results.[3, 13-20] With new FDA clearances for pigment disorders like melasma pigment, practitioners and patients alike can feel confident in the safety and efficacy of the novel PicoSure Pro device.

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