PICOSURE® *pro*
by CYNOSURE®

Innovative Management of Nevus of Ota

Cross-cultural evaluation of the medical literature reveals subtle perceptions about the hyperpigmentation condition called Nevus of Ota, often described as disfiguring. Impacting quality of life, patients may report dissatisfaction with both the condition and readily-available treatments in routine care. Named after Japanese dermatologist Dr. Masao Ota in 1954,[1] the skin condition is a type of dermal melanocytosis in which nevus cells (a type of melanocyte that produces the pigment called melanin) are entrapped in clusters deep within the dermis and in some cases other tissues (eg. ocular tissues, nasal and oral mucosa).[1-3] This results in the characteristic hyperpigmentation areas that are described as bluish-brown or slate-colored.[1-2] Diagnosis and yearly screening is important because, although not typical, complications such as glaucoma and malignant melanoma are associated with this condition[1-2]

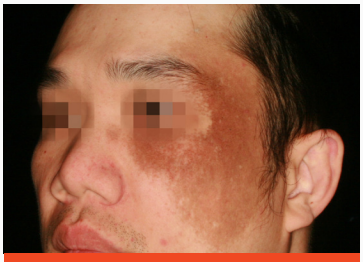
The condition is referred to in the medical literature under several other names as well, including congenital melanosis bulbi because it occurs as a congenital condition in approximately 40-60% of the time (more commonly referred to as a birthmark).[1-2] The rest of the cases may develop during adolescence or become more prominent during adolescence and pregnancy.[2] Nevus of Ota is also known as nevus fuscoceruleus ophthalmomaxillaris, oculodermal melanocytosis, and oculomuco-dermal melanocytosis.[1-2] These names all refer to its location in some capacity (including the cheeks, forehead, nose, and around the eyes). While it is most often unilateral, it is seen bilaterally on occasion.[4-5]

WHO GETS NEVUS OF OTA?

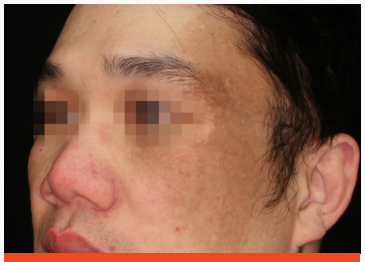
Nevus of Ota is found disproportionately in females (with a 5:1 ratio).[2] It is also found mostly within Asian populations, and sometimes African populations, although cases of males and other ethnicities do occur.[2,6]

ADDRESSING NEEDS WITHIN THE NEVUS OF OTA POPULATION

Due to patient burden, there is a high need to address the aesthetics of hyperpigmentation conditions like Nevus Ota with innovative, individualized treatment. Fortunately, technology develop-ment in Nevus of Ota treatment has evolved in exciting ways to provide safe, effective, individualized care.[8-24]

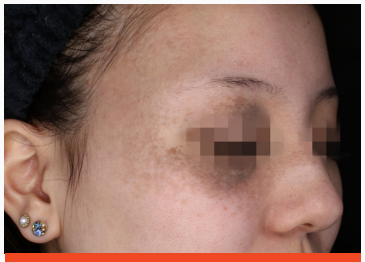


Before



After 4 Treatments

Photos courtesy of Dr. Roy Geronemus



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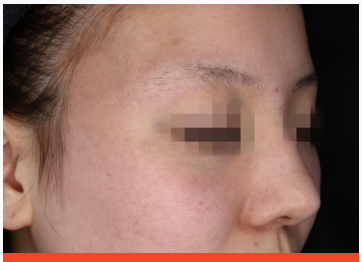

After 3 Treatments

Photos Courtesy of Dr. Kentaro Oku

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.

TREATING NEVUS OF OTA IN FAST, SAFE, INNOVATIVE WAYS

While experts recognized laser treatment as the most cost-effective cosmetic treatment for Nevus of Ota,[2] they also have found that standard lasers like the Q-switch laser therapy required longer treatment courses than picosecond laser technology.[7] What is more, this technology has continued to advance beyond early years (providing not just individualized care but simultaneously addressing multiple conditions through expanded, comprehensive device specifications and accessories).[8-12]

NOVEL PICOSECOND LASER LEADS NEVUS OF OTA TREATMENT

As the first and only picosecond laser granted FDA-clearance for the treatment of Nevus of Ota, Cynosure's (Westford, MA) novel picosecond laser device, PicoSure Pro, is leading the way. Previously approved 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 Nevus of Ota, melasma pigment 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 technology in various models.

The PicoSure Pro 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 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).[8-12] The picosecond pulse duration's photo acoustic mechanisms also lighten (disperse) unwanted pigment.[9-12] As a result, PicoSure Pro 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), with broad customizable pulse durations, spot sizes, fluency, and repetition rate. Treatments are customizable with 2-6 mm, 5 mm, 6mm, 8 mm, and 10 mm spot sizes. The flat optic can address targeted pigmented lesions in all skin types. The photomechanical actions of the PicoSure Pro 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 USE OF NOVEL PICOSURE TECHNOLOGY FOR NEVUS OF OTA

Evaluation of the medical literature revealed 12 publications that characterized the of the PicoSure technology for the treatment of Nevus of Ota.[13-24] Publications included a total of 155 Nevus of Ota patients treated with the PicoSure device using the 755 nm wavelength.[13-24] Specifications and regimens found within the literature included:

- Most common pulse duration at 750 ps
- Number of treatments ranged from 1-6
- Treatment intervals ranged from 4 weeks to 3 months
- Fluences ranged from 0.7-6.37 J/cm^2
- Spot sizes ranged from 2-6 mm
- Frequency set between 2.5-10 Hz

ESTABLISHED SAFETY

As with all treatments with PicoSure Pro, no serious adverse events were found in any of the publications. The side-effects reported in the studies were primarily transient and mild (and included erythema, edema, pain/tenderness, crusting, dyspigmentation, hyperpigmentation, scabbing, bullae formation, erosion, hypopigmentation, blistering, and bleeding).[13-24]

NOVEL PICOSURE TECHNOLOGY EFFECTIVELY TREATS NEVUS OF OTA

Results reported in the medical literature generally showed significant improvement. In the largest study, where 56 participants received up to 6 treatments, Ge et al. reported that **all participants achieved 75% or greater clearance within 6 treatments or less (while 53% of those participants achieved 95-100% clearance).**[21] What is more, participants who received the PicoSure treatments obtained better results than those treated with a Q-Switched Alexandrite Laser.[21] In addition, studies published by Chesnut,[13] Koh,[19] and Oshiro[23] all demonstrated that every subject responded positively to the treatment (there were no cases of non-responders). Luo et al. reported in their study that there were no instances of recurring pigment up to 25 months post-treatment (after only 1 or 2 treatments) in the study participants (6) undergoing treatment.[24]

CONCLUSION

The medical literature supports the treatment of Nevus of Ota with the novel PicoSure Pro device.[8-24] With new FDA clearances for pigment disorders like Nevus of Ota, practitioners and patients alike can feel confident in the safety and long-term efficacy of the novel PicoSure Pro.

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