

A Novel Portable Diode Laser-based Non-Ablative Fractional Device for Treatment of Facial Wrinkles and Dyschromia

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INTRODUCTION

The skin changes over time. These changes become most noticeable on the face and can begin at an early age if much time has been spent exposed to the sun, in particular with lighter skin types.

When skin is exposed to sunlight, these changes may be accelerated through a process known as photoaging. Photoaging is due to damage caused by short wavelength ultraviolet radiation (UVB) injury to the epidermis (outer layer of skin), longer wavelength ultraviolet radiation (UVA) to the dermis (middle layer of skin), and infrared radiation to the deeper dermis and subcutaneous tissue.

Facial photoaging or sun damage causes fine lines, wrinkles, discoloration and textural changes. Aging skin sags and develops wrinkles, lines, and furrows. The severity of these changes in an individual depends on genetics, skin type, and exposure to environmental factors. Fine lines and wrinkles appear through irregular thickening of the dermis and because of a decrease in the amount of water held by the epidermis. This is mostly caused by sun damage and exposure to environmental toxins, particularly tobacco smoke. Deeper lines or furrows may be “dynamic”, appearing with movement, or “static”, unchanged with muscle movement. Dynamic lines eventually become static.

LASER TECHNOLOGY AS A TREATMENT OPTION

There have been major advances in the field of non-surgical skin rejuvenation in recent years. In particular, advances in laser technology have made it possible to treat facial wrinkles, acne scars, surgical scars and a variety of skin lesions with minimal downtime. New developments in the field of skin resurfacing within the last 15 years have led to a huge growth in available technologies. The main laser resurfacing techniques used today are non-ablative fractional

and non-fractional resurfacing systems. Non-laser techniques include Intense Pulsed Light (IPL), radio-frequency systems and plasma skin regeneration. The beauty of non-ablative fractional laser systems is that they target the lower layers of the epidermis and the dermis, leaving the outer layer of the epidermis in place. The results are not as effective as the ablative laser, but the excellent safety profile and more rapid recovery post treatment have made these systems popular. In most cases, patients can apply makeup and return to normal daily life immediately following treatment.

WHY EMERGE™ LASER

Although there are a variety of full-sized non-ablative platforms available on the market today, the Emerge Laser represents the newest technology. It is a novel, compact, 8 pound portable Non-Ablative Fractional Laser (NAFL) system, which harnesses a scanning 1,410 nm diode laser and provides treatment in either a “stamping “ or “gliding” mode configuration. The laser handpiece is detachable from a base unit and replaceable so service requirements are minimal. The Emerge produces pulses of laser energy in the form of a tiny laser beam focused into the dermis and the scanning system delivers each pulsed laser beam to a different skin location where each beam causes a very small zone of coagulation. The “micro-column” of coagulation heals over a few weeks during which time the coagulation zone is replaced by new collagen and elastin, yielding smoother and healthier skin. Per scan, the Emerge laser delivers up to 70 individual pulses of the micro-beam each of which can produce a coagulation column as deep as 450 microns into the dermis while not ablating the upper layers of the epidermis, including the stratum corneum (Image 1). Each 70 pulse scan coagulates about 2.5 % of the skin surface to which the scan was applied, so 97.5% of that skin is not affected.

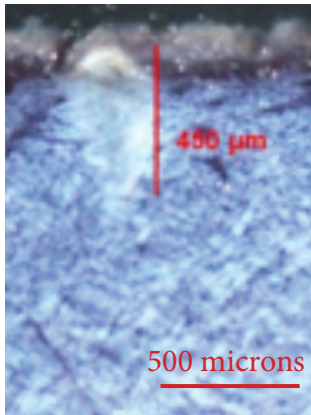


IMAGE 1

Moving the handpiece and repeating scans (passes) over the same skin area increases the density of the coagulated columns and thereby increase the percentage of skin treated. For clarity, the definition of a scan, single pass and multiple pass are as follows:

- Scan—a short automatic sequence where a single laser beam is applied sequentially to different portions of skin in contact with the treatment window to create a fractional treatment pattern in that skin.
- Single Pass—sequentially applying the treatment window to adjacent skin portions across the treatment area (where a scan is applied to each skin portion) without spaces or overlap between scans.
- Multiple Pass—administering more than one pass to the treatment area during the same treatment session.

To achieve the desired density for each treatment session, typically, two to three passes are first applied to target wrinkle and pigment areas having more substantial damage and then an additional two to three passes are applied to the entire face. There will be some erythema (redness) and swelling present immediately after treatment which substantially subside during the day as the normal skin healing process of replenishment and replacement begins. Treatment sessions are usually scheduled for two week intervals in order to minimize discomfort and side effects.

TECHNICAL FEATURES

The Emerge laser has several features that make it easy and simple to use. The optical window of the handpiece is surrounded by a series of contact sensors and when all sensors are in contact with the skin, the handpiece emits a blue light indicating proper skin contact (Image 2). This allows treatments to be performed without the need for specialized eye

safety protection. The Emerge is also programmed with five “PRESET” modes, designed to provide treatment programs for a variety of skin types from lighter skinned to darker skinned patients. In addition, there are customizable manual mode settings so a user can program their favorite settings. The presets provide a specific energy, mj/mb (millijoules/microbeam), ranging from 10 mj/mb to 30 mj/mb and the “pitch” (space between each pulse of the microbeam as it is scanned) is also preset to provide the appropriate density per scan relative to the patient’s skin type.



IMAGE 2 Emerge Laser in use

Recently results of a clinical study of the benefits of Emerge laser treatment on facial wrinkles and pigment were reported at the 2012 ASLMS meeting (1). In the clinical study, three weekly treatments with the Emerge laser were found to yield a consistent reduction in facial wrinkles and pigment. In the standardized methodology, subjects’ photos three months after treatment were compared to photos before treatment and graded in a blinded fashion by three trained evaluators (evaluators did not know which photo was before treatment and which was after). The evaluators rated 19 of 25 (76%) as having noticeable improvement or more (≥ 1 score improvement) using the Fitzpatrick Wrinkle Scale (0-9) with an average grade improvement of 1.1 ± 0.4 , $p < 0.001$. For 24 of 25 (96%) subjects, dyspigmentation was noticeably improved (≥ 2 score improvement) with an average improvement of 2.4 ± 0.6 , $p < 0.001$. This improvement corresponds to approximately a 50% reduction in the appearance of pigmented lesions and dyschromia. Findings from the study illustrate the easy recovery and minimal side effects of treatment and the type of improvement observed.

To demonstrate the rapid recovery and minimal downtime associated with each treatment, one patient returned daily so her recovery could be photographically documented. The patient was treated with the highest recommended setting for her skin type (Pre-set 5) using two full-face passes and an additional two passes at targeted wrinkled and pigmented ar-

reas. The results shown in Image 3 show her before, immediately afterwards, and then 24 and 48 hours later. The redness and swelling immediately after treatment were greatly diminished to a slight pink at 24 hours and nearly gone by 48 hours. The minimal redness shows that the procedure is accomplished so that the patient could feel comfortable enough to resume her normal daily activities within hours after treatment.

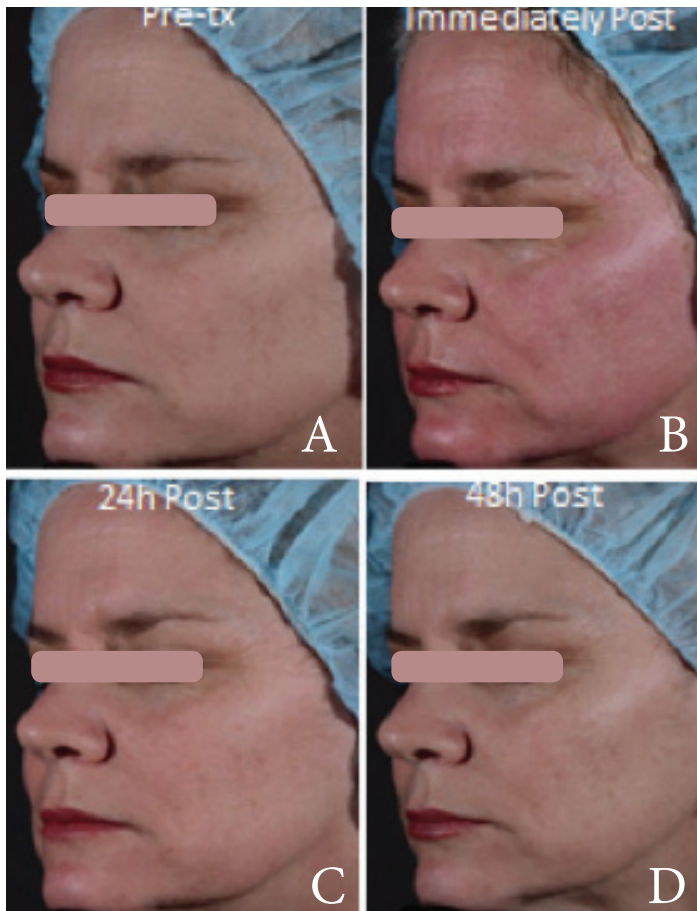


IMAGE 3. Example of the time course of skin response to Preset 5 treatment with the Emerge laser. The patient was treated with the highest recommended setting (Preset 5) using two full face passes and an additional two passes at target wrinkle and pigmented areas. She returned daily for photography. The redness and swelling immediately after treatment were greatly diminished to a slight pink at 24 hours and nearly gone by 48 hours. The rapid recovery enables the patient to resume their normal daily activities by the next day after treatment. Photo courtesy of Sean Doherty, MD, Boston Plastic Surgery Associates, Co-medical director of Palomar Medical Technologies, Inc., Burlington, MA.

The subject shown in Image 4 is an example of the results from the clinical study. This subject has moderate fine lines and wrinkles extending from the eyes to the cheeks. On her cheeks there are discrete pigmented lesions, a rough skin texture and an in-

creased appearance of pores. Her appearance three months after treatment shows a substantial reduction in fine lines and wrinkles and a much smoother skin texture. In the lower left corner of the enlargements (Panel C) before treatment, (Panel D) after treatment the appearance of her pores before treatment is clearly reduced after treatment and her overall skin appearance is much improved. In the second example shown in Image 5, the subject has pigmented dyschromia with a mild roughness to her skin texture. In the post-treatment photos taken three months after treatment there is a noticeable reduction in the redness on her cheeks, a considerable reduction in the appearance of her sun spots (pigmented lesions), and an improvement in the evenness of her skin tone and skin texture.

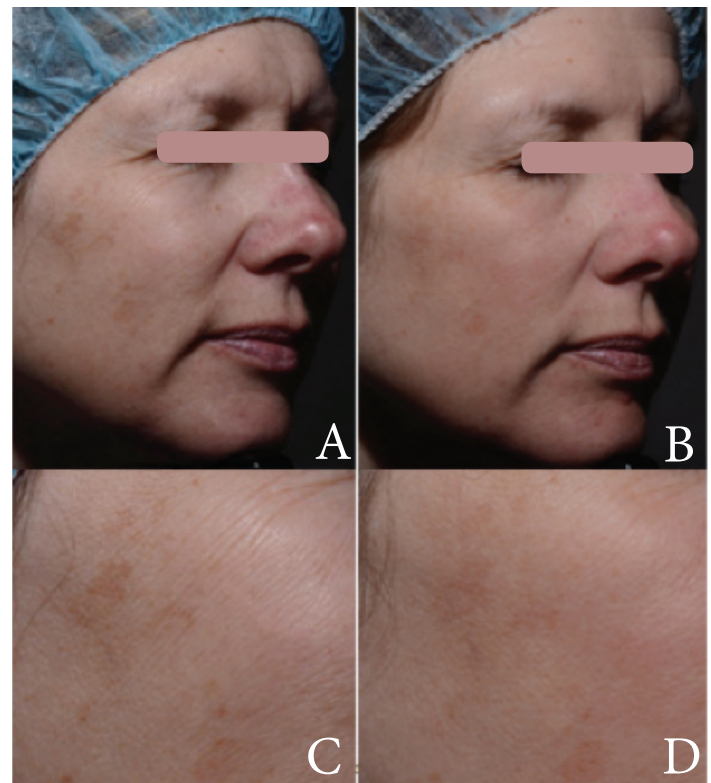


IMAGE 4. An example result of three treatments with the Emerge laser at weekly intervals using Preset 5. Her moderate fine lines and wrinkles shown before treatment (Panel A) extend from the eyes to the cheeks. On her cheeks there are discrete pigmented lesions, a rough skin texture and an increased appearance of pores. Her appearance three months after treatment (Panel B) shows a substantial reduction in fine lines and wrinkles and a much smoother skin texture. In the lower left corner of the enlargements (Panel C) before treatment, (Panel D) after treatment the enhanced appearance of her pores before treatment is clearly reduced after treatment and that her overall skin appearance is much improved. Photo courtesy of Sean Doherty, MD, Boston Plastic Surgery Associates, Co-medical director of Palomar Medical Technologies, Inc., Burlington, MA.

REFERENCES

1. Kauvar A, Seckel BR, Doherty S. Clinical study of a novel diode-laser-based non-ablative fractional device for treatment of facial wrinkles and dyschromia. *Lasers Surg Med* 2012; 44(S24):32.

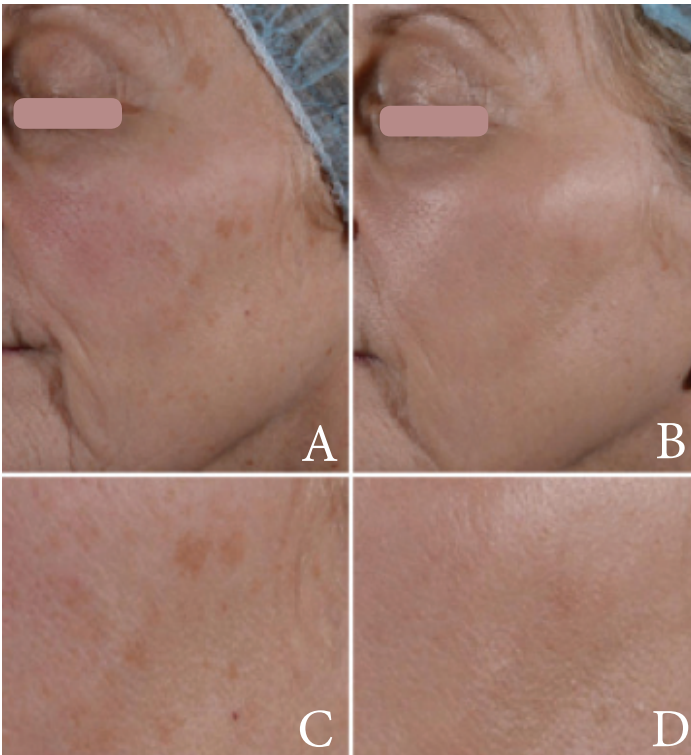


IMAGE 5. An example result of three treatments with the Emerge laser at weekly intervals using Preset 5. The subject has pigmented dyschromia with a mild roughness to her skin texture. In the post treatment photos taken three months after treatment there is a noticeable reduction in the fine lines on her cheeks, a considerable reduction in the appearance of her sun spots (pigmented lesions) as well as an improvement in the evenness of her skin tone and skin texture. Photo courtesy of Sean Doherty, MD, Boston Plastic Surgery Associates, Co-medical director of Palomar Medical Technologies, Inc., Burlington, MA.

The positive outcome of the Emerge treatment was further corroborated by the overall high rates of subject satisfaction (90%) and high percentage (79% – 88%) of subjects agreeing they had improvements in cosmetic aspects of their skin quality including improved skin texture, better skin color, more even skin tone and that their skin looks smoother. The study concluded that multiple low coverage non-ablative fractional Emerge laser treatments at weekly intervals were found to provide good outcomes in the reduction of wrinkles and fine lines as well as pigmented lesions and dyschromia (diffused pigmentation), with minimal downtime.

CONCLUSION

The ability to deliver high patient satisfaction from a small, portable fractional laser is now a reality with the Emerge laser. Ease of operation, excellent flexibility in treatment settings, short treatment times, and consistent results are all features of the Emerge laser.