Clinical evidence of high-power 675 nm laser system equipped with a faster treatment modality for the management of pigmented lesions and skin rejuvenation

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Key words: high-power 675 nm laser; Moveo mode; pigmented lesions; skin rejuvenation.

INTRODUCTION

The number of laser resurfacing procedures is always rising, and they have essentially taken the place of conventional aesthetic treatments such as peeling and dermabrasion. Laser technologies in this field have also developed from ablative lasers to nonablative lasers, which encourage dermal fibroblasts to make new collagen, resulting in reduced skin wrinkles and improved skin texture. Aging is associated with aberrant elastin accumulation in the dermis and collagen degradation; this process results in a loss of elasticity that exacerbates wrinkles and melanin accumulation that causes dyschromia.

Ablative and intense pulsed light laser were the first techniques used in these conditions, ²⁻⁴ but both carried a significant risk of side effects, such as chronic postinflammatory hyperpigmentation. ⁵ Nowadays, during downtime, which usually lasts for a long time, individuals are unable to instantly return to their regular activities. ⁶

The negative implications of these lasers, including infections and scarring, have diminished as technology has developed.⁷

The nonablative lasers "firm" the skin by encouraging the dermis to produce more collagen, which is

Abbreviations used:

DOT: micro-area of denaturation

GAIS: Global Aesthetic Improvement Scale

less damaging than ablative ones. The heat generated within the dermis leads to the coagulation of collagen, thereby initiating the production of dermal collagen and extracellular matrix from scratch throughout the healing process.

However, nonablative lasers are usually only used on individuals with mild to moderate photoaging because they are less effective than ablative ones.^{8,9}

The literature has widely demonstrated that the 675 nm wavelength is useful for the management of pigmented diseases and skin resurfacing, also in darker skinned individuals. ¹⁰⁻¹⁸ Indeed, the 675-nm laser device shows a high affinity for the melanin chromophore. Its effectiveness in treating connective tissue and melanin-based disorders was shown in both preclinical and clinical investigations. ^{9,10,18}

This technology holds promise for treating pigmentary illnesses because of its great affinity for melanin, low interaction with water and vascular

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IRB approval status: The study was conducted in accordance with the Declaration of Helsinki. Ethical approval is not necessary as the study device is already CE marked since 2019.

Data availability statement: Data that support the study findings are available on request from the corresponding author (Dr Fusco).

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components, and extraordinary ability to penetrate tissues with minimum heating. 14

According to a preclinical histologic investigation, a 675 nm laser system causes selective thermal damage to the skin. When compared with the untreated areas, the heating impact denaturates collagen fibers and stimulates the formation of new collagen in the treated areas.¹⁵

In vitro tests also validate the novel 675-nm device's action on collagen. Magni et al¹⁹ examined adult human dermal fibroblast cells after being exposed to doses of 675 nm laser light. Type I collagen was decreased whereas type III collagen significantly increased, according to fluorescence quantification. No dose examined had an impact on the proliferation and viability of cells.¹⁹

The 675-nm laser system's strong affinity for collagen makes it a promising option for facial skin rejuvenation. 14,16

Recent investigation²⁰ supplied real-life data presenting a case series of patients treated with the 675 nm laser who had a considerable skin texture improvement after the treatment.

In addition, the activation of dermal fibroblasts and the generation of new collagen make the 675-nm technology interesting as a technique for acne atrophic scars remodeling.⁸

Furthermore, in younger patients who are genetically or chronically exposed to photoaging, the application of a 675 nm laser system may be suggested because of its ability to increase collagen formation, ¹⁹ thus playing an important role in prejuvenation. ²¹

Preclinical and clinical data on the efficacy and safety in the management of various skin conditions of the newly developed high-power 675 nm laser system are reported in a recent published study. ²² In this investigation, the high-power 675 nm laser was shown to be effective in stimulating cell proliferation in *in vitro* experiments, and it produced excellent results on many kinds of skin conditions such as diffuse pigmented lesions, melasma, skin rejuvenation, acne scars, acne vulgaris, and vascular lesions, without ever causing serious side effects.

In light of the previously published clinical data concerning the efficacy of the 675 nm laser, and the results obtained from the study of Vitale et al,²² this investigation focused on confirming and corroborating the efficacy and the safety of the recent developed high-powered 675 nm laser system, which uses a faster treatment modality (called Moveo)¹⁰ in the management of pigmented lesions, wrinkles, and fine line.

CASE SERIES

In this study, 3 female patients with a mean age of $43.67 (\pm 9.07)$ years old (2 patients with Fitzpatrick

skin type III and 1 patient with Fitzpatrick skin type II) with diffuse pigmentation in the décolletage area and 5 female patients with a mean age of 48.60 (± 7.54) years old (all with Fitzpatrick skin type III,) with fine lines or wrinkles on the face, were included. All patients were treated with Red Touch PRO laser system (DEKA MELA), which emits a wavelength of 675 nm. Through the scanner, a fractional laser beam is emitted, and it is able to generate micro-areas of denaturation (DOTs) of approximately 0.7 mm. The scanner is equipped with a cooling system (the tip of the handpiece is equipped with a sapphire window that can be cooled down to 5 °C) to preserve the epidermis and it can be equipped with a contact sensor to further increase patient safety.

Red Touch PRO can be used in 2 different modes: Standard or Moveo.

In this study, the Moveo mode was selected and evaluated.

When using the standard mode, the handpiece needs to be positioned perpendicular to the skin's surface and remained there until the system has completed the whole scanning area of 13×13 mm. Subsequently, the handpiece must be moved in such a way that there is no overlap between several scanning areas.

In Moveo mode, the scanner performs a single line of DOTs up to 13 mm long, consequently users must move perpendicular to the scan line's axis. This modality creates a line of DOTs on the skin and allows the operator to move faster than in standard mode, resulting in greater treatment efficiency.

The device is very easy to use and, in this mode, allows to change power and number of DOTs, leaving the stack, dwell time, and spacing parameters fixed (which can only be changed in standard mode).

In particular, the DOT number allows the operator to choose the number of microthermal zones in the area to be treated, the stack value indicates the number of pulses delivered consecutively at the same point, whereas the dwell time is the time the laser beam remains at the same point and the spacing is the distance between the microthermal zones.

Patients with photodamaged skin such as pigmented lesions, wrinkles, and fine line were selected for this clinical study. Exclusion criteria were: hypersensitive to light in the near-infrared wavelength region, subjects taking anticoagulant or immunosuppressant and medications that is known to increase sensitivity to sunlight, pregnant women, and patients with personal or family history of skin cancer. Patients were treated with 1 or 2 sessions with Red Touch PRO depending on the severity of the photodamaged skin.

The Moveo mode was selected, with maximum power (15 W) and emitted DOTs between 3000 and 7000, for a treatment duration of 3 to 6 minutes. For very large areas such as décolletage, the right and left sides were treated as 2 separate consecutive treatments, therefore with twice the stated number of DOTs.

Before treatment, the patient should avoid exposure to the sun for at least 4 weeks, thus preventing posttreatment complications, and avoid taking aspirin for several days before treatment to avoid purpura.

Before the treatment the treated areas must be shaved, and they must be cleansed with a cleanser of mild soap and water, in order to remove all surface debris that can absorb the laser energy. No makeup, lotions, deodorant, or oil is allowed on the area to be treated. As a precautionary measure, the patient should be recommended not to wear make-up for 2 days before the treatment.

A skin test was performed on the same area to be treated to determine the correct values for the treatment parameters. The emission parameters were selected according to patients phototypes and to the treatment to be performed. The study system allows to start the treatment with low energy parameters that can be gradually increased depending on the patient's response. A thin layer of aqueous and transparent (not colored) gel was placed between the skin and the sapphire and the handpiece was well in contact with the skin at least a couple of seconds before starting laser emission, to provide effective cooling of the superficial layer of the skin and to ensure that proper fluence is delivered to the skin. The treatment areas were never overlap, in order to not transmit >1 pulse on the same area. Finally, the tested areas were evaluated usually 48 to 72 hours after treatment. The expected end point for rejuvenation treatments is a diffuse reddening of the treated area, whereas paradoxical darkening of the lesions could be added if pigmented lesions are present.

After treatments, a moisturizing emulsion to the skin was applied.

Clinical evaluation and clinical photos were collected at baseline and at 1 or 6 months after the last treatment. In addition, 5-point Global Aesthetic Improvement Scale (GAIS) and patient's satisfaction score were used to assess the efficacy of these treatments. The last one has been evaluated using 5-point (0-4) scale where 0 points indicated a very unsatisfied patient, 1 point indicated an unsatisfied patient, 2 points a neutral patient, 3 points a satisfied patient, and 4 points a very satisfied patient, whereas the GAIS can be scored from 0 to 4: 0 point-no change; 1 point—25% mild improvement; 2 points— 50% moderate improvement; 3 points—75% good



Fig 1. Treatment with the 675 nm laser performed on a female patient on décolletage area. The baseline (A) and the follow-up after 1 month from the last treatment (B) are shown.



Fig 2. Treatment with the 675 nm laser performed on a female patient on décolletage area. The baseline (A) and the follow-up after 1 month from the last treatment (B) are shown. The pigmented lesions are less noticeable at follow-up and the skin appears more relaxed and elastic in the center of the treated area.

improvement; and 4 points-100% excellent improvement. Adverse effects were monitored.

The clinical photos (Figs 1 and 2) show good results on décolletage with regard to a decrease in solar lentigo and an improvement in wrinkles in the center of the area where the skin appear more relaxed and elastic.

Facial rejuvenation cases also showed good results both in terms of wrinkle reduction, especially in the periocular and perioral area, and in terms of skin texture and tone (Figs 3 and 4).

The GAIS score showed a mean value of 3.00 (± 1.00) and 3.40 (± 0.55) for diffuse pigmentations and skin rejuvenation treatments, respectively (Fig 5).

In addition, patient's satisfaction showed a mean value of 3.67 (± 0.58) and 4.00 (± 0.00) for diffuse pigmentations and skin rejuvenation treatments, respectively (Fig 6).

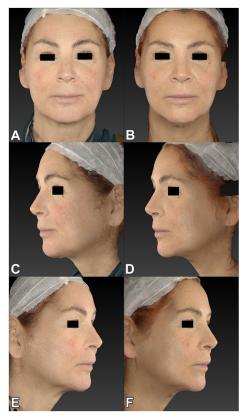


Fig 3. Skin rejuvenation facial treatment with the 675 nm laser performed on a female patient. The baseline (A, frontal view; C, left lateral view; and E, right lateral view) and the follow-up after 3 months from the last treatment (B, frontal view; D, left lateral view; and F, right lateral view) are shown.

These results show that the pain was extremely mild: the mean score was 0.33 ± 0.58 and 0.40(±0.55) points for diffuse pigmented lesions and skin rejuvenation, respectively.

No serious adverse events were reported, only mild crusting that resolved in 7 to 10 days and a first degree burn that resolved in 20 days.

DISCUSSION

Aesthetic medicine continues to encounter difficulties in treating skin conditions such as deep/fine wrinkles, pigmented or vascular lesions, and acne scars. Finding alternative, bearable solutions is important for minimizing patients' downtime even with the wide range of procedures available for changing the appearance of skin.

When compared with the available laser approaches, 675 nm laser technology is capable of creating much lower levels of inflammation after treatments, owing to the system's unique technological advantages.

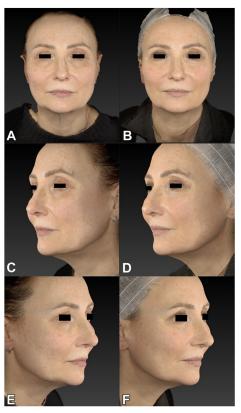


Fig 4. Skin rejuvenation facial treatment with the 675 nm laser performed on a female patient. The baseline (A, frontal view; **C**, left lateral view; and **E**, right lateral view) and the follow-up after 6 months from the last treatment (B, frontal view; D, left lateral view; and F, right lateral view) are shown.

First, as mentioned in the Introduction section, the study device exhibits high selectivity for the melanin chromophore and the vascular vessel wall. Indeed, as hemoglobin absorbs less light than water, the ideal wavelength range for targeting melanin is between 550 and 850 nm. The ideal wavelength of 650 to 700 nm targets melanin; the absorbance of melanin continues to decrease as the wavelength increases. 23,24

Second, it is possible to achieve extremely low energy levels, which are lower than those employed for facial skin rejuvenation.8,14

We hypothesize that the vascular improvement effect shown on the face area after treatment with the study device may be due to the presence of a collagen component in the capillary basal membrane.

Indeed, the collagen type is still a target of the device wavelength even if it differs from larger vessels (type IV vs type I/III). As a consequence, when the laser penetrates the capillary collagen, the vessel lumen contracts, decreasing the vessel diameter, and reducing blood flow.

Additionally, Mathew-Steiner et al²⁵ discovered that collagen types IV and XVIII had antiangiogenic

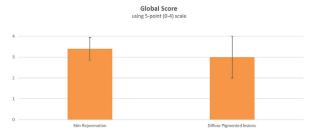


Fig 5. Graphical representation of 5-point Global Aesthetic Improvement Scale (GAIS) mean score for diffuse pigmentations and skin rejuvenation treatments.

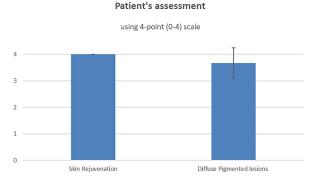


Fig 6. Graphical representation of patient's satisfaction mean score for diffuse pigmentations and skin rejuvenation treatments.

characteristics that inhibited endothelial cell migration and proliferation while causing endothelial cell death. These effects could be amplified by collagen in connective tissue²⁵; in fact, collagen types IV and XVIII were found to have antiangiogenic properties.^{26,27}

Our results, which are in line with the previous study of Vitale et al,²² show promising results for pigmented lesions, wrinkles and fine lines after highpower 675 nm laser treatment.

Indeed, the GAIS score results for diffuse pigmentations and skin rejuvenation treatments, are in conformity with the GAIS values found in the previous study of Vitale et al.²²

Furthermore, concerning pigmented symptoms, the average GAIS values found in this study appeared to be greater than those measured in previously published studies such as that of Coricciati et al, 13 where the GAIS for visible, pigmentary, and vascular values were, respectively, 1.89 \pm 0.96, 2.28 \pm 0.67, and 2.17 \pm 0.79.

In our investigation, one of the new technology's greatest advantages over the older one, which is extensively mentioned in the Introduction section's referenced works, is that it uses a higher power (15 W instead of 10 W of the previous version of this device), allowing the operator to perform a treatment session faster (reducing treatment time) while using the same level of energy.

All of the data were processed to produce a single response and to assess if the results changed depending on the skin conditions that were treated in order to demonstrate the effectiveness and safety of the highpower 675 nm laser system. The current study's findings, using validated scales such as the Patient Satisfaction Scale and the 5-point GAIS, demonstrated that the highpowered 675 nm laser produced good and promising results for pigmented lesions, wrinkles, and fine lines, with a treatment time that was 50% shorter than the old parameters setting \$8,11,14,16,17,24,28 leading to a faster and more patient-satisfied treatment technique.

Furthermore, our results show that the perception of pain by patients was extremely mild demonstrating that the Moveo mode shortens the course of treatment but at the same time results safe and comfortable for the patient.

Since few published studies provide an extensive evaluation of the benefits of 675 nm in skin rejuvenation, another important feature of our study is represented by conducting a follow-up up to 6 months after the end of the last treatment.

Finally, the presence of a skin contact cooling handpiece (5 °C) included in the device, ensures epidermis protection from damage produced by the increase in temperature. As a result, the risk of adverse events was reduced, and patient's posttreatment maintenance was lower.

Clinical data confirm the effectiveness and safety of this high-power 675 nm laser for pigmented lesions and the management of skin rejuvenation, reporting no serious adverse effects and ensuring faster treatments compared with the previous laser system.

Although the 675-nm laser is generally helpful in treating melasma, acne scars, and face rejuvenation, the therapeutic results of the treatments vary depending on the patient's skin type and the pathologic condition being treated. ^{9,14,15,19}

Further comparative clinical and/or histologic studies are needed to confirm the superiority of this technology compared with the other available treatments for these skin disorders. The great advantage of this new 675-nm technology is its good tolerability as demonstrated in all studies cited in the Introduction section. Indeed, the visual analogue scale pain assessed in these investigations never seems to exceed 3 of 10 points.

Additionally, minor burns have been recorded as a side effect of its use, probably caused by improper handpiece placement on the skin. These can be treated with topical medications and resolve completely in a few days. ^{9,14,15,19} The 675-nm laser source may represent a novel therapy with potential implications in the management of a vast range of skin problems.

Regarding the prospects and potential application of this laser technology, it would be interesting to evaluate its combination use with nonlaser treatments; in particular, examining their efficacy in conjunction with injectables for face and neck rejuvenation may be intriguing and it could represent

Lastly, the possible application of the study system in "prejuvenation" management,²¹ which is becoming more popular in cosmetic dermatology, to maintain a youthful appearance represents an important future direction.

a great revolution in the field of aesthetic medicine.

In this regard, younger individuals who are genetically or chronically exposed to photoaging may benefit from the use of a laser that can increase collagen formation without having any toxic side effects. The study's limitations include a small population sample and a lack of long-term follow-up.

Conflicts of interest

Authors Madeddu and Zingoni and Drs Fusco and Gallo were employed by El.En. Group. The other authors have no conflicts of interest to declare.

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