Multifractional Microablative Laser Combined With Spacially Modulated Ablative (SMA) Technology for Facial Skin Rejuvenation

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Background and Objective: Due to the increasing demand for aesthetic procedures, especially facial aesthetic surgery, a new laser technology has been developed for facial skin rejuvenation and wrinkle treatment. The aim of this study was to objectively and subjectively assess the clinical efficacy and safety of Erbium:YAG laser combined with Spatially Modulated Ablation (Er:YAG + SMA) on facial skin rejuvenation.
Study Design/Materials and Methods: Patients with Fitzpatrick skin type's I–IV were prospectively included. Inclusion criteria consisted of having wrinkles and irregular skin texture. All patients underwent two Er:YAG + SMA sessions (1 month apart) to stimulate tissue regeneration. Er:YAG laser emits wavelength at 2,940 nm and when combined with SMA, a resonance effect is produced in the dermis to promote tissue regeneration. Facial skin elasticity and firmness were objectively assessed by Cutometer at baseline and month 6 (M6). Aesthetic improvement was qualitatively assessed using digital photographs. Patient satisfaction with regard to their facial appearance was self-assessed using the validated FACE-Q scale and the patient-perceived age VAS scale at baseline, M1, and M6. Side effects were investigated after each session.
Results: Thirty-four patients were included, 50% (18 patients) had Fitzpatrick skin type III and 41% (14 patients) were smokers. Skin elasticity indices were significantly improved: from 0.335 ± 0.015 at baseline to 0.387 ± 0.021 at M6 ($P = 0.05^{*}$) for *R5* (net elasticity). Skin firmness was assessed through *R7* (biological elasticity) and *R6* (viscoelastic ratio) at baseline and M6: a significant increase from 0.235 ± 0.01 to 0.2709 ± 0.009 ($P < 0.03^{**}$) and decrease from 0.486 ± 0.022 to 0.3918 ± 0.023 ($P < 0.006^{***}$) were respectively observed. A negative value for *R6* corresponded to an improved skin condition. The FACE-Q scores were significantly increased from 39.4 ± 6.7 at baseline to 45.4 ± 9.1 at M1 ($P < 0.006^{***}$) and 50.4 ± 9.8 at M6 ($P < 0.0001^{***}$), reflecting wrinkle reduction and enhanced rejuvenation. According to the age appraisal VAS scale, results showed that patients felt younger by −2.92 years at M1 ($P < 0.0001^{***}$) and −4.13 years ($P < 0.0001^{***}$) at M6. No adverse reaction was reported.
Conclusion: The Er:YAG + SMA technology offers an effective and safe treatment alternative for facial skin rejuvenation. It reduces the recovery time compared to conventional lasers such as carbon dioxide laser. Lasers Surg. Med. © 2016 Wiley Periodicals, Inc.

Key words: laser; microablative; Er:YAG; skin rejuvenation; wrinkle treatment

INTRODUCTION

Skin firmness and elasticity change over time, facial skin in particular. Skin cells are continuously renewed but exogenous and endogenous detrimental factors may affect skin condition, degrading of the dermal elastin and collagen fiber network. This will lead to facial sagging (firmness and elasticity loss) and the appearance of wrinkles and fine lines [1,2].

Different types of laser are available for skin resurfacing and treatment of damaged tissues [3,4]. Through its action on the epidermal and dermal layers, these lasers promote a healing response through activation of fibroblasts, and enhanced collagen and elastin neoformation. This process repairs and restores damaged skin tissues [5,6].

Depending on the type of laser used (fractional vs. non-fractional, ablative vs. non-ablative), features such as the discomfort level, patient time to recovery, post treatment time and final appearance may vary [7].

RecoSMA (Reconstructive Spatially Modulated Ablation) (Linline Medical Systems) is a new non-invasive technology combining the erbium-doped yttrium aluminum garnet (Er:YAG) laser, which operates at a wavelength of 2,940 nm and a specific SMA nozzle. The laser beam is fractionated into thousands of microbeams (about

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10,000/cm^2) of 50 μm in diameter, spaced by 50 μm. The Er:YAG/SMA laser induces a minimal ablative and thermal effect because the beam only penetrates 50 μm into the epidermis. It generates 3–6 mm deep acoustic waves, which deeply destroy the dermal, and hypodermal cells (i.e., fibroblasts and adipocytes), leading to tissue regeneration [8]. Hernández et al. have recently used Er:YAG laser combined with SMA for the treatment of chronic lower extremity ulcers, and they have shown that this new technology is safe, effective and may be used as a therapeutic alternative in the treatment of chronic wound [8]. The aim of this study was to assess the efficacy and safety of the Er:YAG/SMA laser on facial skin rejuvenation.

MATERIALS AND METHODS

Study Design and Patients

Thirty-four patients with Fitzpatrick skin phototypes I–IV were prospectively included. Inclusion criteria were having wrinkles and irregular skin texture, no history of laser treatment or other treatment for skin rejuvenation and no history of facial aesthetic surgery over the last 6 months. Pregnant and breastfeeding women, patients with abnormal wound healing (keloid scars), patients previously treated with photosensitizing agents, patients with vitiligo, photoallergy, skin infection, or suspected skin cancer were excluded. All patients signed a written informed consent form.

Treatment With Er:YAG Laser and SMA Technology

Patients were treated with the Multiline laser device (LINLINE Medical System, Minsk, Belarus) equipped with multiple sources of independent lasers, including erbium, neodymium, ruby and alexandrite, and seven independent high-energy laser transmitters. An Er:YAG laser combined with the SMA technology fixed on the handpiece, in the beam output window, was used. This SMA module (Fig. 1A) when adapted to the Er:YAG hand piece has a sophisticated system of lenses that drill 50 μm holes in the skin. These tiny micro spots form a grid of over 10.000 laser impacts on the skin (Fig. 1B).

The SMA module provided the necessary spatial distribution for laser beam energy.

A scan mode was used with fluences of 2.1 J/cm^2, frequency of 3 Hz and pulse duration of 0.3 microsecond. All patients underwent two laser sessions 1 month apart. During treatment, no anesthetic agent was needed. Patients were asked to use a Cicalfate® moisturizing and restorative skin cream to heal their skin after each session.

Objective Assessment

Skin elasticity measurements. Skin mechanical properties were assessed using a non-invasive suction skin elasticity meter (Cutometer® MAP580, Courage and Khazaka Electronic GmbH, Cologne, Germany). A 2 mm diameter measuring probe was used and a constant suction at 450 mbar for <2 second followed by a relaxation time of <2 second was applied and repeated three times. Measurements were performed at baseline (pretreatment) and 6 months after the two laser treatment sessions (on both the right and left sides of the cheek).

The mechanical parameters *R5*, *R6*, and *R7* were subsequently calculated. *R5* refers to the net elasticity in the absence of viscous deformation and is calculated using the "immediate retraction"/"immediate distention" ratio: $R5 = Ur / Ue$, where a value of one (100%) corresponds to a highly elastic skin. *R6* represents the portion of viscoelasticity on the elastic part of the curve, and is calculated using the "viscoelastic"/"elastic distension" ratio: $R6 = Uv/Ue$. As R*6* measures skin stretching capacity, negative values reflect an improved skin condition. *R7* refers to recovery after deformation and corresponds to the portion of elasticity compared to the final distension. It is calculated using the "immediate retraction"/"final distension" ratio: $R7 = Ur/Uf$, where a value of one (100%) corresponds to a highly elastic skin.

Subjective Assessments

FACE-Q. Patients were asked to complete a FACE-Q scale. The overall satisfaction with their facial appearance and aging appraisal scale scores were assessed at baseline, and 1 and 6 months after the two laser treatment sessions [9].

The FACE-Q scale assessed different facial appearance items, higher scores indicating a greater satisfaction. These questionnaires were translated into French by Mapi Research Trust.

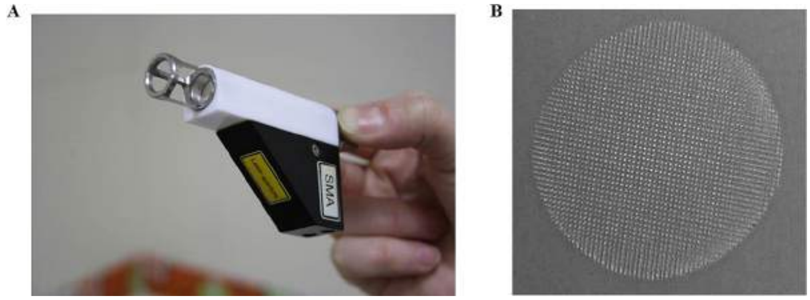

Fig. 1. **A**) SMA module which adapted to the Er:YAG hand piece system. **B**) Micro spots form a grid of over 10.000 laser impacts.

Photography. Digital photographs were taken at baseline, after each treatment session and at month 6 (end of study) using Canon Model DS126231 with macro-photo lens.

Follow-Up Visits

Visits were scheduled at baseline, 1 and 6 months following the second treatment session. During these follow-up visits, the efficacy and safety of SMA laser treatment on biomechanical skin properties were assessed and a self-administered questionnaire of patient satisfaction was also used for subjective evaluation. The side effects and possible complications were investigated at each visit.

Statistical Analysis

The different elasticity parameters were analyzed using PRISM, version 5 (Graph Pad). The change in mechanical parameters was determined using the following equation: Percentage of change $= [(a - b)/b] \times 100$, where "a" was the individual value of *R5*, *R6*, or *R7* at 6 months and "b" was the corresponding zero-time (before treatment) value. The Student's t-test was used to compare the mean values at each time-point to the mean baseline values. $P < 0.05$ was considered statistically significant.

RESULTS

Clinical Assessment

Thirty-four patients with a mean age of 54 ± 10 years (range: 30–72 years) treated with SMA laser technology were included. Among them, 41% were smokers (Table 1) and respectively 50% and 31% had a skin phototype III and II (Table 1). These patients had varying degrees of wrinkles and irregular skin texture.

Regarding satisfaction with facial appearance (FACE-Q scores), a significant improvement in skin wrinkles and rejuvenation was reported 1 and 6 months after the two treatment sessions (Fig. 2). The mean FACE-Q score was 39.4 ± 6.7 at baseline, 45.4 ± 9.1 at 1 month ($P < 0.006^{***}$), and 50.4 ± 9.8 at 6 months ($P < 0.0001^{***}$) (Fig. 2). Patients reported that they felt younger by -2.92 years at 1 month ($P < 0.0001^{***}$) and -4.13 years

TABLE 1. Clinical and Demographic Characteristic of Included Patients

Patient's characteristic	
Age, mean (SD)	54 years (10)
Gender	2M/32F
Smoking, n (%)	14 (41%)
IMC, mean (SD)	22.8 (3.1)
Phototype, n (%)	
I	2 (6%)
II	11 (31%)
III	18 (50%)
IV	5 (14%)

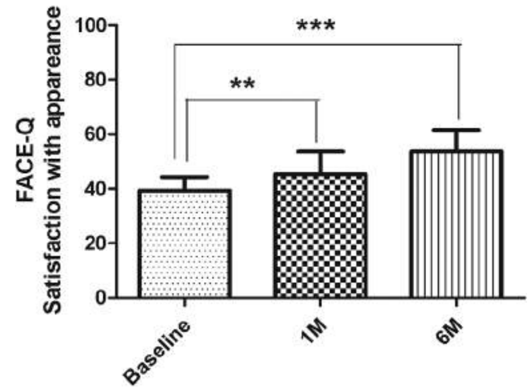

Fig. 2. Evaluation of satisfaction of patients by FACE-Q satisfaction with appearance score at baseline, 1 and 6 months after treatment (mean ± SEM, student's t-test).

at 6 months ($P < 0.0001^{***}$) compared to baseline (Fig. 3). Skin wrinkles, texture and tone were improved in all patients at the final visit after the two laser treatment sessions compared to baseline (Fig. 4). This new technology induced a minimal thermal effect, was painless and no anesthesia was needed. The mean recovery time was 3–4 days. Patients could also go back to work the day after treatment. No scarring, demarcation lines or infection were observed during the follow-up visits.

Objective Assessment

A Cutometer® was used to measure changes in skin elasticity. *R5* (net elasticity) significantly improved between the baseline (0.335 ± 0.015) and the final visit (0.387 ± 0.021; $P = 0.05^{*}$), suggesting that the SMA laser treatment was effective. Similarly, at the final visit, an increase in biological elasticity values (*R7*: elasticity/complete curve) from 0.235 ± 0.01 at baseline to 0.2709 ± 0.009 at 6 months ($P < 0.03^{**}$) reflected a significantly improved skin firmness (Fig. 5).

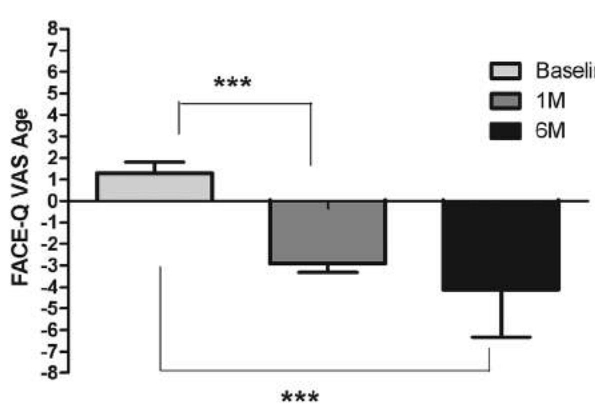

Fig. 3. FACE-Q visual anolog score age appraisal determined by patients at baseline, 1 and 6 month after treatment (mean ± SEM, student's t-test).

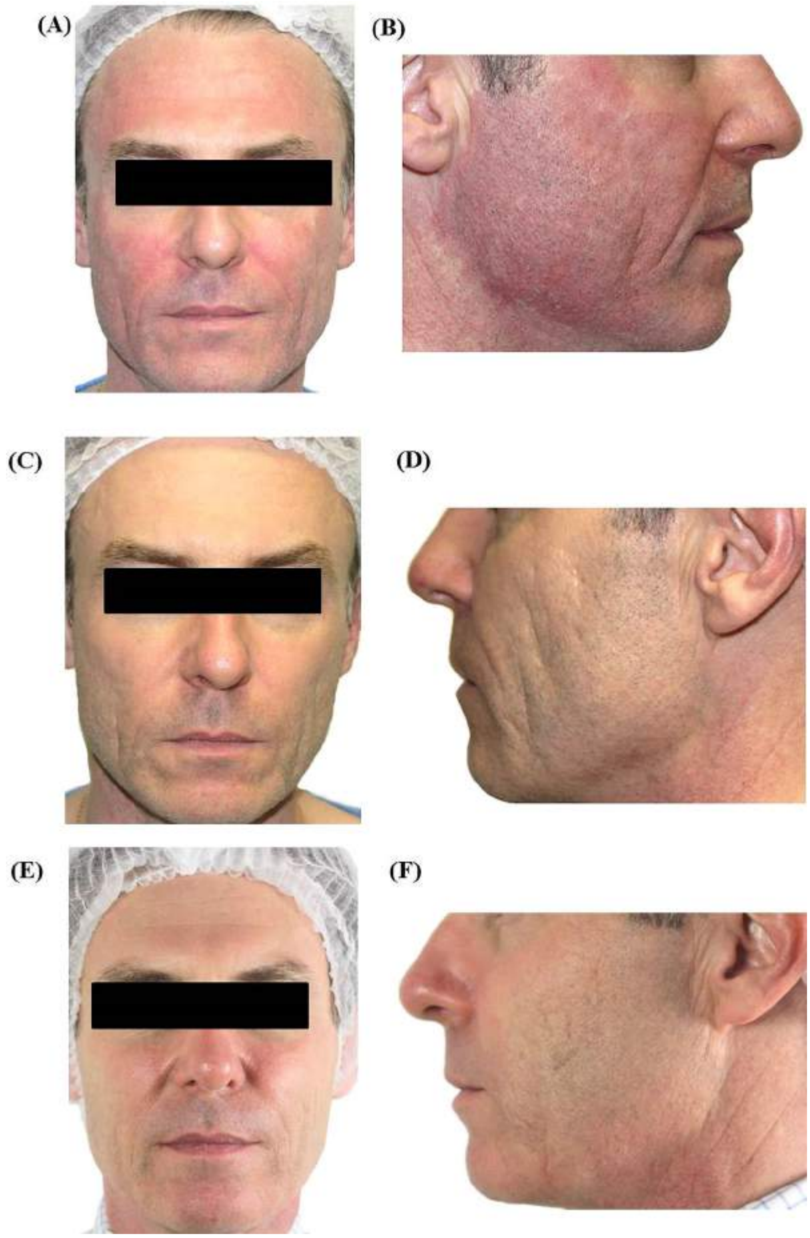

Fig. 4. A 47-year-old men (**A**, **B**) Microablative (frozen effect) after laser session. (**C**, **D**) 1 month after the first laser session, and (**E**, **F**) 6 months after the latest treatment. Skin wrinkle was improved after two session of SMA laser treatment.

The viscoelastic ratio *R6* was significantly decreased from 0.486 ± 0.022 at baseline to 0.3918 ± 0.023 at 6 months ($P < 0.006^{***}$), indicating an improved skin condition.

DISCUSSION

Several laser treatment modalities have been developed over the last decade in the field of skin rejuvenation [10]. Fractional CO_2 laser resurfacing is the gold standard technique for photoaging and skin rejuvenation, but often is associated with pain, significant after care and prolonged healing reaction. They may also occasionally result in adverse events such as infection, hypopigmentation, and scarring. Non-ablative lasers have been developed over the last two decades as an alternative to traditional ablative resurfacing to prevent epidermal layer disruption, including intense pulsed-light systems, radiofrequency systems, non-ablative Erbium lasers, infrared lasers, and light-emitting diodes [7].

In our study, an Er:YAG laser combined with the SMA technology, operating at a wavelength of 2,940 nm strongly absorbed by water, was used to improve skin wrinkles and rejuvenation.

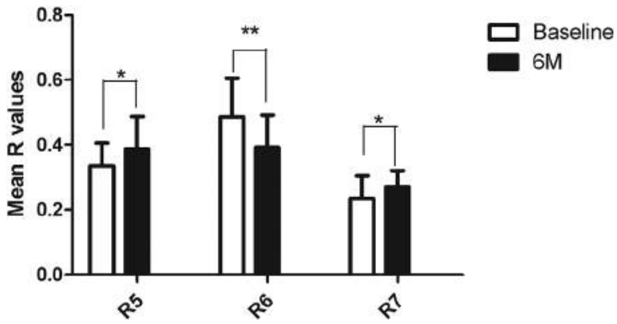

Fig. 5. Values of *R5* (net elasticity), *R6* (viscoelasticity ratio), and *R7* (biological elasticity) parameters at baseline and 6 months after laser treatment (mean ± SEM, student's *t*-test).

The laser SMA Erbium:YAG uses a fractional Erbium YAG laser that is coupled with a microlens system. This creates a large number of micro perforations (10,000/cm^2) with a size of 50 μ in the superficial layers of the skin. This type of radiation, when it is applied to the surface area for treatment, creates microablations of $50 \times 50\,\mu$m and space of 50 μm, thus allowing the superficial epidermal layers to be removed. The advantage of SMA added to the Er:YAG laser allows rapidly performing skin treatments with no need for anesthesia and is associated with a short recovery time.

Using multifractional Er:YAG laser combined with SMA significantly improved skin firmness and elasticity after two treatment sessions (Table 2). Studies investigating the correlation between biomechanical skin parameters have shown that *R5*, *R6*, and *R7* were strongly correlated with age and are therefore optimal parameters for skin aging assessment [11–13]. Our data on skin firmness (*R7*) showed a 15% increase 6 months after treatment. At the final visit, the net elasticity (*R5*) was significantly increased by 14% compared to baseline while *R6* (viscoelastic parameter) was significantly decreased (−19%). Both findings indicate an improvement in skin elasticity. Indeed, some studies have reported the efficacy of Er:YAG laser on facial rejuvenation with an improvement in facial appearance through the stimulation of necollagen synthesis after multiple treatment sessions [14]. Moreover, a study comparing fractional and ablative Er:YAG laser has shown that multiple fractional laser sessions were as effective as a single ablative Er:YAG laser session on collagen synthesis while the superiority of ablative laser was shown on skin elasticity [15].

TABLE 2. Skin Parameters Results on Skin Elasticity and Firmness

	Grade improvement	Change from baseline (%)	*P* values
R5	0.05	14	0.05
R6	−0.09	−19	0.006
R7	0.03	15	0.003

All patients showed a significant clinical improvement at the end of the treatment as well as 1 month after a single laser session, in terms of both facial appearance and that they felt they looked younger by −4.13 years at the final visit. These results show a long-term efficacy of the Er:YAG laser combined with SMA. El-Domayati M et al. have demonstrated, using Er:YAG laser at a fluence of 2–3 J/cm^2 to treat periorbital wrinkles, a short-term efficacy which disappeared after 3 months but the outcome remained better than baseline values [16].

In our study, no complication or adverse reaction was reported. The time to recovery after a treatment session was of 3–4 days. Skin rejuvenation by low-energy (2.1 J/cm^2) ablative multifractional resurfacing is a highly accurate technique due to the absence of thermal damage. Therefore, the advantage of Er:YAG laser combined with the SMA technology compared to conventional lasers is to provide well-tolerated, efficacious treatment with decreased risk of adverse reactions, with more rapid healing and reduced recovery time.

CONCLUSION

The 2,940 nm Er:YAG laser combined with the SMA module offers an effective and safe treatment alternative for facial skin rejuvenation. It clinically improves facial appearance, reduces aging signs and induces biomechanical effects associated with improved skin firmness and elasticity.

Moreover, future studies to learn the mechanism of the improvement that is, *in vivo* confocal microsopy to identify skin changes at both epidermal and dermal level might elucidate the effect on collagen and elastic fiber renewal.

Further, larger long-term controlled studies are needed to investigate the use of this new technology in combination with other regenerative medicine therapies to confirm our findings.

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