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CASE REPORT

## Novel method for facial rejuvenation using Er:YAG laser equipped with a spatially modulated ablation module: An open prospective uncontrolled cohort study

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### ABSTRACT

Facial aging is a complex biological process that affects the skin and superficial musculoaponeurotic system (SMAS). A new technology (RecoSMA) for skin rejuvenation based on acoustic-interference method using Er:YAG laser (2936 nm) equipped with a special module SMA that targets both the dermis and SMAS was evaluated in an open-label prospective cohort study of 100 female patients treated for facial rejuvenation. Measure of clinical improvement included investigator-rated clinical photography using the Modified Fitzpatrick Wrinkle Scale, and ultrasound measurements in the dermis a week, 30 days and six months post treatment. All patients completed the study and no complications were noted. Improvements in skin tone and texture were noted in all participants and significant decrease in wrinkle depth was demonstrated at the six-month follow-up that was confirmed by ultrasound skin measurements. Data presented herein confirm the safety and efficacy of RecoSMA treatment for facial rejuvenation.

### ARTICLE HISTORY

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### KEYWORDS

Er:YAG laser; facial rejuvenation; RecoSMA; SMA module

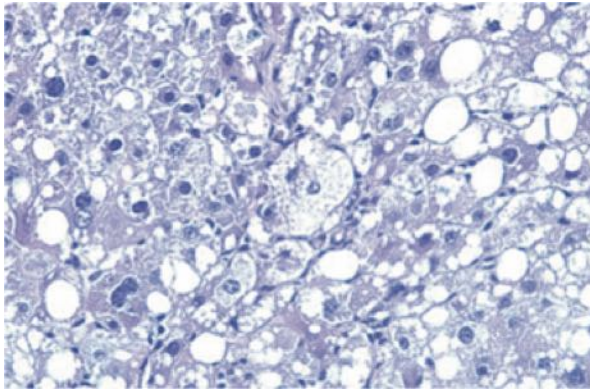
### Introduction

The current concept of age-related changes on the face and neck is based on the alteration of the skin and deeper tissues such as the adipose, skeletal and superficial musculoaponeurotic system (SMAS) (1–3). The superficial musculoaponeurotic system (SMAS), a thin layer of connective tissue that connects the facial muscles to the superficial and deeper facial tissue, undergoes dramatic age-related changes: elastic fibers grow thick and disorganized, collagen degenerates and sarcopenia weakens and tightens the muscles, resulting in drooping features and wrinkles, respectively (2,4–5). Until recently, cosmetic surgery such as rhytidectomy (SMAS facelift) was the main option to change the individual's appearance to a more youthful one (6–8). Given however the current rise in demand for non-invasive face rejuvenation procedures, surgical alternatives have been developed. As such, a novel alternative to the SMAS facelift is the RecoSMA method using an Er:YAG laser (2936 nm) equipped with a special module Spatially Modulated Ablation (SMA).

RecoSMA patented technology is non-thermal, based on the microablation of the upper layer of the epidermis and subsequent formation of explosive acoustic waves (9). According to the manufacturer of the laser equipment, the SMA module permits the redistribution of the laser beam into thousands of microbeams (about 10,000/cm<sup>2</sup>) of 50 µm in diameter, spaced

by 50 µm. The energy fluence is 10 J/cm<sup>2</sup> and the power density is 40 KW/cm<sup>2</sup> (per microspot), which allows for the generation of very powerful acoustic waves that penetrate up to 6 mm in depth. Energy from the interfering acoustic waves leads to the mechanical destruction of cells at the dermal and SMAS tissue level and the creation of microzones of collapsed cells among intact cells, stimulating elastin and collagen remodeling. Unique to the RecoSMA technology is the mechanical damage from the dermis to SMAS level without overheating the tissue or exposing cells to oxygen, thus preventing fibrosis/scarring and other adverse effects while maximizing and stimulating the regenerative capacity of the tissue (Figure 1). The given mechanism of action has been previously assessed via histological examination during the study for facial rejuvenation (9), treatment of chronic lower extremity ulcers (10), while the depth of the laser impact has been demonstrated in the study of liver cirrhosis treatment (11,12).

The effect of the RecoSMA procedure is cumulative and skin rejuvenation continues for 3–4 months post-treatment due to collagen maturation (10,12). In this open-label uncontrolled prospective cohort study, the efficacy of RecoSMA for face rejuvenation was evaluated in 100 female patients. Results demonstrate treatments are safe with high patient satisfaction and positive outcomes in reversing the signs of facial aging.



**Figure 1.** The histologic study of the skin under the influence of the Er:YAG laser (2936 nm) equipped with a special module SMA: mechanical destruction of cell membranes, nucleus and cytoplasm in the dermis.

## Materials and methods

### Patients

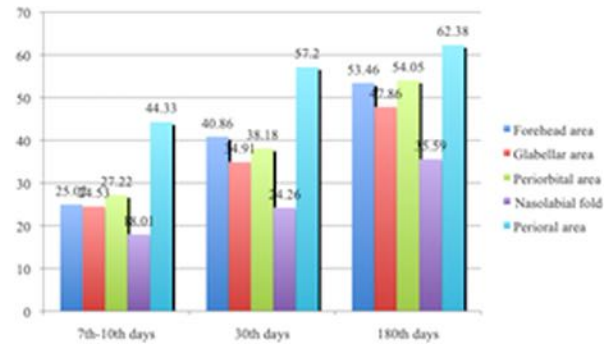
This study was an open prospective cohort study. A total of 100 female patients 29 to 70 years old were enrolled in the study. All patients provided written, informed consent. Exclusion criteria included: pregnancy, breastfeeding, internal chronic disease, infectious disease, active skin disease (infection, psoriasis, eczema, various dermatitis, etc.), autoimmune disease, and skin cancer. Subjects were also excluded if they received any other investigational treatment or had participated in another clinical study within 60 days prior to study enrollment.

### Laser treatment

All patients received one laser treatment session with the Er:YAG Laser and SMA module (LINLINE Medical Systems). Before treatment, patient's skin was cleaned and dried. Treatment parameters were 2.12–2.21 J/cm<sup>2</sup> and 3 Hz and target areas spanned from the hairline to the chin. Periorbital areas including eyelids were treated with “RecoSMA-of surface action” and the other facial areas were treated with “RecoSMA-of deep action.” Laser beams were applied using scan patterns such as “olympic rings.” All patients took systemic acyclovir 1000 mg/day the day of treatment and two days after laser therapy, as an anti-viral preventative measure. Patients applied 5% dexpanthenol cream 2–3 times per day and 0.05% chlorhexidine the digluconate solution forty-eight hours after treatment.

**Table 1.** The wrinkle depth (mm) in different areas of the face according to MFWS.

Area	Wrinkle depth (mm) (MFWS)	
	Range (mm)	Average value
Forehead	0.5–2.5	1.77 ± 0.49
Glabella	0.5–3	1.86 ± 0.54
Periorbital	1–3	2.06 ± 0.41
Nasolabial fold	1–3	2.42 ± 0.52
Perioral	0–2.5	1.05 ± 0.67



**Figure 2.** The relative decrease of wrinkle depth on 7th-10th, 30th, 180th days after the laser therapy in different facial areas.

## Evaluation of clinical efficacy

During the screening visit, patient skin types were documented according to the Fitzpatrick Skin Type and by ultrasound skin examination. Wrinkle depth was evaluated using the Modified Fitzpatrick Wrinkle Scale (MFWS), a validated 7-point rating scale ranging from 0 (no wrinkle) to 3 (deep wrinkle) in different areas of the face (forehead, glabellar, periorbital area, nasolabial fold, perioral area) (Table 1). Clinical efficacy was assessed a week, a month, and six months post treatment by an investigator using the MFWS and ultrasound evaluation. Ultrasound skin examination was carried out on the SkinScanner DUB CUTIS 22 MHz. Clinical photography was done at baseline and at follow-up appointments. All patients were photographed from five sides: full face, right and left side views, right and left three quarter view.

## Statistical analysis

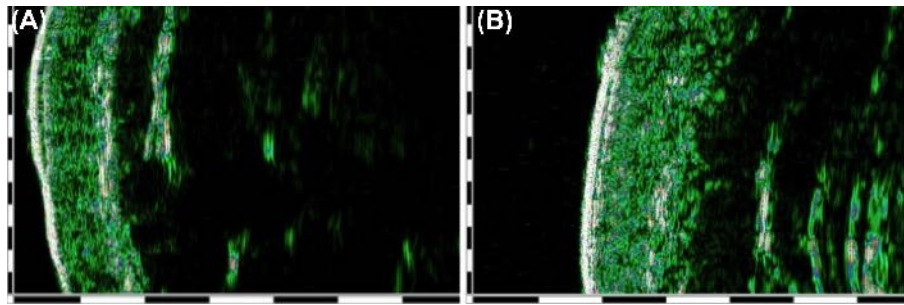
Data were recorded on an IBM SPSS Statistics 22.0 system. Mean ± standard deviation, percentage values were calculated. Calculated p values smaller than 0.05 were accepted as being significant.

## Results

All 100 patients successfully completed the study and experienced improvement of skin structure, decrease of wrinkle depth and lifting of soft tissues immediately after RecoSMA treatment. In the forehead area, decrease in wrinkle depth was 25% after a week, 41% after a month and 53% after six months post treatment (Figure 2). In the glabellar area, wrinkle depth decreased 25% after one week, 35% after a month and 48% six months post

**Table 2.** The comparison of the percentage (%) of decrease in wrinkle depth in different areas of the face between 1 week, 1 month and 6 months after the laser therapy.

Area	1 week	1 month	6 months	P
Forehead	25.02 ± 21.71	40.86 ± 26.14	53.46 ± 25.54	< 0.05
Glabellar	24.53 ± 23.40	34.91 ± 26.34	47.86 ± 20.53	< 0.05
Periorbital	27.22 ± 17.39	38.18 ± 19.41	54.05 ± 13.87	< 0.05
Nasolabial fold	18.01 ± 14.70	24.26 ± 18.45	35.59 ± 20.65	< 0.05
Perioral	44.33 ± 36.92	57.20 ± 37.18	62.38 ± 31.91	< 0.05



**Figure 3.** The results of the ultrasound skin examination before (A) and on 30th days (B) after the laser therapy: increase of dermis thickness and density; increase of SMAS thickness and density.

treatment (Figure 2). Similar decreases in wrinkle depth were noted in the periorbital area (27% a week after treatment, 38% a month after treatment and 54% six months after treatment), and in the nasolabial folds (18% a week after, 24% a month after and 36% six months post treatment) (Figure 2). Rapid skin response was noted in the perioral area where there was a wrinkle decrease of 44% a week, 57% a month and 62% six months after treatment (Figure 2). Statistical analysis revealed that the relative decrease of wrinkle depth a month after RecoSMA treatment was significant in the periorbital and perioral, but not the glabellar and nasolabial fold areas. However the relative decrease of wrinkle depth in all areas of the face remained significant compared to baseline six months after treatment (Table 2). At the 30-day follow-up ultrasound skin examination revealed an increase of dermal thickness and density (25% and 39% respectively), and increase of SMAS thickness and density (29% and 79% respectively) compared to baseline (Figure 3).

Patient satisfaction was also high both in terms of the clinical results and the treatment experience. Some of the notable cases included a 41-year-old female receiving one RecoSMA facial treatment. After one month after treatment there was panfacial improvement in tone, texture and the depth of wrinkles and nasolabial folds were clearly decreased; skin lifting occurred during six months after the treatment (Figure 4). In a 57-year-old female receiving RecoSMA laser treatment, there was

improvement in skin tone and texture, and decrease of wrinkles in the forehead, glabellar, periorbital and nasolabial fold areas was noted one month after the treatment; skin lifting also occurred during six months (Figure 5). In a 62-year-old female there was significant reduction in wrinkles and a lifting effect one month and six months after the treatment (Figure 6).

#### Evaluation of side effects

Overall RecoSMA treatments were very well tolerated. All patients experienced temporary mild-to-moderate erythema post treatment and recovery period lasted from 3 to 7 days. No complications occurred as those often seen with laser treatments such as crusting, infection, blistering, long-standing erythema, hyperpigmentation, or scarring.

#### Discussion

This open-label uncontrolled study was conducted to evaluate the safety and efficacy of RecoSMA treatment using an Er:YAG laser coupled with a SMA module. All 100 patients who were treated demonstrated an 18% decrease in wrinkle depth as early as a week after treatment. Improvements in skin tone and texture continued 6 months after treatment and decrease in



**Figure 4.** A 41-year-old female received RecoSMA facial treatment with the 2936-nm Er:YAG laser system equipped with SMA module. (A) Baseline (B) one month (C) six months after treatment.



**Figure 5.** A 57-year-old female received RecoSMA facial treatment with the 2936-nm Er:YAG laser system equipped with SMA module. (A) Baseline (B) one month (C) six months after treatment.

wrinkle depth was shown to be between 36 and 62%. Facial areas that showed a significant response a month after laser treatment were the forehead, periorbital and perioral areas compared to the glabellar and nasolabial fold areas. At the six-month follow-up all areas of the face showed significant improvement in skin tone, texture and appearance of wrinkles. The variability in treatment response of the different facial areas are likely due to the distinct anatomical features: in the nasolabial and glabellar area there is greater muscle mass, and buccal fat pads that are impacted to a greater degree by gravity. Results derived from investigator scoring of clinical photography were confirmed by ultrasound measurements that demonstrated significant increase of thickness and density in the dermal and SMAS tissue layers. In terms of experience, all subjects were

highly satisfied with the safety and clinical efficacy of the treatment. Recovery period was short and results were noticeable as early as a week post treatment.

In conclusion, the RecoSMA technique is demonstrated to have positive results in panfacial skin rejuvenation without downtime or adverse effects. Since the RecoSMA methodology is not ablative and based on acoustic-interference method of skin rejuvenation using Er:YAG (2936 nm) laser, there is no risk of scars and hyperpigmentation. Further clinical studies are required to evaluate the efficacy of RecoSMA treatment for other indications such as scars and for non-facial sites, but the results shown in this study indicate RecoSMA is a promising new treatment for both clinicians and patients seeking non-invasive solutions to their aesthetic concerns.



**Figure 6.** A 62-year-old female received RecoSMA facial treatment with the 2936-nm Er:YAG laser system equipped with SMA module. (A) Baseline (B) one month (C) six months after treatment.

## Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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