Lasers Med Sci
DOI 10.1007/s10103-016-2010-z

ORIGINAL ARTICLE

A novel method of facial rejuvenation using a 2940-nm erbium:YAG laser with spatially modulated ablation: a pilot study

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Received: 1 October 2015 / Accepted: 24 June 2016

Abstract The objective of this study was to determine the efficacy and safety of a novel method of facial rejuvenation using a 2940-nm erbium:YAG laser with Spatially Modulated Ablation™. A pilot study was performed in 16 women with moderate to severe signs of facial aging relative to chronological age, who underwent two treatment sessions with an Er:YAG laser coupled to the RecoSMA™ technology (Linline, Minsk, Belarus). The whole face was treated in all patients. Clinical efficacy, tolerance, adverse effects, complications, and histological changes due to the treatment were evaluated. Clinical photographs and biopsies were taken before treatment and 3 months after the second treatment session. All patients completed the study and presented no significant complications. Histological changes in the epidermis and dermis as a result of treatment were found. Fine lines, wrinkles, and overall facial aging improved significantly ($p < 0.0001$). The mean reduction of fine lines and wrinkles was 59 % ($r = 40$–75 %). The mean improvement of overall facial aging was 74 % ($r = 55$–90 %). After showing the patients the comparative photographs before and after treatment, 75 % of women stated that they were satisfied or very satisfied and would recommend the treatment. Preliminary results show an excellent safety/efficacy profile for this novel technology, which, based on observed results, can be considered to have advantages over other methods of facial rejuvenation with lasers.

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Keywords Facial rejuvenation · Skin resurfacing · Laser · Spatially modulated ablation

Introduction

The aim of resurfacing with ablative lasers (CO_2 and Er:YAG) is to rejuvenate the skin by causing renewal of the epidermis and stimulation of collagen formation in the dermis. The mechanism of action is by elimination of the epidermis and part of the papillary dermis, thereby generating residual heat that leads to the formation of new collagen, which tightens the skin, removing fine lines and wrinkles and producing a rejuvenation effect [1–4].

The main problem with ablative skin resurfacing is the long recovery period after the intervention, which prevents patients from returning normally to their work and social activities for several weeks. Adverse effects may also be considerable and difficult to treat, particularly cases of prolonged erythema, hyperpigmentation, scarring, and infection [5, 6]. To date, the main alternative for avoiding these unwanted situations was fractional ablative resurfacing [7–10]. The Reconstruction after Spatially Modulated Ablation (RecoSMA™, Linline, Minsk, Belarus) technology was developed as a new potential alternative and is the technology used in this study.

The Spatially Modulated Ablation™ (SMA) technology consists of a sophisticated system of lenses that drill 50-μm holes in the skin using an Er:YAG laser. Tiny microspots of less than a cell in size form a grid of over 10,000-laser impacts/cm^2 on the skin, which are collectively absorbed with absence of apparent lesion to adjacent tissue. According to preclinical trials provided by the manufacturer (not published), the large number of microbeams ablate the epidermis when passing through it, and fibres in the dermis show a

Published online: 01 July 2016

visible increase in the interfibrillar spaces due to the mechanical effect of energy waves pushing the tissue apart, with no histological signs of thermal effect. According to the unpublished clinical experience, the method makes it possible to carry out skin treatments with effective results, few adverse effects, and a short recovery time.

The objective of this study is to evaluate the safety and efficacy of an Er:YAG laser fitted with an SMA module for facial rejuvenation treatments. We report the first clinical and histological results obtained by applying this method for the purpose of skin rejuvenation.

Material and methods

A pilot study was designed to perform a preliminary evaluation of the safety and efficacy of the method for the indication of facial rejuvenation. The trial was predetermined based on our prior experience with this technology for skin rejuvenation.

A heterogeneous group of 16 women, with skin phototypes I–IV, was selected. The inclusion criteria were age between 35 and 70 years, moderate to severe signs of facial aging relative to chronological age, acceptance of the terms and conditions for active participation, and commitment to the follow-up phases of the study. Patients with major organic or psychological conditions, patients receiving oral or topical treatments that might interfere with results, and those who had undergone previous facial procedures of any kind, were excluded.

Two treatment sessions were carried out, with an interval of 3 weeks. The interventions were performed by a single physician, specifically trained to perform the procedure, who did not take part in the evaluation of the results. To evaluate the clinical and histological results, photographs and biopsies were taken before the first treatment session and 3 months after the second treatment session.

Laser device and RecoSMA technology

An Er:YAG ablative laser with a wavelength of 2940 nm (Linline, Minsk, Belarus) was used. The laser beam output window was connected to the module containing the RecoSMA technology. This technology is based on a system of lenses that converts the beam of the Er:YAG laser into thousands of microbeams. The high energy emitted by the laser, in microsecond pulses, interacts with the tissue and modulates spatially, so that the regularized structure of maximum and minimum doses is absorbed at the surface of the tissue and acts on the dermis via the mechanical effect of the resonance waves. Microablation of the epidermis occurs during surface absorption of the laser energy. During transmission to the interior of the dermis, the photoacoustic waves collide with each other thereby causing cell damage and changes to the arrangement of the dermal fibres, which react by means of the corresponding reparative process. The area where the effects take place measures 50 × 50 μm, and the multiple laser beams impact the surface of the epidermis at a distance of 50 μm from each other, with a pulse duration shorter than the thermal relaxation time of the skin. Adjustment of the optimum values for the energy doses (between 3.2 and 4.6 J/cm^2) used in the treatment, together with the length of the laser pulse, achieves a microablation of the layers of skin closest to the surface without exceeding the thickness of the epidermis. Penetration of the laser energy and its action on the dermis is by means of acoustic resonance waves, which cause a mechanical thrust. As the waves move towards the interior of the skin, their power decreases to safe levels that do not affect the viability of the tissue, as no thermal effect is produced. The 10,000 microbeams/cm^2 that interacts on the surface of the skin produces the dense homogeneity of the microareas of ablation of the epidermis and the resonance waves in the dermis. During the multiple impacts of the laser, the mechanical-acoustic effect acts like a series of microexplosions inside the dermis. The multiplication of the resonance effect that occurs when the waves collide with each other causes the mechanical destruction of the intercepted cells, with lysis of the cell membrane. The mechanisms for repairing these microlesions in the dermis lead to the formation of new collagen and regeneration of the tissue.

There are no disposables required for treatment with the device used in this study.

Procedure

Two hours before treatment, a topical anaesthetic containing Lidocaine (Lambdalina, Isdin Laboratories, Barcelona, Spain) was applied using a polyethylene occlusive dressing to the entire face of all patients [11]. Thirty minutes before treatment, patients were administered 5 mg of diazepam and 1 g of paracetamol. No injectable anaesthesia was used. Immediately before the intervention, the face was washed with water and a neutral soap and dried carefully to remove any traces of water or cream. In each treatment session, the laser was passed once over the entire surface of the facial skin. During treatment, the nozzle of the SMA module was placed on the skin surface, and the laser was pulsed at 3 Hz, with a 50 % overlap. A fluence of 3.2 J/cm^2 was used to treat fine lines (wrinkles of grades I and II), and a fluence of 4.6 J/cm^2 was used to treat more aged skins with more pronounced wrinkles (grades III and IV).

Assessment of clinical results

All pretreatment and posttreatment evaluations were carried out based on photographic images viewed on the computer screen. The photographs were taken by the physician performing the treatment, before treatment, and three months after the second treatment session, using the same camera (Canon EOS 400D, Tokina ATX Pro 100 f 2.8 Macro, Sea

& Sea Flash Macro DRF 14, Tokyo, Japan), with the same settings, lighting, and patient positioning.

Two blinded physician investigators, experts on skin resurfacing treatments, viewed the photographs of the faces, out of order, without knowing whether or not they had been treated. Both evaluators were asked to score the severity of (i) fine lines/wrinkles and (ii) overall facial aging on a six-point (0–5) grading scale, where 0 point corresponded to absence of affectation, and 5 points indicated very severe affectation. Scoring of the fine lines/wrinkles took into account the number of lines or wrinkles and their depth (grades I to IV). Scoring of overall facial aging also took into account skin texture, sagging skin, sallowness, and uneven pigmentation.

The same evaluators were then shown the photographs of the faces in order, in pairs showing the faces before and after treatment. They were asked to score the level of improvement of (i) fine lines/wrinkles and (ii) overall facial aging on a scale from 0 to 100 %.

The level of patient satisfaction was measured by the terms very dissatisfied, dissatisfied, somewhat satisfied, satisfied, and very satisfied, after presenting each patient with photographs taken before treatment and 3 months after treatment. Patients were also asked whether they would recommend the treatment.

Assessment of side effects and complications

Any possible complications or side effects were recorded during each treatment session, in the immediate posttreatment stage, and during subsequent follow-up visits. The next day and 3, 7, and 14 days after each session, visual signs on inspection and any discomfort reported by each patient were investigated and recorded in detail in the patient's medical history. The degree of pain was evaluated by means of a questionnaire immediately after each treatment session, using the terms nil, light, moderate, severe, or very severe

Assessment of histological results

Ten of the 16 patients were selected for skin sample biopsies for the pathology study. In these patients, a 2 × 2-cm area of skin was demarcated in the right preauricular region and was treated together with the rest of the face. Biopsies were taken before treatment and 10 min after the end of the first treatment session in four patients. In six patients (three with predominantly grades I and II wrinkles and three with predominantly grades III and IV wrinkles), biopsies were taken before treatment and 3 months after the second treatment session. Samples were obtained under local anaesthetic (Lidocaine 1 % without a vasoconstrictor), using a 1.5-mm punch. The initial and final biopsies were taken inside the demarcated area, with a separation of 1 cm between biopsies. Histological sections of approximately 5 μm in thickness were stained with hematoxylin–eosin (HE/EO) and were examined using a conventional light microscope. An independent expert in dermatopathology viewed the samples in pairs before and after treatment in order to observe potential histological changes.

Statistical analysis

The descriptive statistical data included the arithmetic mean (m), range (r), and standard deviation (SD). In the six-point (0–5) grading scales, the scores obtained before and after treatment were compared using the Mann–Whitney *U* test. The percentage of improvement was calculated as the average of both evaluators.

Results

Clinical results

Fine lines, wrinkles, and overall facial aging improved significantly. The mean (SD) initial severity of the fine lines and wrinkles before treatment was 3.55 (1.24) points, falling to 1.63 (0.89) points 3 months after treatment ($p < 0.0001$). The mean (SD) initial severity of overall facial aging before treatment was 3.87 (1.06) points, falling to 1.78 (0.97) points 3 months after treatment ($p < 0.0001$).

Table 1 shows the improvement percentages established by the evaluators. The mean improvement of fine lines and wrinkles (grades I–IV) in all patients overall was 59 % ($r = 40$–75 %). The mean improvement of overall facial aging (grades I–IV) in all patients overall was 74 % ($r = 55$–90 %).

Figures 1, 2, 3, and 4 show the photographic results of four clinical cases that are representative of the patient sample, showing the disappearance or reduction of fine lines and wrinkles, improvement in skin texture, tightening of loose skin, minimization of sallowness, and reduction of uneven pigmentation.

Of the 16 patients, 2 stated that they were dissatisfied, 2 somewhat satisfied, 5 satisfied, and 7 very satisfied. Thus, after showing the patients the comparative photographs before and after treatment, 75 % of them stated that they were satisfied or very satisfied and would recommend the treatment.

Side effects and complications

All patients completed the study and presented no significant complications. During treatment, most of the patients reported a certain amount of pain, which they mostly rated from mild to moderate, as shown in Table 2. In the hours after treatment, all patients experienced a sensation of heat and burning in several areas of the face.

Table 1 Percentages of improvement in the reduction of fine lines and wrinkles and of overall aging, according to two independent evaluators

Patient	FL/W-1	FL/W-2	Mean	OFA-1	OFA-2	Mean
1	70	50	60	80	70	75
2	60	50	55	80	80	80
3	70	80	75	70	70	70
4	50	70	60	70	80	75
5	80	70	75	80	80	80
6	60	40	50	60	50	55
7	60	40	50	90	90	90
8	70	50	60	80	80	80
9	60	50	55	80	70	75
10	60	70	65	70	60	65
11	60	70	65	80	80	80
12	70	50	60	70	80	75
13	40	60	50	80	70	75
14	50	30	40	80	70	75
15	70	60	65	70	50	60
16	80	60	70	70	80	75

FL/W-1 percentage of improvement in the reduction of fine lines and wrinkles, according to evaluator 1, *FL/W-2* percentage of improvement in the reduction of fine lines and wrinkles, according to evaluator 2, *OFA-1* percentage of improvement in overall facial aging, according to evaluator 1, *OFA-2* percentage of improvement in overall facial aging, according to evaluator 2

After each session, the skin appeared dry and hyperemic. A varying degree of oedema was observed, together with a very fine layer of desiccated epidermal cells that took on a yellowish-beige colour that disappeared between 4 and 6 days. When the fine layer of desiccated cells flakes off, a mild erythema is produced, which can easily be camouflaged using make up; the erythema disappears within 14 days after treatment. No hypopigmentation, hyperpigmentation, or other adverse effects were observed. A tendency towards developing more severe oedema, and erythema was observed in the second treatment session.

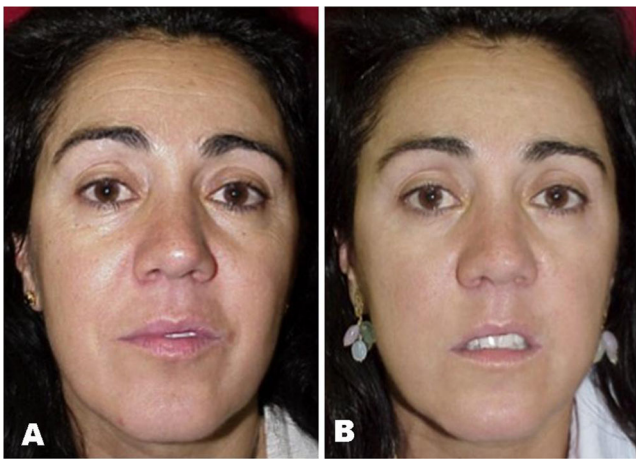

Fig. 1 **a** Female aged 36 years, skin phototypes III and IV, with random display of wrinkles of grades I and II. Observe the wrinkles and lax skin around the eyes and mouth. Skin aspect is dull and lacks luminosity. **b** Three months after the second treatment, lines and wrinkles have disappeared. Tissue laxness is improved, and the skin appears more fresh

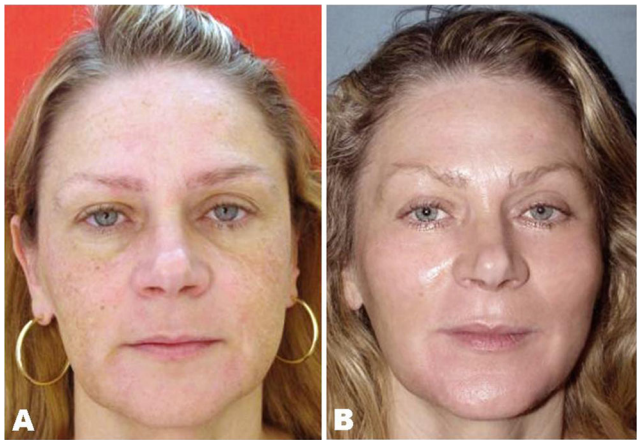

Fig. 2 **a** Female aged 38 years, skin phototype II, presenting fine lines (wrinkles of grades I and II), particularly around the eyes and mouth. Skin is dull and shows signs of sun damage and a lack of luminosity. **b** Three months after the second treatment, the fine lines have attenuated, and the skin appears generally rejuvenated and fresher. Pigmentary epidermal disorder, as a consequence of sun exposure, has disappeared, and the appearance of the skin texture has improved

Histological results

The biopsies taken 10 min after the first treatment session showed partial elimination of the epidermis, and a fine, clearly defined layer of desiccated cells was observed. The dermis showed clear signs of hyalinization, particularly in large areas of the reticular dermis.

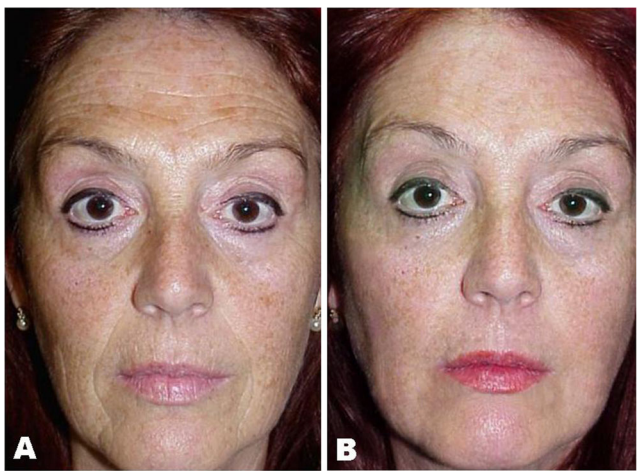

Fig. 3 **a** Female aged 58 years, phototype III, presenting with randomly distributed pigment blotches over the whole face. Visible permanent wrinkles of grade III on the forehead, upper lip, and cheeks. **b** Three months after the second treatment, the entire skin is in a much better condition, looking less flaccid, and most of the pigment has gone. Pigment, which was located deep in the skin, can still be seen. Wrinkles have improved noticeably

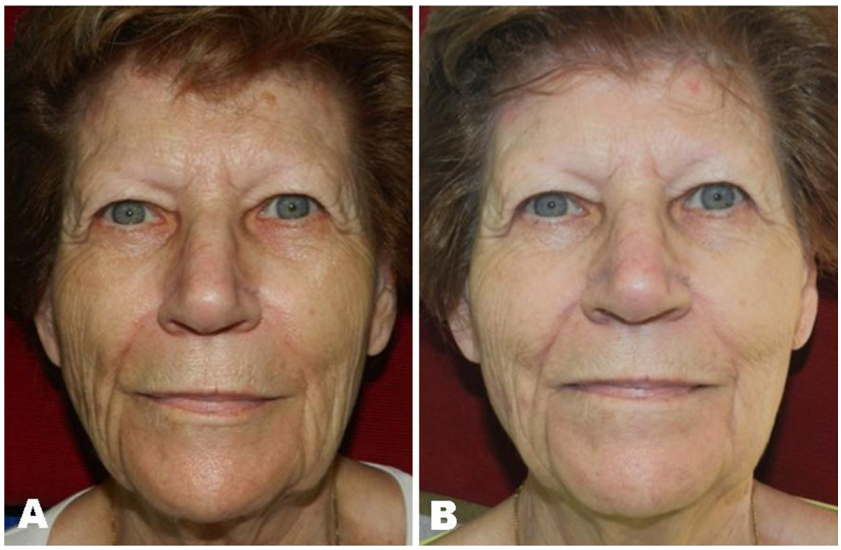

Fig. 4 **a** Female aged 70 years, phototypes II and III, showing multiple wrinkles of grades III and IV and pigment disorder in the entire face. There are multiple signs of ageing with skin laxness, visible folds in the lower third of the face, and redundant skin on upper lids. **b** Three months after the second treatment, the fine lines have attenuated and the skin appears generally rejuvenated and with less pronounced wrinkles and skin laxness. The pigmentary skin disorder has also improved and is now lighter in colour

The biopsies taken 3 months after the second treatment session showed a reduction of the stratum corneum and changes in the thickness of the epidermis, while abundant new collagen fibres in a parallel arrangement were observed below the epidermal–dermal junction. Considerable neovascularization was also observed, with an abundance of dilated microcapillaries, together with an inflammatory infiltrate with polymorphonuclear and basophilic cells.

Figure 5 shows histological images representative of the immediate effects caused by the treatment and of the regenerative changes observed after 3 months.

Discussion

The method used in this study obtained effective facial rejuvenation in all treated subjects, with slight variations in results, which were partly due to the initial differences in the lesions presented by the patients. The histological changes caused by the treatment, verified in the biopsies, are compatible with the mechanisms of action indicated by the manufacturer.

Before starting the trial, we verified that the selection of energy levels has direct consequences for the elimination of wrinkles. A program for pulsed high-energy emission, above the ablation threshold of the Er:YAG laser, produces an effective ablative effect with barely any residual heat in the tissue. Due to the short length of the high-energy laser pulse, part of the keratin and the layers of the epidermis closest to the surface are removed without reaching the dermis. No bleeding or scab formation was observed. The recovery of the epithelium, which follows the elimination of the fine layer of desiccated cells, depends on the energy used, the number of pulses per second, and the number of passes of the laser made during treatment. The good results observed were obtained in a single pass over the entire face at high fluences for pronounced wrinkles (grades III and IV) and at lower fluences, with the same pulse frequency per second for less pronounced wrinkles (grades I and II). Total accumulated energy was 1.28 KJ for wrinkles of grades I and II, and for wrinkles of grades III and IV, the accumulated energy was 1.84 KJ. Thus, the sessions can be repeated without inconvenience every 3 weeks, unlike other treatments with fractional ablative lasers.

Histology immediately after treatment shows no coagulation effects. However, the dermis presents gelification and hyalinization, which can be attributed to the mechanical effect of the resonance waves. Notable changes to the arrangement of the collagen fibres were observed in the reticular dermis; this stimulates the synthesis of new collagen, as shown in the histology at 3 months. The resonance waves, which do not produce a thermal effect, are responsible for the fact that the patient feels no burning sensation during treatment. However, the sensation of heat and burning that appears after each session may be due to the increased blood flow, which increases the temperature in the treated area. More detailed histology studies are required to determine with greater accuracy the effects of the resonance waves on the dermis.

Table 2 Intensity of pain during treatment, reported by the patients in each session

Pain	Nil	Light	Moderate	Severe	Very severe
Session 1	2 (12.5 %)	5 (31.25 %)	8 (50 %)	1 (6.25 %)	0 (0 %)
Session 2	0 (0 %)	4 (25 %)	10 (62.50 %)	2 (12.5 %)	0 (0 %)

Data are shown as number of patients surveyed and percent

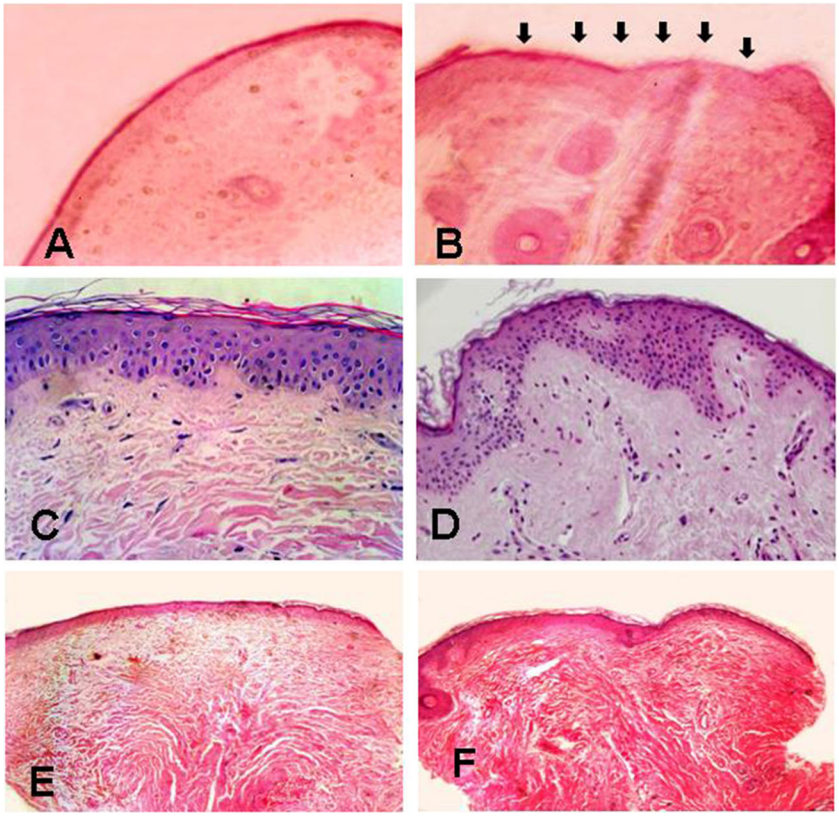

Fig. 5 **a** Skin before treatment (hematoxylin–eosin; magnification ×50). Flat epidermis showing a few layers of cells, covered with a layer of keratin. Lax collagen in the dermis, forming a narrow band of fibres below the epidermal–dermal junction. Signs of elastosis in the reticular dermis and notable interfibrillar spaces. **b** Skin 10 min after treatment with the RecoSMA technology (hematoxylin–eosin; magnification ×50). The epidermis has been partially eliminated (*arrows*). Absence of residual thermal effect and the neighbouring tissue appears normal. Collagen fibres in the dermis appear to be separated as a possible reaction to the pushing force and as a result of oedema caused by the resonance waves produced when the thousands of high-energy laser beams touch the skin surface. Notice the gel-like effect in the dermis, penetrating down to the deep reticular layer. **c** Skin before treatment (hematoxylin–eosin; magnification ×125). Sample corresponds to a patient with wrinkles of grades I and II. The epidermis is well constituted with basket-like keratin and multiple cell layers, presenting papillae at the epidermal–dermal junction. Dermis with parallel collagen fibres below the epidermal–dermal junction. Collagen fibres are separated with notable interfibrillar spaces in the reticular dermis. Few vessels can be observed and signs of mild elastosis can be seen. **d** Skin 3 months after the second treatment (hematoxylin–eosin; magnification ×125). Keratin is scarce, and the epidermis shows rich well compacted collagen fibres and notable papilla formation at the epidermal–dermal junction. **e** Skin before treatment, corresponding to a patient wrinkles of grades III and IV (hematoxylin–eosin; magnification ×30). Thin, flat epidermis with few layers of cells. Little or no keratin present. In the dermis, clear signs of elastosis, with poor collagen and notable interfibrillar spaces. Nodular formation of collagen bundle located in the reticular dermis. **f** Skin 3 months after treatment (hematoxylin–eosin; magnification ×30). The general aspect of the tissue corresponds to a younger skin. Keratin of normal shape and undulating epidermis with multiple cell layers. The dermis is richer in collagen, which is arranged in parallel below the epidermal–dermal junction. Less pronounced spaces between the fibres and the nodular formation of fibres in the reticular dermis appear less compact

The Er:YAG laser used in this study, as is the case with the Fraxel 1550 nm, uses water as chromophore. However, the latter has lower peak absorption by water than the Er:YAG-RecoSMA (2940 nm). Due to the richer water content of the dermis, the 1550-nm wavelength is producing its effects mainly in the dermis, while the 2940-nm wavelength of the Er:YAG is absorbed immediately when it interacts with the epidermis, producing microablation of superficial skin. With the Fraxel 1550-nm laser, however, tissue coagulation is produced without vaporization and the stratum corneum remains intact [12]. Furthermore, the pulses of the 1550-nm Fraxel laser are of 1.5 to 5 ms in comparison with the 250 μs of the Er:YAG laser used in our study. This detail is of essential importance, as pulse length is directly correlated to pain intensity. Because the energy delivered to the skin surface is in the form of 250-μs pulses produced by multiple microablative laser beams, the pain experienced by patients is bearable during treatment.

In conclusion, the RecoSMA technology delivered Er:YAG laser fluences to the skin, which resulted in viable neighbouring tissue due to the absence of thermal effect propagation. Thermal effect for ablation of the skin surface was entirely used for tissue elimination, because the fluences were above the ablation threshold of the Er:YAG laser. Transduction and amplification by resonance of high-energy waves produced microaggressions in the dermis with no

thermal effect. The treatment thus provided good results with less patient downtime, a short recovery period, and excellent prophylaxis of scar tissue formation. The initial results are promising and require further studies to determine the potential advantages or disadvantages of this method in comparison with other conventional fractional treatments with ablative lasers.

Compliance with ethical standards The trial was conducted in accordance with the Declaration of Helsinki and approved by the Antoni de Gimbernat Foundation Ethics Committee. All the patients signed a written informed consent before inclusion in the study.

Conflict of interest The authors declare that they have no conflict of interest.

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