Received: 24 February 2020 | Revised: 11 May 2020 | Accepted: 15 May 2020

DOI: 10.1111/jocd.13510

ORIGINAL CONTRIBUTION

JCD Journal of Cosmetic Dermatology WILEY

Combined microwaves and fractional microablative CO2 laser treatment for postpartum abdominal laxity

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Abstract

Background: Postpartum abdominal changes represent a major esthetic concern affecting women. As the abdomen stretches during pregnancy and some of the muscles lose tone, there is an increased skin laxity and a loss of abdominal elasticity. As a result, the abdomen becomes saggy.

Aims: To evaluate the performance of a combined microwaves and fractional microablative CO2 laser treatment for reshaping and improvement of abdomen texture/laxity and striae distensae in postpartum women.

Patients/Methods: Fifteen women (median age 38 years) received three monthly abdomen treatments with a new microwaves platform, the ONDA Coolwaves® (DEKA) system, followed by a treatment with fractional microablative CO2 laser (SmartXide2; DEKA) a month thereafter. We followed up each patient's weight and nutritional habits. Outcome was assessed using reproducible circumference and abdominal measurements, digital and 3D photography, the laxity score as well as patient satisfaction index.

Results: The overall mean circumferences reduction was 3.6 ± 1.2 cm. Significant improvement in skin laxity and tightening was noted by physicians and patients as well as a reduction of striae distensae. Interestingly, as a result of skin remodeling, repositioning of the umbilicus was also demonstrated. Treatments were well tolerated with no side effects.

Conclusions: Our data showed a sustainable reduction in circumference and improvement in appearance of abdomen in postpartum women, without compromising patients' safety.

KEYWORDS

fractional microablative CO2 laser, microwaves, postpartum, skin laxity, striae distensae

1 | INTRODUCTION

Pregnancy is associated with multiple skin changes, most of which are physiological in nature, being the direct result of expected modifications of the hormonal, vascular, metabolic, or immunologic status.[1,2] As the abdomen stretches during pregnancy and some of the muscles lose tone, there are an increased skin laxity and a loss of abdominal elasticity. As a result, the abdomen appears saggy with localized fat deposits, sometimes with striae distensae.[3-5] The umbilicus may look a little stretched out with an unsightly appearance of a “postage stamp” because of stretching, pigmentary changes and lack of surrounding subcutaneous fat.[2] Many of these alterations regress significantly within the first 6 months postpartum[2] while some of them are persistent, representing a major cosmetic concern with long-term distress for women.

Liposuction and abdominoplasty or brachioplasty have been some of the most popular cosmetic procedures for addressing body contouring and tightening.[6] However, while surgical correction produces the most definitive results, it also requires time for patients and carries inherent risks.[7] Fractional ablative lasers as well as noninvasive devices, such as radiofrequency (RF), high-intensity Focused Ultrasound (HIFU), nonablative Lasers, Infrared (IR), and pressure energy devices, alone or in combination, have also been used to mitigate skin laxity and reduce body circumference, improving the esthetic appearance and self-confidence of patients.[8-10]

In the last years, the demand for esthetic procedures for skin tightening, minimizing downtime and side effects, has increased. Among novel technologies, a new microwaves platform, the ONDA Coolwaves® system (Deka, Florence, Italy), has been developed to treat localized adiposities, edemato-fibro-sclerotic panniculopathy (cellulitis), and skin laxity, with promising results.[11,12] Moreover, a new generation of fractional or microablative CO2 laser (SmartXide^2; DEKA) has proven to be safe and effective not only for facial rejuvenation, but even for body contouring.[13]

In this prospective study, we aimed at evaluating the clinical efficacy and safety of a combined microwaves and fractional microablative CO2 laser treatment for reshaping and improvement of abdomen laxity with or without striae distensae in 15 postpartum women.

2 | MATERIALS AND METHODS

2.1 | Study population

This is a prospective, pilot study conducted in the time-period December 2018-December 2019.

The primary inclusion criteria included abdominal postpartum skin laxity with or without striae distensae. Subjects were required to be at least 18 years of age and at least 12 months postdelivery. Exclusion criteria included: age <18 years; pregnancy or breast feeding (actual or planned); body mass index (BMI) >30; previous surgery (liposuction, abdominoplasty or brachioplasty) in the abdominal area; previous treatment with a laser or other devices in the study area; topical/injective drug application in the abdomen in the last 6 months. Controindications also included present or past history of oncological or systemic diseases, systemic infections and/or immunosuppression, hormone treatments.

The study was conducted in accordance with the Declaration of Helsinki.

Before starting the study, informed consent was obtained from all the participants. Moreover, all the patients gave consent to the use of their photographs for scientific purposes.

Patients were informed to maintain their lifestyle; they were not submitted to any food restriction and were asked to maintain their usual daily activities during the study period.

For each enrolled patient, at first visit, the following data were collected and input into a clinical database: demographic data; anthropometric measurements including BMI, waist circumference (WC), and waist-to-hip ratio (WHR); degree of skin laxity (0-3 scale; 0 = no laxity, 1 = mild, 2 = moderate, 3 = severe); presence/absence of striae distensae; degree of striae distensae (0-3 scale; 0 = no laxity, 1 = mild, 2 = moderate, 3 = severe); medical history; presence of comorbidities; habits (smoking, physical activity).

2.2 | Treatment procedure

After enrollment, each patient underwent a monthly abdominal treatment with the ONDA Coolwaves® system (DEKA, Florence, Italy) for a total of three sessions (three-month treatment) followed by a treatment with fractional microablative CO2 laser (SmartXide^2; DEKA) a month thereafter. Totally, patients underwent four treatments, one month apart. Between the procedures and during the follow-up period, patients were asked to not change their habits and to continue their pretreatment activity.

The ONDA Coolwaves® is a microwaves platform composed by two handpieces, appropriately cooled, directly contacting the cutaneous surface of the body, which provides a calibrated energy transfer by microwaves, avoiding thermal damage of the skin.[11] Standardized parameters, according to sex, treated area, degree of laxity, and fat deposits were used.

The SmartXide^2 consists of a 60 W CO2 laser and a DOT scanning handpiece. The software in the laser allows the scanner to deliver multiple tiny cores of microablative thermal damage (DOT) to the epidermis and dermis.[13] The employed fractional CO2 laser parameters were as follows: power 8 W, dwell time 700 μs, spacing 500 μm, Smart Stack 2, pulse mode: D-pulse (DP). Patients were treated with forced cold air to avoid pain. Immediately after the treatment, cold compresses and 1% hydrocortisone ointment were applied.

2.3 | Objective Assessments

Measurements abdominal circumference was performed at baseline (eg, prior to each treatment), after the final session of treatment, and 8 weeks thereafter. The abdomen was measured at the umbilicus and at the hip, according to the International Guidelines.[14] Subjects were placed in the same standing position, at the same point in the respiratory cycle, for each measurement through the use of a floor mat with a marked footprint. The WHR, the dimensionless ratio of the circumference of the waist to that of the hips, was also calculated.

Objective evaluation involved clinical photography, and three-dimensional (3D) optical skin surface measurement. Digital photographs and 3D imaging with quantitative volume measurements were conducted as objective assessments with LifeViz® digital imaging system (QuantifiCare SA).[15,16] The LifeViz® technology enables quantification of volume, shape, and measurement changes. The circumference measurements (mm) were performed in the same standing position according to an "Alignement Tool." Through a specific software, abdominal volume changes (mL) were also detected. A color map highlighted either positive (warm colors: orange and red) and negative (cold colors: blue) volume variation.

2.4 | Follow-up clinical assessment

Follow-up clinical assessment was performed immediately after the first session, after the final session of treatment, and 8 weeks thereafter. For each patient, a follow-up schedule, including anthropometric measurements, was completed. Any adverse reactions, such as pain, erythema, edema, epidermal burns, adipose tissue atrophy, or contraction, were also recorded.

2.5 | Blood examinations

Specific blood tests (including complete blood count, total cholesterol, LDL cholesterol, triglycerides, creatine kinase, transaminases, and creatinine) were performed immediately before starting the treatment, after the final session of treatment, and 8 weeks thereafter.

2.6 | Subjective Volunteer Assessments

The patient Satisfaction Index was recorded. Patients comfort and satisfaction were evaluated using a fivepoint Likert scale questionnaire, in which the patients were asked to give their degree of satisfaction in terms of skin laxity and tightening based on a 5-point scale ranging from 0 to 4 (0 = worse; 1 = little satisfaction or not satisfied; 2 = fairly satisfied; 3 = satisfied; and 4 = very satisfied).

Questionnaires were given 8 weeks after the final treatment.

2.7 | Statistical analyses

The differences were examined for statistical significance using the Wilcoxon signed rank test. A p value < 0.05 was set as a cutoff for statistical significance. Data are represented as means ± standard deviation (SD).

3 | RESULTS

3.1 | Study population

Study demographics and baseline characteristics of subjects are summarized in Table 1.

A total of 15 women were enrolled. Mean age (± SD) at baseline was 38 ± 4.2 years (range, 32-45 years) and mean BMI was 25.8 ± 1.5 kg/m^2 (range, 23-28 kg/m^2). The study population included 9 (60%) primigravidae and 6 (40%) multigravidae. All pregnancies were completed with natural birth. No patient had undergone cesarean section. Average postdelivery time was 22 ± 8.3 months (range,

12-36 months). At baseline, 60% (n = 9) of the enrolled women did not carry out physical activities while the remaining 40% (n = 6) went walking once a week. They kept their habits for all the study period.

TABLE 1 Demographic and antropometric data at baseline

Patient (n)	Age	Number of pregnancy	Timing (between last pregnancy and treatment)	BMI (kg/m^2)	WC (cm)	Hip (cm)	WHR	Degree of laxity (0-3)	Striae distensae (0-3)
1	36	1	18	23.5	76.4	97	0.8	2	0
2	40	2	14	26	98.5	120	0.8	2	2
3	45	2	36	24	88	114	0.7	2	1
4	35	1	18	28	100	120	0.8	2	0
5	36	2	36	25	95.9	111	0.8	3	1
6	32	1	12	27.5	112	126	0.9	3	3
7	33	1	24	26.2	99	119	0.8	1	0
8	41	1	34	25.5	103.6	128	0.8	1	2
9	39	2	16	27	96	125	0.7	2	1
10	42	1	24	25.4	106.5	130	0.8	2	2
11	44	2	24	26.2	90.6	108	0.8	3	2
12	33	1	14	25.8	104.2	135	0.7	1	3
13	37	1	18	26	102	120	0.8	2	2
14	41	1	20	27.7	95.4	116	0.8	2	2
15	43	2	32	23	99	129	0.7	1	0

Abbreviations: BMI, body mass index; cm, centimeters; Kg, kilograms; m, meters; WC, waist circumference; WHR, waist-to-hip ratio.

TABLE 2 Antropometric data at follow-up 8 weeks after the last treatment

Patient (n)	Age	BMI (kg/m2)	WC (cm)	WHR	Degree of laxity (0-3)	Striae distensae (0-3)	Volume lost (ml)[a]
1	36	23.6	74.8	0.7	0	0	55
2	40	25.9	95.3	0.8	1	1	85
3	45	24	85.9	0.7	1	0	63
4	35	27.8	95	0.8	1	0	88
5	36	25	94.1	0.7	2	0	96
6	32	27.6	108	0.8	2	0	98
7	33	26	95.6	0.8	0	0	108
8	41	25.5	98.8	0.7	0	0	85
9	39	26.9	92.5	0.7	1	0	80
10	42	25.4	102.8	0.8	1	1	84
11	44	26.2	86.7	0.7	2	1	112
12	33	25.4	98.9	0.7	0	1	99
13	37	26	97	0.8	1	1	88
14	41	27.7	93	0.7	1	1	85
15	43	23	95.2	0.7	0	0	96

Abbreviations: BMI, body mass index; cm, centimeters; Kg, kilograms; m, meters; ml, milliliters; WC, waist circumference; WHR, waist-to-hip ratio.
[a]According to LifeViz® digital imaging system (QuantifiCare SA).

3.2 | Anthropometric data

At baseline, mean WC was 97.8 ± 8.4 cm (range, 76.4-112 cm). Mean hip was 119.9 ± 9.8 cm (range, 97-126 cm), while the mean WHR was 0.80 ± 0.06.

Concerning skin laxity, 53.3% (n = 8) of the women showed moderate slight laxity, followed by 26.7% (n = 4) women with slight laxity and 20% (n = 3) women with a severe form.

Striae distensae were present in 73.3% (n = 11) patients. Among them, 27.4% (n = 3) patients had mild striae distensae while 54.5% (n = 6) and 18.1% (n = 2) women presented with a moderate and severe form, respectively.

At follow-up, 8 weeks after the last treatment, all the parameters analyzed were improved ($P < .001$) (Table 2) (Figures 1-2). Mean WC was 94.2 ± 7.7. The average lost WC was 3.6 ± 1.2 cm. Objective data were consistent with LifeViz® measurements.

Overall, there was a great improvement of skin laxity ($P < .001$) (Figures 1-2) with 33.3% (n = 5) women showing no laxity and 46.7% (n = 7) women with mild laxity 8 weeks after the last treatment. Only 20% (n = 3) patients showed a moderate skin laxity. None of the women showed severe skin laxity.

Totally, 4 out of 11 women (36.4%) did not show striae distensae while 6 women (54.5%) showed mild striae distensae and only one patient (9.1%) presented moderate striae distensae.

According to LifeViz® measurements, a median of 88.1 ± 14.9 mL reduction in abdominal volume was also detected (Figure 2D).

Interestingly, the umbilicus got right back to its regular position in 14 out of the 15 enrolled patients, without changing their diet or daily physical activity.

None of the patients presented humbilical hernia or diastasi recti.

Among volunteers, no significant statistical BMI variations were found.

3.3 | Blood examinations

At baseline, total cholesterol was 174.3 ± 15.8 (normal value <200 mg/dL), LDL cholesterol was 108.3 ± 7.7 (normal value < 115 mg/dL), and triglycerides was 115.0 ± 16.4 (normal value < 150 mg/dL). No muscular alterations were detected; in addition, renal and hepatic functionality detection indexes remained stable throughout the whole treatment protocol.

At follow-up, none of the tested patients showed statistically significant changes in blood values, particularly in triglycerides and cholesterol value, neither at 4 weeks after the last session of treatment nor 8 weeks thereafter.

3.4 | Safety and discomfort

An evaluation of overall participant satisfaction after the treatment revealed that 7 out of the 15 participants (46.7%) were very satisfied while 8 (53.3%) patients were satisfied. Patient satisfaction grades almost paralleled levels of clinical improvement.

Overall, the treatment was well tolerated. Patients denied any discomfort during and after the ONDA.

Coolwaves® treatment. No side effects were reported. Concerning the fractional microablative CO_2 laser treatment, the patients described the procedure as mildly uncomfortable. Almost all the subjects experienced transient erythema (93.3%, n = 14) and

FIGURE 1 Abdomen pictures of a 36-y-old female patient before (A-C) and 8 weeks after (B-D) the combined microwaves and fractional microablative CO2 laser treatment

edema (86.7%, n = 13). Other potential adverse events such as bruising, burns, bullae formation, adipose tissue atrophy, contraction, and severe and persistent hyperpigmentation were not observed.

4 | DISCUSSION

The physical changes of pregnancy and childbirth can be dramatic and long-lasting. Many treatments claim to reduce the abdominal fat deposits, tighten the skin, and improve skin texture and striae distensae.[17] The goal of noninvasive tissue tightening is to reverse these changes by rebuilding the collagen and elastic scaffold of the dermis. The common pathway for skin tightening is via the production of heat.[18,19] Indeed, when collagen is denatured by heat, the intramolecular hydrogen bonds rupture and the triple helices "unwind to produce a gel of randomcoil molecules"[20] It has been hypothesized that the long-term skin tightening effects are a consequence of this thermal damage initiating long-term remodeling of the dermis, with new collagen deposition and fibroplasia.[21] The way in which collagen is heated differs for each category of noninvasive skin tightening device. The types of energy that is delivered can be broadly categorized into four groups: RF devices; optical devices such as IR; mechanical (suction, massage) and ultrasound.[10] According to our findings, even microwaves seem to be able to rebuild collagen and elastic fibers in damaged tissue. In a preliminary study on 12 patients with abdominal and trochanteric localized subcutaneous adiposities, the ONDA Coolwaves® system was successfully used with a median abdominal circumference reduction of 3.9 cm after four sessions of treatment.[11] Moreover, in another study on 20 female patients, microwaves have proven to be effective and safe in the treatment of cellulite of the buttocks and posterior thights.[12] Both the studies underlined the improvement in skin laxity.

In the present study, a median WC reduction of 3.6 ± 1.2 cm was also found as well as a reduction of both skin laxity and striae distensae.

The ONDA Coolwaves generates waves at 2.45 GHz which interact with biological molecules and generates localized, controlled heat absorbed by selected biological targets, such as fat, through a biophysical process called "dielectric heating." We hypothesize that microwaves heat directly collagen septa, causing solubilization of the deeper collagen fibers, and activate fibroblasts. As a consequence, the remodeling of collagen fibers leads to an improvement of skin texture. Moreover, microwaves could result in adipocytes a response of functional surcharge in the transporting mechanisms through membranes of the peripheral cytoplasm.[21] As a consequence, the localized dielectric heating could cause the de-arrangement of adipocyte cytoplasm and an irreversible damage to the cell membrane. These processes could activate macrophage, responsible

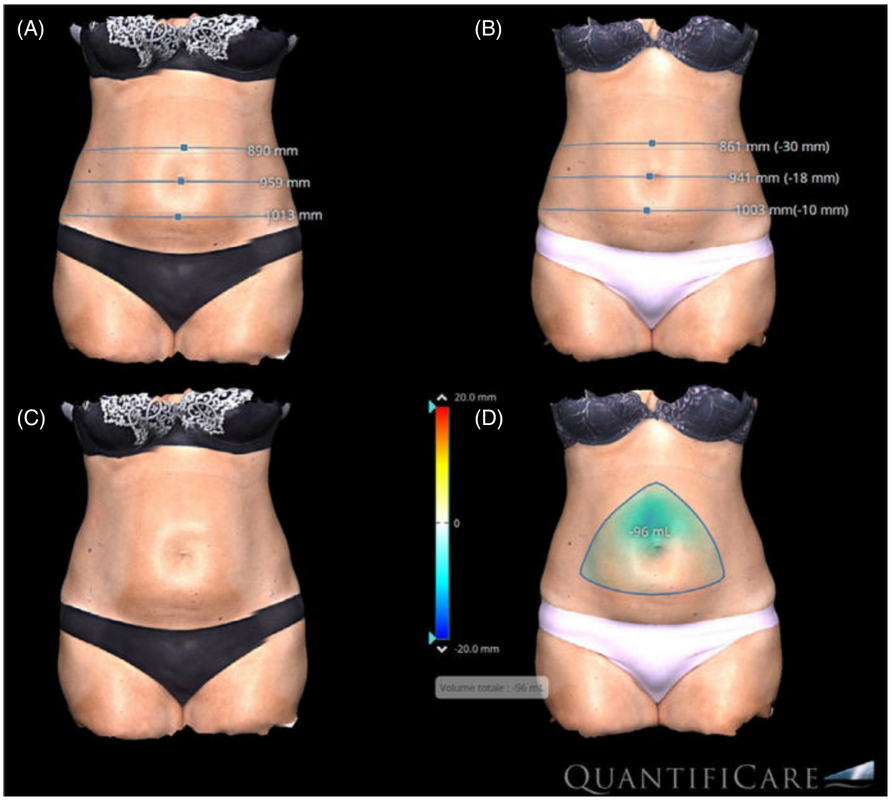

FIGURE 2 Abdomen 3D optical skin surface measurements performed before (A-C) and after (B-D) the combined microwaves and fractional microablative CO2 laser treatment. 3D images were captured with LifeViz® digital imaging system (QuantifiCare SA)

of the removal of adipocytes, thus resulting in reduction of subdermal fatty tissue and reduction in circumference.[12]

In a recent study by Zerbinati et al,[22] authors tried to evaluate the structural modifications of collagen fibers of interlobular septa in vietnamese pigs, after microwaves treatment. Subcutaneous adipose tissue samples stained with Picrosirius red, a dye which not only stains specifically collagen fibers, but also enhances the collagen optical birefringence, demonstrated that compacted collagen fibers constituting fibrotic septa undergo to fragmentation and remodeling, starting few hours following microwaves treatment. Compact fibrotic bundles of collagen I forming interlobular septa appeared reduced or dissolved, in part substituted by the increase of more diffuse and finely reticular collagen III. Remodeling of fibrous collagen was thus confirmed.

In the literature, few studies on postpartum abdominal laxity treatment are nowadays available.

In 2009, Winter et al[23] reported a study on 20 postpartum women who received five weekly abdomen treatments with the VelaShape™ system, a device based on a combination of tissue manipulation, IR and bipolar RF. A mean circumferences reduction of 5.4 ± 0.7 cm was reported. Authors described the procedure as safe and effective in improving skin appearance and circumference of the thighs of postdelivery women.

Brightman et al[6] also reported a clinical trial on 29 patients to evaluate the efficacy and safety of Velashape on additional body sites. Ten subjects underwent four weekly treatments of the abdomen and flanks. A mean abdominal circumference reduction of 1.25 cm at third treatment was demonstrated. Authors described this device as safe and efficacious for the treatment of circumferential reduction and improved skin appearance of the upper arms and abdomen in postpartum patients. Authors suggested that mechanical manipulation could cause vasodilatory effects which enhance lymphatic drainage and improve the microcirculation. Combined IR and RF energies could induce deep tissue heating with collagen contraction, controlled tissue inflammation, and collagen remodeling, thereby inducing skin tightening. Limitations of these studies include lack of extended follow-up evaluations, the lack of proper control groups, and imprecisions of human measurement of circumference.

In the literature, a skin tightening effect was also reported with ablative fractional CO2 resurfacing lasers.[8] These lasers aim to create regularly spaced microscopic columns of thermal and/or ablative damage, leaving intervening areas of normal skin untouched, allowing rapid repair of laser-induced injury photoaging and atrophic skin conditions. The benefits of fully ablative laser procedures, however, come at the expense of prolonged recovery times, with open exudative wounds requiring intensive wound care for up to two weeks, and a risk of infection, transient and long-term pigment changes.[8,24] To reduce side effects and optimize the results, a new generation of fractional or microablative CO2 lasers has been introduced to the marketplace.[10] According to the concept of fractional photothermolysis, these lasers ablate only a fraction of the epidermal and dermal architecture in the treatment area. An array of microscopic thermal wounds is created that ablates the epidermis and dermis within very tiny zones; adjacent to these areas, the epidermis and dermis are spared. The level of dermal penetration varies according to the thickness of the skin and the treatment parameters chosen and ranges from superficial to deep dermal.[10] Compared with ablative fractional CO2 laser, the microablative CO2 laser is more tolerated with fewer side effects. Healing is more rapid compared to fully ablative CO2 laser and downtime is proportionately reduced. In our study, mild transient erythema and edema were reported in almost all the patients immediately after the procedure, with resolution in a few hours, thus reducing recovery time.

The microablative process has proven to be safe and effective even for striae distensae. It seems that the effect of fractional laser in treatment of striae is via collagen increase in extracellular matrix. Fractional photothermolysis stimulates epidermal turnover and dermal collagen remodeling, which leads to significant improvement in several types of scars, including striae distensae.[25,26]

According to the objective assessments reached with combining 3D imaging system and clinical assessments, a significant improvement of both skin laxity and striae distensae was obtained after 4 sessions of ONDA Coolwaves® treatment and one treatment of SmartXide.[2] A median of 88.1 ± 14.9 mL reduction in abdominal volume was also detected. A 3D scanning acquired via stero-visual technology, the LifeViz® digital imaging system (QuantifiCare SA, Valbonne, France), was adopted in order to objectively detect the effects of the combined treatment. Previous studies on leg ulcers and breast cancers showed its utility in clinical practice to compare biometrics parameters and it seems to be a promising tool even to compare treatments in esthetic conditions.[15,16]

To assess the degree of abdominal skin laxity, a *skin laxity score* was used. Based on the present findings, the mean total skin laxity score improved from moderate-to-severe at baseline to mild or absent 8 weeks after the protocol treatment. Concerning striae distensae, the synergistic work of microwaves and microablative fractional CO2 laser determined a great improvement, with only one patient having moderate striae distensae after the combined treatment.

Interestingly, the umbilicus got right back to its regular position in almost all the patients, without the need for surgery. None of the patients had an umbilical hernia but a lower navel position. Since the combined treatment did not act on abdominal muscle but on connective tissue, we hypothesize that, as a consequence of remodeling of collagen and elastic fibers, a contraction of the fibers could have favored the repositioning of the navel in the original area. Moreover, after childbirth, gradual restoration of the abdominal muscles may have contributed to the repositioning of the navel. Furthermore, none of the patients developed diastasi recti (a gap between the left and right side of the rectus abdominis muscle, which covers the front surface of the belly area) which would have required surgery.[27] No complications were reported.

None of our patients showed significant change in blood examinations, valuing the safety of laser procedures. None of the previous studies on postpartum women analyzed these data.

Our patients had no side effects, even the mildest one, making the treatment safe and well tolerated. Moreover, during the monthly intervals between treatments, patients did not reported brusing or other adverse reactions and they continued their daily activities. Thus, almost all the patient declared to be satisfied after the treatment.

Limitations of the present study are the small number of volunteers and the lack of a control group. Therefore, further studies in this area are warranted in a larger number of patients, with longer post-treatment periods and with a control population, in order to confirm our results and to better evaluate variations in treatment parameters.

To conclude, this initial study confirms that the combined ONDA Coolwaves® and SmartXide[2] treatment are safe and effective for the treatment of postpartum skin laxity and striae distensae. Thus, combined treatment could be a promising option for those patients who refuse surgical procedures in the rapidly growing demand for noninvasive esthetic treatment.

ACKNOWLEDGMENTS

Authors would like to thank Federica Coli, skin therapist, for her photographic support.

CONFLICT OF INTEREST

Authors declare no conflict of interest.

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How to cite this article: Bonan P, Verdelli A. Combined microwaves and fractional microablative CO2 laser treatment for postpartum abdominal laxity. *J Cosmet Dermatol*. 2020;00:1–8. https://doi.org/10.1111/jocd.13510