Pregnant pause

We summarise the results of a paper which examines the use of combined microwaves and fractional micro-ablative CO2 laser treatment for post-partum abdominal laxity[1]

The physical changes caused to the body and skin by pregnancy and childbirth can be dramatic and long-lasting for many women. [3-4] As the abdomen stretches and some of the muscles lose tone, there is an increased skin laxity and a loss of abdominal elasticity. As a result, the abdomen appears saggy with localised fat deposits, sometimes with stretch marks.[4-6]

The umbilicus may also look a little stretched out with an unsightly appearance of a "postage stamp" because of stretching, pigmentary changes and lack of surrounding subcutaneous fat.[3] Many of these alterations regress significantly within the first six months post-partum[3] while some of them are persistent, representing a major cosmetic concern with long-term distress for women.

In recent years, the demand for aesthetic procedures for skin tightening, minimising downtime and side effects, has increased. Many treatments claim to reduce the abdominal fat deposits, tighten the skin and improve skin texture and striae distensae.[12]

The common pathway for skin tightening is via the production of heat. Among the novel technologies that have emerged from DEKA/Lynton are a new microwave-based platform – the ONDA Coolwaves system – and a new generation of fractional or micro-ablative CO2 laser – SmartXide2.[7]

A study published in 2020 in the *Journal of Cosmetic Dermatology* evaluated the clinical efficacy and safety of combining these two devices for reshaping and improvement of abdomen laxity in 15 post-partum women.

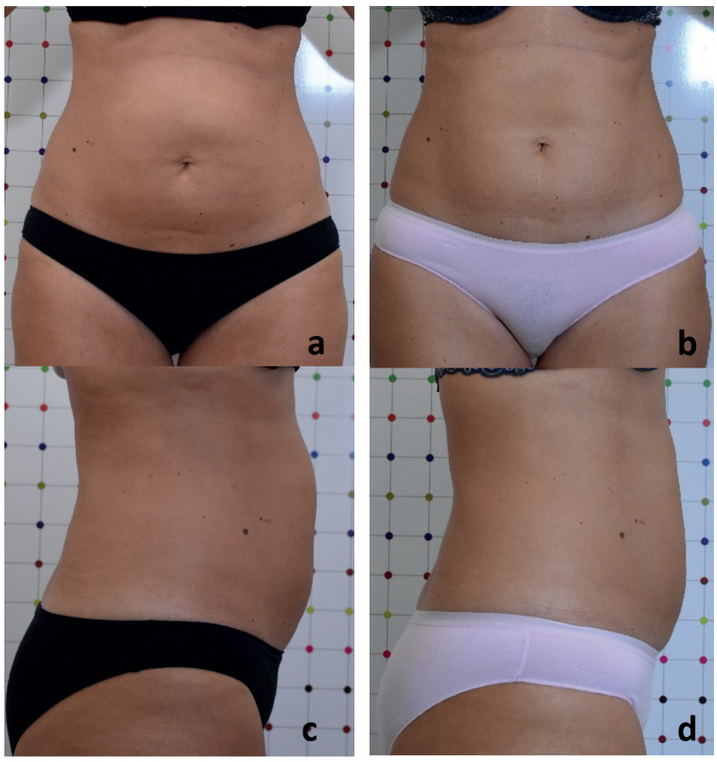
MATERIALS AND METHODS

The primary inclusion criteria for the study was post-partum skin laxity on the abdomen (with or without striae distensae). Subjects were required to be at least 18 years of age and at least 12 months post-delivery.

Women were excluded if they were breast feeding (actual or planned); if their body mass index (BMI) was over 30; if they had had previous surgery such as liposuction, abdominoplasty or brachioplasty in the abdominal area; or if they had had previous treatment with a laser or other devices in the study area.

Patients were asked to maintain their lifestyle. They were not submitted to any food restriction and were asked to maintain their usual daily activities.

Data collected on enrollment included: 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



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laxity, 1 = mild, 2 = moderate, 3 = severe); medical history; presence of comorbidities; habits (smoking, physical activity).

After enrolment, each patient underwent a monthly abdominal treatment with the ONDA Coolwaves system for a total of three sessions followed by a treatment with fractional micro-ablative CO2 laser (SmartXide2) a month later.

Measurements were performed at baseline (e.g. prior to each treatment), after the final session of treatment, and eight weeks after the treatments were complete. The abdomen was measured at the umbilicus and at the hip, according to the International Guidelines.[9]

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 LifeVis digital imaging system.[10,11]

Follow-up clinical assessment was performed immediately after the first session, after the final session of treatment, and eight weeks thereafter. Any adverse reactions, such as pain, erythema, edema, epidermal burns, adipose tissue atrophy or contraction were also recorded.

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

Patient comfort and satisfaction were evaluated using a five-point 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 scale ranging from 0 to 4 (0 = worse; 1 = little satisfaction or not satisfied; 2 = fairly satisfied; 3 = satisfied; and 4 = very satisfied).

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

RESULTS

The mean age of participants in the study was 38 (range 32-45 years) with an average BMI of 25.8 (range, 23-28 kg/m2). No patient had undergone caesarean section.

Average post-delivery 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

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walking once a week.

Overall, there was a great improvement of skin laxity (p<0.001) with 33.3% (n=5) women showing no laxity and 46.7% (n=7) women with mild laxity eight weeks after the last treatment. Only 20% (n=3) patients showed a moderate skin laxity. None of the women showed severe skin laxity.

Four out of 11 women (36.4%) did not show striae distensae while six women (54.5%) showed mild striae distensae. Only one patient presented with moderate striae distensae. According to LifeVis measurements, a median of 88.1 ± 14.9 mL reduction in abdominal volume was also detected.

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.

An evaluation of overall participant satisfaction after the treatment revealed that seven out of the 15 participants (46.7%) were very satisfied while eight (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 micro-ablative CO2 laser treatment, the patients described the procedure as mildly uncomfortable.

Almost all the subjects experienced transient erythema (93.3%, n=14) and 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.

DISCUSSION

The ONDA Coolwaves generates waves at 2.45 GHz which interact with biological molecules and creates localised, controlled heat that is absorbed by selected biological targets, such as fat.

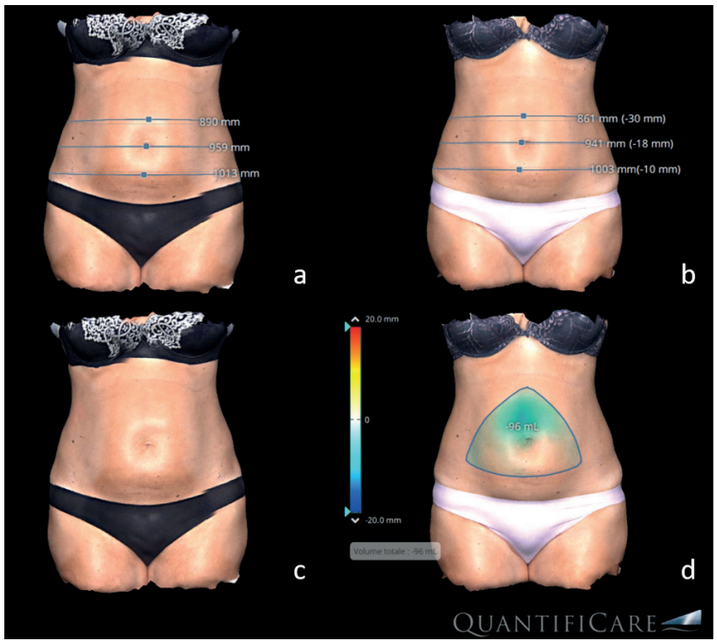
The authors hypothesise that the microwaves directly heat collagen septa, causing solubilisation of the deeper collagen fibres, and activate fibroblasts. As a consequence, the remodeling of collagen fibres lead to an improvement of skin texture. Moreover, microwaves could affect the transporting mechanisms through membranes of the peripheral cytoplasm.[13]

As a consequence, the localised dielectric heating could cause the derangement of adipocyte cytoplasm and irreversible damage to the cell membrane. These processes could activate macrophage activity, which remove the damaged adipocytes, resulting in reduction of subdermal fatty tissue and reduction in circumference.[14]

According to the objective assessments reached in this study by combining the 3D imaging system and clinical assessments, a significant improvement of both skin laxity and striae distensae was obtained after four sessions of ONDA Coolwaves treatment and one treatment of SmartXide2.

A median of 88.1 ± 14.9 mL reduction in abdominal volume was also detected.

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 eight weeks after the protocol treatment. Concerning striae distensae, the synergistic work of microwaves and micro-ablative fractional CO2 laser determined a great improvement,



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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, the authors hypothesise that, as a consequence of remodeling of collagen and elastic fibres, a contraction of the fibres could have favoured 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.

None of the patients showed significant change in blood examinations, valuing the safety of laser procedures. 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 report bruising or other adverse reactions and they continued their daily activities.

Limitations of the study are the small number of volunteers and the lack of a control group. The authors concluded that the combined ONDA Coolwaves and SmartXide2 treatment is safe and effective for the treatment of post-partum skin laxity and striae distensae. They said it offered a "promising option" for those patients who refuse surgical procedures in the rapidly growing demand for non-invasive aesthetic treatment but added that 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 their results and to better evaluate variations in treatment parameters. CM

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