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ORIGINAL CONTRIBUTION

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Reduction of abdominal skin laxity in women postvaginal delivery using the synergistic emission of radiofrequency and targeted pressure energies

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Summary

Objective: This study evaluates clinical efficacy of a novel device which uses combined emission of radiofrequency and targeted pressure energy, for reduction of abdominal skin laxity.

Methods: This was a multicentric, randomized, parallel group-controlled prospective study. Forty-six women 6-36 months after delivery with abdominal skin laxity were randomly assigned to Group A or Group B. Group A received four treatments with BTL UNISON device (BTL Industries Inc, Boston, MA, USA); and, Group B didn't receive any treatments. Skin viscoelasticity was measured using a skin analyzer at baseline and 3 months posttreatments. Standardized digital photographs were evaluated for the severity of skin laxity. Patient comfort and satisfaction were evaluated by standardized questionnaires.

Results: Subjects' weight remained stable. In 95% of treated patients the umbilical circumference decreased (average − 1.43 cm, $P < 0.0001$). The average of skin viscoelasticity changes in individual patients totaled + 37.6%/3.29 Mpa (retraction time − 62.6 ms/−22.5%; suction pressure + 1.21 Mpa/+13.9%) (all $P < 0.0001$). The overall elasticity improved in 90.9% of patients. The control group changes were insignificant. Based on independent photo assessment there was an improvement in the degree of skin laxity in 86% of treated patients. The average laxity score across all treated patients decreased from 1.79 (moderate laxity) at baseline to 1.1 (mild laxity) 3 months posttreatments. Ninety percent of treated patients expressed satisfaction with achieved results. Therapy didn't cause any pain.

Conclusions: We conclude the investigated device can significantly reduce signs of early postpartum laxity in abdominal area. As such, it is a promising alternative to surgical procedures.

KEYWORDS

postpartum, radiofrequency, skin elasticity, skin laxity, targeted pressure energy, viscoelasticity

1 | INTRODUCTION

Pregnancy as well as the actual child delivery result in complex changes to woman's body; loose abdominal skin appears as connective tissue fibers of collagen and elastin stretch.

The demand for noninvasive esthetic procedures for skin tightening increases. Technologies such as Radiofrequency (RF),[1–6] High-intensity Focused Ultrasound (HIFU),[7,8] Laser,[9] Infrared IR),[10] and

pressure energy devices[5] are used to improve the esthetic appearance and self-confidence of patients.

Primary effects of RF heating is the subsequential production of new fibrillar components of connective tissue (collagen and elastin fibers) or their contraction and remodeling which was previously demonstrated in histological examinations.[1,2] In case of RF treatment, thickening of dermal layer can be also observed.[1] These thermal effect-based treatments are used across almost all body areas today.[11–14] Combinations of different modalities are commonly used such as RF with pressure waves.[5] IR energy and/or Vacuum.[2]

Since RF treatment has been used safely both as standalone and in combination with other modalities to treat skin laxity, we sought to determine the clinical efficacy of a novel device which combines emission of RF and targeted pressure energy simultaneously, to treat the abdomen of postdelivery women affected by skin laxity.

2 | METHODS

This was a multicenter, randomized, parallel group-controlled prospective study. Forty-six postdelivery women aged between 21 and 42 years were randomly assigned to Group A or Group B. The primary inclusion criteria included visible abdominal skin laxity, history of a vaginal delivery 6-36 months prior to the time of enrolment, postbreastfeeding, gynecologic examination without complications. Exclusion criteria included any metal implants, pregnancy (current or planned), and/or any other esthetic intervention in abdominal area after the last vaginal delivery. Informed consent was obtained from each patient. Subjects were instructed to maintain their lifestyle and avoid application of any products with risks of changing the appearance of skin.

Subjects in Group A received 4 weekly treatments on the abdomen using the BTL UNISON device (BTL Industries Inc), with each treatment encompassing approximately 12-15 minutes of application. The tissue was heated to surface temperatures of 40-45°C which was verified using the built-in IR thermometer. Initial power setting was set at 60%, but was subject to minor changes later to the treatment depending on individual patient's heat tolerance. After each treatment a Visual Analogue Scale (VAS) form was used to determine patient's comfort level. Subjects in Group B didn't receive any treatment and served as a control group.

Standardized photographs were obtained at the baseline and at 3-month follow-up. Randomized images were evaluated by three clinical specialists for the degree of skin laxity (0-3 scale; 0 = no laxity, 1 = mild, 2 = moderate, 3 = severe). In both Groups, skin elasticity was measured 5 cm below umbilicus (DermaLab skin analyzer, Cortex Technology, Hadsund, Denmark) and waist circumference was measured using a spring-loaded tape. For statistical analysis of obtained results the paired t-test was used at significance level $\alpha = 5\%$. At the follow-up, patients in Group A completed a 5-point Likert scale subjective satisfaction questionnaire. Subject's weight was monitored throughout the study.

3 | RESULTS

Of the 46 patients enrolled, 43 completed the full study protocol (22 in Group A, 21 in Group B). Subjects' weight remained stable (±2 kg of pretreatment weight in all patients except for 3). The average change was found insignificant. See Table 1 for detailed Group A patient data) and Table 2 (for the control group averages).

In over 95% of patients from Group A (n = 21) the umbilical circumference decreased, with a mean loss of 1.43 ± 1.08 cm ($P < 0.0001$). The largest reduction was seen in patient ID14 who lost 4 cm; one subject increased in circumference by 1 cm. In the control group, the change was minor and statistically insignificant (−0.3 ± 1.7 cm; $P > 0.05$).

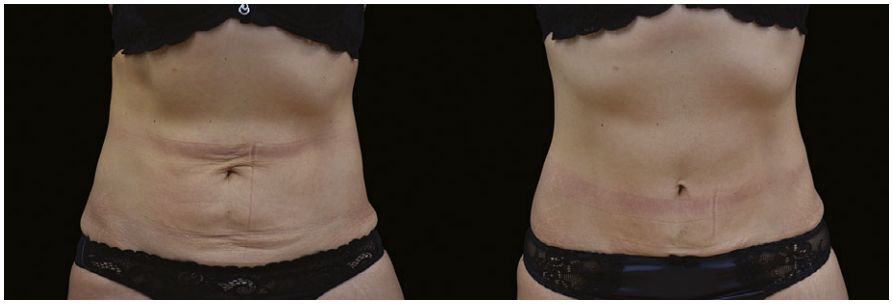

FIGURE 1 Patient images before (left) and 3 months after 4th treatment (right). The patient had severe skin laxity before treatments

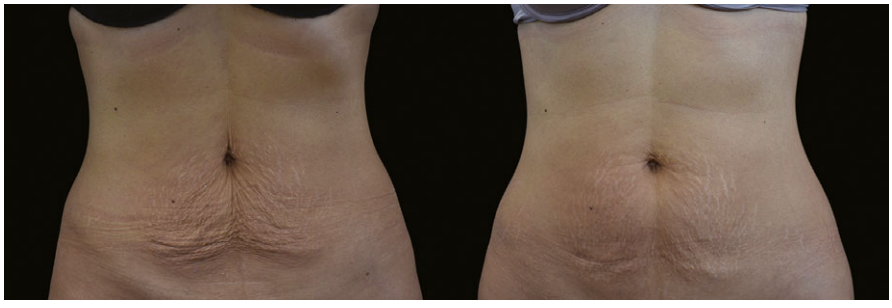

FIGURE 2 Patient images before (left) and 3 months after 4th treatment (right). The patient had severe skin laxity before treatments

TABLE 1 Patient data

		BMI (kg/m)		Waist size (cm)		Skin elasticity (VE/E [Mpa]/Ret[ms])			Average laxity score		
	Age	Before	3 M	Before	3 M	Before	3 M	Change	Before	3 M	Change
ID1	38	26.3	26.3	96.4	95.0	8.4/8.0/276	10.9/9.1/198	2.5/1.1/−78	1.3	1.0	0.3
ID2	28	31.5	30.1	101.7	99.3	11.3/9.1/215	10.9/8.7/203	−0.5/−0.4/−12	1.0	1.3	−0.3
ID3	24	28.7	28.3	100.7	99.8	11.2/10.5/246	14.7/10.7/175	3.5/0.2/−71	1.3	1.0	0.3
ID4	21	21.7	21.7	75.8	75.0	9.6/8.3/209	16.4/9.8/147	6.8/1.5/−62	3.0	1.0	2.0
ID5	41	22.7	22.7	99.8	98.8	9.3/9.7/282	12.9/10.2/203	3.6/0.5/−79	2.3	1.3	1.0
ID6	24	31.2	30.5	115.9	114.0	8.6/6.4/209	7.5/6.0/197	−1.1/−0.4/−12	1.7	1.3	0.3
ID7	39	27.9	27.3	101.7	100.7	7.5/8.8/373	10.7/10.5/273	3.1/1.7/−100	2.0	2.0	0.0
ID8	25	25.2	25.2	104.5	103.0	10.8/8.5/201	17.4/10.4/140	6.7/1.9/−61	2.7	0.3	2.3
ID9	28	22.1	22.1	97.9	97.0	6.1/6.9/278	7.4/7.5/241	1.3/0.6/−37	0.7	0.3	0.3
ID10	42	35.8	35.3	105.5	103.9	11.2/11.3/263	12.4/10.7/209	1.1/−0.5/−54	3.0	2.0	1.0
ID11	38	21.4	21.2	79.0	75.0	7.8/9.2/304	11.0/11.1/220	3.2/1.9/−84	1.7	1.3	0.3
ID12	29	22.3	21.8	89.0	87.5	8.0/7.8/257	13.2/9.5/184	5.2/1.7/−73	2.0	0.3	1.7
ID13	40	27.7	28.0	92.5	92.0	8.9/8.7/267	13.4/10.5/191	4.5/1.8/−76	1.7	1.0	0.7
ID14	35	24.7	25.4	93.0	89.0	7.1/8.6/325	11.1/10.4/225	4.0/1.8/−100	2.0	1.7	0.3
ID15	37	22.7	22.5	82.5	80.5	5.0/7.5/345	7.6/9.1/266	2.7/1.6/−79	0.7	0.3	0.3
ID16	40	19.5	19.4	80.5	79.5	5.5/7.0/342	8.1/8.6/249	2.7/1.6/−93	1.7	1.0	0.7
ID17	30	21.0	20.6	79.0	80.0	11.1/9.7/231	17.6/11.6/164	6.5/1.9/−67	1.7	1.3	0.3
ID18	36	22.1	21.9	83.0	82.5	12.1/10.5/221	20.2/12.5/156	8.1/2.0/−65	2.7	2.0	0.7
ID19	39	26.1	26.0	90.0	88.4	4.7/9.1/485	5.5/9.1/429	0.9/0.0/−56	0.7	0.3	0.3
ID20	33	26.4	26.5	86.0	84.3	10.3/11.5/312	12.2/13.8/275	1.9/2.3/−36	1.0	1.0	0.0
ID21	25	24.8	24.8	97.6	96.8	7.4/7.6/266	8.7/9.3/239	1.4/1.7/−27	2.0	1.0	1.0
ID22	26	25.4	25.5	98.0	96.5	9.8/10.6/284	14.0/12.7/228	4.2/2.1/−56	2.7	2.3	0.3
AVG	32.6	25.3	25.1	93.2	91.7	8.7/8.9/281	12.0/10.1/219	3.3/1.2/−63	1.8	1.1	0.7

In Group A, the average of skin elasticity changes in individual patients totaled + 37.6% or 3.29 Mpa (retraction time – 62.6 ms/ −22.5%; suction pressure + 1.21 Mpa/+13.9%) (all $P < .0001$). The overall viscoelasticity improved in 90.9% (n = 20) of patients; elasticity in 2 patients decreased by 4% and 12%, respectively. The retraction time improved in all patients while the suction pressure increased in 19 of them, remained unchanged in one subject, and decreased in two subjects. The overall deviation in skin analyzer calibration averaged 4.9% and 6.8% for baseline and follow-up measurements, respectively. In the control group, the overall elasticity improved in 11 patients (52%) and deteriorated in 10 patients (48%), with the total change averaging + 4.3% (+0.18 Mpa;−1.95 ms) (calibration deviation 6.0% and 6.1%).

Based on assessment of patients' photographs in Group A, there was an improvement in the degree of skin laxity in 19 (86%) of patients, in two patients (9%) the laxity score remained unchanged, in one patient (5%) the score slightly increased (1.0-1.3). The average laxity score across all patients decreased from 1.91 (moderate laxity) at baseline to 1.1 (mild laxity) 3 months posttreatments. See Figures 1 and 2 for examples of patient photographs.

At the follow-up 90% of treated patients expressed satisfaction with achieved results; the average score totaled 4.32 points on a 1-5 scale. Remaining 10% of patients reported they were neutral (n = 1; 5%) or slightly dissatisfied (n = 1; 5%) with results of the treatments. Therapy didn't cause any pain to the subjects (average VAS score of 1.7 corresponds to very mild to none discomfort).

4 | CONCLUSION

This study presents an initial evaluation of a device which simultaneously emits monopolar RF and targeted pressure energy, when used for abdominal skin tightening.

The data suggest that the application of RF heating and the mechanical component induce changes in the connective and subcutaneous tissues at 3 months posttreatments. This is further supported by results of the control group which didn't show any

TABLE 2 Control group results (n = 21)

	Before	3 M	Change	*T*-Test
Weight (kg)	69.0 ± 11.4	68.6 ± 11.5	−0.3 ± 1.0	$P > 0.05$
BMI (kg/m)	24.2 ± 4.3	24.1 ± 4.3	−0.1 ± 0.4	$P > 0.05$
Wasit size (cm)	89.8 ± 9.1	89.5 ± 9.9	−0.3 ± 1.7	$P > 0.05$
Skin elasticity VE/E (Mpa)/ Ret (ms)	8.3/8.5/ 292	8.6/8.7/ 290	0.4/0.2/−2	$P > 0.05$

significant changes, and in which the results of measurements followed a rather random pattern. In the treated group, both the pressure necessary to pull up the skin and the time needed for the skin to retract to the original position changed; this indicates an overall increase in skin elasticity. Besides other, dermal laxity is generally associated with deterioration in both quality and quantity of elastin and collagen fibers. As such, it's very likely that the change in elasticity is directly driven by stimulation of neocollagenesis and neoelastinogenesis induced by the two applied energies. The loss of circumference was not a primary intended effect, and can potentially be caused either by heat-induced lipolytic reaction or by connective tissue tightening (or by a combination of both).

The clinical improvement observed in patient photographs strongly correlated with the baseline severity of their indication. Patients whose laxity was graded as "severe" at baseline (n = 5) improved on average by 1.33 (from 2.80 to 1.47) whereas patients with "mild" laxity (n = 7) only improved on average by 0.19 (from 0.95 to 0.76). These initial data suggest that patients with severe deterioration of elasticity can most benefit from the treatments. Another conclusion is that before and after photographs are not suitable evaluation methodology for patients with only "mild" laxity; despite their average score improved insignificantly, their abdominal elasticity measured through the suction pressure and retraction time improved in 86% of cases, with the average change of 22% (+0.78 Mpa, −52 ms). No adverse events were reported.

All the results were statistically independent of baseline age, height, and BMI. Weight loss seemed to be negatively influencing skin laxity, as the only three patients with weight loss ≥ 2 kg also showed a decrease in total measured elasticity. Larger cohort study is necessary to confirm or disprove such interpretation. Due to absence of a standardized validated scale for measuring abdominal skin laxity, the results can't be thoroughly compared to previous studies published on other RF-based devices; yet we seem to have observed a higher percentage of patients with visible improvements compared to what authors observed in studies on facial stamping devices.[15,16]

Despite certain limitations and space for further research, we conclude the investigated device can significantly reduce signs of early postpartum laxity in abdominal area. As such, it is a promising alternative to surgical procedures in the rapidly growing demand.

DISCLOSURES

The authors have no commercial interest in BTL and received no compensation for this study. Klaus Fritz, Carmen Salavastru, and Magdalina Gyurova have no relevant conflicts to declare.

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