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ORIGINAL ARTICLE

Concomitant use of radiofrequency and high intensity focused electromagnetic field energies for full-body remodeling: MRI evidence-based prefatory trial

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Abstract

Background: Radiofrequency and HIFEM have been used as standalone modalities in body contouring. The novel device allows their synchronous emission simultaneously in a single applicator.

Objectives: This prelusive trial aims to investigate the safety and efficacy of such treatment when used on multiple body parts on the same day for a full-body remodeling.

Methods: Three female subjects (21.0 ± 2.0 years) underwent 4 treatment sessions. The treatment was applied to the abdomen, saddlebags, inner thighs, and buttocks, during each visit, lasting 30 min for each site. The outcomes were assessed through examination of MRI images acquired at baseline and 3 months post-treatment. Fat and muscle thickness were measured at predefined locations. Weight and waist, hip, and thigh circumference records along with digital photographs were also taken.

Results: Fat thickness measurement showed a reduction of 17.57 ± 3.22 mm in the saddlebag region, 12.43 ± 1.93 mm in inner thighs, and 10.65 ± 1.26 mm in the abdomen. The fat in the buttock region showed negligible changes. The muscle thickness increased on average by 2.98 ± 0.60 mm for rectus abdominis and 7.42 ± 1.56 mm for gluteus maximus. The circumferential reduction was also observed on the waist (7.83 ± 2.25 cm), at the level of outer thighs (2.83 ± 1.53 cm), and inner thighs (3.58 ± 1.84 cm). Digital photographs showed noticeable improvement in the overall body appearance. The treatments were safe, and no side effects were noted.

Conclusion: The preliminary outcomes indicate that the procedure delivering HIFEM and RF simultaneously on multiple body areas on the same day could be an effective and comfortable treatment for fat reduction on multiple body parts, thickening of underlying muscles, and overall improved aesthetic appearance.

KEYWORDS
apoptosis, body contouring, fat reduction, HIFEM, synchronized RF

1 | INTRODUCTION

Nowadays, many people live in a constant hurry and do not have a chance to commit to regular exercise or a demanding diet. To improve their body shape, either by reducing excessive fat or tightening the muscles, they often seek a solution that is not very time-consuming and, at the same time, as effective as the conventional workout. For this reason, there has been a rapid increase in demand for non-invasive aesthetic treatments, and since 2012, the number of performed non-invasive procedures has grown by more than 200%.[1]

There is a wide variety of aesthetic procedures and technologies offering options for treating distinct body areas. However, in terms of reliable body shaping, the high intensity focused electromagnetic field (HIFEM) procedure and radiofrequency (RF) are preferably used to treat excessive adiposity and weakened muscles. HIFEM works through non-invasive electromagnetic stimulation of the striated muscles, representing a very low-frequency range (<10 kHz) that leads to depolarization of neuromuscular tissue thus inducing supramaximal muscle contractions.[2] After several applications, muscles are tightened and thickened due to muscle fiber hypertrophy and hyperplasia.[3–5] Recent studies found that HIFEM is an effective and safe tool for strengthening the abdomen, arms and calves, and buttock lifting[6,7] without significant adverse events.[5,8]

Meanwhile, RF heating is often utilized to reduce the subcutaneous fat layer due to its ability to target adipose tissue selectively, using the frequencies from a range of roughly 20 kHz to 300 GHz.[2] The controlled heating in the range of 42–45°C affects subcutaneous adipocytes by increasing the metabolic rate leading to the breakdown of triglycerides and the induction of lethal damage to adipocytes resulting in controlled cell death termed as apoptosis.[9–11] To allow the simultaneous application of RF synchronized with HIFEM, an entirely new electrode concept was developed. The bipolar, capacitive RF is emitted by the interspaced electrode comprised of 56 segments pairs, creating positive and negative poles (112 segments per applicator in total), to ensure no interference with HIFEM filed.[2]

As shown by recent research,[10,12] concomitant use of HIFEM and RF technologies leads to an overall tightening and reshaping of the treated area. Since both technologies are combined simultaneously, this parallel course provides a considerable body contouring effect. However, the treatment outcomes in previous studies were focused on the examination of a single body part only. Hence, this study investigates the efficacy and safety of such treatment when used on multiple body parts on the same day for full-body remodeling.

2 | MATERIALS AND METHODS

Three female subjects aged 19–23 years with a BMI of 26–35 kg/m^2 participated in this evaluative pilot study. The exclusion criteria included pregnancy, breastfeeding, menstruation, electronic and metal implants, drug pumps, malignant tumor, pulmonary insufficiency, injured muscles, cardiovascular diseases, hemorrhagic conditions, acute inflammations, disturbance of temperature or pain perception, septic conditions, systemic or local infection, contagious skin disease, elevated body temperature, Graves' disease, skin-related autoimmune diseases, poor healing and unhealed wounds in the treatment area(s), and any concomitant medication known to cause bloating or affect weight. The subjects who did not meet any of the exclusion criteria and were willing to undergo the treatment procedure were included.

All subjects underwent four 30 min sessions consecutively applied over the abdomen, inner and outer thighs (saddlebags), and buttocks on the same day, utilizing HIFEM and RF technology (EMSCULPT NEO, BTL Industries). Treatment sessions were scheduled once a week for four consecutive weeks. The ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to. Informed consent was obtained from all participants, and the study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki. Subjects were monitored during the whole study for adverse events, side effects, and deviations from their usual lifestyle (including the diet and sport habits).

The treatments were applied in the following order: Abdomen and inner thighs in the supine position, followed by outer thighs and buttocks in the prone position. Applicators were arranged bilaterally over the treated areas, respecting the anatomy of underlying muscles to obtain intense, homogeneous, and yet comfortable contractions while avoiding the placement of the applicators over bones. The study subjects were requested to move into the half-sitting position with the knees padded by a pillow underneath, and applicators situated close to the groin region for the inner thigh treatments. The initial HIFEM intensity was set according to the patient's tolerance threshold and was further increased during the treatment once the patients got used to the muscle contractions. Most subjects achieved intensities of 80%–100% following the second treatment. The intensity of RF was immediately set to 100% of maximum output power. Based on the treated body area, the skin temperature of 40–43°C was maintained during the therapy with the help of a built-in thermometer. The advanced fat-reducing protocol (desired fat temperature range from 42 to 45°C) was used on the abdomen, thighs, and outer thighs, whereas a gentle protocol that maintains non-apoptotic, low-fat temperatures (below 42°C) was used on the buttocks.[11,13] No anesthesia was required.

The evaluation methods included magnetic resonance imaging (MRI), digital photographs, weight measurements, waist, hip, and thigh circumference. The measurements were planned to repeat at the same part of the day. MRI images were acquired in transverse and sagittal planes at baseline and 3 months post-treatment (3 M FU, ±3 days) and were used to investigate the changes in muscle/fat thickness. Captured body volumes ranged from vertebras T12-S1 for abdomen and iliac crest to the knee joint for buttocks, outer, and inner thighs. Scanning was performed in prone (buttocks, outer thighs) and supine (abdomen, inner thighs) positions, and acquired scans were analyzed in the InVesalius 3.1 software.[14] Fat and muscle thickness on the abdomen was measured approximately 2

inches above and below the umbilicus, and two lateral measurements at the level of center of rectus abdominis were done for each tissue. Also, the width of the abdominal separation (Linea Alba) was evaluated on the same slides, used for the measurements of fat and muscle thickness. Subcutaneous tissue on the outer and inner thighs was assessed at the corresponding level where the fat bulge had the greatest thickness. Buttock was measured at three predefined locations (middle, upper, and lower quarter of m. gluteus maximus) to obtain an average change in fat and gluteus maximus muscle thickness in the treated area. All the 3-month data were compared to baseline and descriptive statistics including the measures of central tendency (mean), and variability (standard deviation) were calculated.

3 | RESULTS

All three study subjects completed scheduled treatment sessions and follow-up visits, including MRI examination. An important finding of this study is documentation of the safety of HIFEM+RF therapies performed consecutively on multiple body parts on the same day. Throughout the whole study course, no adverse event or side effect occurred. Therapy was comfortable since none of the treated subjects asked to interrupt or stop the therapy due to pain, discomfort, or enervation.

The patients did not report any change their lifestyle or dietary intake during the study, yet their BMI decreased by 1 kg/m^2 on average at 3 months follow-up visit. Subjects also showed considerable circumference reduction on abdomen (−7.83 ± 2.25 cm), inner thighs (−3.58 ± 1.84 cm), and at the level of outer thighs (−2.83 ± 1.53 cm) at 3-month follow-up. Digital photographs (see Figures 1 and 2) showed improvement in body contour coinciding with the fat/muscle changes observed in MRI scans (see Figure 3). More specifically, abdominal fat thickness decreased by 28.7% (10.65 ± 1.26 mm) on average, while rectus abdominis thickness increased by 24.3% (2.98 ± 0.6 mm). The adipose tissue in the buttocks was unaffected by the treatments with a negligible increase of 0.3% (0.1 ± 0.4 mm). Nevertheless, the gluteus maximus gained 24.6% (7.42 ± 1.56 mm) of muscle thickness. A substantial fat reduction was observed in the outer thighs (−17.57 ± 3.22 mm) and inner thighs (−12.43 ± 1.93 mm). Finally, the width of rectus abdominis separation was reduced on average by 1.4 mm (18.3%) infraumbilical and 1.9 mm (19.5%) supraumbilical. Since subject 3 did not demonstrate measurable infraumbilical abdominal separation

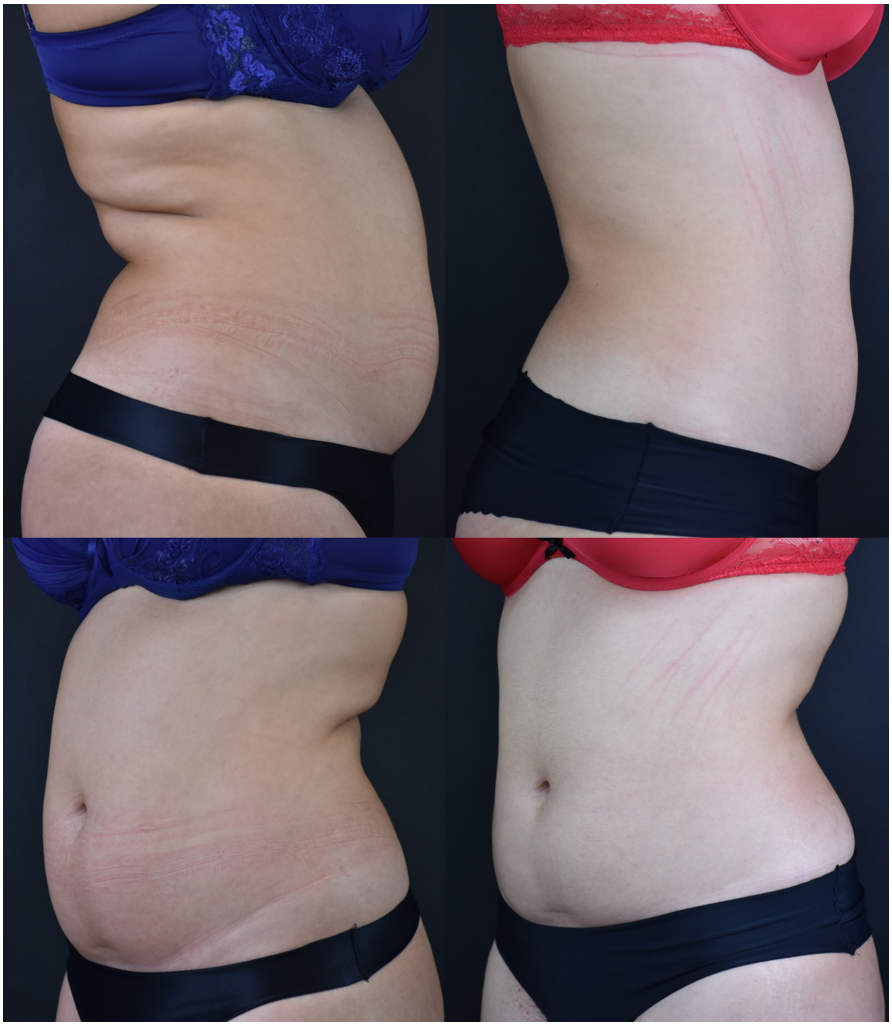

FIGURE 1 Photographs of subject 1 taken at baseline (left) and 3 M FU visit (right). The photographs illustrate gradual progress in the shape of the abdomen

FIGURE 2 Photographs of subject 2 taken at baseline (left) and 3 M FU visit (right). The photographs illustrate gradual progress in the shape of buttocks with noticeable fat reduction on inner thighs

(muscles below the umbilicus held tightly together), the average abdominal separation at this level was calculated based only on subjects 1 and 2. For detailed results, see Table 1.

4 | DISCUSSION

The analysis of the study outcomes suggests that the simultaneous application of HIFEM and RF technology on multiple body parts could be applied on the same day. Observed results do not indicate any signs of discomfort or adverse events on the studies subjects. Each subject responded to the therapy, and substantial changes in subcutaneous fat tissue and muscles were observed in treated body parts.

In all three subjects, the waist circumference decreased over time. MRI imaging (see Figure 3) demonstrated that this decrease was accompanied by a substantial reduction in fat tissue, almost all over the treated body areas, specifically in the outer thighs, inner thighs, and abdomen (Table 1). With a concomitant increase in muscle tissue, the aesthetic appearance of the subjects was enhanced, as seen in Figures 1 and 2. Also, a shortening of the abdominal separation was noted in each subject, although in subject 3 it could be measured only at the supraumbilical level. The magnitude of observed changes was high, matching the recent research findings. This may be attributed to the synergy of HIFEM with synchronized RF, since this unique combination results in the increased levels of permanent adipocyte deletion through inducing its apoptosis while on the other hand, it also positively affects the muscle tissue by the substantial activation of myosatellite cells.[10,11,15] The intense heating and muscle load also may lead to the hydrolysis of triglycerides (ie lipolysis), releasing the free fatty acids (FFA) stored in the adipocytes, which possibly even promotes the effect of the combined treatment on fat reduction.[11] As shown by Weiss and Bernardy, the induced intense muscle activity is initially accompanied by the increased levels of FFA's that are further metabolized as an energy supply with no anticipated change in liver or kidney metabolism.[16]

Furthermore, similar to findings documented in previous studies investigating the effect of HIFEM technology on buttocks,[6,7,17] the increase in gluteal muscle mass was observed in this study. On the other hand, no meaningful changes were observed in the fat tissue

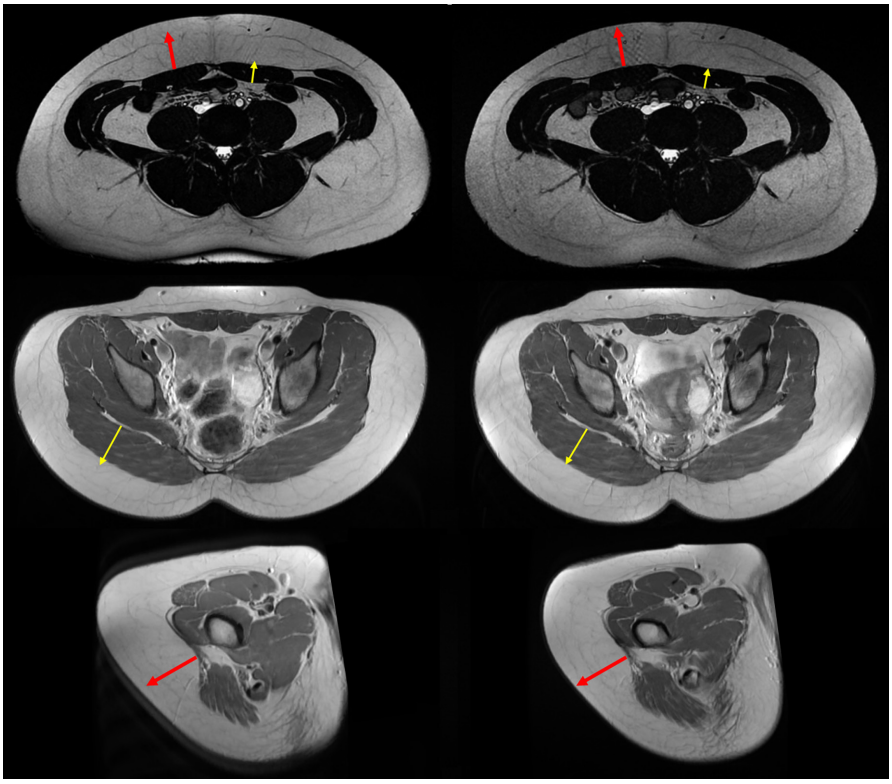

FIGURE 3 MRI images of abdomen (up), buttocks (middle), and outer thighs (down). Baseline images are sorted on the left and 3 M FU images on the right side. The changes in fat thickness (red arrow) and muscle thickness (yellow arrow) are visualized, the arrows correspond to the 3 M FU measurements and are duplicated in the baseline MRI's

TABLE 1 Detailed summary of the MRI measurements

	Subject 1			Subject 2			Subject 3		
	Before [mm]	3 M FU [mm]	Diff [mm]	Before [mm]	3 M FU [mm]	Diff [mm]	Before [mm]	3 M FU [mm]	Diff [mm]
Fat									
Abdomen (infraumbilical)	44.7	31.6	**−13.1**	37.5	27.4	**−10.1**	37.0	26.8	**−10.2**
Abdomen (supraumbilical)	38.2	27.1	**−11.1**	30.3	20.6	**−9.7**	36.1	26.3	**−9.8**
Inner thighs	56.0	41.6	**−14.4**	50.9	38.4	**−12.5**	45.6	35.1	**−10.5**
Outer thighs	74.0	54.3	**−19.7**	68.9	49.7	**−19.2**	49.3	35.4	**−13.9**
Buttocks	34.1	34.6	**+0.5**	36.0	36.0	**0.0**	30.2	30.0	**−0.2**
Muscles									
Abdomen (infraumbilical)	13.8	17.2	**+3.4**	12.3	15.2	**+2.9**	12.6	15.7	**+3.1**
Abdomen (supraumbilical)	14.5	18.3	**+3.8**	10.0	12.4	**+2.4**	10.1	12.3	**+2.2**
Buttocks	31.8	40.1	**+8.3**	25.3	31.7	**+6.4**	33.6	41.1	**+7.5**
Separation									
Abdomen (infraumbilical)	10.3	8.6	**−1.7**	5.8	4.6	**−1.2**	N/A	N/A	N/A
Abdomen (supraumbilical)	8.0	6.3	**−1.7**	10.6	8.3	**−2.3**	10.3	8.6	**−1.7**

Note: Averaged values for each study subject. Bold values indicates significant differences.

on the buttocks since a Gentle protocol was used on the buttocks, which does not heat the adipose tissue to therapeutic temperatures required for adipocyte elimination.[13] Corresponding results were also observed by Palm et al.,[17] who found virtually no changes in adipose tissue on the buttocks after a series of HIFEM treatments, which was attributed to differences in fat metabolism on buttocks. In a study by Palm et al.,[17] gluteus maximus muscle showed an increase in volume by 13.33% following HIFEM treatments. In

comparison, this study revealed a higher degree of increased thickness in the gluteus maximus muscle by +24.6% on average. Although different methods were utilized to assess muscle growth, it may be assumed that volumetric and thickness changes correspond to a certain degree.[18]

One of the outstanding limitations of the present prelusive trial is the subject population, as the study included only three cases, which does not allow for meaningful statistical testing. Nonetheless, the goal was to investigate the feasibility, comfort, and safety of such an approach treating multiple body parts on the same day. The results indicate that such an approach could be effective and viable. However, it is to be noted that future research on a large patient group confirming the safety of multiple body part treatment on the same day is needed to draw any strong conclusion. This work may serve as a basis and source of inspiration for future authors, since researching the concept of multiple consecutive treatments using HIFEM+RF modalities. In the future studies, it would be required to include subjects with a broad range of BMI to observe the consistency in fat tissue decrease and muscle increase in subjects with a different body constitution. It would also be interesting to review the changes in the lipid panel of such patient groups to investigate in detail the nature of events induced by targeting fat tissue on multiple body areas on the same day.

5 | CONCLUSION

The concomitant use of HIFEM and RF technologies has shown to be a safe and effective therapy course for various body parts in the past. Based on the documented findings, this preliminary trial demonstrated that treating multiple body areas on the same day was safe and comfortable for the subjects, and has led to the measurable changes in fat and/or muscle tissues in the treated areas. Total body remodeling resulting from the treatment of multiple body parts gives a promising possibility for subjects who seek solutions to address their body dissatisfaction and improve aesthetic appearance in distinct areas at the same time. Further research on large study groups is needed to confirm the safety and consistency of the treatment effect of consecutive HIFEM+RF application.

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None.

CONFLICT OF INTEREST

B. Katz is a medical advisor for BTL Industries, Inc.

ETHICAL APPROVAL

The authors confirm that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to and the appropriate ethical review committee approval has been received. The US National Research Council's guidelines for the Care and Use of Laboratory Animals were followed.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available upon reasonable request.

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