Spot Reduction of Localized Fat Deposits on the Lateral Thighs by Simultaneous Emission of Synchronized Radiofrequency and High-Intensity Focused Electromagnetic Energy: Magnetic Resonance Multicenter Study

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BACKGROUND Unwanted lateral fat most prominently affects the female population and may cause self-esteem issues.

OBJECTIVE To investigate the effectiveness and safety of synchronized high-intensity focused electromagnetic (HIFEM) + radiofrequency (RF) for the treatment of lateral thigh adipose tissue.

MATERIALS AND METHODS Ninety-three subjects (21–70 year old) received 4, 30-minute HIFEM + RF treatments of the lateral thighs. Magnetic resonance imaging (MRI) of the treated area was obtained at baseline, 1, 3, and 6 months post-treatment to document the changes in fat layer thickness. Furthermore, digital photographs, circumference measurements of the lateral thighs, subjects' satisfaction questionnaires, and therapy safety and comfort were documented.

RESULTS Magnetic resonance imaging revealed a significant reduction of fat tissue in the saddlebag region peaking at 3 months (−18 ± 5.5 mm; $N = 51$). The thigh circumference measured at 3 predefined levels decreased on average by 2.3 cm, with the greatest change at the level of 10 cm below the infragluteal fold (−3.5 cm, 3-month follow-up). Results were maintained at 6 months. No adverse events were recorded. The therapy was found comfortable with a high satisfaction rate.

CONCLUSION High-intensity focused electromagnetic + RF treatment to the lateral thigh area demonstrated effectiveness in long-term fat thickness reduction by MRI imaging. Secondary endpoint showed simultaneous effectiveness and safety.

In women, lateral thigh fat adiposity, referred to as saddlebags, is a common and problematic area where excessive fat is stored.[1] Exogenous factors and female genetic predisposition toward gynoid fat deposition including the lateral thigh can lead to ill-fitting clothing, self-esteem issues, and exploration of treatment options to increase body confidence.[2] In addition, apart from the dissatisfactory body contour, lateral thigh fat accumulation may contribute to structural alterations in the dermis resulting in the formation or accentuation of skin irregularities such as cellulite.[3]

It has been previously demonstrated that adipocyte viability can be safely reduced by delivering the heat above the physiological temperature (~43°C) to the subcutaneous tissue, which is required to initiate fat apoptosis.[4] Therefore, radiofrequency (RF) is often used for heating the subcutaneous fat layer above the average body temperature because of its ability to effectively target adipose tissue. In addition, certain frequencies of the RF spectrum allow for selective heating of subcutaneous fat, subsequently forcing the adipocytes to enter a programmed death sequence termed apoptosis.[5–7]

Furthermore, the effect of RF heating is more pronounced when coupled with the muscle contouring high-intensity focused electromagnetic (HIFEM) field procedure. The simultaneous use of HIFEM + RF reduced fat thickness in the abdominal area by 30.8%.[8,9] As shown by recent studies,[9–12] simultaneous HIFEM and synchronized RF therapy is highly effective for fat elimination on the abdomen, causing overall tightening and reshaping of the treated area. However, there have been no published data to date regarding the effect of HIFEM + RF on the lateral thighs region, although evidence suggests it holds promise as a treatment modality for regions of unwanted, localized adiposity.[7,9] Therefore, this study investigates the efficacy and safety of HIFEM field procedure simultaneously combined with RF energy for the treatment of lateral thigh fat deposits.

Materials and Methods

Study Design

This was a multicenter, open-label, single-arm, prospective study with up to 6 months follow-up conducted at 3 U.S.

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clinical sites. The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki and was conducted in compliance with good clinical practice. Informed consent was obtained before subject inclusion and treatment. Internal Review Board (IRB) approval was obtained by Advarra IRB (Columbia, MD).

Subjects

Eligible subjects were healthy female patients ≥21 years old with a body mass index (BMI) below 35 kg/m^2 seeking improvement in the appearance of the lateral thigh region. The study design required subjects to undergo a total of 4 weekly HIFEM + RF procedures to the lateral thigh region and several follow-up appointments. Subjects needed to possess the ability to undergo several magnetic resonance imagings (MRIs) of the treated region, complete patient questionnaires after treatment, and maintain regular (pre-procedure) diet and exercise habits.

Major exclusion criteria for participation in the study included pregnancy, cardiac pacemakers, implanted electronic devices, metal implants, heart disorders, and any medical conditions contraindicating the use of the HIFEM and RF fields. Those with pulmonary insufficiency, malignant tumors, or impaired or injured muscles were also excluded from participation.

Treatment

All study participants received 4 HIFEM + RF treatments in total, once a week for 4 weeks. Thirty-minute bilateral treatments of lateral thighs were delivered using the EMSCULPT NEO (BTL Industries Inc., Boston, MA) device using simultaneous emission of HIFEM + RF fields. The device applicators were positioned over the saddlebag area and remained fixed during treatment. The treatments were applied in a prone or supine position, based on subject preference. The initial HIFEM intensity was set according to the patient's tolerance threshold. Over a single treatment, most subjects reached 80% to 100% intensity and maintained this level during following treatment sessions. The intensity of RF was immediately set to 100% of maximum output power. With respect to the temperature increase caused by the RF component, the skin temperature was monitored and maintained through a built-in thermometer. No anesthesia was administered during treatment.

Efficacy and Safety Measurements

Magnetic resonance imaging was used as an objective efficacy measurement to examine changes in the thickness of subcutaneous fat tissue at the level of lateral thigh bulge. T2-weighted fast spin-echo scans in axial and frontal planes were acquired from the iliac crest to the midpoint of the femur using a 1.5 T MRI machine, with subjects lying in the prone position. Magnetic resonance imagings were performed at baseline and each follow-up visit. In addition, body weight, lateral thigh circumference, digital photographs, and a 5-point Likert scale subject satisfaction questionnaire were collected. The lateral thigh circumference was taken at the level of the infragluteal fold, 5 and 10 cm inferior to this point. Circumference, weight recordings, and digital photographs were gathered at baseline, after the last treatment, and at all follow-ups. The subject satisfaction questionnaire was completed at the last therapy session and at corresponding follow-up visits.

Safety measures consisted of adverse event monitoring and reporting (following each treatment session and follow-up visits), a 5-point Likert scale therapy comfort questionnaire (1 - strongly disagree, 5 - strongly agree), and a 10-point Visual Analogue Pain Scale (VAS) questionnaire completed after each treatment.

Sample Size and Statistical Analyses

Although sample size calculations were not performed before study initiation, the study planned to enroll 40 subjects to allow for appropriate statistical power. Given study enrollment periods during the novel coronavirus SARS-CoV2 (COVID-19) pandemic, total subject number was increased to account for expected patient discontinuation during this extraordinary time period.

When applicable, the change in measured outcomes was tested for statistical significance. A 2-tailed parametric Student *t*-test for paired variables was used to determine the presence of the significant shift in the measured parameter. In addition, a Pearson coefficient was calculated to identify any correlation in obtained data. The significance level for statistical analyses was set to $\alpha = 0.05$.

Results

Subjects

A total of 93 female subjects with a mean BMI of 25.6 ± 3.4 kg/m^2 (19.0–34.5 kg/m^2), and mean age of 44.8 ± 11.4 years (21–70) were enrolled. All Fitzpatrick skin phototypes were represented in the study subject population; skin types I/II comprised 40.4%, III/IV (44.7%), and V/VI (3.5%). Seventy-seven subjects completed the treatment sessions and immediate evaluation after the last visit. The enrollment period, from November 2019 to November 2020, coincided with the COVID-19 global pandemic. Twenty-seven patients were withdrawn in the course of the study for reasons such as withdrawal by the investigator $N = 10$ (because of various reasons such as subject lost to follow-up, treatments or follow-up visits not completed, patient met 1 of the exclusion criteria) or withdrawal of consent by the subjects $N = 17$ (because of various reasons such as COVID-19, scheduling conflicts, and subject moved out of state).

Effectiveness

Evaluation of MRI measurements showed a significant ($p <$ .001) reduction of the subcutaneous fat thickness on the lateral thighs, which coincided with a measurable decrease of thigh circumference.

In total, MRI's of 71 subjects were analyzed throughout the study. The average baseline thickness of the subcutaneous fat layer averaged 60.9 ± 15.4 mm. This was

TABLE 1. Detailed Summary of Fat Reduction Evaluated in MRI Slices (Average ± SD)

Subject Count	Fat Thickness Measurement (mm)				Difference	
	Baseline	1 mo	3 mo	6 mo	mm	%
N = 60	60.1 ± 15.1	46.6 ± 12.0	—	—	13.5 ± 4.4*	22.4 ± 4.7
N = 51	61.4 ± 16.3	—	43.5 ± 13.1	—	18.0 ± 5.5*	29.9 ± 6.8
N = 54	63.1 ± 14.7	—	—	45.4 ± 11.7	17.7 ± 4.9*	28.4 ± 5.7

* Significant results with a *p*-value < .001. Given the multiple tests, the significance level was adjusted to α/3.
MRI, magnetic resonance imaging

reduced by 13.5 mm (22.4%) at 1 month, by 18.0 mm (29.9%) at 3 months, and by 17.7 mm (28.4%) at 6 months post-treatment. Two subjects showed only mild improvement of approximately 3.1% to 4.5% and were considered nonresponders. Examination of the subjects who responded to the treatments showed more pronounced results with each subsequent visit window. Subjects achieved a mean reduction of 13.8 mm (23.0%) in fat thickness at 1 month, 18.6 mm (30.9%) at 3 months, and 18.3 mm (29.4%) at 6 months. Detailed MRI findings can be found in Table 1.

Magnetic resonance imaging measurements of fat reduction were fairly consistent, peaking at 3 months. Fat reduction at 3 months in the respondent group ranged from −11.2 mm (22.0%) to −33.5 mm (40.9%). Almost 94% of subjects exceeded the level of 25% fat reduction. Interestingly, despite the slight but insignificant decline in the magnitude of observed outcome, even higher consistency was found at 6 months, where 98% of subjects exceeded the level of 25% fat reduction.

Mean thigh circumference reduction immediately after the fourth HIFEM + RF treatment was 1.6 cm (*N* = 57). Further improvement was observed at each of the follow-up visits (Table 2). The most pronounced and significant thigh circumference reduction was observed at the level of 10 cm below the infragluteal fold. A 2.2 ± 3.5-cm mean reduction was measured at 1 month (*N* = 35), 3.5 ± 6.9 cm at 3 months (*N* = 43), and 3.2 ± 5.4 cm at the optional 6-month (*N* = 41) follow-up visit. For the remaining 2 measurement levels (0 and 5 cm below the gluteal fold), the thigh circumference reduction ranged throughout the study duration from 1.2 to 3.3 cm. Twenty patients were excluded from the evaluation of thigh reduction measurements because of the systematic measurement error.

Both nonresponders, indicated by MRI analysis, reported substantial changes in their lifestyle related to the COVID-19 pandemic, leading to a decline in physical activity and fluctuations in their weight. However, there was no relevant change in the group's average weight (155.1

TABLE 2. Detailed Summary of Thigh Circumference (Average ± SD)

Measured Level	Subject Count	Circumference (cm)					Difference (cm)
		Baseline	After Tx	1 mo	3 mo	6 mo	
0 cm	*N* = 57	103.0 ± 9.2	101.8 ± 8.9	—	—	—	1.2 ± 3.2
5 cm		98.4 ± 10.3	96.8 ± 9.8	—	—	—	1.6 ± 4.5†
10 cm		92.3 ± 10.7	90.3 ± 9.5	—	—	—	2.0 ± 5.2†
0 cm	*N* = 36	102.3 ± 9.5	—	100.6 ± 9.4	—	—	1.6 ± 4.5†
5 cm		97.0 ± 10.4	—	95.0 ± 10.9	—	—	2.0 ± 4.2†
10 cm		90.7 ± 10.1	—	88.5 ± 10.2	—	—	2.2 ± 3.5*
0 cm	*N* = 43	103.5 ± 9.6	—	—	102.3 ± 9.5	—	1.2 ± 4.3
5 cm		98.6 ± 11.2	—	—	96.3 ± 10.5	—	2.3 ± 5.4†
10 cm		92.1 ± 11.6	—	—	88.6 ± 10.0	—	3.5 ± 6.9†
0 cm	*N* = 41	103.6 ± 9.3	—	—	—	101.1 ± 9.3	2.5 ± 4.4*
5 cm		99.0 ± 10.8	—	—	—	95.7 ± 10.9	3.3 ± 4.6*
10 cm		92.6 ± 11.2	—	—	—	89.4 ± 10.6	3.2 ± 5.4*

* Significant results with a *p*-value < .001.
† Significant results with a *p*-value < .01. Given the multiple tests, the significance level was adjusted to α/3.

Figure 1. A 40-year-old woman with a BMI of 24.6 kg/m^2; comparison photos taken at baseline (left), 3-month follow-up (middle; −21.2 mm), and 6-month follow-up (right; −20.9 mm). BMI, body mass index

± 22.4 lbs pretreatment and 155.2 ± 25.0 lbs at 6-month follow-up) or BMI, because it remained stable throughout the study. There was also no correlation between weight fluctuation and change in fat thickness or thigh circumference. Nonetheless, the subjects with higher BMI tend to have thicker fat deposits on the lateral thigh $r(69) = 0.60$, $p < .001$ at baseline. However, there was no clear relationship between the subject's constitution and relative change in fat thickness $r(49)$ = -0.18, $p = .22$; meaning that improvement in percentage was not correlated with subject's BMI.

Safety and Subject Satisfaction

No adverse events were documented during the treatment sessions or the follow-ups. Study participants reported the treatments as comfortable and showed high satisfaction scores, peaking after the fourth treatment and at the 3-month follow-up visit.

Results from the HIFEM + RF therapy comfort questionnaire showed that patients found the treatments highly comfortable, with the average score totaling 4.2 ± 0.8 points (1 = strongly disagree, 5 = strongly agree). According to the VAS score, most subjects (91.0%) felt no discomfort during treatment.

The analysis of the satisfaction questionnaire revealed that after completion of the fourth therapy, no subject was dissatisfied with the treatment results. Compiled patient satisfaction results showed a peak immediately after the last therapy and again at 3 months, when most of the subjects agreed that the appearance of the lateral thigh area was improved. Contour improvement in the outer thigh area corresponding to fat reduction in the treatment zone was also clearly noticeable on the digital photographs (Figures 1–3). The subjects were generally satisfied with the treatment outcomes throughout the study (81.8%), reporting that the treatment area felt more toned post-treatment (84.4%).

Figure 2. A 49-year-old woman, BMI 22.4 kg/m^2, baseline (left) and 1-month follow-up (right). The dotted line visualizes the change in lateral thigh contour; average 1-month fat reduction of 14.4 mm. BMI, body mass index

Discussion

This study demonstrated the simultaneous emission of HIFEM and RF fields to be a safe and effective means of treating the localized fat deposits of the lateral thigh. The results showed a significant reduction in fat thickness and high patient satisfaction, maintaining the improvement rate and consistency at all follow-up visits through 6 months. The HIFEM + RF therapy did not cause significant discomfort or adverse event to the study participants. Overall, the treatments resulted in an aesthetic improvement in the saddlebag region, with a noticeable fat reduction by serial digital photography.

The proportion of fat in the body changes during life and differs for both genders. As Jackson and colleagues[13] showed, on average, female fat mass is about 10% higher than male counterparts when controlled for BMI. The fat distribution is different as well. Women tend to accumulate more adipose tissue mass around the waist and thighs, which correlates with a lower risk of metabolic diseases, such as diabetes mellitus Type II.[14] Excessive fat deposits on lateral thighs, however, often lead to unpleasant pear-shaped body contours, affecting a woman's self-esteem.[2,15]

The present study evaluated the efficacy and safety of the HIFEM field procedure simultaneously combined with synchronized RF energy. As evidenced by previous research,[9] this combination effectively targets the fat and muscle tissue, eventually leading to improved body contour and visual appearance of the abdomen with considerable fat thickness reduction reaching up to 30.8%. In this study, the analysis of MRI scans and thigh circumference measurements revealed a substantial reduction of fat deposits at 1-, 3-month, and optional 6-month follow-up. The MRI scans showed a significant change in subcutaneous fat thickness as early as 1 month after treatment, with an average fat

Figure 3. Ghosting overlap of baseline (lateral, semitranslucent outline) and 3-month follow-up photos of a 40-year-old woman from Figure 1, average fat reduction 21.2 mm.

reduction of 13.5 ± 4.4 mm (22.4%). The fat thickness further decreased at 3 months with an average fat reduction of 18.0 ± 5.5 mm (29.9%) and 18.6 mm (30.9%) when excluding the nonresponders. Our findings also suggest that this improvement rate did not relate to the patient's body type because the change in percentage was not correlated with BMI. In the subjects who attended optional 6-month follow-up visit, the average fat reduction was maintained at −17.7 ± 4.9 mm (28.4%). Except for the maintenance of treatment outcomes, the results may also suggest persistence of results, because 98% of patients exceeded the 25% fat reduction level at 6 months.

Objective measures in fat reduction studies are important, with MRI imaging considered the gold standard of fat evaluation. Less predictable measures, such as thigh circumference measurements, are less favored in evaluating treatment results compared with imaging studies. Despite the lesser precision and predictability of tape measurements, in this study, the thigh circumference reduction trended with the decrease of fat thickness observed in MRI imaging. Mean thigh circumference reduction measurements varied during the study and ranged from 1.2 to 3.5 cm, depending on the measurement level. The most significant changes in circumference were found at the level of 5 to 10 cm below the infragluteal fold, corresponding to the treated area on the lateral thigh.

Besides the excessive fat accumulation, insufficient muscle tone may also contribute to the formation of saddlebags. In this study, 84.4% of subjects reported increased muscle tone in the treated area in response to the treatment. High-intensity focused electromagnetic + RF, therefore, seems to be a logical combination of technologies for treating the complexity of the saddlebag region, delivering muscle toning and fat reduction effects. The fat-reducing effect is hypothesized to be the effects of both modalities. The RF component aided by the delivery of HIFEM energy results in increased metabolic activity and levels of adipocyte apoptosis, leading to reduction of fat cell area and count respectively.[16]

Modern medicine provides several ways of addressing unwanted and localized adipose tissue. Using MRI for evaluation of liposuction results, Swanson[17] reported a 1.2-to-1.8-cm reduction at the 3.5-month follow-up. Stevens and Bachelor[18] used a cryolipolysis prototype applicator and ultrasound measurements to achieve a mean normalized fat reduction of 2.6 mm (range: +1.5 to −10.0 mm) in the saddlebags area at 16 weeks post-treatment. McDaniel and Samková[19] published a study using contactless RF treatments to the inner and outer thighs, which resulted in a significant thigh circumference reduction exceeding 3 cm when measured over both thighs. Finally, based on the results of 1 case reported by Fatemi,[20] high intensity focused ultrasound treatment on the outer thighs may result in fat reduction as measured by thigh circumference changes after treatment.

One of the major limitations of this HIFEM + RF saddlebag study is the unexpectedly high rate of subject study discontinuation. The global COVID-19 pandemic and government restrictions interfered with study treatment and follow-up windows for some study participants. Therefore, the subject count varied considerably throughout the study. Nonetheless, because of the enrollment of a relatively large number of subjects, the study still can provide a comprehensive analysis of the obtained data. Despite study challenges during the time of the pandemic,

Figure 4. Illustrative MRI scans at baseline (left) and 1-month follow-up (left) in a frontal plane; average reduction of 19.6 mm. MRI, magnetic resonance imaging

the data set shows result consistency and conformity between objective and subjective measures including MRI imaging, lateral thigh circumference measurements, digital serial photography, and patient questionnaires. Finally, this open-label study lacked a control group, which may encourage future study design and investigations to corroborate our results independent of a placebo effect.

Conclusion

The simultaneous use of HIFEM and synchronized RF seems to be a safe and effective tool for localized reduction of adipose tissue on the lateral thighs. The achieved results last through 6 months after treatment and are consistent with previously published findings in the abdominal region. High-intensity focused electromagnetic + RF seems to offer a nonsurgical alternative for fat reduction strategies in the saddlebag region.

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