

# A Novel Approach to Shaping the Lateral Abdomen: Simultaneous Application of High-Intensity Focused Electromagnetic (HIFEM) Therapy and Synchronized Radiofrequency at the Flanks: A Multicenter MRI Study

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## Abstract

**Background:** An accumulation of adipose tissue on the lateral abdomen (flanks) coupled with muscle deconditioning negatively affects core stability, muscular balance, and the intrinsic strength essential for maintaining optimal body mechanics and posture. This lateral fat accumulation and diminution of muscle result in an unfavorable abdominal profile and present challenges in finding appropriately fitting attire.

**Objectives:** The aim of this study was to explore the effectiveness and safety of the simultaneous application of high-intensity focused electromagnetic (HIFEM) therapy and synchronized radiofrequency for sculpting the lateral abdomen.

**Methods:** All patients were scheduled to undergo four 30-minute treatments at approximately weekly intervals and then subsequent follow-up visits at 1 month and 3 months after the last treatment. The primary evaluation assessed changes in the oblique muscles, adipose tissue thickness, and cross-sectional area (CSA) by MRI performed at baseline and follow-ups. The secondary outcomes included digital photographs of the treated areas, a Subject Satisfaction Questionnaire, and a Therapy Comfort Questionnaire. Adverse events and side effects were monitored throughout the study duration.

**Results:** The muscle tissue showed a substantial increase in thickness (+27.2%) and CSA (+29.0%). The adipose tissue measurements showed a decrease of –30.5% in CSA and –28.8% in thickness. As secondary outcomes, 81.8% of patients reported feeling more toned, and 84.9% of patients found the treatment comfortable and reported less than mild pain.

**Conclusions:** Based on the evaluation, the study suggests that the simultaneous application of HIFEM and synchronized radiofrequency is safe and effective for reducing adipose tissue and strengthening muscle in the area of the lateral abdomen.

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## Level of Evidence: 1



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Both adipose and muscle tissue form the shape of the waistline. The muscle tissue of the lateral abdomen (external oblique, internal oblique, and transverse abdominis) plays a significant role in core stability and posture. The lateral abdominal muscles provide stability and support to the spine and pelvis.<sup>1</sup> These muscles are engaged in various activities that involve twisting, turning, bending sideways, core strength, and maintaining an upright posture. The excess fatty tissue accumulating above the hip bones and around the oblique muscles is colloquially called “love handles” or “flanks.” Genetics,<sup>2,3</sup> diet,<sup>4,5</sup> exercise,<sup>6,7</sup> and overall body composition can contribute to developing love handles.

Bulky flanks are not part of the ideal body contour in either men or women.<sup>8,9</sup> Liposuction (belt lipectomy) can improve the appearance of love handles. However, like every surgical procedure, it carries potential risks of complications and downtime. One current nonsurgical approach for reducing love handles is cryolipolysis, which applies subzero temperatures to induce apoptosis in adipose cells,<sup>10</sup> but this only targets adipose tissue and does not enhance the musculature. So far, only exercise is known to increase muscle strength and fat loss, but there is no such thing as “spot reduction,” and considering the nature of the area of the flanks, factors such as hormones or genetics may prevent the desired flank appearance being achieved.<sup>11,12</sup>

A noninvasive approach that combines simultaneous high-intensity focused electromagnetic (HIFEM) and radiofrequency (RF) of the central abdomen to decrease adipose tissue and enhance muscle was introduced in 2020. Since its introduction, the effectiveness and safety of HIFEM with synchronized RF has been verified in the aesthetic field for fat reduction and muscle strengthening in the central abdomen,<sup>13</sup> including reduction of visceral fat,<sup>14</sup> buttocks,<sup>15</sup> inner thighs<sup>16</sup> and saddlebags,<sup>17</sup> and upper arms,<sup>18</sup> and has made it possible to explore the connection between muscle increase and muscle functionality.<sup>19-21</sup> HIFEM technology is based on alternating magnetic fields, depolarizing the motor neurons in skeletal muscle tissue, leading to brain-independent supramaximal contractions. These forces resemble resistance exercises, but are of higher intensity, and cause muscle fibers to be stretched and relaxed during the contractions, resulting in microruptures in the fibers as the muscle adapts to the workload.<sup>22,23</sup> The muscle tissue responds to the work by recruiting and augmenting the signaling molecules responsible for regeneration and muscle growth, heat shock proteins, which can induce hypertrophy

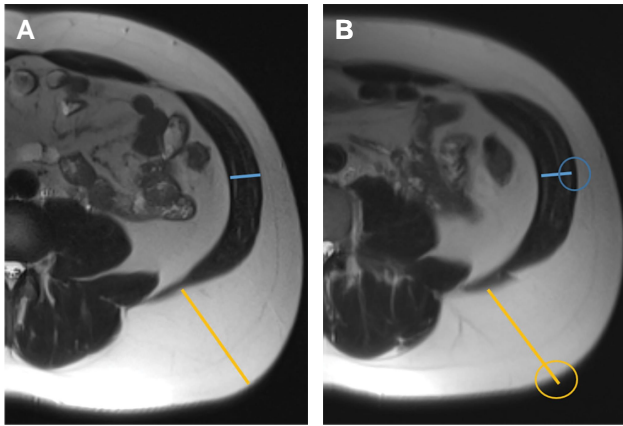
by promoting muscle protein synthesis.<sup>24,25</sup> RF is an oscillating electrical current causing collisions between charged molecules and ions in the tissue, transforming the kinetic energy into heat.<sup>26</sup> Adipose tissue has a lower density of blood vessels than muscle tissue and lower thermal conductivity, and therefore accumulates the heat within itself.<sup>27,28</sup> The RF-induced temperature in the adipose tissue reaches between 42°C and 45°C for most of the treatment time, initiating a natural death process—apoptosis—thereby reducing the sizes and amount of adipocytes without triggering an inflammatory response<sup>29-31</sup>.

Furthermore, in the muscle tissue itself, the temperatures reach a safe 40°C, and in synergy with the HIFEM procedure, RF recruits myosatellite cells, leading to regeneration and further strengthening of the muscles.<sup>32</sup> A novel applicator for the flanks consists of 2 movable parts to fit all sizes. The front part simultaneously emits the HIFEM and RF energies to target both adipose and muscle tissues in the lateral part of the flank; the rear part, applied to the posterior part of the flank, emits RF only. Cross-synchronized electrodes generate a homogeneous RF distribution, including around the applicator hinge, to ensure that the entire area of the flanks is evenly heated to therapeutic levels.

The aim of this pilot study was to evaluate the effectiveness and safety of the novel applicator for fat reduction and muscle strengthening of the posterior and lateral area of the flanks.

## METHODS

This prospective, multicenter, open-label, single-arm study received authorization from the IRB Advarra and was registered at ClinicalTrials.gov (NCT05260164). The study was approved in April 2022 and terminated in August 2023. Patients who expressed interest in treatment to improve the appearance of their flanks, were older than 22 years, and had a BMI below 35 kg/m<sup>2</sup> were screened for the following exclusion criteria: pregnancy and nursing, cardiovascular disease, metal-contacting implants, and other medical conditions contraindicated for the application of electromagnetic and RF energies. Seventy-three subjects were enrolled in the study. All enrolled subjects were introduced to the study protocol and signed the informed consent form. Patients were instructed to adhere to a pretrial regimen regarding diet and physical exercise, which was documented by the



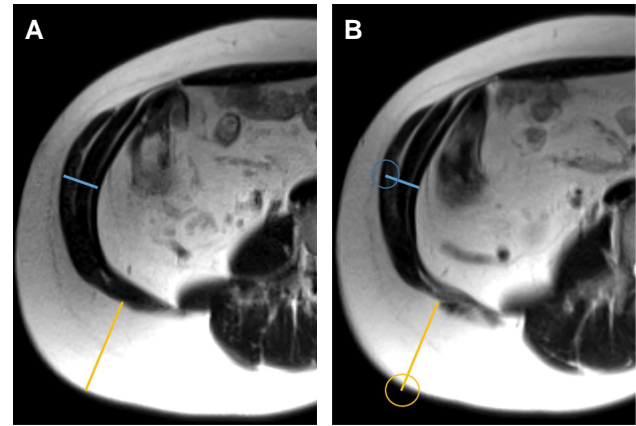
**Figure 1.** MRI of a 52-year-old female patient: (A) baseline; (B) at 3-month follow-up. The subject showed an average increase of 1 mm in muscle thickness and an average decrease of  $-10$  mm in fat thickness.

Lifestyle Change Questionnaire (LSCQ) after the last treatment and at 1-month and 3-month follow-up visits. The LSCQ contained 3 questions regarding changes in exercise routine, dietary intake, and stress levels.

The four 30-minute bilateral treatments were spaced 5 to 10 days apart, and were performed with the flank “Edge” applicator connected to an Emsculpt Neo device (BTL Industries Inc., Boston, MA). During the procedure, the patient was in a supine position with a velcro belt holding the applicators in the treatment area away from the hip bones and ribs, with no clothes and accessories covering the treatment area. Both emitted energies were adjusted according to the patient's feedback (0%-100%). No therapy was administered at the follow-up visits.

## Primary Analysis

The effectiveness of the treatment for noninvasive lipolysis and flank toning was examined by evaluating changes in adipose and muscle tissue before and after treatment based on MRI findings. The changes in the thickness and cross-sectional area (CSA) of the anterior and posterior flank adipose tissue and muscles of the lateral abdomen (external oblique, internal oblique, and transverse abdominis) were evaluated via scans obtained at baseline and at both follow-up visits. A standard 1.5 T MRI device, utilizing a T2-weighted fast spin echo with a breath-hold sequence, was used to acquire images in both the axial and frontal planes from vertebrae T12 to S1 in DICOM format. The protocol was as follows: repetition time, 2000 ms; echo time, 78 ms; slice thickness, 6 mm; spacing, 6 mm (center-to-center); field-of-view, sufficient to capture the whole scanned area with matrix size adjusted accordingly. During the scanning, patients were prone and avoided compression of the flank area, with 2 breath holds recommended. Semiautomatic



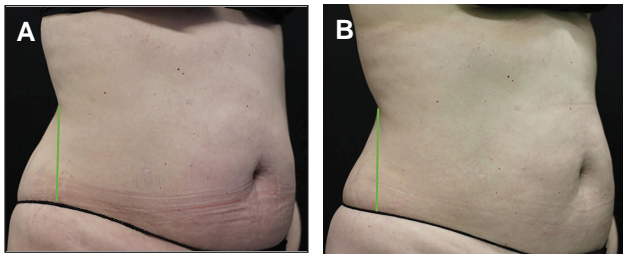
**Figure 2.** MRI of a 40-year-old female patient: (A) baseline; (B) at 3-month follow-up. The subject showed an average increase of 2.3 mm in muscle thickness and an average decrease of  $-5.3$  mm in fat thickness.

evaluation of the treatment area was performed by software (3D Slicer, v. 5.1.0-2022-08-08) utilizing a Sandbox extension to evaluate the CSA. The changes in adipose and muscle tissues were calculated at the mid-L3 vertebra level, for both thickness and area separately.<sup>33</sup> The CSA of the adipose tissue was measured on the left and right sides of the body and averaged. The cross-sectional measurements for muscle tissue were also performed in the same fashion. The muscle thickness was measured for each muscle on both sites. Then, the values were averaged for each muscle separately. Fat thickness was measured laterally and posteriorly from the center of the applicator. The values were averaged to obtain the mean reduction on the lateral and posterior parts of the flanks.

## Secondary Analysis

The secondary outcomes aimed to discover the subjects' satisfaction with the results and the comfort of the treatments through a Subject Satisfaction Questionnaire (SSQ) and a Therapy Comfort Questionnaire (TCQ). The SSQ was collected after the last treatment and at follow-up visits. The SSQ contained 5 statements regarding the improved appearance of the treated area, feeling more toned after the treatments, general improvement in the treatment area, improved confidence in one's clothes, and satisfaction with the results. Subjects were asked to express how much they agreed with the statements based on a 5-point Likert scale (1=strongly disagree and 5=strongly agree). The values collected during the study for each question were averaged.

The TCQ was collected only after the last treatment. It included a single statement, “I found the treatment comfortable,” and subjects were asked to express how much they agreed with the statements based on a 5-point Likert scale



**Figure 3.** A 52-year-old female patient with a BMI of  $31.6 \text{ kg/m}^2$ : (A) baseline; (B) at 3-month follow-up. The patient feels more toned after the treatment (4 out of 5 on the 5-point Likert scale).

(1 = strongly disagree and 5 = strongly agree). Additionally, the TCQ also included a numerical analogue scale, where subjects expressed the level of pain during the treatment based on a scale of 0 (no pain) to 10 (worst possible pain). The questionnaires were filled out on paper, with the subject's ID as the only identification (see [Appendix](#)).

Digital photographs were taken at baseline, on the day of the last therapy, and at each of the follow-up visits to document the changes during the study. The photographs taken at baseline and 3-month follow-up were evaluated by 3 independent evaluators according to the Global Aesthetic Improvement Scale (GAIS), which rates results on a 5-point scale from  $-1$  (worse compared to the original condition) to 3 (very much improved).

In addition, the subjects' weights at baseline (together with height), after the treatments, and at follow-up visits were recorded to calculate their BMI.

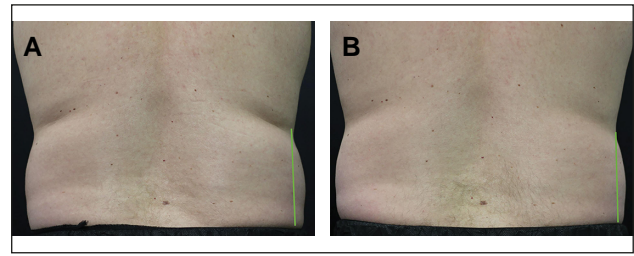
Finally, the procedure's safety was monitored by visually evaluating the treatment area to assess and evaluate any adverse events or side effects that may occur during the treatment.

## Statistical Analysis

The descriptive analysis (average and standard deviation [SD]) and statistical analysis of the collected data were completed in an Excel spreadsheet. Repeated-measures analysis of variance with Tukey's honestly significant difference test was used to observe the significance of the changes throughout the study. An *F*-test was used to establish the equality of variances, followed by a 2-sample *t*-test to determine the statistically significant difference between the means of the left and right flanks.

## RESULTS

Out of the 73 enrolled subjects (52 females, 21 males), 71 subjects (50 females, 21 males; age, 22-60 years; BMI,  $20.2\text{-}33.9 \text{ kg/m}^2$ ; skin types, I-VI) attended the baseline visit, 66 subjects finished all the treatments and the 1-month



**Figure 4.** The 52-year-old female patient shown in [Figure 1](#) with a BMI of  $31.6 \text{ kg/m}^2$ : (A) baseline; (B) at 3-month follow-up. The patient feels more toned after the treatment (4 out of 5 on the 5-point Likert scale).

follow-up visit, and 64 subjects completed the 3-month follow-up visit. Seven ( $n = 7$ ) subjects were dropped due to: scheduling issues ( $n = 1$ ), leaving the specific state of the treatments ( $n = 2$ ), withdrawing consent ( $n = 3$ ), and not enough fat tissue in the treatment area ( $n = 1$ ) before the start of the treatments.

The LSCQ documented that, on average, 97% of patients did not make any significant changes in their workout routine, 94% of patients did not change their eating habits, and 92% experienced no change in their stress levels at 1-month follow-up. Similarly, 91% of patients did not change their workout routine, 94% did not change their eating habits, and 91% experienced no change in their stress levels at 3-month follow-up. At the 3-month follow-up, subjects reported taking less exercise ( $n = 3$ ), taking more exercise ( $n = 3$ ), changed eating habits ( $n = 4$ ), and increased levels of stress ( $n = 6$ ).

The average baseline BMI was  $26.9 [3.3] \text{ kg/m}^2$  ( $n = 71$ ) and showed no statistically significant changes throughout the study ( $P = .9$ ): the 1-month ( $n = 66$ ) and 3-month ( $n = 64$ ) BMI values were  $27.1 [3.3] \text{ kg/m}^2$  and  $27.07 [3.1] \text{ kg/m}^2$ , respectively.

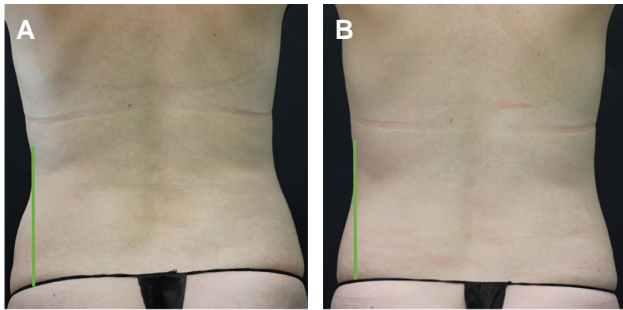
## Primary Outcomes

Only subjects with legible baseline, 1-month, and 3-month scans were included in the MRI evaluation. Therefore, the primary outcome calculations included 61 subjects (45 females, 16 males; age, 22-60 years; average age, 40.7 [10.8] years; BMI,  $20.2\text{-}33.9 \text{ kg/m}^2$ ; skin types, I-VI). Out of the 73 enrolled subjects, 7 subjects ( $n = 7$ ) had no scans taken, 3 ( $n = 3$ ) subjects were excluded from the evaluation because they missed 1 of the follow-up scans, and 2 ( $n = 2$ ) subjects did not have scans of a quality suitable for evaluation.

## Muscle Tissue

The average baseline CSA of the muscle tissue was  $1685.66 \text{ mm}^2$  for subjects with legible baseline, 1-month, and 3-month scans. At the 1-month follow-up scans, an





**Figure 5.** The 40-year-old female patient shown in Figure 2 with a BMI of 23.3 kg/m<sup>2</sup>: (A) baseline; (B) at 3-month follow-up. The patient is satisfied with the results (4.0).

occurred: 1 subject reported a mild case of local erythema at the area in which the applicator had been placed the day after the second treatment. The redness disappeared within a day, and the subject was cleared to continue with the treatment schedule.

## DISCUSSION

This clinical investigation aimed to evaluate the effectiveness and safety of novel applicators emitting HIFEM and RF simultaneously to improve the contour of the flanks. The results described above demonstrate the effectiveness of the technology: the primary outcomes documented highly significant changes in adipose and muscle tissues. Secondary outcomes report the overall satisfaction with the treatment and visibility of the results. The safety of the novel applicator was supported, with subjects reporting high comfort and less than mild pain during the treatments. Additionally, only 1 mild adverse event (blister) and 1 minor side effect (erythema) occurred, both of which were resolved without any additional medical care, supporting that the treatments are safe.

Although the unformed flanks are not solely linked to increased health issues, finding well-fitting clothes and social pressure may cause feelings of discomfort or low self-esteem. Cosmetic approaches to help reduce the amount of subcutaneous fat in the area of the flanks were introduced because exercise and a healthy diet do not ensure the envisioned outcomes. Tumescence liposuction is a popular approach for several body areas, including the flanks. The procedure itself is considered safe because it does not require general anesthesia. Despite the procedure's popularity, it is nevertheless an invasive approach, requiring adjustments of habits, and downtime of several days is expected. Additionally, induced swelling means it can take up to 3 to 6 months before the results are truly visible.

Noninvasive methods include cryolipolysis, RF, low-level laser therapy, and high-intensity focused ultrasound.<sup>34</sup>

Coleman et al reported a 25.5% reduction in fat with cryolipolysis treatment at 6 months posttreatment.<sup>35</sup> The energies from the opposite heat spectrum, such as stand-alone RF, achieved a 22% reduction in fat thickness at 12 weeks after treatment,<sup>36</sup> with laser technology reducing fat thickness by 13%.<sup>37</sup> The last modality, high-intensity focused ultrasound, triggers necrosis in the adipose tissue to achieve a 4.6-cm reduction in waist circumference 3 months after treating the abdomen and flanks.<sup>38,39</sup> All of these technologies focus only on the adipose tissue; HIFEM, however, targets muscle tissue. The weakened muscles of the lateral abdomen may lead to poor posture and low core stability,<sup>40</sup> lower back pain,<sup>41,42</sup> and increased risk of injuries,<sup>43</sup> and can impact breathing patterns<sup>44-46</sup> and bowel movement.<sup>47</sup> The results of the present study show the superiority of the combined HIFEM + RF treatment: both adipose and muscle tissues were positively affected, with MRI revealing a significant fat reduction of -30.5% in fat CSA and up to -28.8% in fat thickness.

In comparison, muscle tissue showed a significant increase of +29.0% in CSA and +27.2% in overall thickness. Additionally, subjects felt more toned (81.8%), were satisfied with the results (77.3%), and felt more comfortable in their clothes (72.7%). The ability to wear clothes that make us comfortable increases confidence and concentration while reducing stress. Additionally, the LCQ revealed that the majority of subjects (92%) did not make any significant lifestyle changes. The few subjects who modified their lifestyle did not affect the outcomes and scope of the study as the BMI of the study population showed no significant changes during the study.

The main strength of this study is the MRI evaluation of CSA and thickness for both adipose and muscle tissue, as well as the inclusion of questionnaires. The combination of objective and subjective methods allowed us to show the anatomical and psychological impact of the treatment. The large sample size ensured that the 12% drop-out had little to no effect on the validity of any evaluation. The methodological limitations are the uneven male and female representation, the absence of a control group, and the lack of randomized groups comparing HIFEM + RF synergy with standalone procedures, which should be considered in future studies. Additionally, future research would benefit from prolonging the follow-up observation, which would also help establish the treatment frequency needed for maintenance.

## CONCLUSIONS

The results presented in this study demonstrate that a novel applicator simultaneously utilizing both HIFEM + RF presents a unique noninvasive alternative for treating both muscle and adipose tissue on the flanks. The treatment was found to be

effective based on MRI evaluation. Subjects were satisfied and more confident. No serious adverse effects occurred.

## Supplemental Material

This article contains [supplemental material](#) located online at [www.aestheticsurgeryjournal.com](http://www.aestheticsurgeryjournal.com).

## Disclosures

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