Ultrasound Assessment of Subcutaneous Abdominal Fat Thickness After Treatments With a High-Intensity Focused Electromagnetic Field Device: A Multicenter Study

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BACKGROUND High-intensity focused electromagnetic (HIFEM) technology is intended for muscle toning, firming, and strengthening.

OBJECTIVE The goal of this study is to quantify the effect of HIFEM treatments on subcutaneous fat.

MATERIALS AND METHODS A total of 33 patients participated in the study. Each subject underwent 4 treatments on the abdomen with the HIFEM device. Ultrasound images were obtained measuring the thickness of the subcutaneous fat from 4 standardized measurement points. Ultrasound images were taken before treatment and at 1-month and 3-month follow-up visits. Photographs were captured using both 2D and 3D cameras. Weight measurements were taken, as well as surveys assessing both patient comfort, satisfaction, and adverse events.

RESULTS A significant reduction in the subcutaneous fat thickness across the abdomen was observed, averaging 19.0%/4.47 ± 3.23 mm ($p < .01$) at 1 month after treatment and 23.3%/5.78 ± 4.07 mm 3 months after treatment. At 1 month, the most significant reduction in subcutaneous fat was measured subumbilically (26.6%/6.25 ± 4.70 mm; $p < .01$) and epiumbilically (21.6%/5.08 ± 3.69 mm; $p < .01$). No discomfort was reported, and 91% of study participants were satisfied with their result.

CONCLUSION Based on the ultrasonographic and photographic observations, the authors conclude that the application of an HIFEM field is an effective option for the noninvasive treatment of subcutaneous fat.

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As adult obesity rates have increased, so has the number of people considering fat-reducing procedures. In 2016, 58% of the US population considered a body-sculpting procedure.[1] There are various surgical[2] (e.g., abdominoplasty and liposuction) and noninvasive[3] options to consider that offer a permanent solution to fat reduction.

Such procedures may or may not necessarily lead to an overall increase in patient satisfaction. Many patients remain unsatisfied with their aesthetic appearance after abdominal fat removal due to bulging and/or flaccidity around their midsection, which, in most cases, result from weak abdominal muscles and/or diastasis recti. The removal of excess fat does not solve the problem of muscle flaccidity developed through increased intra-abdominal pressure and reduced muscular and aponeurotic tension.[4]

There have been surgical attempts to treat this condition with the submuscular application of alloplastic mesh,[4] but physical exercise before the procedure is

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normally recommended to prevent muscle laxity. In addition to physical exercise, both electrical[5,6] stimulation and low-level magnetic[7–9] stimulation have been used to try and assist muscle strengthening. It has been observed that a high-intensity magnetic stimulation penetrates deeper into the tissue without a risk of burns or nociceptive activation, which is often associated with electrical stimulation methods.

Recent studies suggest that a high-intensity focused electromagnetic (HIFEM) field based on focused magnetic stimulation can simultaneously induce muscle growth and reduce subcutaneous fat (Kent DE, presented at ASLMS, Dallas TX, April 2018; Kinney BM, presented at ASLMS, Dallas TX, April 2018) when applied to the abdomen. Although the effects of magnetic stimulation on muscle are well established and have been described in several studies,[7–10] its effects on fat tissue have not yet been thoroughly investigated.

This study investigates the effects of HIFEM technology treatment on subcutaneous fat using ultrasound imaging evaluation. Simultaneous muscle strengthening and the magnetic field's effect on fat could help avoid abdominal bulging and flaccidity, which most patients find aesthetically unsatisfactory.

Methods

The subject group was composed of 33 subjects (mean age 40.8 years and mean body mass index [BMI] 24.5 kg/m^2). For the study, the following inclusion criteria were respected: BMI 20.0 to 30.0 kg/m^2, age 21 to 65 years, stable weight (maximum weight change 2.2 kg in the preceding month), and sufficient thickness of the abdominal fat layer (0.5–3 cm). The exclusion criteria included previous abdominal surgery or other aesthetic procedures in the abdominal area, use of medications known to affect weight levels, and any of the contraindications stated in the device manual. Patients were instructed to maintain their daily routines. Basic biometric data were also collected before the treatment.

Each subject received 4, 30-minute treatments using the HIFEM device (Emsculpt; BTL Industries, Inc., Boston, MA). The treatments were performed over a 2-week period, spaced by a minimum of 2 days between each session as outlined in the Institutional Review Board-approved protocol and as conforming to the ethical guidelines of the 1975 Declaration of Helsinki. The patients were placed in a supine position, and the treatment was administered on the abdomen.

For the study, a single applicator was used over the treatment area. The applicator itself consists of a focused circular coil that generates electromagnetic pulses with intensities reaching up to 1.8 Tesla. The magnetic field can penetrate to depths of 7 cm. The center of the applicator was centered directly over the umbilicus to stimulate the musculus rectus abdominalis. All clothing and jewelry were removed from the treated area. During the treatment, the intensity of the magnetic field was gradually increased until the patient's tolerance threshold was reached. Most patients were able to tolerate 100% intensity of the stimulator output by the end of the first 30-minute treatment. All the patients reached 100% intensity by the end of the second treatment and were able to tolerate this intensity during the remaining treatments. Abdominal muscle stimulation was closely monitored to ensure equal stimulation bilaterally. A fixation belt was used to secure the single applicator during all treatments.

Patients were evaluated at the baseline, 1 month, and 3 months after the final treatment.

The primary evaluation of the subcutaneous fat layer thickness was measured with a diagnostic ultrasound. The ultrasound devices GE Voluson E8 with linear probe SP10-16-D (General Electric; GE Healthcare, Chicago, IL) and Sonosite Micromax Turbo with linear probe HFL50x (Sonosite, Bothell, WA) were used for this study. An external template was used on all patients to ensure the consistency of the 4 different measurement points. The template measuring points were at a distance of 5 cm from the umbilicus: epiumbilical, subumbilical, lateral right, and lateral left (Figure 1). To avoid any fat compression errors, the ultrasound probe was placed above a given site without any pressure by using a thick layer of ultrasound gel between the probe and the skin. All ultrasound scans were evaluated by a board-certified radiologist.

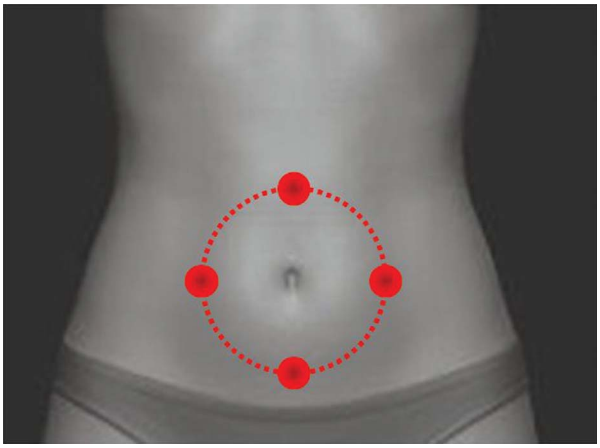

Figure 1. Visualization of ultrasound measurement points.

Standardized 2D and 3D digital photographs were taken to document any further changes in the appearance of the abdominal area. Patient satisfaction was assessed at the 1-month and 3-month follow-up evaluations with a standardized 5-point Likert scale questionnaire. A visual analog scale (0—no discomfort and 10—unbearable discomfort) was also used to evaluate the patient's comfort during treatments.

Patients were monitored and encouraged to report any adverse events related to the treatment.

The significance of the obtained data/results was verified by paired *t*-tests. The significant level α was set to 5%.

Results

All patients completed the study protocol and underwent evaluation during the 1-month follow-up visits. In total, 21 of 33 patients attended the 3-month follow-up visits. During the 1- and 3-month follow-up evaluations, the data showed a significant reduction in the subcutaneous fat thickness of the treated area. Weight change for all patients was insignificant. The digital photographs showed aesthetic improvement in the abdominal area, which correlated with relatively high patient satisfaction.

Ultrasound Measurements

When compared with the baseline, a statistically significant reduction in subcutaneous fat was observed in each of the 4 measurement points at 1 month and at 3 month after treatment (all $p < .01$). At 1 month, the most significant reduction was observed in the epiumbilical and subumbilical regions (21.6% and 26.6%, respectively), with a lower reduction observed in the lateral regions (12.9% and 14.8%). The total average reduction across all patients and all measurements totaled 19.0% (4.47 ± 3.23 mm; $p < .01$). An average reduction exceeding 10% was observed in 25 of 33 patients (76%). See Figure 2 for a histogram of the changes.

During 3-month evaluations, the fat thickness measurement of the 21 evaluated patients was further reduced (Table 1), ranging from 18.2% (left lateral point) to 30.8% (subumbilical point). The total average reduction across the whole abdomen was 23.3% (5.78 ± 4.07 mm; $p < .01$). Changes observed in individual patients were rather consistent, as the average abdominal fat thickness decreased in each of the treated patients at both follow-up visits. None of the patients had an increase in the average fat thickness.

All presented data were compared with the baseline (Table 1).

Digital Photographs

The evaluation of digital photographs showed a volumetric reduction and visual aesthetic improvement, which correlated with the changes documented by the ultrasound measurement. See Figure 3 for an example of 2D and 3D photographs and corresponding ultrasound images.

Patient Comfort and Satisfaction

Patient satisfaction questionnaires showed relatively high patient satisfaction with the results of the therapy at 1 month after treatment. In total, 30 of 33 subjects (91%) reported they were satisfied or strongly satisfied with the results (≥4 on the Likert scale), 2 patients (6%) were unsure about their satisfaction, and 1 patient (3%) expressed dissatisfaction. See Table 2. The visual analog scale showed that the patients found the treatments highly comfortable, with the average score across all patients totaling 1.05 (little to no discomfort). As a general observation, besides mild

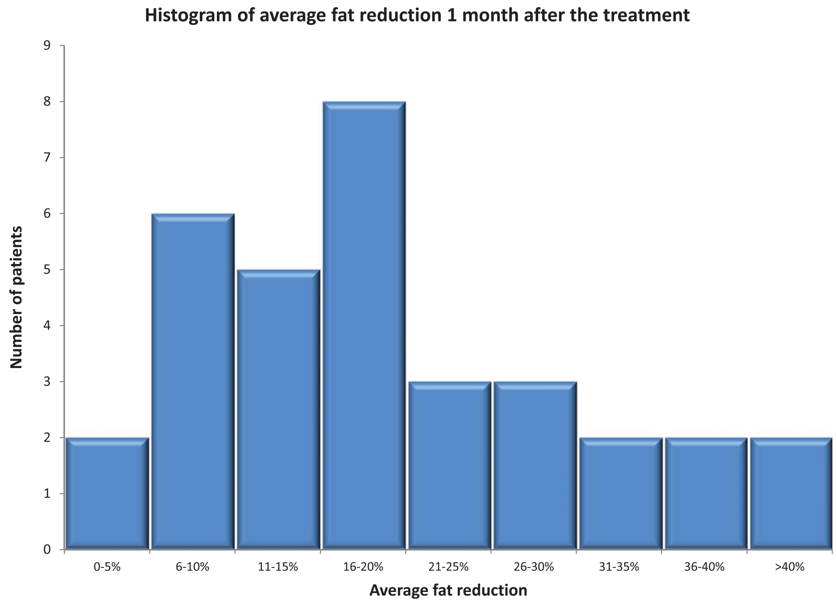

Figure 2. The distribution of the average fat reduction calculated from the 4 measurement points obtained during the 1-month follow-up.

muscle fatigue and soreness on the day after the treatment, no adverse events were recorded or observed during the treatments or during the 3 months of follow-up.

Discussion

The effects of HIFEM treatments on subcutaneous tissue were recently investigated by Weiss and colleagues, who studied the apoptotic and biochemical processes associated with intense magnetic stimulation in a porcine model (Weiss R, presented at ASLMS, Dallas TX, April 2018). In the histology evaluation, they observed a statistically significant increase of 91.7% in the number of apoptotic nuclei in fat tissue after a single HIFEM treatment. This observation was coupled with an increased presence of RNA proapoptotic markers as a response to the treatment.

The data presented herein show a substantial reduction in subcutaneous fat in comparison with the baseline. The ultrasonography revealed that 1 month after 4 treatments, every single patient showed a reduction in the fat layer (average 19.0%), and this reduction was retained at the 3-month evaluation (average 23.3%). These results strongly correlate with other recent research that used the HIFEM technology: Kent and colleagues (Kent DE, presented at ASLMS, Dallas TX, April 2018) found an average

TABLE 1. Changes in Fat Layer Thickness Measured by Ultrasound (Average ± SD)

Measurement	Baseline Fat Thickness (mm)	1-Month Data: Reduction in mm	1-Month Data: Reduction in %	3-Month Data*: Reduction in mm	3-Month Data*: Reduction in %	Significance
Epiumbilical	23.72 ± 8.9	5.08 ± 3.69	21.6	5.47 ± 3.18	22.2	$p < .001$
Subumbilical	22.96 ± 9.9	6.25 ± 4.70	26.6	7.54 ± 4.89	30.8	$p < .001$
Left lateral	17.75 ± 10.1	3.17 ± 4.57	12.9	4.93 ± 5.32	18.2	$p < .001$
Right lateral	17.77 ± 10.0	3.38 ± 4.53	14.8	5.19 ± 5.92	21.9	$p < .001$
Average	20.55 ± 10.01	4.47 ± 3.23	19.0	5.78 ± 4.07	23.3	$p < .001$

*3-month calculations are based on data from 21 subjects.

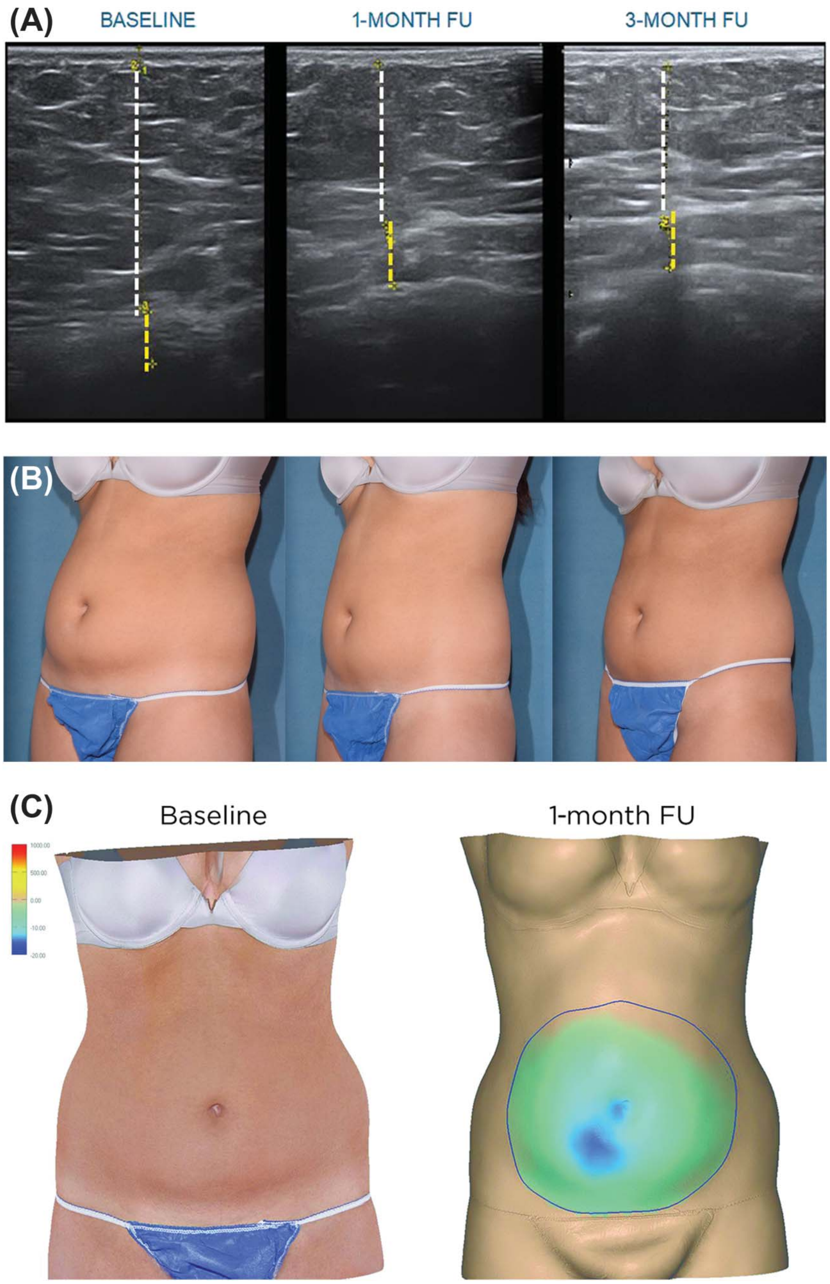

Figure 3. Example of results (Patient ID3, 24 years old). (A) Ultrasound images showing the subumbilical fat layer thickness. The white lines mark the fat layer, and the yellow lines represent the muscle layer. The fat layer thickness reduced by 10 mm (32%) from 31 mm at baseline to 21 mm at the 1-month follow-up and to 20 mm at the 3-month follow-up. (B) 2D photographs captured at baseline (left), 1 month (center), and 3 months (right) after treatments. (C) 3D images obtained at the baseline and at 1-month follow-up. The volumetric changes in the abdominal area are shown on the right image. Courtesy of Bruce Katz, MD. FU, follow-up.

reduction of 19.2% in fat thickness 1 month post-HIFEM treatments when using computed tomography (CT) evaluation, and Kinney and colleagues (Kinney BM, presented at ASLMS, Dallas TX, April 2018) also reported an average reduction of 18.6% in abdominal fat at 2 months after four HIFEM treatments evaluated by magnetic resonance imaging (MRI). Similar results from different clinical trials and evaluation methodologies suggest that the treatments can cause a consistent and repeatable localized reaction in adipose tissue. The difference between 1-month data (19.0%) and 3-month data (23.3%) was not

TABLE 2. Patient Satisfaction Data

Level of Satisfaction	*No. of Patients* N *(%)*
Strongly satisfied	7 (21%)
Satisfied	23 (70%)
Neither satisfied nor dissatisfied	2 (6%)
Dissatisfied	1 (3%)
Strongly dissatisfied	0 (0%)
Average	4.09

statistically significant ($p > .05$); however, the tendency suggests a continuation of fat reduction. This phenomenon could be attributed to the lingering effects of the apoptotic process, since fat cells can continue to flush out for up to 4 months.[11] An additional possible mechanism could be explained by an increase in the basal metabolism, due to the increase in the abdominal muscle mass/tissue, which was found to have occurred in the MRI and CT studies by Kinney and colleagues and Kent and colleagues Finally, this tendency could also be explained by the patients' enhanced motivation to maintain a healthier lifestyle, including maintaining dietary and workout routines after seeing significant post-treatment improvements.

The observed changes in the fat tissue are comparable with thermal-based technologies, which routinely report reductions ranging between 20% and 29%.[12–16] Yet, contrary to heating or cooling devices that externally affect the cellular membrane of a fat cell to cause an apoptotic effect, HIFEM works from within, on the muscle, causing supramaximal contractions, which affects fat internally through an extreme hypermetabolic reaction. This rather natural process of affecting fat can potentially explain the absence of nonresponding patients in the authors' study; yet, such a hypothesis will require further investigation.

The reduction of the fat layer measured by ultrasonography was also coupled with changes observed in abdominal body contours by 2D/3D photographs. Patients were treated with a single-applicator prototype, which did not cover the entire abdomen, particularly in larger patients. This may help to further explain the more significant reduction observed in the central abdomen (epiumbilically and subumbilically) compared with the lateral measurements. Future research is expected to further explore this technology using dual-applicator protocols.

Conclusion

Based on ultrasonographic observations, the authors conclude that the application of an HIFEM field is a unique, safe, and effective alternative for the non-invasive reduction of subcutaneous fat thickness. This study confirms and conforms to other recent HIFEM research observations; however, to assess the full clinical potential of this technology, further research is required.

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