# Radiofrequency Heating and High-Intensity Focused Electromagnetic Treatment Delivered Simultaneously: The First Sham-Controlled Randomized Trial

Julene B. Samuels, M.D.
Bruce Katz, M.D.
Robert A. Weiss, M.D.

*Louisville, Ky.; New York, N.Y.; and Hunt Valley, Md.*



**Background:** Radiofrequency-based and high-intensity focused electromagnetic (HIFEM)-based devices have proved effective and safe for abdominal body shaping. Radiofrequency is known to reduce adipose tissue, whereas HIFEM treatment is effective for muscle definition. The authors investigated the efficacy of a novel device delivering synchronized radiofrequency and HIFEM treatment simultaneously for abdominal toning and fat reduction.

**Methods:** Seventy-two patients were enrolled and randomly divided into active ($n$ = 48; age, 45.5 ± 13.0 years) and sham groups ($n$ = 24; age, 44.6 ± 12.3 years). Both groups received three treatments on the abdomen once a week. The intensity in the active group was set to maximum tolerable level; in the sham group, the intensities were set to 5 percent. Ultrasound images were taken before treatment and at 1, 3, and 6 months after treatment to examine changes in subcutaneous fat and rectus abdominis muscle thickness. Digital photographs were taken, and satisfaction and therapy comfort were assessed.

**Results:** Ultrasound images of the active group at 1 month showed significant ($p <$ 0.05) reduction in adipose tissue thickness by 20.5 percent (4.8 ± 2.6 mm), whereas rectus abdominis muscle thickness increased by 21.5 percent (2.0 ± 0.8 mm). Results at 3 months improved to 28.3 percent (7.6 ± 3.7 mm) and 24.2 percent (2.3 ± 0.9 mm), respectively. Improvements were maintained at 6 months after treatment in the active group, whereas the sham group showed no significant changes. Treatments were found to be comfortable. The active group showed higher satisfaction with outcomes.

**Conclusion:** Active treatment utilizing simultaneous application of radiofrequency and HIFEM therapy resulted in a significant increase in rectus abdominis thickness and subcutaneous fat reduction, exceeding previously published results for separate HIFEM and radiofrequency treatments. (*Plast. Reconstr. Surg.* 149: 893e, 2022.)

**CLINICAL QUESTION/LEVEL OF EVIDENCE:** Therapeutic, II.

*From private practice; the Juva Skin and Laser Center, and Maryland Dermatology, Laser, Skin, & Vein Institute.*
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The popularity of noninvasive body contouring procedures remains high as patients seek ways to avoid downtime and risks associated with surgical procedures.[1] Radiofrequency is one of the most popular procedures for noninvasive fat reduction. Radiofrequency is used to increase the temperature of adipose tissue, leading to heat-induced damage of adipose cells.[2] High-intensity focused electromagnetic (HIFEM) technology has been cleared by the U.S. Food and Drug Administration for muscle strengthening, toning, and firming, and is currently one of the most widely utilized procedures in body shaping.[3]

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HIFEM treatment triggers supramaximal muscle contractions that result in subsequent muscle strengthening and growth.[3]

Both radiofrequency heating and HIFEM treatments aim to improve the body's appearance and support patients' efforts for improved self-image. These two modalities are typically used individually and separately increasing treatment time as standalone procedures for both muscle toning and fat reduction. Currently, treatments need to be delivered in a consecutive manner, with an average HIFEM treatment lasting 30 minutes and radiofrequency treatments ranging from 15 minutes to 60 minutes.[3,4] Consecutive treatments also do not allow for a synergistic physiological effect of simultaneous tissue heating and muscle stimulation.

Tissue-heating devices work with electromagnetic waves in the medium to very high-frequency spectrum (range of megahertz), whereas HIFEM treatment's energy is positioned in the very low-frequency spectrum (3 to 30 kHz). Importantly, a clinically applicable simultaneous emission of the two fields has been thought to be technically impossible due to mutual adverse interactions between the two energy sources.

A novel technology has now been developed that combines radiofrequency heating and HIFEM treatment simultaneously in the same application area. Proprietary engineering and technology have overcome the problem of interfering magnetic and radiofrequency waves by using a patented synchronized radiofrequency solution in which the unique design allows a radiofrequency electrode to be largely transparent to magnetic fields. This unique design enables the emissions of both wave types without inducing anticipated eddy currents within the applicator's metallic parts. Based on submitted data, this novel device received Food and Drug Administration clearance in December of 2019 for noninvasive breakdown of fat of the abdomen.

The simultaneous delivery of synchronized radiofrequency and HIFEM treatment is more beneficial than just reduced treatment time in comparison to consecutive treatments. Previous studies showed that heated muscle contractions lead to enhancement of the muscle protein synthesis and thus promote the hypertrophic effect.[5–8] In addition, radiofrequency is considered to be an effective procedure for inducing adipocyte apoptosis,[9,10] whereas HIFEM treatment was found to increase the metabolic activity in the adipose tissue.[11] We hypothesized that the simultaneous application of HIFEM treatment and radiofrequency would lead to enhanced muscle hypertrophy and increased fat elimination when compared to individual or consecutive treatments. So the benefit of simultaneous delivery should enhance fat elimination while improving the rate of muscle remodeling. This study investigates the simultaneous application of HIFEM treatment and synchronized radiofrequency for abdominal body shaping with focus on safety and results and demonstrates synergistic effects of HIFEM treatment and radiofrequency on muscle and adipose tissues.

## PATIENTS AND METHODS

The study was designed as a multicenter, single-blind, two-arm study. A total of 72 patients were enrolled and randomly assigned into one of two study groups, active group and sham group, at a ratio of 2:1, respectively. Patients in both groups were required to complete a full abdominal treatment protocol by a device utilizing simultaneous delivery of radiofrequency and HIFEM energies (EMSculpt Neo; BTL Industries, Inc., Boston Mass.). The procedure consisted of three 30-minute treatments delivered once a week for 3 consecutive weeks. After the procedure, the patients were asked to participate at three follow-up visits, at 1 month, 3 months, and 6 months after the last treatment. The study protocol was approved by the Advarra institutional review board and conformed to the 1975 Declaration of Helsinki's ethical guidelines with fully informed consent.

The treatments were administered with the patient in a supine position, and the applicators were placed on their abdominal area (Fig. 1). One or two applicators were used according to the patient's body shape and size. A Velcro belt was used to position the applicators. For the active group ($n$ = 48), the intensities of HIFEM energy were set to maximum tolerable levels, and the intensity of radiofrequency energy was set to 100 percent. The patients belonging to the sham group received the treatments with intensities of both HIFEM energy and radiofrequency energy set to 5 percent of their maximum output.

Muscle and subcutaneous adipose tissue changes were evaluated by ultrasound imaging (Voluson E8, Terason uSmart 3300; Terason, Burlington, Mass.). Measurements were taken at 2 inches right and left of the umbilicus. The subcutaneous adipose tissue and the muscle thickness were measured and recorded. During the collection of ultrasound images, a thick layer of ultrasound gel was applied upon which the transducer


**Fig. 1.** Applicator affixed by the fixation belt placed over the umbilical area during the treatment.

was gently placed to avoid any pressure. A board-certified radiologist evaluated ultrasound images.

Patient weight was recorded as well as documentation of adverse events and patient's experience of pain or discomfort after each procedure. Patient satisfaction was evaluated through a 5-point Likert scale satisfaction questionnaire including statements such as "I am satisfied with the treatment results" and "My appearance in abdominal area has been improved after the treatments." Therapy comfort has been assessed using by a 10-point visual analog scale questionnaire (0 = no discomfort, 10 = unbearable discomfort). Moreover, photographs of the treated area were taken. The skin type, according to the Fitzpatrick skin type scale, was noted for each patient.

Evaluations were performed at baseline and at 1-month, 3-month, and 6-month follow-up. Significance of changes ($p < 0.05$) between pretreatment and posttreatment measurements was verified using Welsch analysis of variance followed by the Games-Howell post-hoc test.

Evaluations were performed at baseline and at 1-month, 3-month, and 6-month follow-up. Significance of changes ($\alpha = 0.05$) between pretreatment and posttreatment measurements was verified using Welsch analysis of variance followed by Games-Howell post-hoc test. The Shapiro-Wilk normality test was used to verify whether the variables were normally distributed. All statistical tests were run by using R version 2.11.1 environment for statistical computing (R Foundation, Vienna, Austria).

## RESULTS

A total of 72 patients (active group, 48; sham group, 24) were enrolled into the study. The entire treatment protocol was completed by 67 patients (active group, 48; sham group, 19), who also attended the 1-month follow-up visit; five patients were withdrawn from the study as they did not complete their treatment procedures. Fifty-six patients (active group, 40; sham group, 16) attended their 3-month follow-up visit, representing a 16.7 percent drop-out rate in the active group and 15.8 percent drop-out rate in the sham group. A total of 28 patients (active group, 21; sham group, 7) were evaluated at 6-month follow-up visit. The number of patients who attended the follow-up visits and especially the 3-month and 6-month visits was strongly influenced by the COVID-19 pandemic because of the overall increase in patient anxiety and the pressure from medical practitioners to focus only on urgent patient cases.

The average age of the entire study population was 45.3 ± 12.7 years; for the active group, the average age was 45.5 ± 13.0, and for the sham group, the average age was 44.6 ± 12.3. The average baseline body mass index was 25.8 ± 4.0 $kg/m^2$ for the active group and 25.6 ± 3.4 $kg/m^2$ for the sham group. Fitzpatrick skin types included in the study are detailed in Table 1.

The average baseline weight was 155.9 ± 24.9 lbs, and no statistically significant ($p > 0.05$) changes were observed in any of the follow-up visits, as the average weight was 155.8 ± 24.6 lbs at 1 month and 153.4 ± 24.0 lbs at the 3-month follow-up. At 6-month follow-up, it was 151.6 ± 22.5 lb. Neither weight, body mass index, nor skin type showed a correlation with observed improvement ($p > 0.05$).

**Table 1. Skin Type Distribution**

| Skin Type | No. |
|---|---|
| I | 4 |
| II | 29 |
| III | 17 |
| IV | 5 |
| V | 5 |
| VI | 7 |

### Ultrasound Imaging

In the active group, the thickness of subcutaneous adipose tissue reduced significantly ($p < 0.05$) on average by 20.5 ± 8.6 percent (−4.8 ± 2.6 mm) at a 1-month follow-up ($n = 48$). The fat thickness was further reduced at a 3-month follow-up visit as the average reduction was 28.3 ± 5.4 percent (7.6 ± 3.7 mm; $n = 40$). One patient in this group did not show any improvement at a 1-month visit (+6.3 percent), but at 3 months, all active group patients showed significant improvement. Only four patients out of 40 showed a reduction lower than 22 percent at 3 months. The 21 patients of the active group who attended 6-month follow-up showed minor, but not statistically significant ($p > 0.05$), decline of the improvement gained at 3 months, as the improvement of this group reduced from 27.7 percent at 3 months to 25.8 percent at 6 months.

The sham group did not show any statistically significant ($p > 0.05$) changes at any of the follow-up visits compared to the baseline. Observed changes were of negligible magnitude (maximum average change of 1.1 percent) as the fat layer thickness at baseline, 1 month, 3 months, and 6 months was 23.3 ± 9.9 mm, 23.0 ± 9.9 mm, 22.6 ± 8.8 mm, and 23.2 ± 10.4 mm, respectively. See Figure 2 for fat thickness progression over time.

The muscle thickness measurements in the active group showed statistically significant ($p < 0.05$) thickening at all follow-up visits compared to baseline. The average thickening at 1 month ($n = 48$) was measured to be 2.0 ± 0.8 mm, corresponding to a 21.5 percent increment. At 3 months ($n = 40$), additional statistically significant increase was observed as the average thickening compared to baseline was 24.2 ± 8.5 percent. At 1 month after treatment, there was only one nonresponding patient with a 1 percent difference from baseline. However, the same patient's ultrasound images collected at 3 months after treatment showed 14.83 percent thickening compared to baseline. At 3 months, all patients did respond to the treatment as all of the patients showed improvement higher than 10 percent. Moreover, the level of improvement seen in the active group did show consistency as 35 out of 40 patients had an improvement higher than 15 percent, and in 22 patients, the improvement exceeded 20 percent. See Figure 3 for muscle thickness progression over time.

The 6-month data obtained from 21 patients of the active group who attended the follow-up visit showed that the results were maintained at the level seen at 3 months, although showing a slight insignificant ($p > 0.05$) improvement. The group

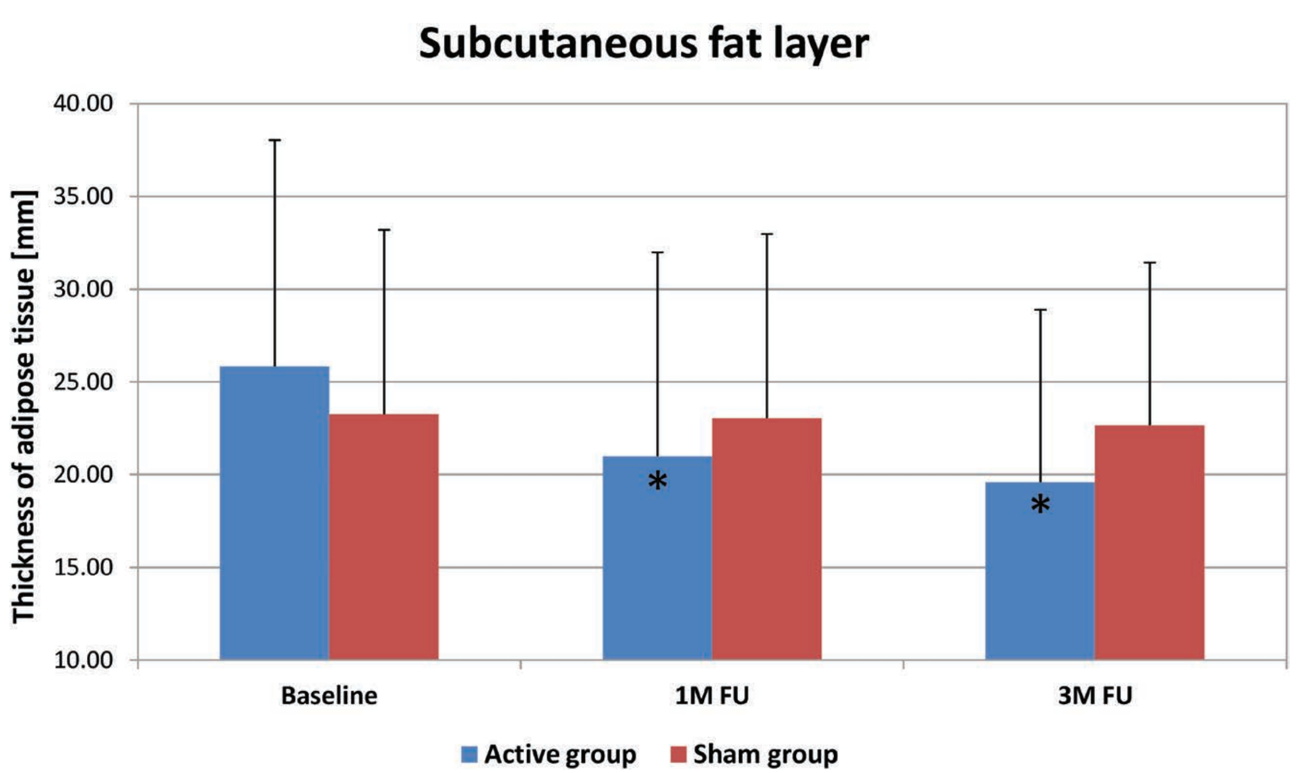


**Fig. 2.** Average subcutaneous fat layer by ultrasound for the active and sham groups at baseline, 1-month, and 3-month follow-up visits. The *asterisks* mark the statistically significant ($p < 0.05$) change in comparison to baseline data set.

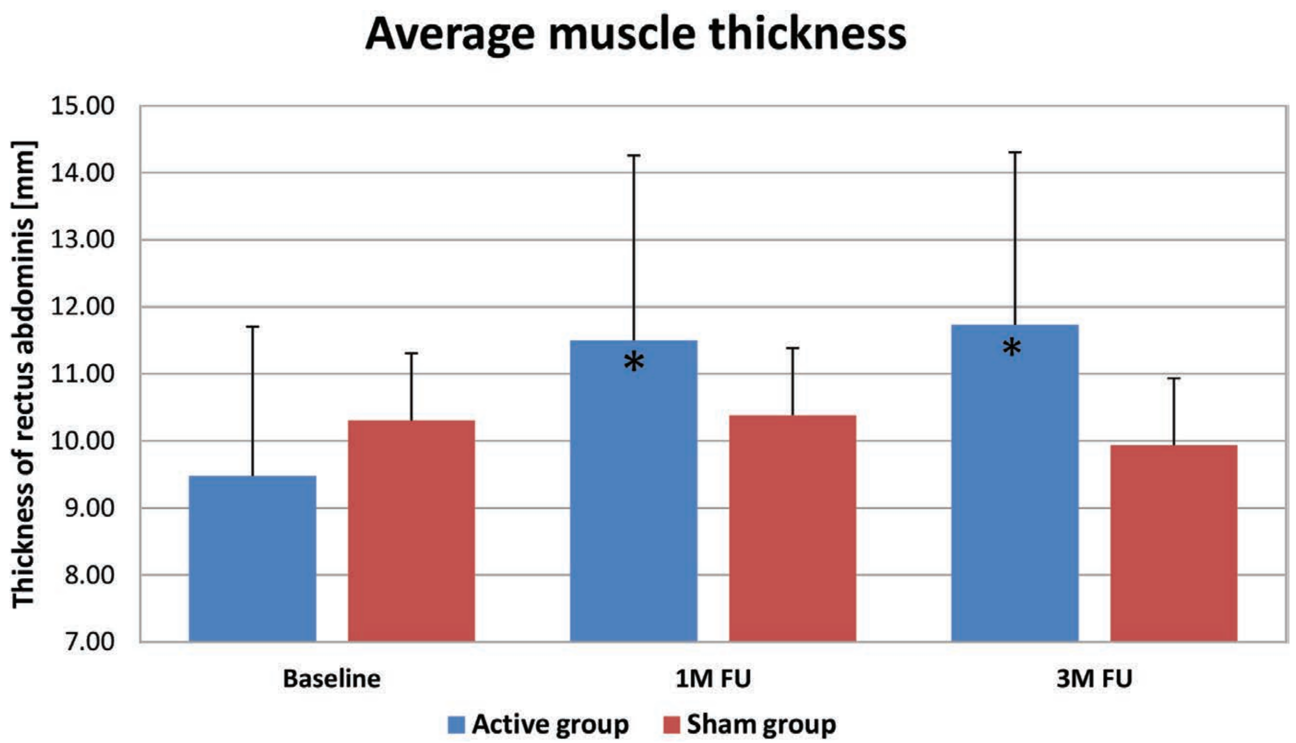


**Fig. 3.** Average rectus abdominis muscle thickness under ultrasound for the active and sham groups at baseline, 1-month, and 3-month follow-up. The *asterisks* mark the statistically significant ($p < 0.05$) change in comparison to baseline data set.

showed 23.0 percent thickening at 1 month, 23.6 percent thickening at 3 months, and 24.4 percent thickening at 6 months after treatment compared to the baseline values.

Contrary to that, the sham group patients' ultrasound images did not show any statistically significant ($p > 0.05$) changes in any direction. The average change was 0.8 ± 2.4 percent at 1 month and 0.9 ± 2.0 percent at the 3-month follow-up. At 6 months, the change was 0.7 ± 2.5 percent. Examples of collected ultrasound images can be seen in Figure 4.

### Patient Satisfaction and Safety

In the active group, 93.9 percent of patients reported satisfaction with the treatment results, whereas in the sham group, only 40.0 percent of patients were satisfied. In the active group, 89.8 percent of patients observed improvement in both abdominal muscles and reduced fat, whereas in the sham group, 31.6 percent observed improvement. The treatments were found comfortable, as the average score on the 10-point visual analog scale questionnaire (0 = no discomfort, 10 = unbearable discomfort) was 2.9 in the active group and 0.4 in the sham group. After treatment, mild erythema was present in several patients from active group but resolved within a few hours. Several patients in the active group reported mild muscle fatigue on the day after their first treatment. Several patients commented on their subjective perception of improvement in posture and back pain. No adverse events or other side effects were reported throughout the study. An example of a patient result documented in a digital photograph can be seen in Figure 5.

All the outcomes shown were independent of the patients' skin type, sex, age, or body mass index as no statistically significant correlation was found among the various data points.

## DISCUSSION

This is the first sham-controlled study investigating the combined effects of simultaneously applied synchronized radiofrequency heating and HIFEM modalities for abdominal fat reduction and muscle toning. Ultrasound measurements detected significant changes in both adipose and muscle tissues in all active group patients. No changes were found in the muscle or fat tissue in the patients of the sham group.

A significant effect on fat and muscle tissues was seen in the active treatment group at the 1-month follow-up visit, with the best improvement seen at 3 months after treatment. In regard to the fat reduction, we believe that the outcome

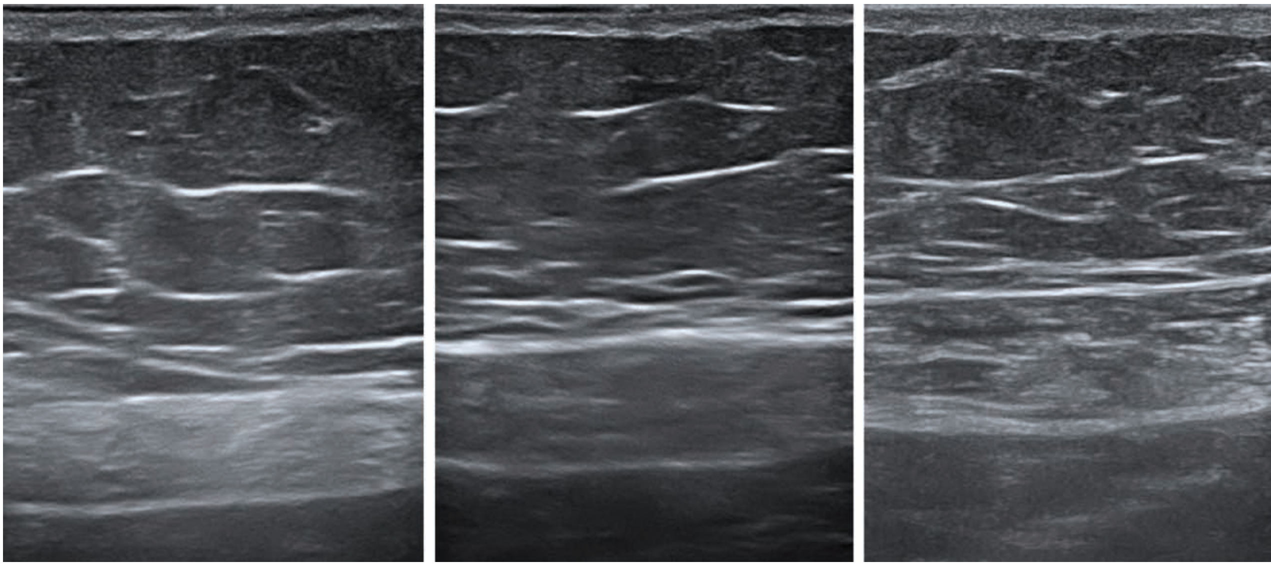

**Fig. 4.** Ultrasound images of a patient from the active group taken at baseline (*left*), 1 month after treatment (*center*), and 6 months after treatment (*right*). The images are showing continuously reducing fat layer with increasing thickness of rectus abdominis.

peaking at 3 months can be attributed to the late onset of the apoptotic processes as it has been shown that a portion of the adipocyte may enter apoptosis even several weeks after the exposure to the heat stress.[12,13] In addition, the clearing process of damaged cells takes time, prolonging the final outcome manifestation. In the muscle, the difference between 1-month and 3-month results is not that pronounced as seen in fat tissue. Yet, also in muscle tissue, the results peak at 3 months after treatment. We hypothesize that the reason for such observation could be increased hyperplasia in the tissue because the simultaneous tissue heating and supramaximal contractions have shown positive effects on the myosatellite cell activation.[14] It could thus be assumed that portion of the activated satellite cells form new muscle fibers that grow over time to match the size of existing fibers, further improving the 1-month results at 3 months after treatment.

Measurements performed at 6 months after treatment suggest that treatment outcomes can be maintained for up to 6 months. However, some of the patients did show a slight decrease in the fat-reducing effect at 6 months after treatment. Future studies will investigate the effect of

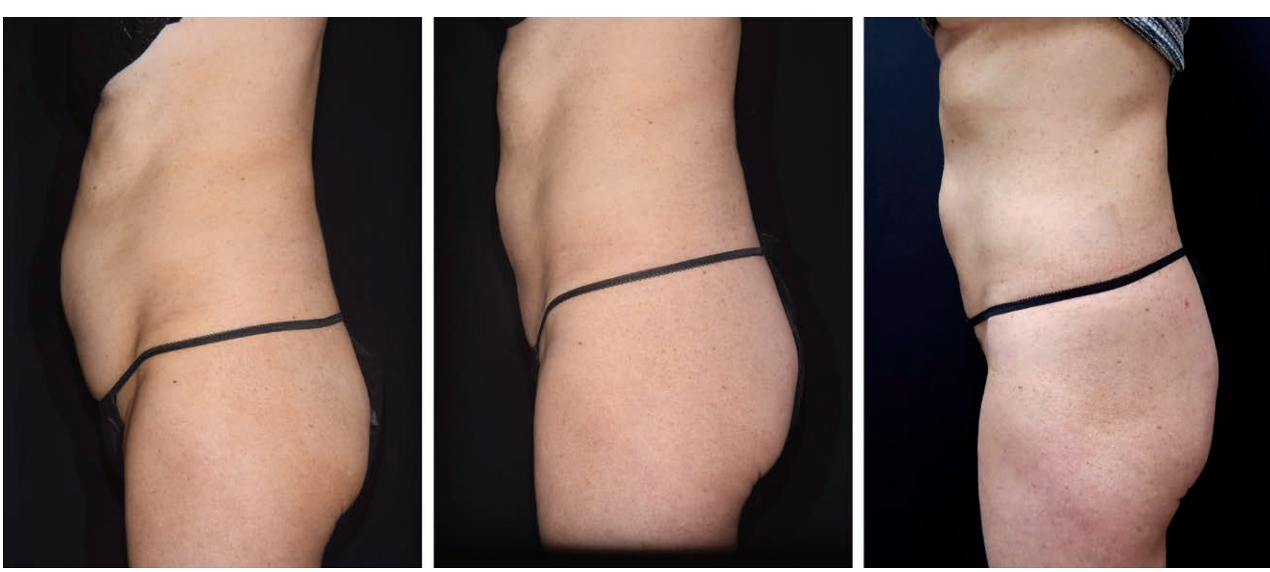

**Fig. 5.** Digital photographs of a patient from the active group taken at baseline (*left*), 3 months after treatment (*center*), and 6 months after treatment (*right*).

maintenance treatments in terms of optimal interval and frequency.

Other modalities for fat reduction include cryolipolysis, lasers, and high-intensity focused ultrasound. These modalities are generally accepted as effective technologies. Clinical studies showed that the fat-reducing effect of cryolipolysis[15–18] for the abdomen ranges from 14.7 to 23 percent. Studies investigating the efficacy of abdominal laser treatments[19,20] reported a fat thickness reduction ranging from 11.5 to 17 percent. For high-intensity focused ultrasound, the published results[21–24] are between 11.7 and 26.4 percent of fat thickness reduction.

Our study found an average fat reduction of 28.3 percent with the combination of radiofrequency heating and HIFEM treatment, which corresponds with the results of two previous studies[25] submitted to the U.S. Food and Drug Administration. Based on publicly available information from the Food and Drug Administration's database, one of the studies reported 29.8 ± 3.4 percent reduction in fat thickness assessed by ultrasound imaging and 88 percent patient satisfaction. The other study was based on histological evaluation of adipose tissue, revealing changes such as pyknotic nuclei and adipocytes membrane degeneration leading to noninvasive lipolysis (i.e., the breakdown of fat). This study found a 24.2 percent increase in the thickness of rectus abdominis. In contrast, previous research published on HIFEM-only treatments found thickening ranging from 14.8 to 15.4 percent.[26,27] Enhanced results in our study are thought to be a direct result of simultaneous use of the two modalities as it has been shown that muscle hypertrophy can be enhanced by both mechanical and heat stimulation.[5,6] Comparison of our study results versus standalone HIFEM results confirm previous research. Goto et al.[8] found that simultaneous application of heat and contractions results in significantly higher expression of heat shock proteins than the application of heat or mechanical stimuli alone.

The posttreatment outcomes were maintained for a 6-month period, although some declines were present.

High longevity of results has already been reported in a study investigating the standalone HIFEM procedure.[26] In this article, we contribute the longevity of the results to the structural changes related to activation of skeletal myosatellite cells, which has been shown in a study by Halaas et al.[14] In addition, although the patients were asked to maintain regular diet and exercise regimen, the lifestyle of the patients was not controlled during the study. The role of increased exercise activity also cannot be ruled out. The patients could easily become more motivated to perform exercise on regular basis after seeing initial improvements after the treatments.

Future studies should include a cohort with the consecutive application of HIFEM treatment and radiofrequency to fully understand the synergistic effects. They should employ histological evaluations that could be directly compared between the groups. Although we recruited 49 patients in the active treatment group, future studies are underway to validate these outcomes on a larger population. A focus on specific patient groups, such as individuals with higher body mass index or age-limited populations, would help to elucidate whether outcomes could be modified by personalization of treatment settings to specific populations. Although this study was for the abdomen, studying the effects for different body parts (e.g., buttocks or thighs) using this simultaneous treatment should be a subject of further research. To receive a better and detailed patient perception of the treatment and their satisfaction with the treatment outcomes, the BODY-Q should be considered in future trials as a patient-reported outcome instrument.

## CONCLUSIONS

This innovative and novel technology, which combines high-intensity focused electromagnetic therapy with synchronized radiofrequency in a simultaneous application to the abdomen, improves results of single-modality treatment delivered separately. This outcome is objectively confirmed by ultrasound measurements of fat reduction and muscle thickness.

*Julene B. Samuels, M.D.*
9419 Norton Commons Boulevard, Suite 101
Prospect, Ky. 40059
jsamuels@awomanstouchmd.com
Instagram: @julenesamuelsmd_facs

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