MRI and CT Assessment of Abdominal Tissue Composition in Patients After High-Intensity Focused Electromagnetic Therapy Treatments: One-Year Follow-Up

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Abstract

Background: Several studies investigating high-intensity focused electromagnetic (HIFEM) treatments have recently been published. However, due to the novelty of the procedure, long-term data are still missing.

Objectives: The aim of this study was to evaluate changes in abdominal tissues on average 1 year after a series of HIFEM treatments, to determine the long-term durability of patients' original body responses.

Methods: Magnetic resonance imaging (MRI) or computed tomography (CT) scanning were performed on 21 patients a mean of 332.6 [88.5] days after their original HIFEM treatment series. The scans were evaluated by a blinded radiologist for abdominal muscle thickness, subcutaneous fat changes, and abdominal separation. The results were compared with the MRI/CT-assisted measurements taken at baseline and 6-week follow-up. Correlations between collected data sets were calculated and tested. The incidence of any adverse events related to earlier treatments was monitored.

Results: When comparing the 1-year follow-up measurements with the baseline, the MRI/CT-assisted calculations revealed mean reductions of 14.63% (2.97 [2.11] mm) in fat, 19.05% (1.89 [0.88] mm) in muscle thickening, and 10.46% (1.96 [1.71] mm) in diastasis recti. All changes were significant ($P < 0.05$) and not related to weight fluctuations ($P > 0.05$). The baseline width of diastasis positively correlated with the degree of improvement at follow-up. No adverse events were reported.

Conclusion: The HIFEM-induced muscle hypertrophy, fat reduction, and reduction in abdominal separation were maintained 1-year posttreatment. This suggests long-term durability of the original bodily response, which needs to be verified by continuing follow-up of this group and by further studies.

Level of Evidence: 4

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In the 1980s, aesthetic medicine, previously predominantly represented by surgical procedures such as liposuction, breast augmentation, and deep-layer facelifts, began to evolve. The emergence of new technologies, and the FDA's clearance of the first cosmetic hair-removal lasers in the 1990s, initiated a shift in trend; since then, noninvasive aesthetic procedures have been growing at a faster

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pace than their surgical peers.[1] The major advantages of nonsurgical, and especially noninvasive, body-shaping solutions are their relative safety, fast protocols, reduced (or even eliminated) downtime, and often the absence of any incision-induced permanent tissue damage. However, the physiologic response to various noninvasive technologies usually cannot compare to immediate appearance alterations caused by surgical interventions such as volumetric tissue removal or the insertion of implants. Another concern relates to the long-term efficacy of noninvasive body-shaping procedures. Long-term clinical trials remain scarce but are needed to minimize medical uncertainty.

High-intensity focused electromagnetic (HIFEM) technology is a noninvasive procedure that has been the subject of multiple recent studies.[2-5] The technology delivers rapidly changing alternating magnetic fields, with intensities of up to 1.8 T and frequencies of up to 3 kHz, which induce electric currents in the underlying tissue. Motor neurons are highly sensitive to propagating electric currents and are thus stimulated, which leads to muscle contraction. An appropriate combination of pulse parameters, such as frequency, pulse width, and pulse intensity, leads to supramaximal involuntary muscle contractions. HIFEM treatment has been found to simultaneously affect the muscle tissue as well as the subcutaneous fat. Its body-contouring effects are based on the principle of a supraphysiologic response of muscle[6] and consequent rapid boost of fat metabolism.[5] Subjects with fat deposits thicker than 3 cm are recognized not to be ideal candidates for this procedure. Peer-reviewed data so far report muscle hypertrophy,[3] core strengthening, subcutaneous fat reduction,[3,7,8] and reduced abdominal separation.[3,7] The most extended published or presented follow-up data are from 6 months posttreatment.[3,4]

The objective of this study was to collect 1-year follow-up data of patients who had undergone HIFEM treatment. In total, 21 subjects were recalled on average 1 year after their original treatment series to evaluate, by magnetic resonance imaging (MRI) or computed tomography (CT), the long-term effects of the procedure.

METHODS

Study Population

The original study included 44 patients. One year after the original treatment series the patients were telephonically contacted by the practice clinical coordinator; only those patients who had not undergone any other aesthetic procedures of the abdomen, had not experienced a >10-lb (4.5-kg) weight change, or had not started taking weight-affecting medication since the original follow-up were asked to participate in the 1-year follow-up visit.

In total, 23 out of the 44 original subjects were excluded from the study due to additional abdominal procedures (abdominal skin tightening/cellulite radiofrequency treatment, n = 4; additional HIFEM treatments, n = 3; not available, n = 1); weight change exceeding 10 lb (n = 5); weight-affecting medication (n = 4); having moved away (n = 3); or not expressing interest in the follow-up visit (n = 3).

Twenty-one patients (16 women, 5 men) met the inclusion criteria, and were successfully recalled for evaluation.

Study Design

The study was a multicenter, open-label, single-arm study conducted between March 2017 and August 2018. Historically, the patients underwent MRI/CT scans at baseline and 1-2 months (average, 6 weeks) post-HIFEM procedure. Our study did not include administration of any additional treatments and the patients did not receive any other body-shaping-related treatments in the meantime.

The subjects included in the follow-up examination underwent abdominal MRI or CT scanning on average 332.6 days after completing a series of four to eight 30-minute abdominal HIFEM treatments (EMSCULPT, BTL Industries Inc, Boston, MA). The original treatments were applied with the patient lying in a supine position. Initially, the center of the device applicator was positioned over the umbilicus in an upward-facing direction and stimulation of mild intensity was delivered (up to 15%). The position of the applicator was individually adjusted to create homogeneous contractions across the abdomen, and the intensity was then increased to therapeutic levels just below the patient's tolerance threshold. The intensity was further adjusted during the treatment according to the patient's feedback. A fixation belt served to prevent any applicator movements during the course of the treatment. The clinical protocol was approved by an institutional review board committee (Advarra, Columbia, MD) and conformed to the ethical guidelines of the 1975 Declaration of Helsinki. Signed written informed consent was acquired from all patients. The individual follow-up length ranged from 231 to 509 days. MRI/CT scanning methodology was identical with the original baseline and posttreatment evaluation (T12 to S1 vertebrae determination, axial planning, and maximum spacing 50 mm).

Evaluation Methodology

Extracted MRI/CT images were evaluated by a single certified radiologist for the thickness of musculus rectus abdominis, abdominal subcutaneous fat, and the width of abdominal separation. Evaluation of matching bodily sections was then compared with the original baseline and posttreatment evaluation data. Cross-sectional

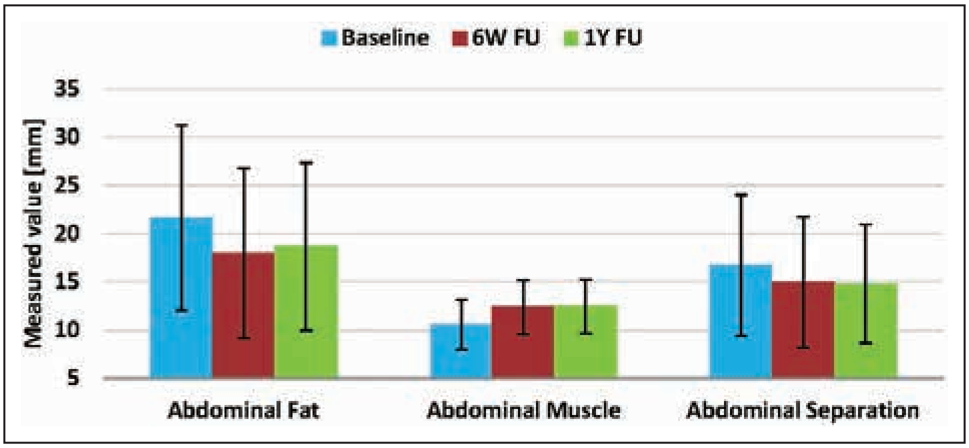

Figure 1. Magnetic resonance imaging/computed tomography–assisted measurements of abdominal fat, abdominal muscle, and abdominal separation (n = 21). Values are plotted in millimeters. The vertical lines represent standard deviations. 6W FU, 6-week follow-up; 1Y FU, 1-year follow-up.

dependence was statistically tested to reveal possible links among the different measurements taken. On the day of their MRI/CT scanning, patients were also screened for any adverse events and side effects that could relate to the initial treatment series, and their weight was measured.

The statistical difference between baseline and follow-up measurements was determined with a paired *t* test. Pearson's correlation tests were run to investigate the interdependence between the various sets of collected data; the significance of resultant *r* values was also tested.

RESULTS

The 21 patients who were successfully recalled for the follow-up and met the inclusion criteria had a mean age of 40.1 [10.4] years (range, 23-54 years), and a mean body mass index (BMI) of 24.1 [3.2] kg/m^2 (range, 18.4-30.4 kg/m^2).

Changes in Abdominal Tissue at 1-Year Follow-Up

At the 1-year follow-up, the MRI/CT-assisted measurements showed that the subcutaneous fat thickness remained reduced in 19 out of the 21 patients compared with baseline; 1 patient did not show any change (+0.3%) and the fat layer increased in another patient (+6.3%). Overall, the mean change was a 14.63% (2.97 [2.11] mm) reduction compared with baseline, which represents a minor, but not statistically significant, decline from the original 6-week measurements (17.46%, 3.67 [2.20] mm reduction).

At the initial 6-week follow-up, all 21 patients showed bulking of abdominal muscles when compared with their pretreatment evaluation, with the mean change measured from the MRI/CT scans being +17.66% (1.79 [0.73] mm). This muscle-thickening effect was maintained at the 1-year follow-up (+19.05%, 1.89 [0.88] mm). In all 21 patients the rectus abdominis thickness was increased on both sides at the 1-year follow-up compared with baseline; 11 patients further improved between the 6-week and the 1-year follow-ups, but the overall difference between 6-week and 1-year follow-ups was not significant.

A statistically significant narrowing in the abdominal separation was observed at the 6-week evaluation when compared with baseline (–10.76%, –1.82 [1.46] mm). When remeasured in the 1-year scans, this effect remained unchanged (–10.46%, –1.96 [1.71] mm). See Figure 1 and Table 1 for a summary of observed changes in all measured abdominal tissues.

All tissue changes between the baseline and the 6-week follow-up, as well as between the baseline and the 1-year follow-up, showed a high statistical significance through paired *t* tests ($P < 0.05$). However, no statistically significant difference between the 6-week and 1-year measurements was found for any of the assessed tissues ($P > 0.05$). In addition, no statistical difference was found between the patients who completed 4 vs 8 treatments.

Weight changes were insignificant in both the original as well as the 1-year follow-up. None of the patients reported any side effects or adverse events that could be linked to the original treatment.

Mutual Correlations

Statistically speaking, most variables proved to be unrelated to each other, yet the data suggest 3 significant correlation trends. See Table 2 for an overview of results.

A moderately strong positive correlation ($r = 0.53$; $P = 0.01$) was found between the baseline BMI and the absolute subcutaneous fat thickness at baseline. A weak

Table 1. Average Changes in Abdominal Tissues Over Time

	6 weeks to baseline	1 year to baseline	1 year to 6 weeks
Abdominal fat thickness	–3.67 mm; $P < 0.05$	–2.98 mm; $P < 0.05$	+0.7 mm; $P > 0.05$
Abdominal muscle thickness	+1.8 mm; $P < 0.05$	+1.9 mm; $P < 0.05$	+0.11 mm; $P > 0.05$
Abdominal separation width	–1.83 mm; $P < 0.05$	–1.96 mm; $P < 0.05$	–0.14 mm; $P > 0.05$
Weight	–0.36 lb; $P > 0.05$	+0.42 lb; $P > 0.05$	+0.78 lb; $P > 0.05$

A paired *t* test was used to test the significance of the changes.

Table 2. Correlations Between the Measured Parameters

	Baseline fat, mm	Fat reduction, mm	Baseline muscle, mm	Muscle growth, mm	Baseline abdominal separation, mm	Reduction in separation, mm	Weight loss, lbs
Fat reduction	0.18; 0.43	–	–	–	–	–	–
Baseline muscle thickness, mm	–0.26; 0.26	0.40; 0.07	–	–	–	–	–
Muscle thickness growth, mm	–0.14; 0.54	–0.10; 0.67	–0.48; 0.03	–	–	–	–
Baseline abdominal separation, mm	0.03; 0.91	–0.29; 0.21	–0.08; 0.72	–0.08; 0.72	–	–	–
Reduction in abdominal separation, mm	0.13; 0.59	0.26; 0.25	0.10; 0.66	–0.14; 0.54	–0.49; 0.02	–	–
Weight loss	0.07; 0.78	–0.10; 0.65	–0.04; 0.85	0.22; 0.33	–0.09; 0.69	–0.02; 0.93	–
Baseline BMI, kg/m^2	0.53; 0.01	0.34; 0.13	0.19; 0.42	–0.05; 0.84	–0.14; 0.54	0.21; 0.35	–0.17; 0.45
Length of FU, days	NR	–0.33; 0.14	NR	–0.35; 0.12	NR	–0.39; 0.08	0.15; 0.52
Number of treatments	NR	–0.32; 0.16	NR	–0.25; 0.27	NR	–0.22; 0.33	–0.30; 0.19

The first number in each cell is the Pearson correlation coefficient (r), and the second number is the value of significance (P). Fat reduction, muscle thickness growth, reduction in separation, and weight-loss parameters were calculated as the difference between the baseline measurement and the 1-year follow-up measurement. Duplicate calculations were omitted. BMI, body mass index; FU, follow-up; NR, not relevant.

yet statistically significant negative relation ($r = –0.48$; $P = 0.03$) was observed between the patients' muscle thickness before treatment and the percentage change in this thickness measured at the 1-year visit. Furthermore, a correlation ($r = –0.49$; $P = 0.02$) was measured between the initial size of the abdominal separation and its reduction at the 1-year follow-up visit.

DISCUSSION

In this study, we present data of the longest follow-up yet reported on patients treated with HIFEM for abdominal body shaping; previous studies have evaluated patients between 1 and 6 months posttreatment.

At the 1-year follow-up, 19 (90.5%) patients showed statistically significant lasting improvement in all 3 of the evaluated tissues (reduced fat, bulked muscles, shortened muscle separation); the remaining 2 patients had a lasting improvement in 2 out of the 3 measurements. The coefficient of variation of observed changes increased compared with the original 6-week follow-up measurements (from an average of 53.4% at 6 weeks to 68.7% at 1-year posttreatment).

This suggests that after the initial treatment series, patients are likely to preserve the induced changes over a span of many months, yet with a higher variability probably affected by individual lifestyle and physical/dietary habits. This also means that patients may maintain a visible aesthetic improvement in the long term. See Figures 2-4 for examples of patient images.

Although based on a limited-size sample, an interesting observation was the absence of any significant correlation

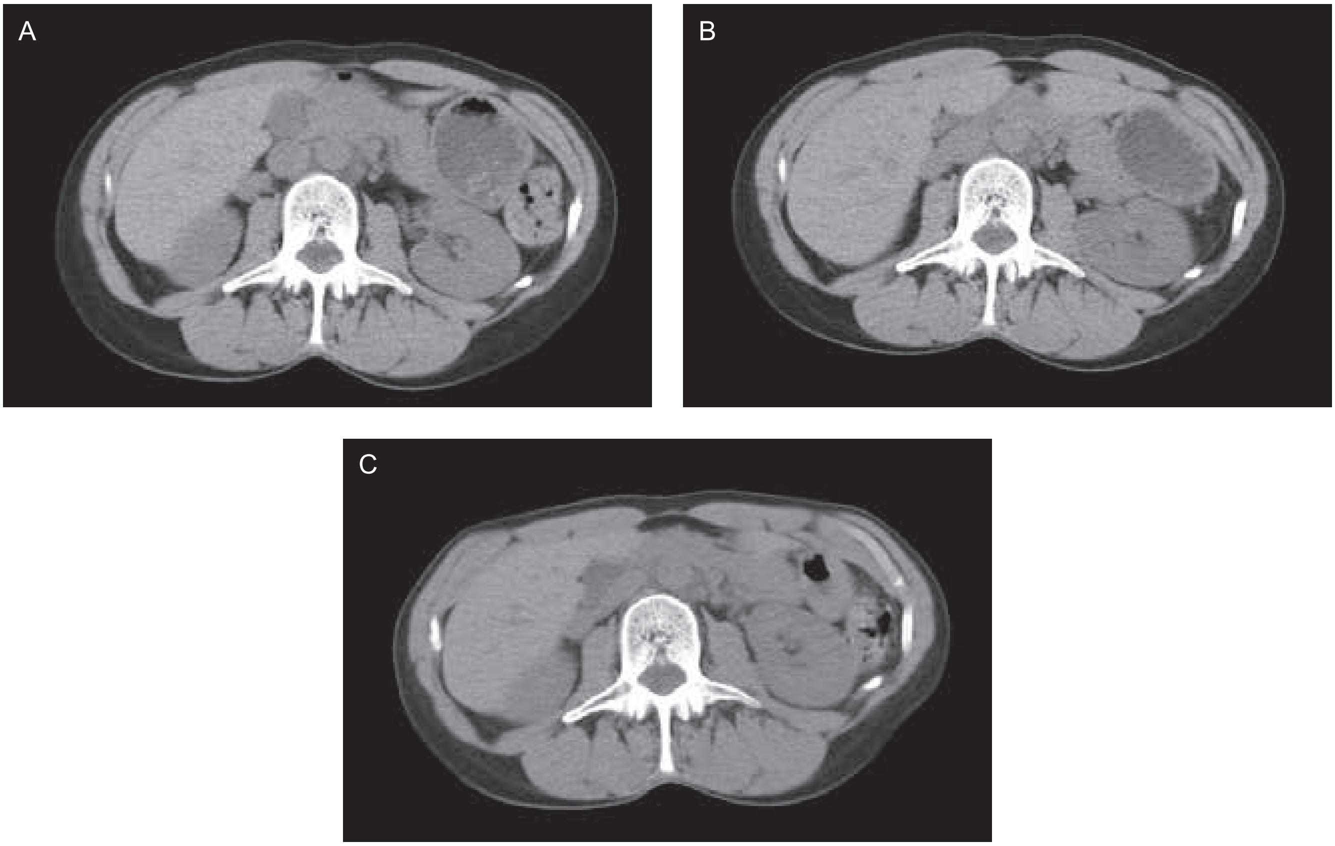

Figure 2. Computed tomography of a 37-year-old female patient at (A) baseline, (B) 1 month posttreatment, and (C) 1 year posttreatment. The fat reduction from 1 month (–10.7%) was improved at the 1-year visit (–40.5%). The thickening of the rectus abdominis muscle at 1 month (+32.0%) was slightly reduced to +26.1% at the 1-year follow-up.

between the exact length of the follow-up and the degree to which patients preserved their improvements. This suggests that the original changes in abdominal tissues do not follow a linear trend of decline, but larger-cohort studies will be needed to verify such a hypothesis.

A moderately strong positive correlation ($r = 0.53$; $P = 0.01$) between the baseline BMI and the baseline absolute subcutaneous fat thickness was expected, on the basis that larger BMI values are usually associated with accumulation of abdominal fat. Data processing also revealed a weak, yet statistically significant, negative relation between muscle thickness before treatment and the percentage change in thickness measured at the 1-year visit. This suggests that patients with initially more severe abdominal muscle disuse atrophy are likely to respond with more profound hypertrophic effects. Another significant weak correlation was measured between the initial size of abdominal separation and its reduction at the 1-year visit. This again shows that patients with more severe separation are more likely to see a better improvement 1 year after treatment.

Although the differences in muscle (+19.05%) and fat (–14.63%) are nearly the same and the patients' fat loss might seem to be compensated by muscle gain, we can still see circumferential reduction in these patients due to the correction of abdominal muscle laxity. Because the fat layer is reduced and muscle mass increased, the muscle definition below the skin is much more visible, which contributes to the athletic look that many patients desire. However, it is true that in patients with large fat deposits, the muscle effect cannot be seen very well because the muscles are hidden below the fat layer. In these patients only a reduction in fat can be seen. It should be noted, however, that patients with high fat deposits are not considered ideal candidates for HIFEM treatment.

A minor decline in the original fat reduction over time was expected as any lifestyle alterations may stimulate abdominal fat redeposition and lipolysis, and a subsequent adipocyte resizing effect may also play a role. Regarding muscle, not only preservation but even a minor continuous improvement is a result that does not correlate with previous research on muscle response to exercise, especially when our patients reported an unchanged lifestyle. Although no direct evaluation of hypertrophy has been reported, various studies have observed a decline in muscle strength, which starts between 1 and 6 months after the last

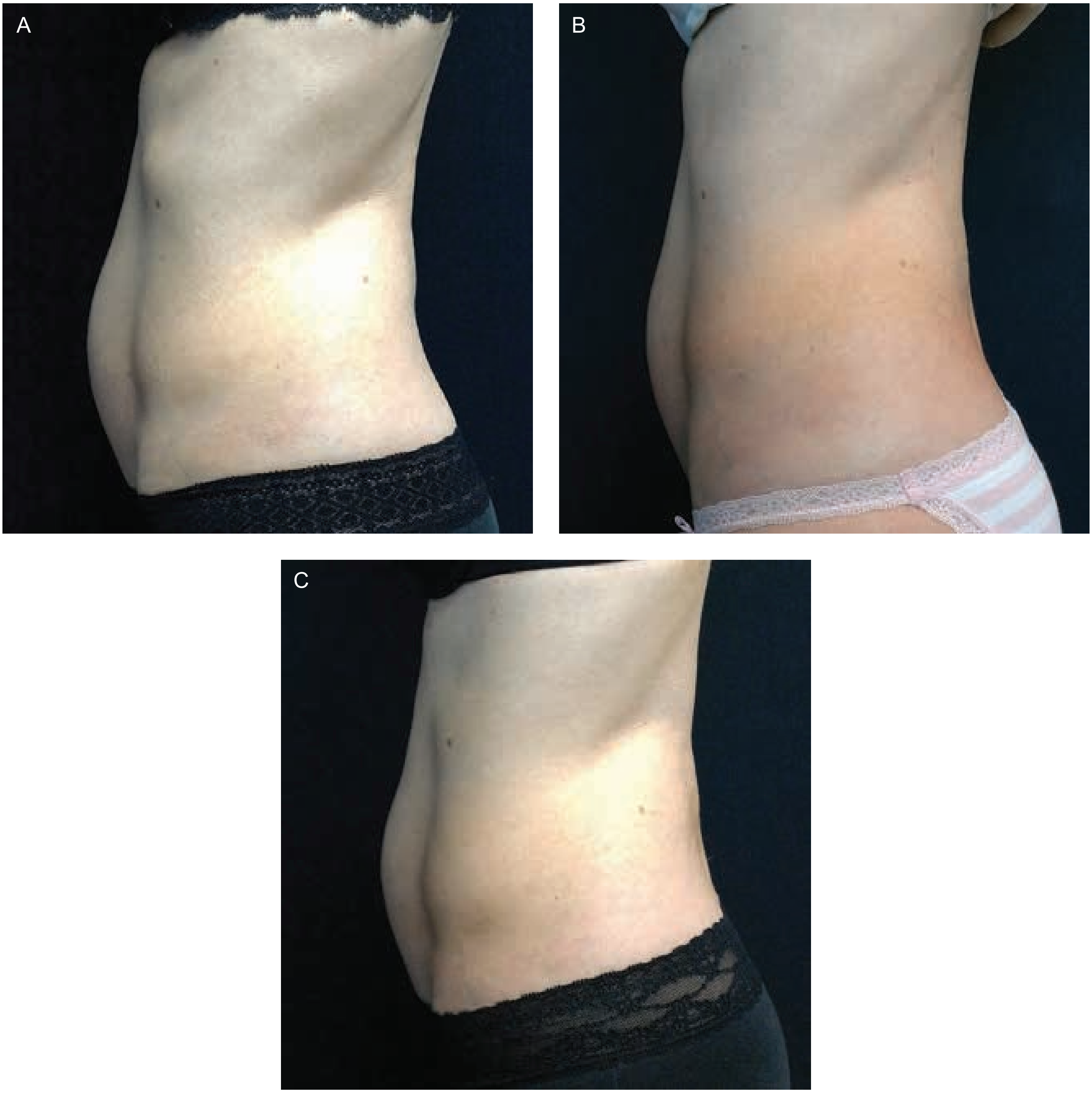

Figure 3. Digital photographs of a 37-year-old female patient (the same patient featured in Figure 2) at (A) baseline, (B) 1-month posttreatment, and (C) 1-year posttreatment.

exercise.[9-11] Duncan and Dinev[6] evaluated porcine muscle histology after HIFEM application and proposed a possible hyperplasic effect of the treatments. Their data are not conclusive, but if true, could explain that even without lifestyle changes, long-lasting muscle bulking occurs due to a higher number of muscle fibers in the patient's tissue. Any future research on human muscle biopsies could also provide better insights as to whether there is any effect of the treatments on myosatellite cells.

Based on circumferential measurements, Kent and Jacob[7] suggested that the application of 8 HIFEM treatments does not necessarily result in more profound changes in abdominal tissues compared with the application of 4 treatments. In this study group no significant

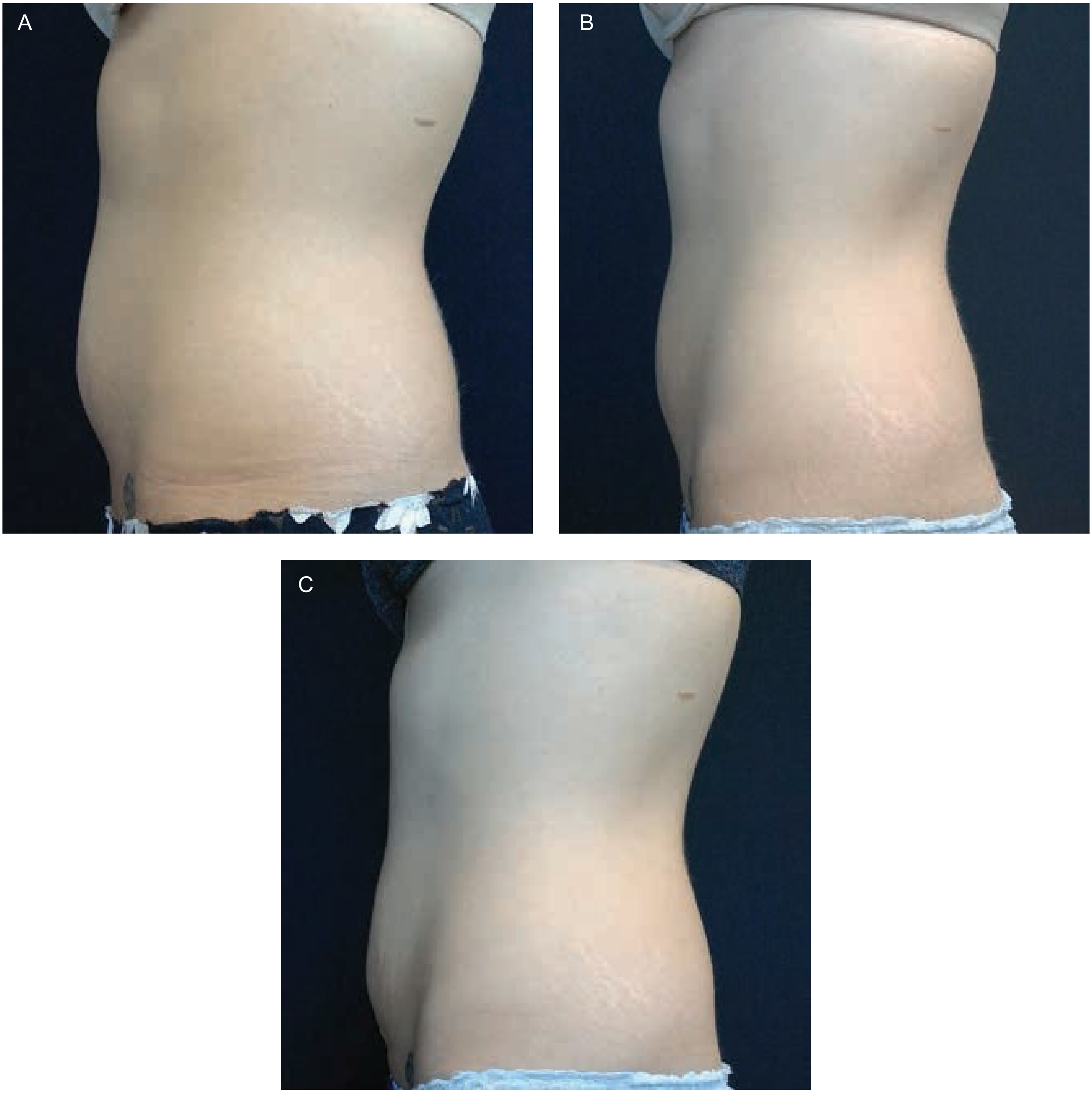

Figure 4. Digital photographs of a 51-year-old female patient at (A) baseline, (B) 1 month posttreatment, and (C) 1 year posttreatment.

relation was found between the number of treatments received and the degree of change in evaluated tissues at the 1-year follow-up. An explanation for this observation remains unknown, and future research may focus on investigating why there is a higher potential for HIFEM-induced changes in abdominal tissues in the first few sessions rather than following any additional treatments.

One limitation of such long follow-up is the inability to control the patients' lifestyles. After this long period of time the results may thus not be solely attributed to the treatment itself. It could be a combined effect of the treatments, following a balanced and healthy diet, together with incorporating exercise into their daily activities. Although our inclusion criteria were intended to reduce such bias, the effect of lifestyle cannot nevertheless be entirely ruled out. A lack of patient satisfaction evaluation can also be considered a limitation of this study as patient satisfaction is a crucial outcome in aesthetic medicine. However, the current study was focused solely on objective evaluation free of subjectivity, which is high according to satisfaction questionnaires. Another limitation of the study is associated with the MRI/CT interslice spacing. The spacing between the individual slices was 5 mm. Because the MRI/CT scans were obtained at different times, the exact slice location could have moved slightly relative to the baseline scans, resulting in a maximum of 5 mm difference between the compared slices. However, we believe that a difference of up to 5 mm does not affect the final results. Furthermore, the study included only 21 patients out of the original patient group (n = 44) and this sample may not be representative of the entire general population. It is necessary to collect data from a larger group of patients post-HIFEM procedure to investigate whether the same patterns are also present on a larger scale.

CONCLUSIONS

Twenty-one patients who received HIFEM treatment were evaluated on average 1 year after their procedure in order to understand trends in the long-term evolution of their original body responses. Our results show that in those patients, HIFEM-induced muscle hypertrophy, fat reduction, and reduction in abdominal separation are maintained for at least 1 year posttreatment. Maintenance treatments can be used to prevent decline in individual patients.

Disclosures

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