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ORIGINAL ARTICLE

Retrospective analysis of high-intensity focused electromagnetic procedure synchronized with radiofrequency energy for visceral fat reduction

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Abstract

Background: Visceral adipose tissue (VAT), present in the abdominal cavity, oftentimes contributes to an unpleasant aesthetic appearance and can be correlated with serious health issues. High-intensity focused electromagnetic field (HIFEM) technology with synchronized radiofrequency (RF) was recently used for abdominal body shaping through subcutaneous fat reduction and muscle growth.

Aim: This study aimed to assess the effect of HIFEM + RF technology on VAT tissue.

Methods: Data of 16 men and 24 women (22–62 years, 21.2–34.3 kg/cm^2) from the original study were retrospectively reviewed. All subjects received three 30-min HIFEM + RF abdominal treatments once weekly for three consecutive weeks. The VAT area was measured in the axial plane of MRI scans at two levels: L4–L5 vertebrae and 5 cm above this level. The VAT was identified, segmented, and calculated, yielding total area in square centimeters per scan at both specified levels.

Results: By thoughtful review of the subject's post-treatment MRI scans, no other changes in the abdominal cavity were found except for VAT. The evaluation showed a VAT reduction of 17.8% ($p < 0.001$) on average at 3-month follow-up, maintaining the results up to 6 months (−17.3%). Averaging the values obtained from both measured levels, the VAT, occupied an area of 100.2 ± 73.3 cm^2 at the baseline. At the 3-month follow-up, the subjects achieved an average reduction of 17.9 cm^2, preserving the results at 6 months (−17.6 ± 17.3 cm).

Conclusion: This retrospective analysis of MRI images objectively documented the effect of HIFEM + RF abdominal therapy on VAT. The data indicates considerable VAT reduction without serious adverse events following the HIFEM + RF procedure.

KEYWORDS
abdominal fat reduction, HIFEM, non-invasive lipolysis, radiofrequency, visceral fat reduction

1 | INTRODUCTION

Fat is a fundamental part of the human body, functioning as energy storage, insulator, protector of vital organs, co-builder of the cell wall, and initiator of many chemical reactions of basal metabolism.[1] Many types of fat tissue are recognized based on their location in the body (subcutaneous, visceral, bone marrow, and breast tissue) and function (white, brown, beige).[2] The most abundant subcutaneous adipose tissue (SAT) is found beneath the skin and serves as a metabolic sink where the excess energy intake (free fatty acid (FFA) and glycerol) is primarily stored as triglycerides (TG) in adipocytes[3]–the basic building blocks of the fat tissue. In contrast, visceral adipose tissue (VAT) occupies the abdominal cavity to protect vital organs, and besides energy storage, it acts as an endocrine and paracrine organ, influencing insulin resistance, body weight, the pathogenesis of diabetes mellitus, lipid metabolism, or inflammation.[4] The accumulation of fat is sex-specific[5] since a majority of premenopausal women tend to store the adipose tissue in the femorogluteal region resulting in a pear-shaped body contour, while a minority of women and most men tend to store the adipose tissue in the abdomen area, resulting in a displeasing apple-shaped body contour.[6] The different distribution is due to sex-specific hormones[7] and the unequal dietary fat intake between the sexes.[6] As men generally have a higher dietary intake of fat, they are expected to produce bigger lipoproteins (chylomicrons) that promote fat accumulation in the abdominal visceral area.[6]

The increasing VAT amount coincides with numerous health issues, especially long-term. The visceral fat cross-sectional area (CSA) at the umbilical level exceeding 100 cm^2 is associated with elevated risks of coronary heart disease (CHD) or metabolic problems such as diabetes mellitus, further increasing the risk when the VAT area exceeds 160 cm^2.[8] However, the amount of VAT tends to be independent of BMI, as individuals with normal BMI can also exhibit significantly increased VAT amounts and be at risk of CHD; referring to the term "metabolically obese normal weight" (MONW).[9] Fortunately, since VAT is more sensitive to lipolysis than SAT[10] (a metabolic pathway of TG hydrolysis to produce FFA and glycerol released into the bloodstream to be used by the body as an energy source[11]), it can be maintained and even reduced by diet combined with exercise routine.[4]

There are solutions for combating excessive VAT, such as bariatric surgery, for example, a roux-en-Y gastric bypass, pharmacotherapy, and exercise.[12,13] Despite the significant VAT reduction, to successfully maintain the beneficial results after surgery or pharmacotherapy, there is a demand for lifestyle changes in regards to diet and physical activity, that many cannot hold on to.[12,14] Today, proven and effective technologies in aesthetic practice may offer an alternative to such demanding lifestyle modifications. Particularly, the high-intensity focused electromagnetic field procedure (HIFEM), based on inducing supramaximal contractions, was evidenced to induce profound muscle fiber hyperplasia and hypertrophy.[15] In a retrospective analysis by Kent and Kinney,[16] the VAT-reducing effect of the HIFEM technology was firstly evidenced. Since then, a new technology combining the simultaneous application of HIFEM and synchronized radiofrequency (RF) has evolved. The addition of RF to the HIFEM energy deepens the muscle strengthening effect as it heats the muscle up to 40°C, leading to a significant increase in activation of satellite cells that regenerate and strengthen the muscle fibers.[17] This creates a more profound impact on muscle strengthening, since the results of HIFEM + RF treatments were observed to be comparable to 12–16 weeks of intensive workout.[17]

Based on the previous research,[16,17] we hypothesized that the simultaneous application of HIFEM + RF technology might induce favorable changes in the VAT due to increased muscle metabolism.

2 | METHODS

2.1 | The original study population and treatment setup

This study is a retrospective analysis of a previously published prospective, multicentre, open-label, single-arm MRI study by Jacob et al.[18] After a review of the subject's medical history, 41 subjects were recruited (22–62 years, BMI 21.2–34.3 kg/m^2, skin Types I–VI) out of which were 17 men (22–59 years, BMI 21.2–34.3 kg/m^2) and 24 women (24–62 years, BMI 21.3–34.2 kg/m^2), to participate based on inclusion (above 21 years old, BMI below 35 kg/m^2) and exclusion criteria (pregnancy, postpartum, breastfeeding, menstruation during the treatment, injury in the treated area, cardiovascular disease, cancer, and other medical condition that contraindicate the use of electromagnetic field and RF). The study protocol was approved by Institutional Review Board and followed the 1975 Declaration of Helsinki guidelines. Before initiating the study, all patients signed the informed consent forms and received detailed information about the study. These subjects were instructed not to change their lifestyle and eating habits throughout the study, which was controlled by a Lifestyle questionnaire filled out at a 3-month follow-up visit. They received three 30-min treatments once a week on the abdomen delivered through the applicator simultaneously emitting HIFEM and RF energies (Emsculpt NEO, BTL Industries Inc.) and are equipped with real-time temperature sensors. Patients were positioned in a supine position with an affixed applicator centered on and covering their umbilicus. The intensity of HIFEM was set according to the maximally tolerated level (0%–100%), while RF was set to 100% from the beginning. The data collection included magnetic resonance imaging (MRI) of the treated area taken at baseline, 1-, 3-and 6-month follow-up visits. The subjects' study visits (treatment visits and follow-up visits) were scheduled for similar times within business hours of the practice, including the MRI appointments.

2.2 | The visceral fat evaluation

The study's MRI (Matrix 380 × 380, slice thickness 5 mm, spacing 1 mm, transverse plane) data were used in this retrospective analysis.

The MRI scans were newly analyzed to evaluate the changes in VAT. The scans in DICOM format were semi-automatically evaluated using software to reconstruct MRI images (InVesalius 3.1). The CSA corresponding to VAT was identified on two levels (L4–L5 vertebrae and L4–L5 + 5 cm, Figure 1), which closely relates to the VAT volume in the abdomen.[19] First, the threshold method was used to detect the pixels corresponding to adipose tissue automatically. Furthermore, the scans were manually checked to include only VAT in the calculations, subtracting any of the SAT-marked areas. The visceral fat CSA was then computed on both levels separately and averaged. The MRI assessment was performed by a blinded radiologist.

To determine the statistical significance of VAT change in the study, One Factor ANOVA Repeated Measures followed by Tukey HSD post-hoc test was used. The difference between the genders and measured levels was tested by two-sample Student's *t*-tests. The correlation between the BMI and changes in VAT was tested by Pearson's correlation coefficient. The significance level α was set at 5% for all statistical analyses. Descriptive statistics were used to characterize the results as a mean ± SD.

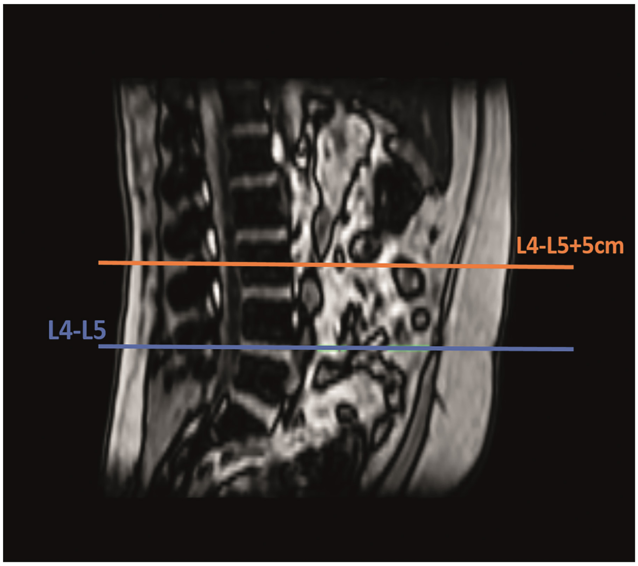

FIGURE 1 Visualization of the levels used for retrospective evaluation of VAT using MRI scans from original study,[18] midsagittal plane.

3 | RESULTS

In total, 16 men and 24 women ($n = 40$) completed the treatment visits and 1-month follow-up in the original study. A total of 29 and 20 subjects arrived for 3-month and 6-month follow-up visits, respectively, including the MRI scan visits. This drop-out was mainly attributed to the outbreak of the COVID-19 global pandemic, which restricted the patients from attending to their scheduled follow-up visits. However, one patient met the exclusion criteria, with one patient being withdrawn due to noncompliance with the protocol. The lifestyle questionnaire revealed that no patient made any changes in their exercise routine, one patient reported a change in his leisure time, as he traveled more and had less time. Four patients disclosed a change in their diet, as holidays made them eat more ($n = 3$), and one patient cut off on alcohol. And finally, three patients admitted higher stress levels due to work.

The procedure was safe without serious adverse events, one patient developed a small blister that resolved normally within a few weeks and no additional medical care was needed. Based on the MRI, the visual examination of abdominal organs in the vicinity of the treated area (such as liver, kidneys, spleen, etc.[20]) did not demonstrate any structural changes or abnormalities during the study, indicating that the treatment presumably does not affect tissues other than skeletal muscles and fat. No significant fluctuations in weight were observed either ($p > 0.05$).

The retrospective evaluation of MRI scans revealed a gradual and significant ($p < 0.001$) decrease in the VAT during the study. At 1-month follow-up, patients showed an average relative decrease of 15.3% in VAT with a peak at 3 months (−17.8%). The improvement rate was maintained at a 6-month follow-up visit, showing a − 17.3% decrease. There were no non-responsive patients as the range of relative reduction was 10.6%–19.7% at 1 month, 15.5%–21.8% at 3 months, and 15.1%–20.2% at 6 months. When assessing the two levels individually, the decrease was of the same magnitude in relative numbers, yet slightly but insignificantly higher at the L4–L5 + 5 cm level in absolute numbers, especially at 6 months ($p > 0.05$, see Table 1). There was no correlation between the BMI and the decrease in VAT during the study, $r(27) = 0.21$, $p = 0.27$, and $r(18) = 0.15$, $p = 0.52$ at 3-month and 6-month follow-up visits, respectively.

TABLE 1 The average decrease in VAT represented in percentage (%) and cross-sectional area (CSA, in cm^2) calculated from baseline; mean ± standard deviation. All differences against baseline were significant at the level of $p < 0.001$.

	Average		L4–L5		L4–L5 + 5 cm	
	cm^2	%	cm^2	%	cm^2	%
Baseline	100.2 ± 73.3	-	93.5 ± 54.1	-	106.9 ± 88.7	-
1-month follow-up change ($n = 40$)	−15.8 ± 12.7	−15.3 ± 2.4	−14.6 ± 9.3	−15.2 ± 2.4	−17.1 ± 15.5	−15.3 ± 2.5
3-month follow-up change ($n = 29$)	−17.9 ± 15.4	−17.8 ± 2.0	−16.7 ± 10.5	−17.7 ± 2.1	−19.1 ± 19.3	−17.9 ± 1.8
6-month follow-up change ($n = 20$)	−17.6 ± 17.3	−17.3 ± 1.9	−15.3 ± 9.7	−17.2 ± 1.9	−19.9 ± 22.6	−17.3 ± 1.8

At baseline, 21 subjects showed a VAT area above 100 cm^2, out of which 12 patients had a VAT area greater than 160 cm^2. These high-VAT individuals showed an average CSA of 149.2 ± 45.0 cm^2 at the L4–L5 level, with 164.0 ± 94.6 cm^2 at the L4–L5 + 5 cm level at baseline. The VAT reduction was similar on both levels, showing a peak at 3-month follow-up with −17.9% (−27.4 ± 9.6 cm^2) at L4–L5 level, and −17.7% (−33.1 ± 24.0 cm^2) at L4–L5 + 5 cm, both $p < 0.001$. At the end of the study, only nine patients showed VAT above 100 cm^2, out of which only three had VAT above 160 cm^2.

When comparing the decrease in VAT between the sexes, male subjects showed an average VAT reduction of 17.6% (−23.2 ± 21.5 cm^2, $p < 0.001$) at 3-month follow-up, while the females experienced an average reduction of 17.9% (−14.3 ± 7.4 cm^2, $p < 0.001$). Women showed lower VAT at baseline (82.9 cm^2) than men (126.2 cm^2) on average; therefore, even though both genders achieved similar relative differences in percentage, CSA reduction was greater and more significant in men ($p < 0.001$).

The decrease in VAT amount impacted the overall visual appearance of the treated abdominal area when inspecting the subject's digital photographs. Changes in the abdominal contours can be seen in Figures 2–5.

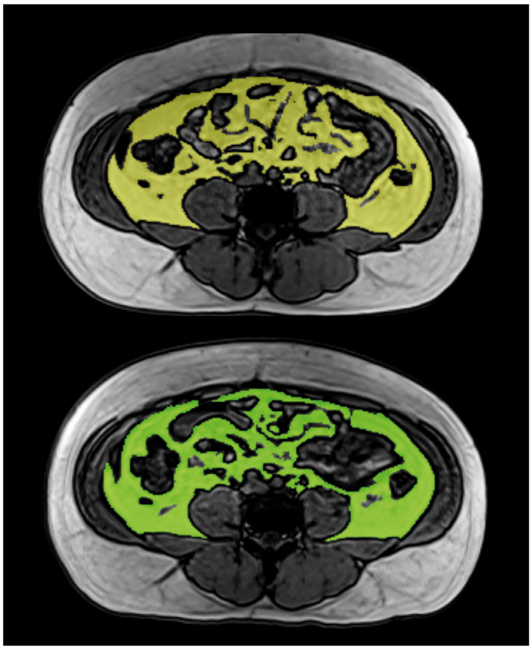

FIGURE 2 A visualization of the segmented VAT area at baseline (yellow) and 3-month follow-up (green); a 34-year-old male subject with BMI 29.5 kg/m^2, L4–L5 + 5 cm level in the axial plane. Baseline CSA of 159.6 cm^2 was reduced by 17.4%–131.9 cm^2 after the HIFEM + RF procedure.

4 | DISCUSSION

The main focus and objective of this retrospective study were to document the hypothesized effects of the synchronized application of HIFEM + RF on VAT. Apart from the favorable changes to muscle and fat thickness shown by the original study,[18] our investigation revealed the safety and efficacy of the HIFEM + RF procedure to reduce VAT. The retrospective analysis of CT scans by Kent and Kinney[16] showed that patients treated with standalone HIFEM procedure achieved an average VAT reduction of 14.3% (16.7 cm^2), suggesting the differences between sexes, however, due to a low number of male subjects ($N = 3$), this tendency could not be verified statistically. This study on the synchronized application of HIFEM + RF discovered an average VAT reduction of 17.8% (17.9 cm^2) sustainable at a minimum of 6 months.

Furthermore, VAT reduction at both measured levels showed analogous percentage differences, which indicates uniform and homogenous results across the treated area. Similarly, although men lost higher amounts of VAT area in total, the relative loss was more than comparable between the sexes (17.6% in men, 17.9% in women) which illustrates the corresponding effectiveness of HIFEM + RF treatments regardless of gender. In addition, at the end of the study, 12 out of 21 subjects (57.1%) have fallen below the 100 cm^2 CSA threshold, indicating possible depreciation of health risks stemming from the high VAT amount.

FIGURE 3 A comparison of digital photographs of a 34-year-old male taken at baseline (left) and 6-month follow-up visit (right, an average VAT reduction of 16.8%).

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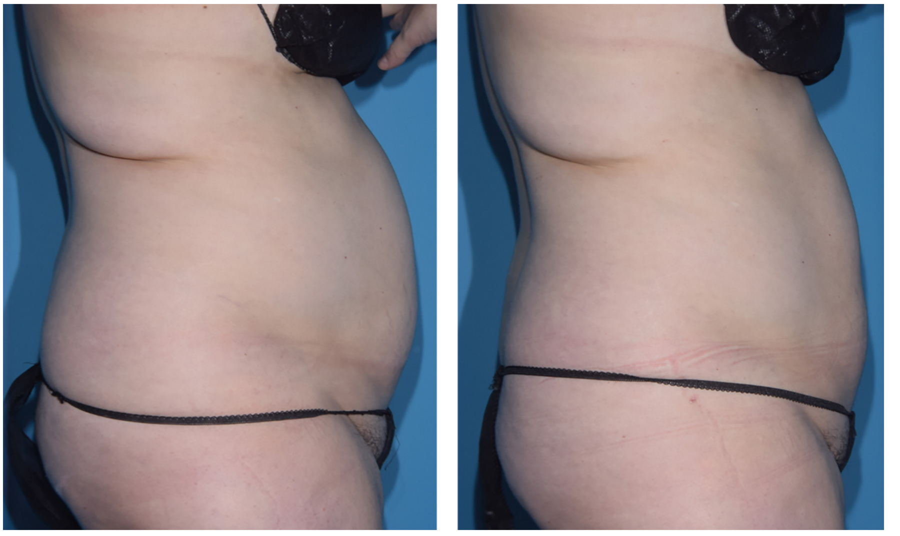

FIGURE 4 A comparison of photographs of a 34-year-old female with a BMI of 28.9 kg/m^2. The photographs were taken at baseline (left) and 1-month follow-up visit (right, an average VAT reduction of 19.7%).

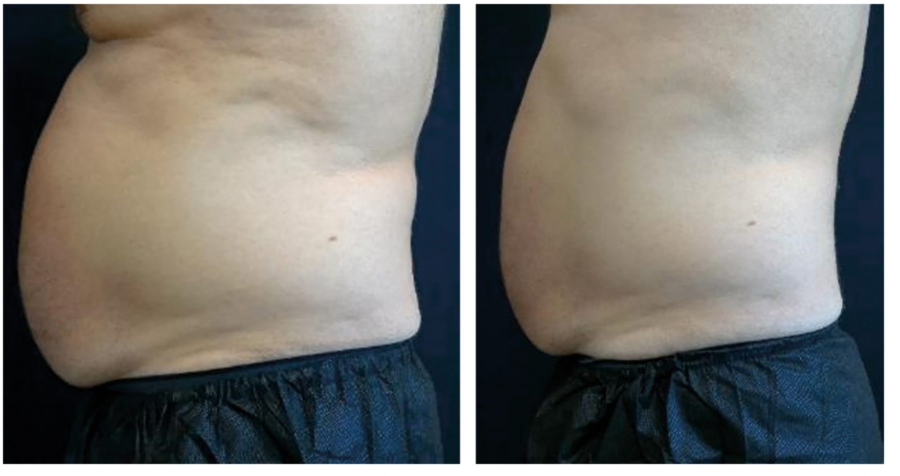

FIGURE 5 A comparison of photographs of a 57-year-old male with a BMI of 32.8 kg/m^2 taken at baseline (left) and a 1-month follow-up visit (right, an average VAT reduction of 17.0%).

The synchronized application of HIFEM + RF induces structural changes in the treated muscle tissue, as documented by Halaas et al.[17] The supramaximal contractions that are elicited by HIFEM impulses do not allow the muscle to relax during the contraction as what happens naturally during voluntary exercise. Therefore, it increases the workload and deepens the adaptation of the muscle in the form of the growth of existing (hypertrophy) and new (hyperplasia) fibers. Adding RF synchronized with HIFEM leads to muscle heating within the safe limits (up to 40°C), forcing the muscle tissue to work more effectively, thus further enhancing muscle hypertrophy.[17] Furthermore, satellite cells that respond to both muscle exercise and heat are consequently activated during the 14 days post-treatments, promoting again the hypertrophy and hyperplasia of muscle fibers. The important source of energy for demanding muscle load is the adipose tissue. Therefore, due to lipolysis the TG are broken down to a form of FFAs and glycerol and released into the blood-stream to supply the energy demand.[11] Since the VAT is highly active in terms of lipolysis,[10] we assume that the reduction of VAT observed in this study is strongly linked with this metabolic effect.

Besides the non-invasive body-contouring, exercise and a healthy diet are the alternative ways of SAT and VAT reduction as shown by van Gemert et al.[21] Corresponding to HIFEM + RF treatments, their study inferred that 4–6 weeks of the intense exercise program aided with diet resulted in −3.8 cm^2 (14.6%) decrease in VAT. However, the exercise requires considerable time-investment and commitment. Moreover, as documented in the meta-analysis by Rao et al.,[22] one-third of subjects do not adhere to the exercise routine, indicating a possible loss of motivation or dissatisfaction during the exercise course. On the contrary, even though subjects were instructed to maintain their eating and lifestyle habits in this study, the results yield high effectiveness of the non-invasive HIFEM + RF therapy on VAT, surpassing the 4–6 week exercise program. Therefore, we believe this approach poses an attractive solution for a broad spectrum of patients, considering that only a few sessions are required to achieve significant and sustainable VAT reduction.

The strengths of this study include mid to long-term follow-up of 6 months, approximately equal representation of both sexes, and enrollment of Fitzpatrick skin Types I-VI. The major strength is the use of MRI scans to evaluate the VAT CSA, as it offers reproducible and objective results.[23] Nonetheless, although MRI is considered a gold standard diagnostic technique for tissue visualization, it barely provides an insight into the exact metabolic patterns happening in the

VAT during the treatment. Acknowledging this limitation, we strongly encourage future prospective studies to implement other means of evaluation such as blood draws or possibly acquiring the visceral tissue specimens for detailed analysis, identifying the VAT response and corresponding patterns leading to herein proposed metabolic reduction. Furthermore, the decrease in VAT area may not be inherently linked with an immediate impact on body health, which is likely to be propagated in the long-term.[24] Thus the benefits of VAT reduction following the non-invasive therapies should be examined further.

5 | CONCLUSION

This retrospective study documented the effectiveness and safety of the HIFEM+RF procedure to reduce VAT. The results shown above demonstrate the consistency in VAT reduction regardless of sex and BMI peaking at the 3-month follow-up. The significant VAT reduction was maintained up to 6 months post-treatment.

AUTHOR CONTRIBUTIONS

David E. Kent, Carolyn Jacob, Brian M. Kinney performed the study, David E. Kent wrote the manuscript, Carolyn Jacob and Brian M. Kinney contributed to the finalization of the manuscript.

FUNDING INFORMATION

This study was sponsored by BTL Industries.

CONFLICT OF INTEREST STATEMENT

All authors, Dr. Kent, Dr. Jacob, and Dr. Kinney are clinical investigators for BTL and do not have any potential conflicts of interest with respect to the research, authorship, and publication of this article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The study followed the Declaration of Helsinki and all study participants signed informed consent.

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