### ORIGINAL CONTRIBUTION



# The effect of high-intensity focused electromagnetic procedure on visceral adipose tissue: Retrospective assessment of computed tomography scans

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### Abstract

**Background:** High levels of visceral adipose tissue (VAT) are associated with abdominal obesity and increased risk of metabolic deterioration. Recent studies showed that intensive physical exercise results in the reduction of subcutaneous and visceral fat.

**Aims:** This study investigates the effect of supramaximal muscle contractions induced by a HIFEM procedure for abdominal VAT changes.

Methods: Computed tomography (CT) scans of 22 subjects (47.3  $\pm$  8.4 years, BMI of 23.5  $\pm$  3.5 kg/m²) who received 8 HIFEM treatments of the abdomen (2-3 days apart) were retrospectively evaluated for the changes in VAT. The CT scans were obtained at baseline and 1 month after the last treatment. The transverse slices at umbilical, infraumbilical, and supraumbilical levels were used to determine the cross-sectional area (CSA) of VAT through a semi-automated segmentation method.

**Results:** Analysis of the CSA revealed a significant (P = .004) and uniform reduction of the abdominal VAT area by 14.3% (-16.7 cm<sup>2</sup>) from 110.6  $\pm$  69.0 cm<sup>2</sup> to 93.9  $\pm$  54.6 cm<sup>2</sup>. In general, a higher relative improvement was seen infraumbilically (17.1%), followed by supraumbilical (15.5%) and umbilical (10.7%) levels. The reduction of VAT was strongly correlated to the reduction of subcutaneous fat (r(17) = 0.66; P = .002). A decrease in VAT volume contributed to the overall aesthetic enhancement visible on digital photographs.

**Conclusions:** The outcomes indicate that HIFEM technology has a positive effect on VAT. However, further studies are necessary to validate these outcomes and to clarify the exact mechanism of a VAT reduction. Based on our results, the HIFEM procedure may be a beneficial treatment option for patients with high VAT deposits.

# KEYWORDS

computed tomography, electromagnetic fields, subcutaneous fat, visceral fat

# 1 | INTRODUCTION

Unlike the subcutaneous adipose tissue (SAT), which is located superficially under the skin, visceral adipose tissue (VAT) accumulates

predominantly intra-abdominally in the vicinity of internal organs. Besides the differences in distribution inside the human body, the visceral fat and subcutaneous fat also differ functionally. It has been described that VAT is metabolically more active, more sensitive to

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lipolysis, and more insulin resistant when compared to SAT. Visceral fat is also considered to behave as an endocrine and paracrine organ since it affects several metabolic processes by releasing various cytokines and bioactive markers, which may influence body weight, lipid metabolism, inflammation, and pathogenesis of diabetes mellitus.<sup>2</sup>

Given the essential regulatory functions of VAT, the maintenance of healthy body weight should not be underestimated. Excessive accumulation of VAT in the abdominal area, referred to as central or abdominal obesity, is closely linked to various health disorders. These include elevated blood pressure, cardiovascular disease, type 2 diabetes, or cancer. As shown by computed tomography (CT), patients who exceed a VAT cross-sectional area of 100 cm² at the umbilical level are suggested to be at increased risk of metabolic deterioration while exceeding 160-200 cm² implies high risk. Such high VAT values are frequently associated with the unpleasant aesthetic appearance of so-called "pot or beer belly," which progresses in advanced age, especially in men.

Controlled physical exercise programs may lead to favorable changes in body composition achieved by the overall reduction of fat tissue. 11,12 A dose-response relationship between training volume and fat reduction may be suggested, as Irving et al showed that the intensity of performed exercise determines the improvement rate. This means that better outcomes are seen when patients are subjected to a high-intensity endurance training. 12 It has been found that such reduction is not selective to the SAT only, but it also involves changes in VAT since the decrease of subcutaneous and visceral fat after the exercise is correlated. 2

HIFEM procedure that is based on the principles of electromagnetic induction was found to be an effective body shaping modality for multiple body parts. <sup>13-15</sup> HIFEM selectively and noninvasively stimulates the striated muscle tissue by utilizing supramaximal contractions performed with higher tension than those achieved during regular exercise. Besides the muscle enlargement due to the muscle fiber hypertrophy and hyperplasia, <sup>16</sup> various imaging techniques including CT, <sup>17</sup> MRI, <sup>14</sup> and diagnostic ultrasound documented SAT-reducing effect of HIFEM when applied to the abdomen. Although it could be assumed that a reduction of VAT may have accompanied SAT changes, none of the previous studies focused on assessing abdominal VAT after the HIFEM treatments.

This study aims to investigate whether the HIFEM-induced supramaximal contractions effectively promote changes in the volume of visceral fat when applied to the abdomen.

# 2 | MATERIALS AND METHODS

### 2.1 | The original study set up

This is a retrospective evaluation of CT scans, initially collected for measurement of abdominal fat and muscle tissue after HIFEM procedure in previously published single-center study.<sup>17</sup> This evaluation

did not involve any treatment intervention or collection of any additional patient data.

The original study included participants aged 21-65 years and excluded subjects that reported a weight change of five lbs or more in the preceding month, pregnancy, implanted electronic devices and metal implants, heart disorders, or any medical condition which may contradict application of the electromagnetic field. The study conformed to ethical principles for medical research involving humans (Declaration of Helsinki).

Based on the specified inclusion criteria, 22 subjects (three men, 19 women) with an average BMI of  $23.5 \pm 3.5 \text{ kg/m}^2$  and  $47.3 \pm 8.5$  years were recruited. After signing the informed consent, they underwent eight abdominal HIFEM procedures in supine position with the EMSCULPT device (BTL Industries Inc.) spaced 2-3 days apart. The device utilizes a circular coil embedded in the applicator that generates time-varying magnetic field achieving magnetic flux densities of 1.8 Tesla. The applicator was positioned over the umbilicus and secured by a Velcro belt. During each 30-minute session, the intensity of the HIFEM field was gradually increased to 100% to induce intense muscle contractions. Posttreatments, the subjects were instructed to avoid major diet and lifestyle changes and all of them successfully completed a 1-month follow-up visit.

CT imaging (General Electric VCT 64 slice Lightspeed CT scanner) was performed before the first treatment and at the 1-month follow-up. The scanned area was delineated by T2 and S1 vertebrae to capture the whole treated volume of the abdomen. Throughout the study, visual appearance, waist circumference (measured by anthropometric tape at the upper edge of the umbilicus), and safety of subjects were monitored.

# 2.2 | Visceral fat assessment

To investigate changes in subject's VAT, original transverse (axial) CT scans in DICOM format were subjected to additional analysis. By using a semiautomated segmentation (InVesalius 3.1.1 software), the cross-sectional area (CSA) of visceral fat inside the abdominal cavity was identified at the three levels including umbilical (L3-L4 vertebrae), infraumbilical (L4-L5 vertebrae) and supraumbilical (L2-L3 vertebrae). A simple thresholding method was used to automatically label the voxels of densities between -200 and -50 Hounsfield units indicating adipose tissue. Automatic segmentation using this threshold was then followed by manual checking of the abdominal cavity boundary separating VAT from the SAT. Only the area occupied by VAT was considered for evaluation, and area of subcutaneous tissue was excluded. The final CSA referring to VAT was calculated for each level separately.

The 1-month results were compared with baseline and mean difference in VAT area was tested for statistical significance by paired t test ( $\alpha=0.05$ ). Pearson's r correlation coefficient was calculated to determine any possible relationship between VAT and previously measured variables.

# 3 | RESULTS

The average baseline BMI of  $23.5 \pm 3.5 \text{ kg/m}^2$  remained unchanged since it was equal to  $23.4 \pm 3.4 \text{ kg/m}^2$  at the follow-up. The waist circumference decreased on average by  $3.9 \pm 3.1 \text{ cm}$  from 81.1 cm at baseline to 77.2 cm after the last treatment.

CT scans of all enrolled subjects were found eligible for evaluation. HIFEM procedure was safe since the posttreatment scans did not show any signs of abdominal trauma. Out of 22 treated subjects, 18 (82%) showed a measurable decrease in VAT at 1-month follow-up, and 15 subjects (68%) exceeded the reduction of VAT by 10%. On the other hand, two subjects did not show any improvement (change up to ±1%), and the remaining two subjects showed an increase in VAT when compared to baseline. All non-responding subjects were females with average age (44.3 years) and BMI (22.4) that not significantly differ from study group values, nevertheless their average CSA was held below the 100 cm<sup>2</sup>, indicating healthy VAT levels. Although they did not show any plausible changes in visceral fat, they still achieved an average reduction of 16% in SAT. In general, the average posttreatment decrease of VAT in the study group was statistically significant while there was no significant difference among the umbilical, supraumbilical, and infraumbilical levels individually (see Table 1).

The average reduction of the VAT cross-sectional area was 14.3% (16.7 cm²; P = .004). Male subjects (N = 3) showed greater values of visceral CSA and greater average improvement rate (19.9%) when compared with females (13.5%), however, due to their limited numbers, this tendency could not be statistically verified although the difference in VAT improvement between the sexes was 42.3 cm². As shown in Table 1, the greatest amount of VAT was observed at the L3-L4 level. Therefore, although the absolute differences of CSA were similar in all the three examined regions, the relative improvement rate slightly differed. The greatest VAT reduction was seen infraumbilically (17.1%; P = .002), followed by supraumbilical (15.5%; P = .003) and umbilical (10.7%; P = .002) level.

When conjoined with recently published data,  $^{17}$  it was found that improvement in VAT is considerably related to improvement in SAT. After removing two outliers from the VAT data set (patients with an increase of visceral CSA), this mutual relationship showed a significant, positive, and strong correlation with r(17) = 0.66 at the significance level of P = .002. In addition, subjects with well-developed musculature inclined to lower baseline values of visceral CSA (r(20) = 0.48; P = .03) and subjects with greater muscle increase tend to have slightly better improvement rate.

**TABLE 1** The average CSA (mean  $\pm$  standard deviation) of visceral fat in the abdominal cavity at the predefined levels measured at baseline and 1-mo follow-up

Measured level	Supraumbilical (L2-L3)	Umbilicus (L3-L4)	Infraumbilical (L4-L5)	Average
Baseline CSA (cm <sup>2</sup> )	$107.0 \pm 77.8$	$124.3 \pm 72.0$	$100.5 \pm 59.6$	110.6 ± 69.0
1 mo CSA (cm <sup>2</sup> )	90.5 ± 63.6	$108.0 \pm 57.0$	$83.3 \pm 47.8$	93.9 ± 54.6
Difference in cm <sup>2</sup> ( <i>P</i> -value)	16.5 (<.01)	16.3 (<.05)	17.2 (<.01)	16.7 (<.01)

The individual CT results can be seen on Figures 1 and 2. The significant decrease of visceral volume is clearly noticeable as the segmented CSA at the 1 month (green) occupies much lesser area than baseline (blue). With decreased SAT thickness, enlargement and toning of abdominal muscles, the subjects' body image has been substantially improved. The overall improvement of body contour achieved by the aforementioned changes was documented by the digital photographs which complemented the CT analysis (see Figures 1 and 2).

# 4 | DISCUSSION

The main outcome of this study is the documentation of the VAT reduction after a set of HIFEM abdominal treatments. HIFEM safely and effectively induced desirable aesthetic improvement of body contour through a significant decrease of both subcutaneous<sup>17</sup> and visceral fat.

Body contouring depends on the individual body composition including the distribution of VAT inside the abdominal cavity. As seen in this study, the individuals with better-developed musculature were more likely to have a lesser portion of VAT at baseline which may limit the magnitude of its reduction. However, the subjects with sedentary lifestyle and noticeable "pot belly" showed greater potential for a change in VAT (see Figures 1 and 2) and SAT correspondingly. Either way, regardless of the degree of improvement, this study documented that HIFEM-induced VAT reduction presumably contributes to the improvement of overall aesthetic appearance.

Previous studies found that HIFEM affects the SAT through intensive lipolysis, the breakdown of lipids to free fatty acids (FFA) stored inside the fat cells. <sup>19</sup> Validity of this mechanism in regards to VAT reduction after HIFEM is not clear yet. However, considering that VAT is more susceptible to lipolysis, it is most likely that VAT and SAT respond similarly when the muscle is exposed to supramaximal contractions. Also, the VAT has a greater capacity to generate FFAs, <sup>5</sup> which may explain its significant reduction when energy expenditure is elevated during and postexercise, and the muscle mass increase elevates the metabolic rate.

Our results correspond to general findings in the literature, since we found demonstrable difference in VAT deposits between men and women, <sup>20</sup> positive correlation between VAT and SAT reduction, <sup>2</sup> and between rectus abdominis fitness and low VAT values. <sup>21</sup> Also, the shift of group average CSA toward values below the threshold of 100 cm<sup>2</sup> indicates a decreased risk of visceral

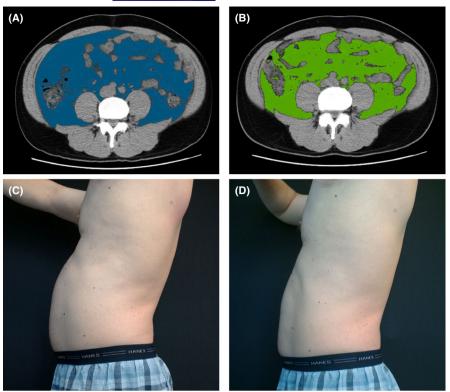


FIGURE 1 Male subject with high visceral fat ratio, 48 years old. Upper row—Infraumbilical VAT area before (A) and 1 month posttreatments (B); average VAT reduction of 19.9%, average SAT reduction of 18.2%. Bottom row—digital photographs showing improvement of the abdominal body contour from baseline (C) to 1 month (D); circumference reduction of 5 cm

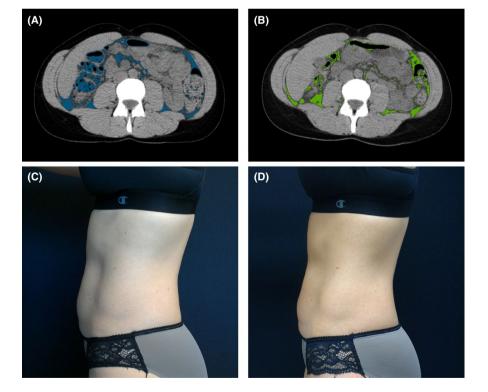


FIGURE 2 Female subject with low visceral fat ratio, 37 years old. Upper row—umbilical VAT area before (A) and 1 month posttreatments (B); average VAT reduction of 39.0%, SAT reduction of 26.0%. Bottom row—digital photographs showing improvement of the abdominal body contour from baseline (C) to 1 month (D); circumference reduction of 2 cm

obesity.<sup>9</sup> Nevertheless, the results mentioned above represent only preliminary findings of the cause-effect relationship between HIFEM and VAT. They do not concern the examination of the hypothesized beneficial effect of lowered VAT levels on human health. Interestingly, two patients showed an increase of visceral fat at 1 month, which may be attributed to the imbalance in food

intake and energy expenditure, <sup>22</sup> possibly followed by a compensatory increase in VAT due to the significant SAT reduction, bolstered by a lack of physical activity. <sup>23</sup> Also, there is increasing evidence that body fat distribution is controlled by genetic factors which may explain the outliers observed in our study; however, the polygenic background of visceral obesity has not been fully

identified and outlined yet to infer decisive conclusions.<sup>24</sup> Future studies should, therefore, aim for more in-depth assessment to determine any changes of metabolic parameters or proposed compensatory fat redistribution.

One of the strengths of this study is the use of CT imaging, which is considered to be a highly reliable modality for adipose tissue evaluation and has been already used by numerous authors to determine the amount of abdominal VAT. 4,25,26 In addition. VAT has shown to be uniformly distributed in the measured L2-L5 range, <sup>25</sup> which only further contributes to the reliability of our results. Nevertheless, the study has some limitations. The greatest drawback is a relatively limited sample size with unbalanced numbers of male and female subjects that do not allow unbiased comparisons. Also, the study group mainly consisted of patients with BMI of 20-26 kg/m<sup>2</sup> thus validity of results in higher range BMI subjects should be ascertained. Lastly, the exact mechanism of VAT reduction with possible health-related benefits and longevity of the results has not yet been examined. In the future, more research is needed for an enhanced explanation of documented results.

# 5 | CONCLUSIONS

To our knowledge, this is the first study that documents the effect of HIFEM procedure on the visceral fat. In conclusion, the results of this study revealed a significant VAT-reducing effect induced by HIFEM resulting in the improved aesthetic appearance of the abdomen. Further research is needed to determine whether patients may also benefit from this technology to maintain the healthy VAT levels which may possibly diminish a risk of metabolic deterioration.

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### **CONFLICT OF INTEREST**

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### DATA AVAILABILITY STATEMENT

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

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