RCEC
Revista Científica de Estética & Cosmetologia

HIGH INTENSITY FOCUSED ULTRASOUND EFFICACY ON ABDOMINAL FAT REMODELING IN FEMALE RUNNERS

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ABSTRACT

The search for aesthetic treatments has become increasingly frequent nowadays and one of the dysfunctions that bothers women the most, especially, is lipodystrophy, popularly called “localized fat”. High Intensity Focused Ultrasound (HIFU) can reach a specific volume (in millimeters) within the body cavity without damaging other tissues. This study aimed to evaluate the effectiveness of HIFU in reshaping abdominal fat in female runners. A Randomized Clinical Trial was conducted with 46 participants, aged between 18 and 65 years, using HIFU for 30 min/week, for 6 weeks. The primary outcome was the change in adipose tissue thickness through anthropometric and ultrasound measurements, in the eighth week post-treatment and the secondary outcomes were adverse events and participant satisfaction. The HIFU group had a mean reduction in waist circumference of 1.7 cm ($p<0.001$), umbilical circumference of 3.5 cm ($p<0.001$), and abdominal circumference of 3.8 cm ($p<0.001$), in addition to a significant reduction in several variables (opposite to the control group), except for lean mass and visceral fat. No moderate or severe adverse effects were observed on physical examination. Only 5 of the 23 patients in the HIFU group described mild erythema, which resolved spontaneously within one day. Through the application of a questionnaire on the degree of satisfaction, all 23 participants in the intervention group reported complete satisfaction. We conclude that the HIFU protocol is effective and safe in reshaping abdominal fat in female runners.

Keywords: Intensive Focused Ultrasound Therapy; Abdominal adipose tissue; Women runners

INTRODUCTION

The search for aesthetics treatments has become increasingly frequent nowadays and one of the most bothering dysfunctions for both men and women is lipodystrophy, popularly called “localized fat”. The motivation to seek aesthetics interventions usually stems from low self-esteem, due to the lack of body conformity in relation to physical overvaluation, which causes dazzles and the constant search for the perfect body. Among the physical dissatisfactions of women, the major one is localized fat [1].

The hypertrophy of unilocular fat cells generates localized fat; within the fat cells are triglycerides, which are the main lipids stored in adipocytes. Adipocytes are cells that form adipose tissue, and the excess of this tissue can promote the accumulation of subcutaneous fat in the abdominal region and around the organs, contributing to the incidence of metabolic disorders, reducing life

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DOI: https://doi.org/10.52051/rcec.v5i1.154. Artigo recebido em 21 de abril de 2025; aceito em 25 de abril de 2025; publicado em 7 de maio de 2025 na Revista Científica de Estética e Cosmetologia, disponível online em http://rcec.com.br. Todos os autores contribuíram igualmente com o artigo. Os autores declaram não haver conflito de interesse.

expectancy and increasing the risk of developing heart disease, coronary artery disease, hypertension, diabetes, osteoarthritis and certain types of cancer [2]. For these fat deposits, there is a slower, weight loss resistant, genetically coded metabolism keeping family characteristics. This change in metabolism explains the difficulty of reducing these measures and this adiposity ends up being an aesthetics dysfunction, resulting in the constant search for innovative and safe aesthetics resources that avoid taking these patients out of their routines [3]. Body fat, especially in the abdomen, hips, waist and flanks is associated to overweight and low quality of life [1].

Adipose tissue has the function of energy storage and thermal insulation, being a type of connective tissue, and has its main component, the adipocytes. The abdomen is one of the sites of greater adipocyte accumulation, being composed of intra-abdominal adipose tissue and subcutaneous adipose tissue, becoming a site of difficult adiposity reduction, because there are a significant number of triglycerides [4]. Localized fat presents itself as an irregular development of the subcutaneous connective tissue, with adipocytes appearing enlarged in specific regions with irregularity and wavy appearance [5].

Decreased physical activity, genetic factors, ethnicity, age, gender, culture, socioeconomic patterns, eating habits, family environment, school and friends favor weight gain [6]. This excess weight can lead to serious psychological and physical consequences associated with a higher risk of morbidity and mortality from chronic non-communicable diseases, as well as increasing waist circumference due to excess adipocytes in the subcutaneous tissue [7].

Ward and Bar-Or (1986) [8] reviewed 13 studies based on regular aerobic exercise from 9 weeks to 18 months, where the fat percentage dropped by 5 to 10 percent in all the exercises analyzed. Aerobic exercises have been helpful in the process of reducing fat percentage, although not always enough to end localized fat; that is why we thought of working with female runners in this project [8]. Women seek effective and minimally invasive intervention to eliminate this aesthetic and health problem. Several promising techniques have been developed, such as High Intensity Focused Ultrasound (HIFU), which meet the clinically targeted expectations [9,10].

Ultrasound has been seen to be promising due to its non-invasive, low cost and safety. Ultrasonic therapy involves mechanical vibration, where gamma sound waves are generated by means of transducers. Compared to normal ultrasound, where the waves are reabsorbed and deflected through tissue, the HIFU can reach a specific volume (in millimeters) within the body cavity without damaging other tissues [11].

The wide range of aesthetic treatments aimed at size reduction, the scarce scientific information on the subject and the few studies with more rigorous methodologies on the efficacy and toxicological effects, have led to the choice of HIFU, which has been proven effective in carrying out a well conducted scientific study that demonstrates real value as useful procedures in aesthetic treatments. Among several resources for the reduction of localized fat, the High Intensity Focused Ultrasound is a non-invasive technology with the purpose of enhancing the fat cavitation phenomenon at the cytoplasmatic interface, promoting adipocyte degradation.

Lipolysis is provided by intense convergence of energy delivered to the adipose tissue, and this focal point energy results in cellular damage by a thermodynamic process. Besides the ablation of the subcutaneous tissue, this technology promotes the thermal remodeling of collagen by contracting these fibers [12,13]. This technique is becoming increasingly popular in clinics due to its effectiveness and safety, combined with the relative absence of complications and patient downtime. In addition to this, it acts not only on people's self-esteem, but also on their health and quality of life.

This study aims to determine the efficacy of HIFU on abdominal fat remodeling in female runners by evaluating adipose tissue thickness changes between treated group and the control group using anthropometric measurements and ultrasound imaging. It is hypothesized that HIFU is effective in remodeling abdominal fat in female runners.

MATERIAL AND METHODS

Design and participants

This single-center, doble-arm, non-blinded randomized clinical trial (RCT) was conducted at Moana Clínica Estética, Porto Alegre, RS, Brazil The study was approved by the Research Ethics Committee (CEP) of the Methodist University Center of IPA (No. 43945821.8.0000.5308) and by the Ethics and Bioethics Committee of the Italian Institute of Rosario (CEB IUNIR No. 38/22). Informed consent was obtained from all patients.

The recruitment of the research participants was done by invitation and has been advertised among the running groups of the city of Bento Gonçalves (Rio Grande do Sul, Brazil) during October to December 2021.

The participants: were women, aged 18 to 65 years, with skinfolds greater than 15 mm, who run at least 15 kilometers per week and having good overall health were eligible.

Women obese or overweight, with a sedentary lifestyle, premenopausal or menopausal, taking oral anticoagulant therapy, pregnant or breastfeeding, diabetic, with hypertension, liver disease and/or a history of hepatitis, metallic implants and/or pacemakers, deep vein thrombosis or catastrophic venous state, abdominal hernia, epilepsy, neoplasms, dermatological alterations and ulcers, were excluded from the study.

Participants absent from any treatment session, injured or unable to run or keep training, became pregnant or contracted an illness during treatment, were eliminated from the study.

Sample size was calculated as in Rotunda et al., 2009 [14]. The calculation was performed using the EPIDAT v3.0 program, with significance power of 99% and the acceptable error set in 5%.

Forty-six patients agreed to participate and agreed not to change their diet or exercise routine during the study period.

 DOI: https://doi.org/10.52051/rcec.v5i1.154

The participants were randomly assigned to one of the groups of 23 participants each. HIFU Group(G1) received the application of High Intensity Focused Ultrasound intervention (1 MHz with the maximum power of 8W). Control group 2(G2) received no intervention.

Interview and Anamnesis

The anamnesis was carried out in a structured way, in a 15-minute interview and a health conditions questionnaire completion. Subsequently, an anthropometric evaluation was performed, with primary measurements such as weight, height, skinfolds and circumferences and secondary measurements(combined) such as body mass index (BMI), ideal weight, sum of skinfolds, being designated as the best parameter to evaluate the nutritional state of population groups, allowing individual and collective diagnoses [15]. After the anamnesis and anthropological measurements, the patients underwent imaging to measure the thickness of the adipose tissue before and after the procedure in the test group, and before and after the same period in the control group. The groups were randomly divided and the test group submitted to high-intensity focused ultrasound.

Ultrasound Examination

The Ultrasound Examination to obtain the measurements was performed on a Samsung device RS85 Prestige, version 2.02, using linear transducers with a frequency of 11 or 18 MHz. The examination was preferably performed with an 18-gauge transducer. The 11 MHz transducer was used when skin thickness exceeded 4.0 cm.

Subcutaneous measurements were taken at the following locations: 3 cm to the left, 3 cm above, and 3 cm below the navel. The measurement points were inserted at the dermis/hypodermis transition and at the hypodermis/aponeurosis transition.

High Intensity Focused Ultrasound Intervention

Bioset Indústria de Tecnologia Eletrônica LTDA is the manufature of Lipofocus. The device comes with focused type ultrasonic transducers, with selectable focal distances between 1, 2 and 3 cm, so that the operator can use according to the indicated treatment, applying 1 cm for cutaneous folds between 15 to 25 mm, 2 cm for cutaneous folds between 25 and 35 mm, and 3 cm for measurements larger than 35 mm. It was applied point by point in the abdominal region, totalizing 4 passes. Subsequently, the stereo dynamic transducer was used for 6 minutes, which contains the three focal distances, allowing the operator to perform a three-dimensional scan (x, y and z), stimulating the lymphatic system (Soriano e al., 2000). Ultrassonic therapy involves mechanical vibrations with a frequency above 20,000 Hz. The equipment has a power supply frequency of 60 Hz, with 230 V consumption. Its timer varies from 1 to 30 minutes. The ultrasound frequency is 1 MHz sine wave form, with maximum power of 8W [16].

All participants in the group who received this type of treatment were instructed not to change their respective routine activities [17].

All the individuals received treatment with Lipofocus equipment, at a frequency of 1 MHz and 80 W power, with intensity of 70-100%, applied continuously with pulses of 2 and 6 seconds off [16].

After applying a thin layer of gel in the area to be treated, the tip was lightly pressed onto the skin, on the marked area, applying point by point, totalizing 4 passes. Afterwards, lymphatic stimulation was performed with the stereodynamic transducer, performing circular and elliptical movements without uncoupling the electrodes from the patient's skin, totalizing 6 minutes. The time for each session was 30 minutes long with the patient in a horizontal dorsal decubitus position. The applications were once a week, for 6 weeks, totalizing 6 sessions [16].

At the end of the session, data on adverse effects were collected through a patient questionnaire. On the last day of the study, together with the collection of the imaging exam and anthropometric evaluation, the participant answered a questionnaire about the degree of satisfaction (excellent, good, regular, dissatisfied).

Data Analysis

The analyses were performed using the Statistical Package for the Social Sciences (SPSS) program (version 25.0). A p value of <0.05 was considered statistically significant. Data matrixes were constructed and percentages calculated with their confidence intervals for the qualitative variables and for the quantitative variables means with their respective confidence intervals. To test the normality of the distribution, the Kolmogorov-Smirnov Test was applied. Two independent samples were tested; if parametric, the T-Test for independent samples was performed, otherwise, Mann-Whitney. Paired sample testing was also done; if parametric, T-Test for paired samples, if non-parametric, sign rank test of Wilcoxon.

RESULTS

The intervention group consisted of 23 female runners with an average age of 36.2 years and normal body mass index of 24.7 kg/cm^2. The control group included 23 women with an average age of 34.2 years and Body Mass Index of 23.2 kg/cm^2. Table 1 shows the measurements taken at baseline.

Baseline differences between HIFU group and control group were found in the following variables: abdominal circumference on umbilical scar (p = 0.027), abdominal circumference on largest region (p = 0.016), fat mass (p = 0.016), lean mass (p=0.045), visceral fat (p=0.019), metabolic age (p = 0.029), abdominal fold (p = 0.002), upper (p=0.003), lower (p = 0.006) and right (p=0.008), being these values normally higher in the test women except for the lean mass and height. Random assignment into groups did not allow us to control for these differences. Even though the women had high training frequency, they presented skinfolds of fat located in the abdominal region greater than 15 mm. Table 2 shows the measurements taken at baseline and after the intervention in both groups.

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Table 1. Comparison of variables at baseline.

Variable	Test	Control	T	U	P
Age (years)	36.2±7.4	34.2±6.8	0.889		0.379[1]
Weight (kg)	65.2±8.0	62.1±9.3		278	0.152[2]
Height (cm)	162.6±5.9	163.1±5.8	0.262		0.794[1]
Waist (cm)	75.3±6.0	72.7±6.0	1.418		0.164[1]
Abdominal circumference on Umbilical Scar (cm)	84.1±7.3	79.5±6.5		308.5	0.027*[2]
Abdominal circumference on largest region (cm)	87.8±8.1	82.4±6.8		317	0.016*[2]
Body Mass Index (kg/cm²)	24.7±3.1	23.2±2.8		293.5	0.068[2]
Fat Mass (cm)	35.4±4.3	30.9±7.0	2.510		0.016*[1]
Lean Mass (cm)	27.5±1.6	29.4±3.3		140.5	0.045*[2]
Visceral Fat(mm)	5.6±1.7	4.4±1.2		311.5	0.019*[2]
Metabolic Age (mm)	40.0±10.7	33.3±8.2	2.266		0.029*[1]
Metabolic Rate (mm)	1355.2±95.3	1336.0±110.5	0.603		0.550[1]
Abdominal fold (mm)	18.5±2.9	13.9±5.6	3.298		0.002*[1]
Suprailiac fold (mm)	12.6±3.3	10.5±4.2	1.795		0.08[1]
Upper[3] (cm)	2.4±0.9	1.6±0.8	3.137		0.003*[1]
Right[3] (cm)	2.2±0.7	1.5±0.9	2.797		0.008*[1]
Lower[3] (cm)	2.9±0.9	2.0±1.1	2.898		0.006*[1]

Average ± Standard Deviation *Significant - 1-T test for independent samples - 2-Mann-Whitney U test - 3-Ultrasound imaging measurement.

Table 2. Before and after variables at the groups.

	Test Group				Control Group			
Variable	Delta (After – Before)	T	V	P	Delta (After – Before)	T	V	P
Weight (kg)	-0.9 ± 1.1	-	170	**0.002*[2]**	-0.4 ± 1.5	-	103	0.459
Waist (cm)	-1.7 ± 1.0	7.513	-	**<0.001*[1]**	0.1 ± 1.1	-0.295	-	0.771
Abdominal circumference on umbilical scar (cm)	-3.5 ± 1.6	-	231	**<0.001 *[2]**	-0.2 ± 1.2	-	60	0.302
Abdominal circumference on largest region (cm)	-3.8 ± 1.7	-	231	**<0.001*[2]**	0.4 ± 1.2	-	41.5	0.287
Body Mass Index (kg/cm²)	-0.3 ± 0.4	-	168.5	**0.003*[2]**	0.0 ± 0.8	-	103	0.762
Fat Mass (cm)	-1.0 ± 1.6	2.804	-	**0.011*[1]**	0.2 ± 3.2	-0.289	-	0.775

 DOI: https://doi.org/10.52051/rcec.v5i1.154

Lean Mass (cm)	0.4 ± 1.1	-	63.5	0.073	-0.1 ± 1.7	-	109.5	0.848
Visceral fat (mm)	-0.2 ± 0.5	-	24	0.073	0.0 ± 0.7	-	25	0.739
Metabolic Age (age)	-1.2 ± 1.3	4.110	-	**0.001**[*1]	1.0 ± 4.6	-0.952	-	0.349
Metabolic Rate (kcal)	-6.7 ± 13.0	2.374	-	**0.028**[*1]	-6.9 ± 13.0	1.308	-	0.206
Abdominal Fold (mm)	-4.0 ± 1.4	12.962	-	**<0.001**[*1]	0.0 ± 0.9	0.237	-	0.815
Suprailiac Fold (mm)	-2.4 ± 1.4	7.759	-	**<0.001**[*1/]	0.0 ± 0.9	0.252	-	0.803
Lower (cm)	-0.4 ± 0.2	7.930	-	**<0.001**[*1]	0.1 ± 0.3	-1.907	-	0.071
Right (cm)	-0.2 ± 0.3	3.203	-	**0.004**[*1]	0.0 ± 0.2	-0.767	-	0.452
Upper (cm)	-0.2 ± 0.3	3.214	-	**0.004**[*1]	0.1 ± 0.3	-2.120	-	**0.047**[*1]

Average ± Standard Deviation *Significant - 1-T test for paired simples (T) - 2-Wilcoxon test (V).

In the test group, all the variables showed statistically significant differences indicating a reduction in them, except for Lean Mass and Visceral Fat.

The reduction in the mean values of the waist of 1.7 cm, in the abdominal circumference in the umbilical scar of 3.5 cm and the abdominal circumference of the largest region of 3.8 cm are the main results that show the effectiveness of the treatment.

There was observed also a reduction in metabolic age (1.2 years) and metabolic rate (6.7 kcal). Regarding the abdominal fold and the suprailiac fold, reduction the mean values of4 and 2.4 cm respectively were observed.

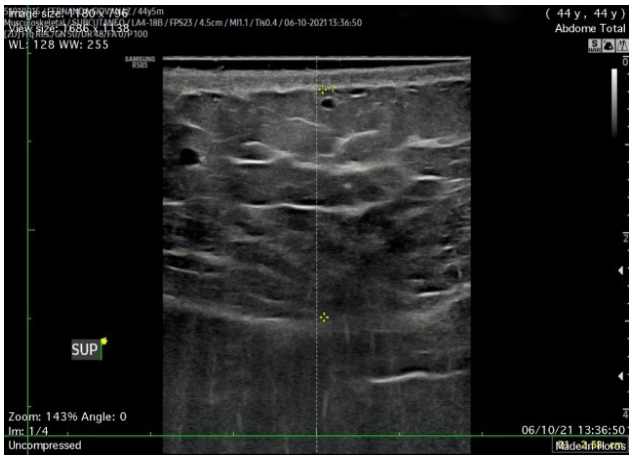
The ultrasound for the determination of the fat tissue thickness showed that in the HIFU group there was a significant decrease in the upper, right and lower measurements.

In control group, Variables weight (p=0.459), abdomen on umbilical scar (p = 0.302), lean mass (p = 0.848) and metabolic rate (p = 0.206) did not show significant differences when measured before and after the intervention, although there was a reduction.

The imaging ultrasound applied before and after the procedure showed a reduction in fat tissue thickness measured at 5 cm on the right side of the navel after the intervention (HIFU).

The significant reduction of waist circumference, at the abdomen on the umbilical scar and in the largest abdominal region in the test group after the intervention, and ultrasound imaging measurements can confirm the effectiveness of the intervention (**Figure 1)**.

Figure 1



A

B

DOI: https://doi.org/10.52051/rcec.v5i1.154

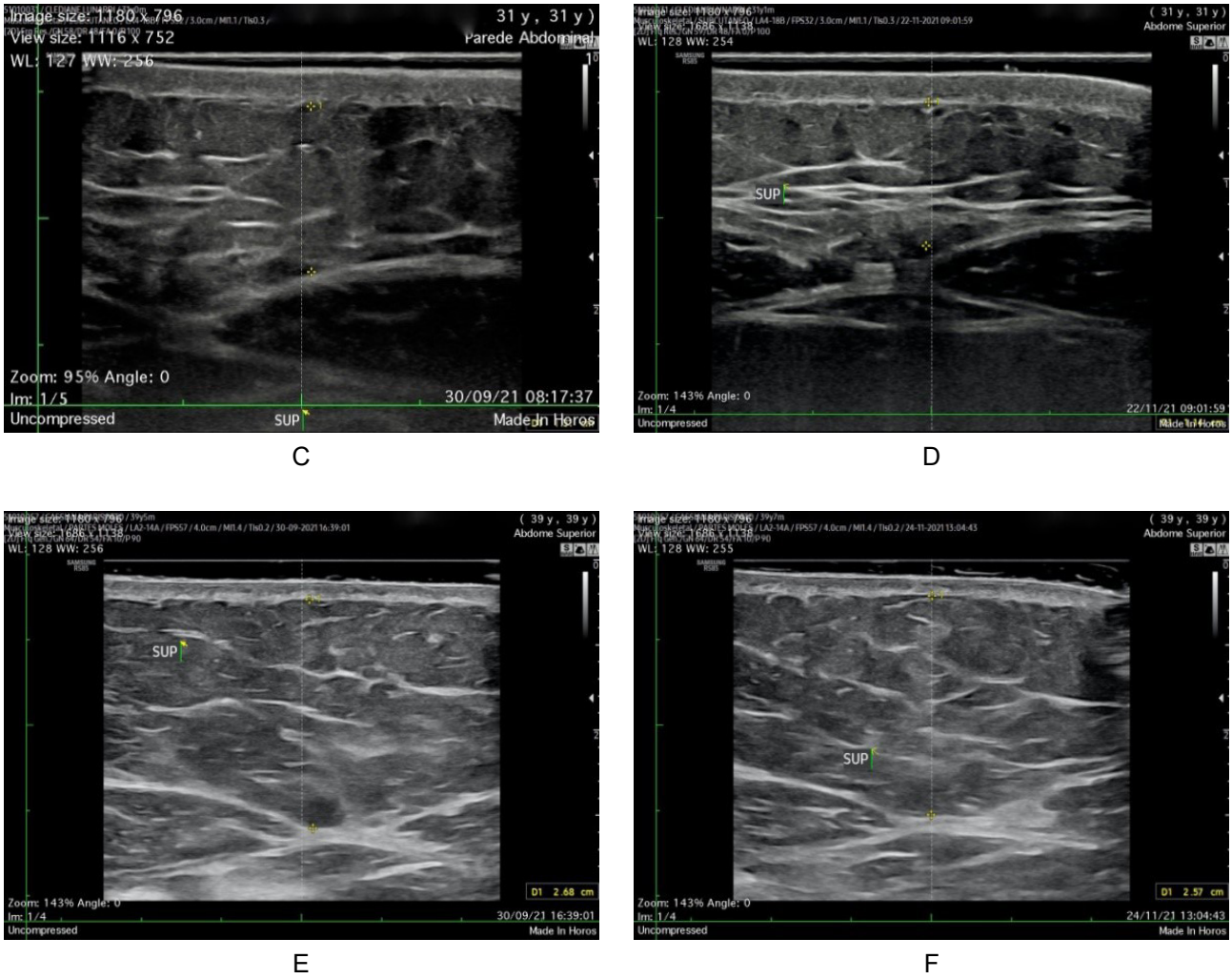


Figure 1. Imaging Ultrasound results.

The letters “a” and “b” refer to the same patient before(a) and after(b) the intervention; the same is true for letters “c” and “d” and “e” and “f”. There was a reduction of adipose tissue on the upper and right side in all three cases exemplified.

Adverse effects

No moderate or severe adverse effects were observed from the physical examinations. Only 5 patients of the 23 in the HIFU group described mild erythema, which resolved spontaneously within a day.

Satisfaction

Through the application of a questionnaire on the degree of satisfaction, all 23 participants in the intervention group reported plain satisfaction.

DISCUSSION

We evaluated female runners because based in a previous survey conducted in Brazil, including more than 5,000 runners, showed that approximately 45% of these women practice this physical activity to improve quality of life and 49% of these are between 35 and 45 years old [18]. It is believed that the results here obtained are mainly due to the effectiveness of the High Intensity Focused Ultrasound protocol applied.

The use of Focused Ultrasound is considered safe and highly effective procedure for body remodeling, being a non-invasive alternative to conventional liposuction for patients with small to medium amount of localized lipodystrophy Hong and colleagues (2020) [19] concluded that High Intensity Focused Ultrasound is an effective and safe treatment modality for reducing waist circumference in non-obese individuals with focal fat accumulation.

The significant decrease in waist circumference in the test

 DOI: https://doi.org/10.52051/rcec.v5i1.154

group after the intervention is in line with the results of previous studies [19-21]. Previous studies have also shown that High Intensity Focused Ultrasound affects subcutaneous adipose tissue through intensive lipolysis, that is, the breakdown of lipids into free fatty acids stored in adipose cells [22].

Adults with BMI > 30 kg/m^2 and abdominal subcutaneous adipose tissue thickness > 2.5 cm were treated with HIFU, and the effects were evaluated by ultrasound. An average reduction of 3.43 in waist measurement occurred after the eighth week, and the treatment effect was cumulative, with a steady reduction in waist circumference and fat thickness [19].

In a study evaluating HIFU in 152 healthy volunteers, there were no reports of increased or worsened skin laxity or even rippling associated with HIFU treatment [23].

The non-significant reduction of lean mass and visceral fat may suggest that localized fat is not related to visceral fat and lean mass, confirming that the results were limited even in the action of localized fat.

As observed, there was a significant reduction in the variables weight, waist, abdomen or umbilical scar, abdomen on largest region, body mass index, fat mass, metabolic age, metabolic rate, abdominal fold, suprailiac fold, upper, lower and right only in the test group. The upper variable was significantly increased in the control group.

The main limitation of this study is the small sample size, as well as the very specific population: female runners in their thirties and with a BMI below 25 kg/cm^2; in addition, there was no control of the participants' diet. Another limitation was the fact that the study was not double-blind.

CONCLUSION

Based on our results, we conclude that the application of High Intensity Focused Ultrasound can be effective and safe in abdominal fat remodeling in female runners. We understand that this is a good method to be performed in aesthetics clinics, for being a non-aggressive resource and offering productive results for the treatment of localized adiposity. This study confirms and is in accordance with others recent research observations in this field; however, to evaluate the full clinical potential of this technology, more research is needed, with diet control and larger sample size.

Conflicts of interest

The authors declare no conflicts of interest.

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