

ORIGINAL ARTICLE

Evaluation of safety and efficacy of a new device for muscle toning and body shaping

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Abstract

Background: The spread of non-invasive procedures for fat deposits removal has increased rapidly in recent years. In the field of esthetic medicine, high-intensity focused electromagnetic field (HIFEM) technology has recently been introduced, as a tool for toning and strengthening muscles, which goes far beyond normal physical exercise.

Objective: The purpose of this study is to evaluate the efficacy and safety of a new device for body remodeling.

Methods: A set of 15 patients (7 males and 8 females, BMI $24.05 \pm 2.01 \text{ kg m}^{-2}$, age 32–57) participated in this study. Patients were enrolled at Dermatos center, Montesilvano, Abruzzo, Italy. The technology used is FMS (Flat Magnetic Stimulation): 6–8 treatment sessions were performed. The sessions must be repeated twice a week, with a minimum of 2 days between each session. Treatment duration varies from 20 to 45 min, depending on patients.

Results: During 1-month follow-up after the last treatment evaluations, the results showed tonification, the strengthening of muscles, and the reduction of localized adiposity. There is a significant reduction in waist circumference ($80.7 \pm 4.3 \text{ cm}$ vs $77.3 \pm 5.6 \text{ cm}$, $p < 0.001$). All patients showed relatively high satisfaction immediately after the last treatment.

Conclusions: Our data show that intense muscle activity is generated by FMS treatments, suggesting that this technology could be used as a convenient and effective muscle toning tool.

KEYWORDS

body toning, FMS (Flat Magnetic Stimulation), lipolysis

1 | INTRODUCTION

A large number of people of both sexes (about 80%) are affected by problems involving excess weight and localized adiposity. The risk of cancer or cardiovascular disease is increased due to abdominal obesity, which gives evidence of the presence of fat around the bowels.¹ The most effective and fast treatments for the remodeling of

the body shape are certainly the surgical ones; also in 2017, liposuction was the most popular cosmetic surgical procedure.² Cosmetic surgery is undoubtedly the most effective as regards the reduction of localized fat, but this type of treatment cannot intervene in any way on muscle toning, which therefore remains at the complete discretion of the patient. Furthermore, after such surgical procedures, some patients may be dissatisfied with their esthetic appearance; in fact, the removal of abdominal fat, for example, does not solve the

Manufacturer	DEKA MELA S.r.l
Manufacturer's geographical location	Italy
Device type	Focused magnetic stimulator
Energy type	Electromagnetic fields
Number of applicator/paddles	2
Number protocols	3
Type protocols	Aerobic/shaping/strength
Intensity	Up to 2.5 tesla (T)
Pulse repetition frequency	1–150 Hz
Pulse duration	250 μ s $\pm$ 20%
Size and Weight	41 cm $\times$ 73 cm $\times$ 126 cm (LxPxA)–60 kg
Duration of each treatment session	20–45 min
Frequency of treatment	2 treatments done per week
Skin cooling	Liquid cooling system

TABLE 1 Features and parameters of the device

problem of muscle flaccidity, due to the weakness of the abdominal muscles.³

The spread of non-invasive procedures for fat deposits removal has increased rapidly in recent years: Radiofrequency, cryolipolysis, focused ultrasound and low-level laser therapy are the most used for the treatment of localized fat and their efficacy has been demonstrated.⁴ However, despite more than a third of our body, it is made up of muscles, no body-shaping technique takes into consideration the underlying muscles, which are significantly responsible for a toned and esthetically attractive abdominal appearance. Muscle training generally takes place thanks to physical activity or by electrical or electromagnetic stimulation; electromagnetic stimulation is superior to electrical stimulation as it penetrates deeper into the tissue without causing any pain.^{5–8} The possible effects of electromagnetic fields on the human body (neuropsychiatric, musculoskeletal, and urogynecological disorders) have been studied for a long time.⁹ In the field of esthetic medicine, high-intensity focused electromagnetic field (HIFEM) technology has recently been introduced, as a tool for toning and strengthening muscles, which goes far beyond normal physical exercise.

Since electromagnetic stimulation has been shown to strengthen muscles^{10,11} and that intensive muscle training induces lipolysis,^{12,13} we can hypothesize that electromagnetic stimulation can be used to shape the body.

The activation of the muscles voluntarily in humans is never complete due to the conductivity of the neural pathways^{14,15}; the electromagnetic stimulation instead directly stimulates the motor neurons of the muscles, bypassing the involvement of the nervous system.

Furthermore, since the frequency of the impulses delivered is high, the muscle is unable to relax between one contraction and another and undergoes a supramaximal muscle contraction. In order to adapt to these extreme stresses, the muscle tissue starts a profound remodeling of its internal structure with an increase in the number of myofibrils that make up the muscle fibers, therefore an increase

in the volume of muscle fibers (muscle hypertrophy) and with an increase in the number of muscle fibers (muscle hyperplasia). The increase in density and volume leads to greater definition and better muscle tone.¹⁶

In this study, we evaluated the efficacy and safety of Schwarzy (DEKA MELA): The technology used is FMS (flat magnetic stimulation); it is a technology capable of making a muscle to move independently from the commands given by the brain; in fact, motor neurons are stimulated, and thus, a muscle contraction is caused.

Flat magnetic stimulation is a new technology dedicated to firming the body with stimulation of muscle mass through neuromuscular stimulation; in fact, it is used to increase muscle strength both as muscle training and as muscle rehabilitation medicine. The magnetic stimulation also avoids the perceptual pain sensation typical of electrostimulation, as cutaneous receptors are affected in a limited way. The magnetic field has the ability to penetrate up to 7 cm deep.³ Indeed, magnetic stimulation is able to activate the motor neurons in depth, and it is possible to reach wide and deep muscle contractions.

2 | MATERIALS AND METHODS

2.1 | Patient selection

A set of 15 patients (7 males and 8 females, BMI 24.05 ± 2.01 kg m⁻², age 32–57) participated in this study. Patients were enrolled at Dermatos center, Montesilvano, Abruzzo, Italy. The exclusion criteria are as follows: pregnant patients or patients with implanted electronic/metallic devices, cardiac pacemakers, and/or any type of medical condition contraindicated for the use of the electromagnetic field and subjects undergoing other treatments for body remodeling. All the participants during the whole treatment period were not subjected to dietary restrictions. A limitation of this study was represented by the restricted number of patients.

2.2 | Study protocol

6–8 treatment sessions were performed. The sessions must be repeated twice a week, with a minimum of 2 days between each session as specified in the protocol approved by the Institutional Review Board and in conformity with the ethical guidelines of the Declaration Helsinki (1975). Treatment duration varies from 20 to 45 min, depending on patients.

The treatment was performed on the patients' abdomen using a Flat Magnetic Stimulation device (Schwarzy, DEKA MELA). The FMS device is equipped with a circular coil which is located inside the applicator and at the level of which an alternating electric current is created which in turn generates electromagnetic pulses with an intensity up to 2.5 Tesla (see Table 1). The technology uses three types of different protocols: aerobic, muscle shaping and muscular strengthening, it is customizable based on muscle condition, and it adapts to the needs of each type of patient. No anesthesia was required; in fact, the treatment is comfortable because there is none dermo-epidermal interaction with electromagnetic fields and the liquid cooling system, of the handpieces, guarantees high performances while avoiding warming of the treated area and painful sensations.

The non-invasive device acts on different body areas thanks to its paddle handpiece that you adapt to the abdomen, buttocks, arms, and legs causing muscle contractions thanks to the focused magnetic energy. At the abdominal level, all muscles are involved: the straight, oblique (which form the waistline), and transverse ones. The latter are the deepest abdominal muscles, essential for stability especially in the lumbar region.

During the treatment, the two applicators of the device (previously fixed to avoid any movement) are positioned above the navel, affecting the rectus abdominis and the external and internal obliques (Figure 1). At the beginning of the treatment, the applicator position was adjusted in order to have homogeneously distributed contractions. The rapid change of magnetic fields, generated by the device, transmits current directly to the muscle tissue in depth, contracting it and releasing it. More specific, the advantage of our device is due to the greater homogeneity of magnetic field distribution on a wider area (see Figure 2), that allows a greater recruitment of muscle fibers (involving larger muscle's areas) and does not create regions of different stimulation intensity. This mechanism allows the muscle to work at the same intensity in all treatable areas. Furthermore, the system allows supramaximal stimulation that is higher than that which can be reached voluntarily by the patient in physical activity and is also used in subjects with abdominal obesity or overweight. During treatment, the intensity of the magnetic field was gradually increased until it reaches the patient's tolerance threshold.

2.2.1 | Primary outcome

In order to assess the effectiveness of the treatment, abdominal ultrasound measurements were performed to evaluate changes in fat and muscle tissue thickness. Abdomen ultrasound

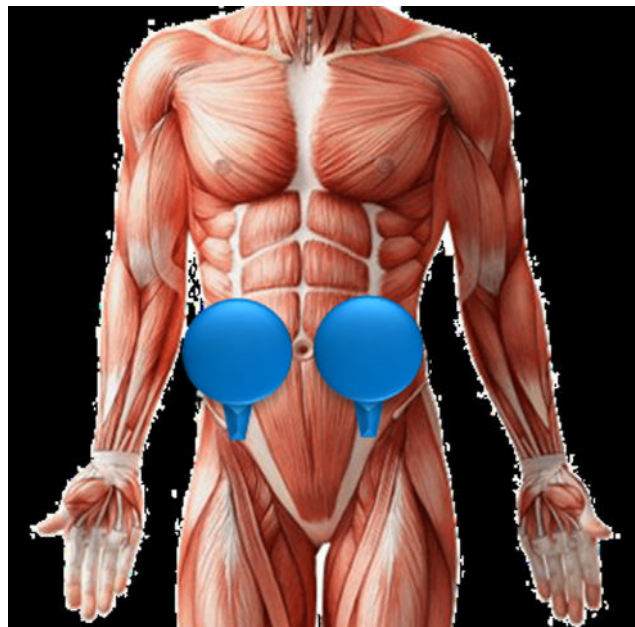


FIGURE 1 Graphic representation of device placement on patient's abdomen

measurements were performed on each patient who was relaxed and lying in a supine position. The 4 abdominal sites (upper abdomen, lower abdomen, lateral abdomen, and rectus abdominis diastasis) evaluated with echographic observations were taken at the same distance from the navel. For the upper and lower abdominal ultrasound measurements, the probe was placed 5 cm below and above the navel and from there moved laterally for a distance corresponding to half dimension of the probe. For the lateral abdominal ultrasound measurements, the probe was placed on both lateral sides of the navel for a distance corresponding to half dimension of the probe. The images were acquired using ultrasound scanner (MyLab One, Esaote).

2.2.2 | Secondary outcomes

In addition, abdominal subcutaneous fat and muscle tissue thickness and waist circumference measurements were performed. Frontal and lateral digital photographs were taken before treatment and during 1-month follow-up after the last treatment. To measure abdomen's waist circumferences, a flexible but inelastic anthropometric tape was used and the circumference measurement was taken 1 cm above the navel.¹⁷ To measure the abdomen's subcutaneous fat thickness, a skinfold caliper was used. A written patient consent was released and archived. The study protocol is completed by all patients, who underwent visit evaluation after 1 month from treatment.

2.3 | Statistical analysis

Paired Student's *t* test was used to analyze data. Statistical significance is accepted to be $p < 0.05$. Data are shown as means $\pm$ standard

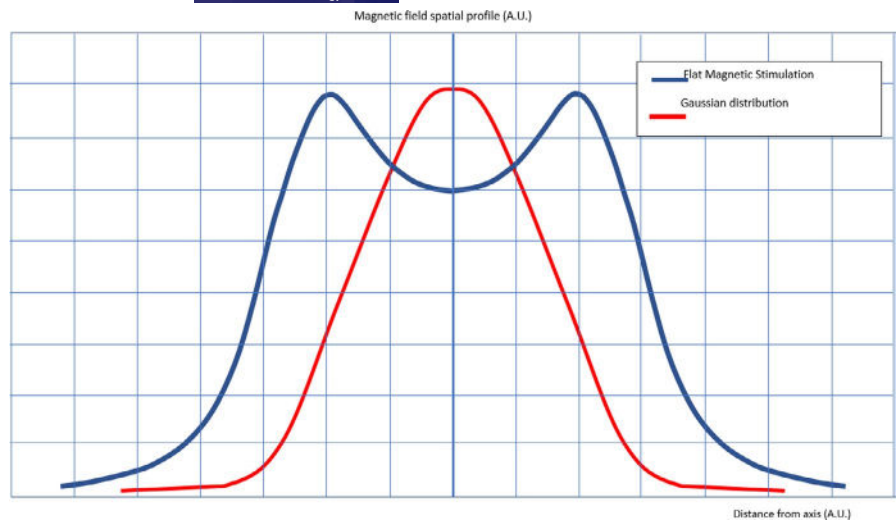


FIGURE 2 Magnetic field spatial profile considered from the center of the axis of the handpiece, shown in arbitrary units (A.U.)

Measurements	baseline	1-month FU	Significance
Skinfold (subcutaneous fat) thickness	26 ± 6 mm	21 ± 6 mm	<i>p</i> < 0.001
Waist circumference	80.7 ± 4.3 cm	77.3 ± 5.6 cm	<i>p</i> < 0.001

TABLE 2 Average change in Waist circumference and subcutaneous fat thickness

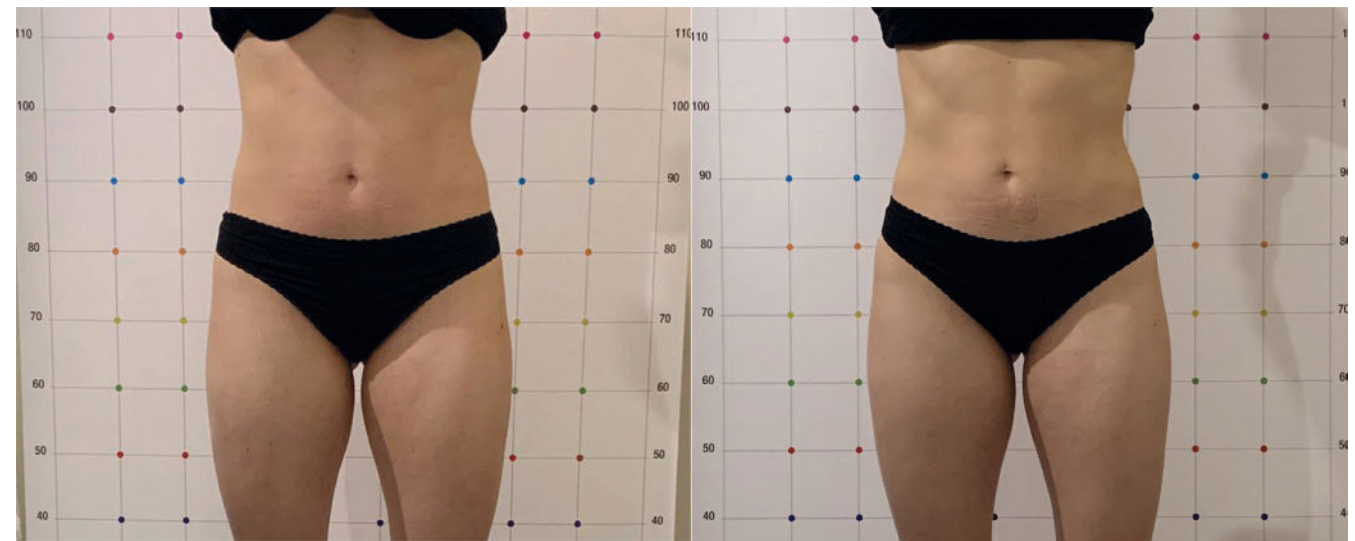


FIGURE 3 Frontal view of a 35-year-old patient before and 1 month after the last treatment

deviation (SD). Statistical interpretations were carried out with the SPSS program version 25.0 (IBM).

3 | RESULTS

During the 1-month follow-up evaluations, the results showed tonification, the strengthening of muscles, and the reduction of localized adiposity; the device is capable to reproduce the same metabolic effects by offering strengthening results, muscle toning, and firming of affected areas.

An improvement in fat reduction and muscle thickness in the abdominal area is showed by echographic images. All patients show high treatment satisfaction.

Echographic evaluation results were also coupled with waist circumference changes: We can observe a significant reduction in mean waist circumference (80.7 ± 4.3 cm vs 77.3 ± 5.6 cm, *p* < 0.001) and in the mean skinfold (subcutaneous fat) thickness (26 ± 6 mm vs 21 ± 6 mm, *p* < 0.001) 1 month after the last treatment (see Table 2). Frontal and lateral digital photographs were taken before treatment and during 1-month follow-up after the last treatment (see Figures 3–6). There is a significant improvement in average abdominal muscle

tissue thickness 1 month after the last treatment in all treated areas: Upper abdomen (9 ± 2 mm vs 11 ± 1 mm, $p < 0.001$), lower abdomen (10 ± 2 mm vs 13 ± 2 mm, $p < 0.001$), lateral abdomen (11 ± 2 mm vs 13 ± 3 mm, $p < 0.001$), and rectus abdominis diastasis (25 ± 4 mm vs 22 ± 4 mm, $p < 0.001$) (see Table 3). A visible improvement of upper abdomen's muscle thickness is shown by abdominal echographic image (Figure 7). Also, a significant average fat thickness reduction at lower abdomen level (12 ± 4 mm vs 11 ± 4 mm, percentage change -7% , $p < 0.001$) was observed by echographic findings.

Stimulation intensities ranging from 50 to 100% were also well tolerated by most patients already at the end of the first session and during subsequent remaining treatments. The treated area becomes more toned. No adverse events were recorded during all the treatment period. The only side effect found was muscle fatigue, which resolved within 48 h.

4 | DISCUSSION

Most body-shaping treatments (surgical or non-invasive) target the subcutaneous fat layer, but none are concerned with muscle strengthening, which is performed only through physical workout plan.

The magnetic stimulation technology induces over-maximum muscle contractions (20 000 per session) that cannot be reached through voluntary contractions, acting simultaneously on both muscle remodeling and the reduction of localized fat. The working conditions to which the muscle is subjected during magnetic stimulation are absolutely not comparable to the activity that takes place in the gym, neither with functional training, nor with exercise with weights. Muscle tissue adapts to this intense contraction, encountering phenomena of muscle hypertrophy (increase in the volume of muscle fibers) and hyperplasia (increase in the number of muscle fibers), as demonstrated in other studies.¹⁸⁻²¹ In fact, recent studies have evaluated, in addition to hypertrophy, normally accepted

by the scientific community, even muscle hyperplasia after a series of exercises.²²

The effects of HIFEM technology on abdominal composition using ultrasound imaging evaluation were investigated by several studies, including that of Katz and colleagues,³ showing excellent results. Histological examination by Duncan and Dineve²³ showed that HIFEM treatments induced volumetric growth in individual muscle fibers (hypertrophy 12.15%) and an increase in the number of muscle fibers (hyperplasia 8.0%), although the latter was not statistically significant. In addition, the formation of new capillaries has also been observed, as an adaptive response to the high load induced by HIFEM treatments to provide nourishment to the increased muscle mass.

The Schwarzy system with its 3 pre-set programs (Aerobic, Shaping, and Strength) and customizable based on muscle condition, it adapts to the needs of each type of patient. Schwarzy protocols have been programmed with active phases alternating with rest phases, so they allow optimal muscle recovery of the patient and avoid the onset of lactacidosis. The recovery phases in which the muscle is revascularized in fact are very important and approachable to a regular practice of stretching, which should favor the increase in the number of sarcomeres in series that make up the muscle fibers (hyperplasia): These new sarcomeres are would add to the ends of the myofibrils themselves and would be responsible for the possible increase in muscle length. This aspect is fundamental for a hypertonic muscle (ie, in excess of tone) which will tend not to independently recover its original length even if it is relaxed: continuous exercise, in fact, involves the maintenance of a shortening memory of the contractile fibers that it is reversible only thanks to the practice of stretching/recovery.

Moreover, the protocols developed for the subject device are able to train both types of fibers present in the muscle (both type I fibers, also called red, slow twitch, and type II, intermediate or white, fast twitch), leading the patient to have an improvement in both muscle tone and volume.

The protocols have been developed in order to involve all types of fibers that are present, adapting to the different distribution



FIGURE 4 Lateral view of a 35-year-old patient before and 1 month after the last treatment

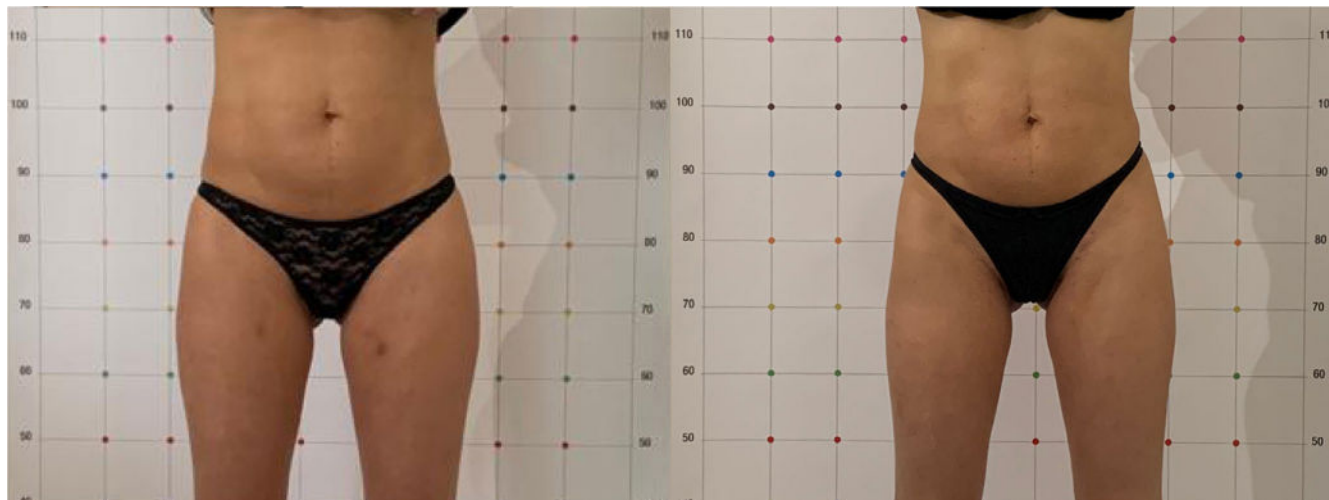


FIGURE 5 Frontal digital image of a 50-year-old patient before and 1 month after the last treatment

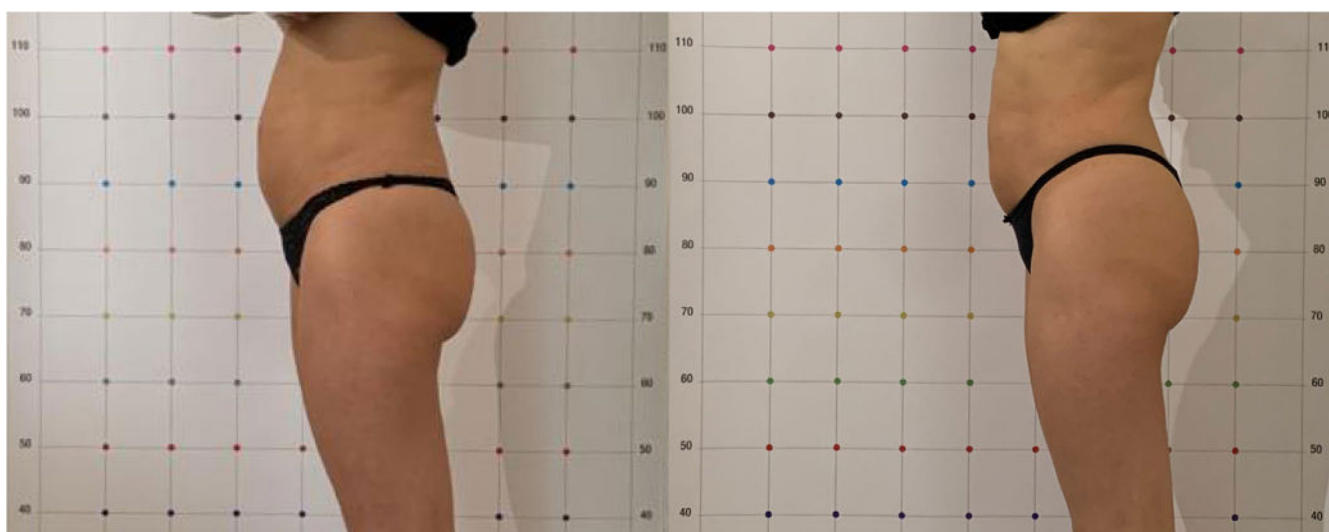


FIGURE 6 Lateral digital image of a 50-year-old patient before and 1 month after the last treatment

TABLE 3 Average changes thickness of abdominal muscle tissue in treated subjects

Area	Muscle thickness (mm) baseline	Muscle thickness (mm) 1-month FU	Percentage %	Significance
Upper abdomen	9 ± 2 mm	11 ± 1 mm	+23%	$p < 0.001$
Lower abdomen	10 ± 2 mm	13 ± 2 mm	+23%	$p < 0.001$
Lateral abdomen	11 ± 2 mm	13 ± 3 mm	+14%	$p < 0.001$
Rectus abdominis diastasis	25 ± 4 mm	22 ± 4 mm	-11%	$p < 0.001$

percentages of the latter in the various muscles, in particular in the gluteus muscle (50%: fibers I, 20%: fibers IIa, and 30%: fibers lib) and in the rectus of the abdomen (46%: fibers I and 54%: fibers lib).

In the literature, it has been shown that muscle training performed at high intensity induces a degradation in the adipose tissue adjacent to the contracted muscle.²⁴ To produce contractions, the muscles need energy which derives mainly from adenosine

triphosphate (ATP) and secondly from creatine phosphate and glycogen. When these are exhausted, the body's catabolic processes take place in the form of lipolysis, or the breakdown of lipids (triglycerides) into free fatty acids (FFA) and glycerol, which represent a source of energy necessary for the body's metabolism. During low-intensity aerobic exercise, the muscles mainly use the free fatty acids (FFAs) available in the blood. On the contrary, during

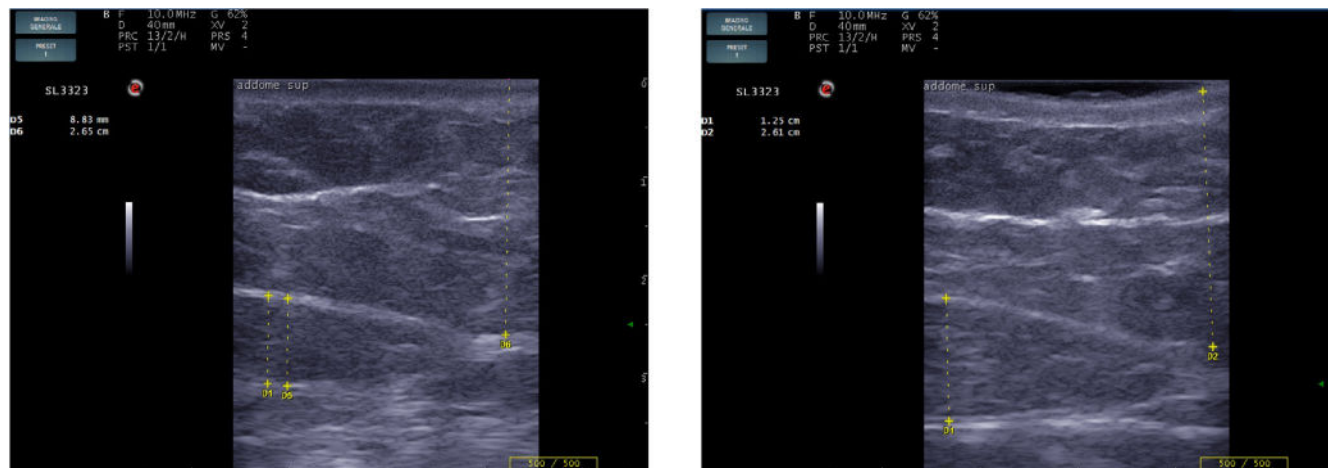


FIGURE 7 Abdominal echography of a 30-year-old patient before and 1 month after the last treatment. An improvement of patient upper abdomen's muscle mass in the treated area is shown

high-intensity exercise, (since the levels of lipids in the blood begin to decrease) the body begins to use the lipids deposited in the adipose tissue.

During a magnetic stimulator treatment, the muscles are contracted to supramaximal levels. In this phase, there is a great release of adrenaline which results in a supramaximal lipolysis, which in turn determines a release of FFA that exceeds normal levels; FFA then begin to accumulate intracellularly in the surrounding adipocytes leading to their dysfunction. This catabolic and supramaximal lipolysis effect occurs mainly in the area near the contracting muscles, due to the paracrine substances released by the contracting muscles and to the increase of blood flow in the adipose tissue. The release and accumulation of FFA in the cytoplasm of adipocytes induces a decrease in pH levels with consequent activation of apoptotic markers, such as MMP9, TXNIP, TNF- α , BCL-2, and BAX. Recent histological studies and molecular biochemistry results have reported a significant increase in the apoptotic index of adipocytes and an increased presence of mRNApro-apoptotic markers, after a HIFEM treatment in pigs.²³ Schwarzy-induced electromagnetic stimulation offers a number of advantages over electrical stimulation: It induces pain-free supramaximal stimulation.

5 | CONCLUSIONS

Our data show that intense muscle activity is generated by FMS treatments, suggesting that this technology could be used as a convenient and effective muscle toning tool. Schwarzy represents a promising device in the field of body remodeling. Therefore, further studies on muscle toning and lifting in trained subjects on different body areas are already in progress, as it could be used not only by sedentary and overweight subjects but also by athletes who want to strengthen their muscle structure and improve their

performance. Finally, it should be noted that Schwarzy does not use consumable materials with great economic advantages, ecological and warehouse: In fact inside the clinic, there is no need of a storage for replacement material. However, to assess the full clinical potential of this technology, we will consider to use MRI method, when we would have the opportunity, for our future studies.

CONFLICT OF INTEREST

No conflict of interest to declare.

AUTHOR CONTRIBUTIONS

A.L, D.P, and C.C performed the research and contributed substantially to the study design, interpretation, and data acquisition/analysis; I.F and L.P contributed to the manuscript writing. All authors were involved in the drafting and revision of the manuscript and given final approval of the version to be published. Each author has agreed to be responsible for all aspects of the job to ensure that issues relating to the accuracy or integrity of any part of the job are properly investigated and resolved.

ETHICAL APPROVAL

The authors confirm that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to and the appropriate ethical review committee approval has been received.

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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