

# Efficacy study of a high intensity magnetic field device for muscle toning and fat loss.

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**Reference Medical Productos y Servicios S.L.**

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## **EXPERIMENTATION SITE, PARTICIPANTS**

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## **2. SUMMARY OF THE STUDY**

### **2.1 Objective**

The objective of this study is to evaluate the in-vivo efficacy of the High Intensity Electromagnetic Field Muscle Stimulator Cm Slim (Daeyang Medical, South Korea) to tone the abdominal muscles, induce abdominal fat loss and produce changes in the body contour.

The evaluation is performed using:

- **Clinical Photographs**
- **3D Volume and Circumference Measurement**
- **Echographic Subcutaneous Fat Thickness Measurement**
- **Capacitive Weight and Body Analysis**
- **MRI for Abdominal Muscle and Subcutaneous Fat Thickness Measurement**

The study lasts 4 weeks following the first treatment. Due to budget constraints only 7 subjects were selected for the MRI evaluation.

### **2.2 Population**

21 subjects are selected for the study.

The subjects selected for this study are healthy males and females, aged between 21 and 61 years old.

These subjects are selected according to the inclusion / non inclusion criteria listed in paragraph 3.1.

### **2.3 Study Schedule and Duration**

Pre-inclusion : 1-14/11/19

Beginning of the study: 18/10/19

End of the study : 23/12/19

Scheduled Procedures:

	D0	D28
<b>Clinical Photographs</b>	<b>X</b>	<b>X</b>
<b>3D Volume and Circumference Measurement</b>	<b>X</b>	<b>X</b>
<b>Echographic Subcutaneous Fat Thickness Measurement</b>	<b>X</b>	<b>X</b>
<b>Capacitive Weight and Body Analysis</b>	<b>X</b>	<b>X</b>
<b>MRI for Abdominal Muscle and Subcutaneous Fat Thickness Measurement</b>	<b>X</b>	<b>X</b>

Table 1. Techniques and population for the tests carried out at D0 and D1.

## 2.4 Study design

- Comparative study.

## 3. STUDY PROTOCOL

### 3.1 Subject selection

The study panel is composed of subjects selected on the basis of their medical record, which they agreed to be consulted for this purpose prior to the study that provides details of their medical history, possible allergies, diet and exercise habits, as well as a certain amount of administrative information.

The selection procedures are elaborated in order to guarantee that the subjects receive all possible information about the aims of the study and the consequences of their participation.

This selection procedure includes:

- A preliminary interview, during which the following points are explained to the subjects: the study's modalities, its practical considerations, possible reward, as well as any possible cosmetic benefits, inconveniences or potential risks.
- The information form, which is specific to the study, including all essential information is then read.
- The consent form is read, approved, and signed by the subject to substantiate the fact that they freely accept the conditions of the study, which has been described to them
- The consent form which was filled in freely and intentionally by the subject after

it had been fully explained to them, in the event of any claims for damages, enables them to benefit from the terms of the insurance policies taken out by both the investigator and/or by the study sponsor as soon as the subject is accepted onto the study by the study manager.

The subject must respect the following conditions: (as well as those already mentioned):

- Available for the entire duration of the study
- Motivated to freely participate in the study
- Willing to follow the full application procedure
- Able to justify a permanent address
- Capable of reading the consent documents and able to accept the participation conditions
- Benefiting from Social Security medical cover

The subjects selected for the study are chosen under the supervision of the investigator and study manager, on the basis of the inclusion/non inclusion and proscription/restriction criteria listed below.

A selection of 21 subjects is made for this study.

The results given include all of the present and assessable subjects at each examination.

### **3.1.1 Inclusion criteria**

#### **General criteria**

- Male or Female
- Healthy
- Between 21 and 70 years of age
- Skin at assessed area is healthy (free of psoriasis, eczema, erythema, edema, scars, wounds or lesions)

#### **Specific criteria**

- BMI between 20 and 30
- Not being under a diet or an exercising routine
- Having had a stable lifestyle for at least three months

### **3.1.2 Non-inclusion criteria**

#### **General criteria**

- Failing to meet the aforementioned inclusion criteria
- Being in remanence, at the beginning of the study, on the studied area(s), following another cosmetic, dermatological, or medical test
- Having undergone any body contouring treatment during the previous six months
- Having undergone any major surgery in the previous year
- Having undergone plastic surgery on the studied areas
- Taking part or intending to take part in another study liable to interfere with this study
- Being diabetic
- Being asthmatic
- Having participated in skin or periorcular tolerance testing in the past two weeks and/or in sensitization trials in the past four months
- The refusal to give their assent by signing the consent form
- Being pregnant or breastfeeding in the past three months
- Intending to become pregnant during the study
- Having changed their cosmetic habits (especially related to body contouring products) in the 14 days preceding the start of the study or intending to change them during the study on the concerned areas
- Having cutaneous hypersensitivity or a skin allergy to cosmetic products
- Following or intending to follow a chronic medicinal treatment comprising any of the following products taken orally: aspirin-based products, anti-inflammatories, anti-histamines, corticotherapy, anti-depressants, anti-migraine medication and neuroleptics, DHEA (the only medication permitted is paracetamol)

### **Specific criteria**

- Having been on a weight-loss diet or received a treatment at a spa in the three months preceding the start of the study
- Having started, changed or stopped a hormonal treatment (Hormone Replacement Therapy, thyroid) in the past three months
- Intending to start, change or stop a hormonal treatment (Hormone Replacement Therapy, thyroid) during the study
- Having started, changed or stopped a means of oral contraception in the past three months
- Intending to start, change or stop a means of oral contraception during the study
- Intending to modify their sporting habits during the study
- Having applied firming products or thinning products in the six months preceding the start of the study
- Having made injections (Botox, collagen, hyaluronic acid...) in the studied area previous 6 months

### **3.1.3 Proscriptions and restrictions**



### **General proscriptions and restrictions**

- Being pregnant during the study
- Having changed their cosmetic habits during the study
- The use of any of the following products taken orally is proscribed for the entire duration of the study: aspirin-based products, anti-inflammatories, anti-histamines, corticotherapy, anti-depressants, anti-migraine medication and neuroleptics, DHEA (the only medication permitted is paracetamol)
- The days on which the measurements are to be taken, the application of any other cosmetic product and/or make up
- During the study, the application of any other cosmetic product to the studied areas is proscribed.
- Having exposed themselves to artificial UV light and/or to the sun during the study

### **Specific proscriptions and restrictions**

- Having started, changed or stopped a hormonal treatment (Hormone Replacement Therapy, thyroid) during the study
- Having started, changed or stopped a means of oral contraception during the study
- Having begun a diet or body contouring treatment during the study
- Having modified their sporting habits during the study

## **3.2 The treatment**

### **3.2.1 Presentation of the device**

The device used for this study was the Cm Slim (Daeyang Medical, South Korea). The specifications of the device are as follows:

Power	Power Input	230 V 50/60Hz
	Maximum Power Consumption	2.3 kVA
Magnetic Stimulation	Magnetic induction amplitude (intensity)	0~7 Tesla
	Shape of stimulation pulse	Biphase
	Pulse duration	300 $\mu$ s
Dimension	Size (height x width x depth)	420 x 660 x 1150 (mm)
	Weight	70kg
	Safety type	B

**Table 2.** Cm Slim Specifications.



Figure 1: Cm Slim.

The device comes with two applicators and a series of velcro belts that allow them to remain on a fixed position on the body. Depending of the indication the user may choose to use both applicators or only one of them. In this study only one applicator was used.

The study sponsor is responsible for supplying the device as well as the technical assistance that could be required.

### 3.2.2 Treatment Protocol

The subjects received 2 sessions per week on non-consecutive days for two weeks (in total 4 sessions). Only one applicator was used over the patients lying on a stretcher. The applicator was placed at the center of the abdominal muscles and held in position thanks to the velcro belt (Figure 2). The time duration of the session was set at 30 minutes. All subjects were treated on the abdominal area with the ABS program. This program has 5 modalities:

- HIIT, for fat burning.
- Hypertrophy, for muscular volume gain.
- Strength, for muscular contraction capacity gain.
- Combo 1, a mix of the HIIT and Hypertrophy programs.
- Combo 2, a mix of the Hypertrophy and the Strength programs.



Figure 2: Cm Slim Applicator placement for the study.

All the subjects were treated with the Combo 1 procedure. This program has 4 levels of intensity. At beginning of the first session all patients started at Level 1 and every 90 seconds the level was raised until they reached Level 4 at 4:30 minutes and stayed at that level until the end of the session. For all the remaining sessions the subjects started directly at Level 4.

### **3.3 Study design**

- This study is an observational cohort study. No allocation of the treatment was randomized as all subjects followed the same CM Slim Protocol.
- This is a comparative study in which the results obtained at one time point (4 weeks) are compared with those obtained prior to the subjects exposure to the device.

### **3.4 Randomization**

There is no randomization in this study.

### **3.5 Study procedures**

#### **3.5.1 Clinical Photographs**

##### *3.5.1.1 Acquisition of source data*

###### Principle

This technique consists in obtaining high-resolution photographs of the body at  $0^\circ, \pm 45^\circ, \pm 90^\circ, \pm 135^\circ$  and  $180^\circ$  in complete reproducible lighting conditions, in semi diffused light in order to produce shadows that allow to assess the skin appearance.

Photographs are taken with a Nikon D5300 (Nikon Corp., Japan) using a lens LifeViz Body (Quantificare S.A., France). Two flashlights are incorporated to the LifeViz objective. The camera tripod is in a fixed established by the camera objective thanks to two pointes that converge at the right focal position.

In order for the photographs to be highly reproducible and consistent through the study a setup with a turning platform for the subject and fixed positions for the camera tripod, the flashes and the platform were established.

###### Acquisition methodology

- Environmental conditions

The evaluation is carried out in a room with grey walls, under controlled temperature and relative humidity (temperature  $23,8^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ; hygrometry:  $43\% \pm 10\%$ ).

- Subject

The subject is standing with the arms crossed over the chest on a mat where the different angles are indicated as shown in the figure bellow.

The camera tripod, the tripod height and the flashes remain in the same positions throughout the study

A 15-minutes period of acclimatization in the room is respected prior o the photographs.

- Studied areas and marking

No measurements are performed.

- Measures

The camera is positioned vertically. The visualization of the initial digital photograph (D0) at D28 ensures a good repositioning of the subject at each time.

### 3.5.1.2 Treatment of source data

#### Methodology and treatment software

The subject is standing on the photographic acquisition system and wears a disposable underwear over the panties (in the case of females) or instead of their underwear (in the case of males). Women were allowed to keep their bra.

After the photographs are taken they are named according to image processing criteria: study name (5 alphanumeric characters) \_volunteer code (5 alphanumeric characters) \_camera position (1 letter)\_type of lighting (2 letters)\_time (2 numbers. Example: END02\_VOL01\_F\_CP\_00).

#### Mathematical treatment

There is no mathematical treatment.

#### Parameters

There are no parameters.

#### Exploitation

There is no exploration. The photographs are taken to have a visual reference of the subject state at each visit.

### 3.5.2 • 3D Volume and Circumference Measurement

#### 3.5.2.1 Acquisition of source data

##### Principle

This technique consists in obtaining high-resolution stereoscopic photographs of the body at  $0^\circ, \pm 45^\circ, \pm 90^\circ, \pm 135^\circ$  and  $180^\circ$  in complete reproducible lighting conditions, in semi diffused light in order to produce shadows that allow to assess the skin appearance.

These captures are taken with a Nikon D5300 (Nikon Corp., Japan) using a lens LifeViz Body (Quantificare S.A., France). Two flashlights are incorporated to the LifeViz objective. The camera tripod is in a fixed established by the camera objective thanks to two pointes that converge at the right focal position.

In order for the photographs to be highly reproducible and consistent through the study a setup with a turning platform for the subject and fixed positions for the camera tripod, the flashes and the platform were established.

Afterwards a computer program reconstructs the 3D shape of the eight stereoscopic captures in an analogous way as our brain does and stiches the 8 captures to reobtain a full 3D mesh of the whole abdomen.



Figure 3. Quantificare 3D capture system.

##### Acquisition methodology

- Subject

The subject is standing on the photographic acquisition system and wears a disposable underwear over the panties (in the case of females) or instead of their underwear (in the case of males). Women were allowed to keep their bra.

- Studied areas and marking

The measurements are performed on the abdominal area.

- Measures

8 3D captures are performed with the subject turning around on the motorized platform.

### 3.5.2.2 Treatment of source data

#### Methodology and treatment software

The 3D captures are loaded on a software that stitches them together and extrapolates the three-dimensional coordinates of the body thus creating a 3d mesh. That mesh is exported in the .obj format and loaded on the AEVA software where meshes are aligned in order to share a same reference point (the umbilicus). Afterwards the software trims the mesh in order to keep only 5cm above the umbilicus and 10cm below. With this we have standardized the segment of the body where the volume and circumference will be evaluated.

#### Mathematical treatment

For each mesh a volume and umbilical circumference are obtained. The average and standard deviation of these measurements is calculated for every evaluation time.

#### Parameters

Volume (mm<sup>3</sup>): Represents the abdominal volume for the 15cm trimmed abdominal mesh.

Circumference (cm): Represents the abdominal circumference at the umbilical level.

#### Exploitation

A decrease in the volume or circumference means a fat loss and or a remodeling effect, while an increase means a worsening of the subject condition.

### **3.5.3 • Echographic Subcutaneous Fat Thickness Measurement**

#### 3.5.3.1 Acquisition of source data

##### Principle

Ultrasound waves are produced in pulses, not continuously, because the same crystals are used to generate and receive sound waves, and they cannot do both at the same time. In the time

between the pulses, the ultrasound beam enters the patient and is bounced or reflected back to the transducer. These reflected sound waves, or echoes, cause the crystals in the transducer to deform again and produce an electrical signal that is then converted into an image displayed on the monitor. The transducer generally emits ultrasound only 1% of the time; the rest of the time is spent receiving the returning echoes. The depth of penetration of the ultrasound wave is inversely proportional to the frequency of the crystal pulses. In this study we used a Mindray M5 (Mindray Medical International Limited, China) with a 10MHz linear probe capable of penetrating several centimeters into the body.

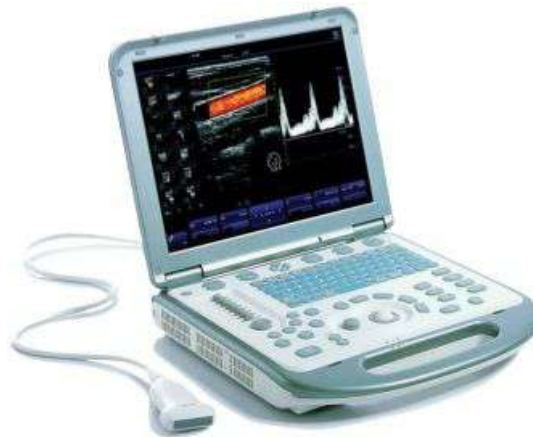


Figure 4. Mindray M5 with lineal probe system.

#### Acquisition methodology

- Subject

The subject is laying upwards on a stretcher. A thick layer of echography gel is applied over the probe in order to absorb part of the pressure the evaluator may exert over the tissue. Nevertheless, the evaluator will try to exert no pressure at all while performing the echography. The probe is placed next to the umbilicus, at the right side. After asking the subject to release all the air and hold his/her breath for a few seconds the echographic information is captured.

- Studied areas and marking

The measurements are performed on the abdomen, at the right side of the umbilicus.

- Measures

The handheld device is placed over the subject's face without compressing the skin while the measurement takes place.

Three measurements are recorded on the CRF on a given measurement site, at each time point of the study.

#### 3.5.3.2 Treatment of source data

## Methodology and treatment software

On every site and time one measurement is obtained and recorded on the CRF.

A USB drive is connected to the echograph. The echography image from the device is transferred to the USB drive as a .bmp file.

## Mathematical treatment

The average and standard deviation of these measurements is calculated for every evaluation time.

## Parameters

Subcutaneous Fat Thickness (mm): The length of a transversal segment of subcutaneous fat measured within the echograph.

## Exploitation

An increase in the subcutaneous fat thickness means the patient has gained fat while a decrease means the patient has lost fat.

## **3.5.4 Capacitive Weight and Body Analysis**

### **3.5.4.1 Acquisition of source data**

#### Principle

The weight measurement is carried out with a digital scale BC-545 Inner Scanner (Tanita, Japan). The principle behind digital scales lies in high precision pressure sensors converting the mechanical pressure of the body weight into an electrical signal. The intensity of the electrical signal is proportional to that mechanical pressure. Additionally, several currents are emitted through feet and hands electrodes. The resistance presented by the different tissues to the electrical current allows the device to quantify these tissues weight for each leg, arm and the body trunk, as well as estimate the basal metabolism of the subject.

Body weight is not constant. Fluctuations are to be expected based on the time of the day, the physical activity, menstruation, etc. Changes around  $\pm 1000\text{g}$  are not considered weight gain.

## Acquisition methodology

- Subject

The subject stands on the device when the signal to proceed to the weighting appears onscreen.



The subject wears disposable underwear and the bare skin of the feet plants is in contact with the scale electrodes.

- Studied areas and marking

In this case the whole body is evaluated, and no marking takes place.

- Measures

The subject is placed in the scale as shown in the figure. Weight values are obtained and written down on the CRF.

#### 3.5.4.2 Treatment of source data

##### Methodology and Treatment Software

On every visit the subject the weight values are obtained.

##### Mathematical treatment

At each visit 1 measurement is taken.

##### Parameters

Body weight (Kg), BMI, Trunk Muscle Weight (kg), Trunk Fat Percentage, Basal Metabolic Expenditure (Kcal), Visceral Fat Level.

##### Exploitation

A gain in weight greater than 1kg indicates that the subject may not have followed the study instructions related to physical activity or eating habits but a loss greater than 1kg indicates real weight loss.

Trunk muscle weight variation will be directly proportional to muscle gain therefore, if this variable increases the subject will have gained muscle mass and, if it decreases, they will have lost muscle mass.

Trunk fat Percentage will indicate subcutaneous and/or visceral fat gain or loss. If it increases the subject will have gained fatty tissue; if it decreases the subject will have lost fatty tissue.

Basal Metabolic Rate increase is directly related to muscle mass increase as the more muscle there is, the more calories the body expends at rest. If the subjects gains muscular tissue the basal metabolic expenditure will increase while if he or she loses muscular tissue the metabolic expenditure will decrease.

Visceral Fat Level is directly proportional to the amount of visceral fat. If there is a visceral fat decrease the level will decrease and inversely, if there is a fat increase, the level will increase.

### 3.5.5 Magnetic Resonance Imaging

#### 3.5.5.1 Acquisition of source data

##### Principle

Magnetic resonance imaging (MRI) is an important tool in the diagnosis and evaluation of diseases. In the early 1970s, Paul Lauterbur and Raymond Damadian applied nuclear magnetic resonance (NMR) technology to the imaging of living organisms, generating images referred to as zeugmatographs. Subsequent refinements in image acquisition and processing, developed by Sir Peter Mansfield and others, allowed improved visualization of anatomic detail and broader clinical application of MRI. The system used in this study was a Philips Achieva 1,5T (Koninklijke Philips N.V., Netherlands).



Figure 5. Philips Achieva 1,5T

##### Acquisition methodology

- Subject

The scanned body volume was defined by T12 and S1 vertebrae and the array coil system was set up in such a way to minimize any pressure on patient's torso. The images were acquired using the T2FFE CLEAR and the T1W\_FFE\_IP CLEAR that are the equivalent to the and the BH-Ax-T2-FIESTA and BH-Ax-T1-FSPGR sequences used in the *High Intensity Focused Electromagnetic Therapy Evaluated by Magnetic Resonance Imaging: Safety and Efficacy Study of a Dual Tissue Effect Based Non-Invasive Abdominal Body Shaping* paper by B.M. Kinney et al.

- Studied areas and marking

The body volume was defined by T12 and S1 vertebrae.

- Measures

Rectus abdominalis thickness, subcutaneous fat thickness and abdominal separation were measured at the umbilicus level. The area of the evaluated section is also measured and a

qualitative assessment of the reshaping of the before and after of the sections is carried out.

### 3.5.5.2 Treatment of source data

#### Methodology and Treatment Software

For each patient, umbilical slices of the same sequence (T1W\_FFE\_IP) and of the same bodily section were extracted in cooperation with a qualified radiologist (experienced in reading abdominal scans).

#### Mathematical treatment

The measurements were taken in multiple points which were laid out laterally in the range between patient's iliac crests. Direct umbilical area was excluded from evaluation due to absence of the muscle structure (linea alba) and adipose layer (the navel). The average and standard deviation of these measurements is calculated for every evaluation time.

#### Parameters

**Rectus abdominalis thickness (mm):** Average thickness of the rectus abdominalis segment visible in the umbilical slice.

**Subcutaneous fat thickness (mm):** Average thickness of the rectus subcutaneous fat thickness visible in the umbilical slice.

**Abdominal separation (mm):** Average length of the gap separating both sides of the rectus abdominalis visible in the umbilical slice.

**Slice area (cm<sup>2</sup>):** Area corresponding to the umbilical slice of the T1W\_FFE\_IP sequence.

**Reshaping (Yes/No):** Qualitative assessment of whether the body slice has changed shape before and after the treatment.

#### Exploitation

A change in length greater than 0,5cm indicates that the subject may not have followed the study instructions related to physical activity or eating habits.

## 3.6 Examination schedule

The effect of the products is evaluated over a 24 hours period. The scheduled measurement procedures are as follows:

#### Preinclusion

- Checking of the inclusion/non inclusion criteria
- Clinical observation and description of the quality of the skin at the measuring areas

#### ***At DO before the application of the products:***

- Acknowledgement, reading and signature of the consent form

- Checking of the inclusion/non inclusion criteria
- Clinical observation and description of the quality of the skin at the measuring areas
- Location of the measuring areas
- Clinical Photographs
- 3D Volume and Circumference Measurement
- Echographic Subcutaneous Fat Thickness Measurement
- CapacitiveWeight and Body Analysis
- MRI for Abdominal Muscle and Subcutaneous Fat Thickness Measurement

#### **At D28**

- Clinical observation and description of the quality of the skin at the measuring areas
- Location of the measuring areas
- Clinical Photographs
- 3D Volume and Circumference Measurement
- Echographic Subcutaneous Fat Thickness Measurement
- CapacitiveWeight and Body Analysis
- MRI for Abdominal Muscle and Subcutaneous Fat Thickness Measurement

### **3.7 Data analysis and statistics**

#### **3.7.1 Data analysis of technical data**

The results include:

- Raw values for each subject at each examination.
- Differences, in relation to D0 for each subject during the study ( $D0+n - D0$ ).
- Means, medians, maximum, minimum and standard deviations of the raw values and of the differences in relation to D0 obtained by all of the panel.
- Variations, in relation to T0 expressed as a percentage calculated from the mean values.
- Numbers and percentages of subjects presenting an improvement.

#### Comparison in time, for each product

Given the limited size of the samples there will be no comparison.

#### Comparison of the two products

Given the limited size of the samples there will be no comparison.

## **4. ETHICAL AND LEGAL CONSIDERATIONS**

#### **4.1 Study personnel**

The investigator assures that the study manager and everyone who participates in this study have the required qualifications and abilities to carry it out.

#### **4.2 Data archiving**

The documents are archived for 10 years for non-interventional studies. Using both paper and IT storage media ensures dual archiving.

Paper files are archived by a service provider until the end of the archiving period.

Electronic files are archived on the cloud and a large capacity USB hard disk. The disk is stored for 10 years in one of the Instituto de Fotomedicina Facilities.

The investigator keeps the original case report form, questionnaires and all associated documents, the consent forms, and all project-related documents of any type for a 10-year period following delivery of the final report.

All these documents are accessible upon request for inspection by the study sponsor, their representative or by administrative authorities.

The records of the undesirable events are stored for 10 years.

The documents for biomedical studies are archived for 15 years (food supplements and medical devices) or for 10 years (cosmetic products).

#### **4.3 Insurance**

The investigator is insured for civil liability under the terms of the following policy:

**WR Berkley Insurance - Contract N°65g086103194**

#### **4.4 Declaration to the AEDP**

In compliance with the organic law 15/1999 and 1720/2007 (LOPD) dated 13<sup>th</sup> December 1999 and 21<sup>st</sup> December 2007, relating to the protection of natural person regarding the treatment of data of a personal nature and which amends the article 18 from Spanish Constitution from, files and freedom the automatic treatment of personal data are subject to a declaration to the AEPD (Agencia Española de Protección de Datos).

The study sponsor cannot have access to the confidential data relative to the subjects registered in the database of Instituto de Fotomedicina.

#### **4.5 Anonymity of the subjects**

The subjects are identified for the study sponsor using a three-character alphanumeric code and a number. The investigator makes a commitment not to raise the anonymity of the subjects.

#### **4.6 Consent to participate in the study**

An information form is given to each subject providing full details about the study as well as:

- Its objectives, methods, and duration;
- Possible expected aesthetic benefits, constraints, and potential risks;
- The non-inclusion period, the right of access to data files and their later destruction.

This information enables the subjects to sign their participation consent form freely and unequivocally, in the knowledge that they are fully aware of the testing details.

#### **4.7 Use of image**

If the study involves the use of photographs, the volunteers are informed, in the consent form that Instituto de Fotomedicina may use their image without direct identification all over the world, with no time limit on this usage. The volunteers are also informed that Instituto de Fotomedicina may also provide images to the promoter for publishing or duplication.

The volunteers who refuse to allow their image to be used sign a refusal of image use form.

#### **4.8 Confidentiality**

All the information, data, and results of the study are confidential. Everyone having access to such data are informed of their confidentiality.

Any medical information concerning a subject's state of health and the results of the clinical examinations carried out during the recruitment, selection and admission phases before a study is subject to the medical secrecy regulations, in no case should such information be communicated to the study sponsor using a subject's identity.

#### **4.9 Quality Assurance**

The entire dossier of a study (quotation, protocol, results, report, and any other study-related documents) is subject to a Quality Management audit which conforms to the regulatory texts and procedures in force.

The investigator cooperates in ensuring any additional auditing required by the study sponsor to ensure that the study progresses in accordance with regards the protocol and the current procedures.

#### 4.10 Regulations

This study is carried out in conformity with the most recent recommendations of the World Medical Association (Declaration of Helsinki 1964, amended in Seoul, Korea, 2008).

This study is qualified as “non interventional” because it does not comply with the public health code which defines “biomedical research” as any research organized and carried out on human beings in order to develop biological and medical knowledge.

This study does not fall under the field of application of the new Public Health law relative to the protection of subjects participating in biomedical research, the counsel of the Advisory Board is not sought, and no information is communicated to the National file of subjects participating in biomedical research.

However, the spirit of law and Good Clinical Practices are respected.

### 5. RESULTS

#### 5.1 Absence

No absences to report.

#### 5.2 Population considered in the expression of the results

At D0, 21 subjects were recruited.

Techniques	D0	D28
Clinical Photographs	X	X
3D Volume and Circumference Measurement	X	X
Echographic Subcutaneous Fat Thickness Measurement	X	X
Capacitive Weight and Body Analysis	X	X
MRI for Abdominal Muscle and Subcutaneous Fat Thickness Measurement	X	X

Table 3. Techniques and population for the tests carried out at D0 and D1.

#### 5.3 Description of the exploited panel

The exploited panel consisted of **10 men and 11 women**.

The following table summarizes the average age of the panel at D0.

The details of the characteristics of the panel are presented in appendix XX.

n=21	Mean	Minimum	Maximum
Age (years)	39,43	21	61

Table 4. Study's subjects age demographics.

#### 5.4 Studied par Digital Photography

There is no numerical parameter on this section as the main goal of the Clinical Photography was to have clinical evidence of the well-being of the volunteers as well as to be able to visually asses any possible improvement observed with the other techniques. Here's a recollection of the observed results on some subjects:



Figure 6. A. Front photo of subject 16 before the first treatment. B. Front photo of Subject 16 2 weeks



after the last treatment. C. Side photo of subject 16 before the first treatment. B. Side photo of Subject 16 2 weeks after the last treatment.



**Figure 7.** A. Front photo of subject 18 before the first treatment. B. Front photo of Subject 18 2 weeks after the last treatment. C. Side photo of subject 18 before the first treatment. B. Side photo of Subject 18 2 weeks after the last treatment.

## 5.7 3D Volume and Circumference Measurement

Studied parameters:  
Volume (mm<sup>3</sup>)  
Circumference (mm)

### 5.7.1 Observed results on each side

The following tables present the means and the standard deviations on the raw values and the percentages of variation for the volume and circumference at D0 and D28 as well as the corresponding statistical results for the evolution in time (Student- *t* , two-tailed for paired groups at 5%, after checking the normality of the distributions by a Shapiro-Wilk test and Kolmogorov-Smirnov; if the result is statistically significant the *p*-value will be colored in red).

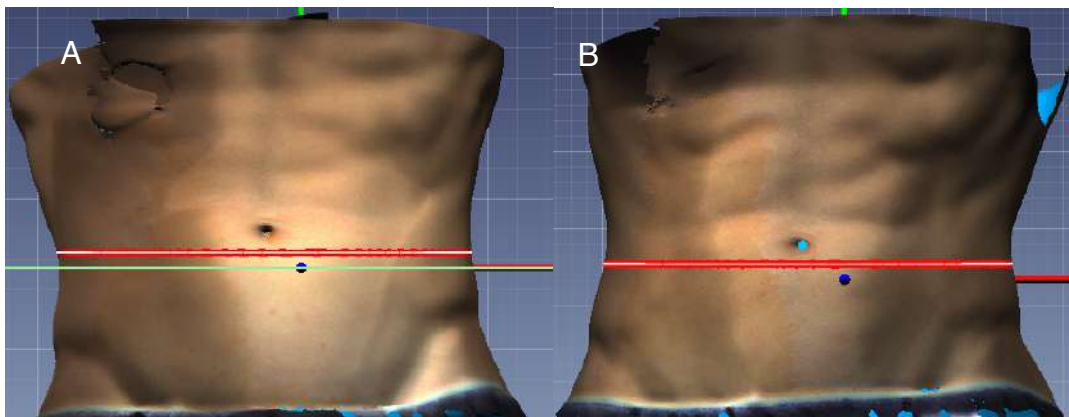


Figure 7. A. Abdominal 3D of subject 18 before the first treatment. B. Abdominal 3D of Subject 18 2 weeks after the last treatment.

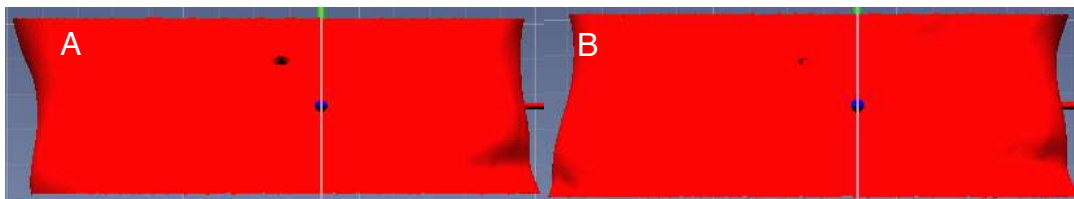


Figure 8. A. Selected 3D abdominal section of subject 18 before the first treatment. B Selected 3D abdominal section 3D of Subject 18 2 weeks after the last treatment.

#### Volume

	D0	D28	%ΔD28-D0
<b>Average</b>	3098344,48	2898836,81	-6,59
<b>Std. Dev.</b>	640513,46	672109,25	8,69

Table 5. Abdomen Volume Average and Standard Deviation for the treatment at D0 and D28.

#### Circumference

	D0	D28	%ΔD28-D0
<b>Average</b>	88,36	85,31	-3,57

<b>Std. Dev.</b>	17,74	17,64	1,91
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**Table 6.** Abdomen Circumference Average and Standard Deviation for the treatment at D0 and D28.

## Statistics

	<b>p</b>
<b>Volume</b>	<b>p &lt; 0,005</b>
<b>Circumference</b>	<b>p &lt; 0,0001</b>

**Table 7.** Statistical results of all the comparison at D0 and D28 for both treatments. P-values in red mean statistical significance.

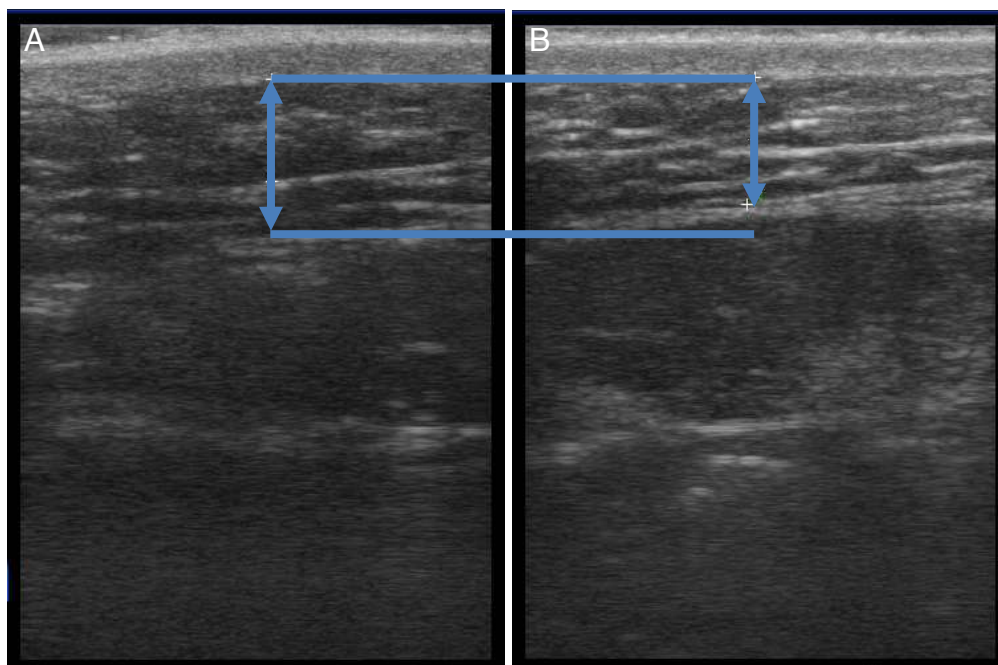
## 5.7 Echographic Subcutaneous Fat Thickness Measurement

Studied parameters:

Subcutaneous Fat Thickness (mm)

### 5.7.1 Observed results on each side

The following tables present the means and the standard deviations on the raw values and the percentages of variation for the subcutaneous fat thickness at D0 and D28 as well as the corresponding statistical results for the evolution in time (Student- t, two-tailed for paired groups at 5%, after checking the normality of the distributions by a Shapiro-Wilk test and Kolmogorov-Smirnov; if the result is statistically significant the p-value will be colored in red).



**Figure 9.** A. Skin echography of subject 18 before the treatment. The blue arrow indicates where the subcutaneous fat thickness was measured. B Skin echography of Subject 18 2 weeks after the last treatment. The blue arrow indicates where the subcutaneous fat thickness was measured.

### Subcutaneous Fat Thickness

	D0	D28	%ΔD28-D0
<b>Average</b>	2,03	1,82	-9,85
<b>Std. Dev.</b>	0,69	0,74	22,45

**Table 8.** Subcutaneous Fat Thickness Average and Standard Deviation for the treatment at D0 and D28.

### Statistics

	p
<b>Subcutaneous Fat Thickness</b>	<b>p &lt; 0,0001</b>

**Table 9.** Statistical results of all the comparison at D0 and D28 for both treatments. P-values in red mean statistical significance.

## 5.7 CapacitiveWeight and Body Analysis

Studied parameters:

Body Weight (kg)

BMI

Trunk Fat Percentage

Trunk Muscle Mass (kg)

Basal Metabolic Expenditure (kcal)

Visceral Fat Level

### 5.7.1 Observed results on each side

*The following tables present the means and the standard deviations on the raw values and the percentages of variation for the Body weight (Kg), BMI, Trunk Muscle Weight (kg), Trunk Fat Percentage, Basal Metabolic Expenditure (Kcal), Visceral Fat Level. at D0 and D28 as well as the corresponding statistical results for the evolution in time (Student- t and Wilcoxon Signs test when corresponding, two-tailed for paired groups at 5%, after checking the normality of the distributions by a Shapiro-Wilk test and Kolmogorov-Smirnov; if the result is statistically significant the p-value will be colored in red).*

#### Body weight

	D0	D28	%ΔD28-D0
<b>Average</b>	71,81	70,83	-1,31
<b>Std. Dev.</b>	12,53	12,13	0,89

**Table 10.** Body Weight Average and Standard Deviation for the treatment at D0 and D28.

### BMI

	D0	D28	% $\Delta$ D28-D0
<b>Average</b>	24,47	24,14	-1,31
<b>Std. Dev.</b>	3,18	3,07	0,89

**Table 11.** BMI Average and Standard Deviation for the treatment at D0 and D28.

### Trunk Fat Percentage

	D0	D28	% $\Delta$ D28-D0
<b>Average</b>	0,26	0,24	-9,34
<b>Std. Dev.</b>	0,07	0,07	10,44

**Table 12.** Trunk Fat Percentage Average and Standard Deviation for the treatment at D0 and D28.

### Trunk Muscle Mass

	D0	D28	% $\Delta$ D28-D0
<b>Average</b>	28,12	28,99	3,23
<b>Std. Dev.</b>	5,51	5,54	4,51

**Table 13.** Trunk Muscle Mass Average and Standard Deviation for the treatment at D0 and D28.

### Basal Metabolic Expenditure

	D0	D28	% $\Delta$ D28-D0
<b>Average</b>	1594,95	1631,90	2,32
<b>Std. Dev.</b>	320,89	329,28	2,38

**Table 14.** Basal Metabolic Expenditure Average and Standard Deviation for the treatment at D0 and D28.

### Visceral Fat Level

	D0	D28	% $\Delta$ D28-D0
<b>Average</b>	6,52	5,86	-9,73
<b>Std. Dev.</b>	5,14	4,83	15,90

**Table 15.** Visceral Fat Level Average and Standard Deviation for the treatment at D0 and D28.

### Statistics

	<b>p</b>
<b>Body Weight</b>	<b>p &lt; 0,0001</b>
<b>BMI</b>	<b>p &lt; 0,0001</b>
<b>Trunk Fat Percentage</b>	<b>p &lt; 0,0001</b>
<b>Trunk Muscle Mass</b>	<b>p &lt; 0,0001</b>
<b>Basal Metabolic Expenditure</b>	<b>p &lt; 0,0001</b>

<b>Visceral Fat Level</b>	<b>p &lt; 0,0001</b>
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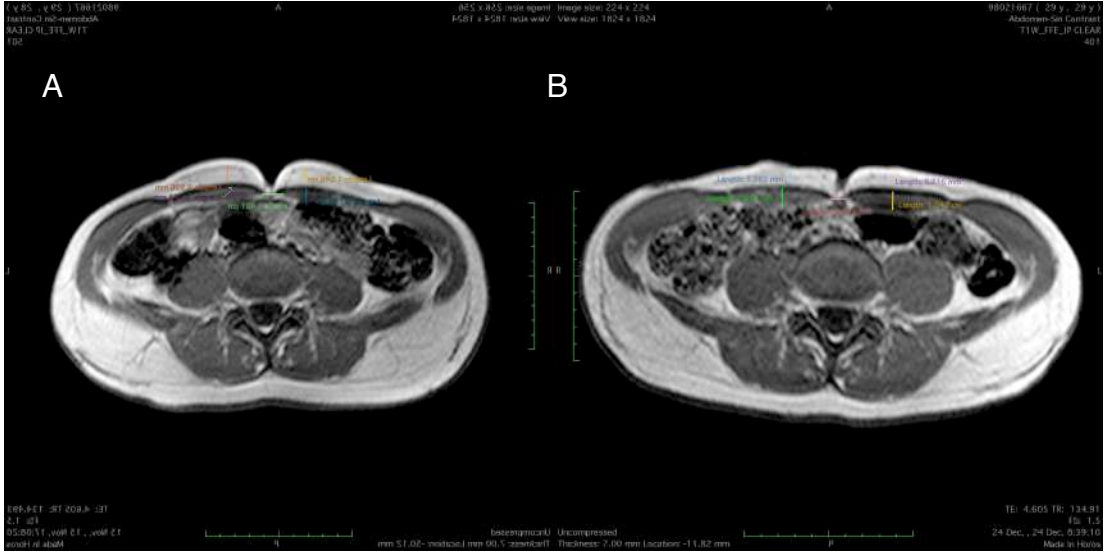
**Table 16.** Statistical results of all the comparison at D0 and D28 for both treatments. P-values in red mean statistical significance.

**5.7 MRI**

Studied parameters:  
 Rectus abdominalis thickness (mm)  
 Subcutaneous fat thickness (mm)  
 Abdominal separation (mm)  
 Slice area (cm<sup>2</sup>)  
 Reshaping (Yes/No):

**5.7.1 Observed results on each side**

The following tables present the means and the standard deviations on the raw values and the percentages of variation for Rectus abdominalis thickness, subcutaneous fat thickness, Abdominal separation, slice area and reshaping at D0 and D28 as well as the corresponding statistical results for the evolution in time (Student- t and Wilcoxon Signs test when corresponding, two-tailed for paired groups at 5%, after checking the normality of the distributions by a Shapiro-Wilk test and Kolmogorov-Smirnov; if the result is statistically significant the p-value will be colored in red).









**Figure 11.** Shape comparison of the Before and After slices of subject 08 for the reshaping assessment. In violet the slice of the MRI realized before the first treatment and in green the slice of the MRI realized 2 weeks after the last treatment.

#### *Rectus Abdominalis Thickness*

	<b>D0</b>	<b>D28</b>	<b>%ΔD28-D0</b>
<b>Average</b>	8,71	9,71	11,83
<b>Std. Dev.</b>	1,38	1,70	11,51

**Table 17.** Abdomen Volume Average and Standard Deviation for the treatment at D0 and D28.

#### *Subcutaneous fat Thickness*

	<b>D0</b>	<b>D28</b>	<b>%ΔD28-D0</b>
<b>Average</b>	12,86	10,57	-18,32
<b>Std. Dev.</b>	5,93	5,29	11,36

**Table 18.** Abdomen Volume Average and Standard Deviation for the treatment at D0 and D28.

#### *Abdominal Separation*

	<b>D0</b>	<b>D28</b>	<b>%ΔD28-D0</b>
<b>Average</b>	19,14	14,71	-22,46
<b>Std. Dev.</b>	4,22	4,99	21,23

**Table 19.** Abdomen Volume Average and Standard Deviation for the treatment at D0 and D28.

#### *Slice Area*

	<b>D0</b>	<b>D28</b>	<b>%ΔD28-D0</b>
<b>Average</b>	508,145	465,855	-8,342



<b>Std. Dev.</b>	118,851	114,532	6,123
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**Table 20.** Abdomen Volume Average and Standard Deviation for the treatment at D0 and D28.

### Reshaping

	<b>Reshaping</b>
<b>Vol 08</b>	Yes
<b>Vol 09</b>	Yes
<b>Vol 13</b>	Yes
<b>Vol 14</b>	Yes
<b>Vol 16</b>	Yes
<b>Vol 18</b>	No
<b>Vol 21</b>	No

**Table 21.** Abdomen reshaping assessment for all the MRIs after comparing D0 and D28.

### Statistics

	<b>p</b>
<b>Rectus Abdominalis Thickness</b>	<b>p &lt; 0,05</b>
<b>Subcutaneous Fat Thickness</b>	<b>p &lt; 0,005</b>
<b>Abdominal Separation</b>	<b>p &gt; 0,05</b>
<b>Slice Area</b>	<b>p &lt; 0,01</b>

**Table 22.** Statistical results of all the comparison at D0 and D28 for both treatments. P-values in red mean statistical significance.

## 6. DISCUSSION

### 6.1 Clinical Photographs

The clinical show some improvement in the subjects, both on the leaner ones and the moderately thicker ones. Subjects in the higher BMI range present little to no perceivable visual improvement. Considering how the quantitative results presented a much starker difference it is striking to see how in the case of this body contouring technique photographs may not be the best suited tool to assess the degree of success of the treatment. Additionally, these photographs are also indicative that no skin damage was produce in any subject during the treatment, thus confirming its safety.

### 6.2 3D Abdominal Volume and Circumference measurements

From the visual point of view, the 3D captures experience the same limitations of photographs in the sense that they don't allow to grasp the real impact of the treatment. Their

advantage, however, is that they allow to perform some quantification and those numbers are more indicative of the results. Circumference measurements showed an average reduction of 3,05cm which is equivalent to more than half a size reduction. In addition, a 6,59% of average abdominal volume reduction was observed with some subjects experiencing a volume loss around 18%. Those are extremely positive results given the little time and effort required to obtain them (2 hours) with. No dieting or additional exercising allowed. Furthermore, those results were statistically significant with a robust p-value that shows that these results are both consistent and reproducible among a wide variety of individuals.

### **6.3 Echographic Subcutaneous Fat Thickness Measurement**

This test is clinically very relevant as it showed, with very strong statistical significance, that subcutaneous fat loss was taking place because of the treatment. The magnitude of that loss is not as impactful as the one that can be gained from other body contouring techniques, but given that fat loss is not the main goal of the treatment, it is a most welcome collateral effect. Looking closer at the numbers, the standard deviation is strikingly low. All subjects experienced a similar fat loss. This is relevant as it is indicative of one of the main differences of this body contouring technique. Most techniques are energy-based, meaning that the tissue is absorbing at least a part of that energy and this there is some proportionality relationship between the amount of tissue, the amount of energy absorption and the amount of expectable results. Here, however, a constant and equal effort is provided independently of the amount of tissue. Even if some differences may be expected based on the body weight and the sporting habits, this technique is based on an amount of effort provided instead of energy absorption. Given a similar effort it is understandable that similar results ensue. The impact of those results may not be the same however. Losing 5mm of subcutaneous fat over a 35mm fat layer (thick individual) or over a 14mm fat layer (thin individual) will have very different visual and clinical effects.

### **6.4 Capacitive Weight and Body Analysis**

A lot of information was provided by this test, making it probably the most suited to perform as the de facto clinical follow-up for the treatment. It allowed to perceive the muscle gain that would be later confirmed in the MRIs, to observe the fat loss reported on the echography and even perceive some visceral fat loss that sadly could not be confirmed by other means but that is likely to take place given how even the metabolic expenditure was raised. This last variable makes a sound case for the use of this technology as a way to help overweight individuals into dieting and exercising as it simultaneously tones the muscle and raises the daily energy expense even when not exercising. Here again, the robustness of the statistical analysis reinforces the consistency of the treatment in producing results.

### **6.5 MRI**

MRIs confirmed the subcutaneous fat loss observed with the echography as well as the muscle gain suggested by the capacitive body analysis. Furthermore, it allowed to both quantify and visualize that muscle gain, which was similar on all subjects, independently of the gender,

the age or the exercising habits, reinforcing this paradigm switch of expectative with effort-based body contouring. In addition, it confirmed the capability of the treatment into reducing the abdominal diastasis that had been observed with other devices. However, the most striking finding was the reshaping capabilities of this treatment. 5 out of 7 subjects experienced a very notorious change in their body contour as can be observed in the figures 10 and 11. Those changes seem to come from the muscular tissue restructuring and reinforcement as they are independent of the gender or age but also independent of the volume or circumference loss. When measuring the slice area some of the most striking reshaping took place while maintaining the total body surface, as only a 3 to 4 % of area difference was seen. They seem to be at least partially dependent on the exercising routines of the subjects as the two most sedentary subjects were the ones where no reshaping was observable. If true, this would be the first real reshaping treatment where the change of shape is not given by the applicators criteria but rather by the patient health and exercising habits.

## **7. CONCLUSION**

This tests confirms high intensity magnetic field muscle stimulation is capable of producing an increase of muscle mass and tone, reduce subcutaneous (hypodermic fat), restructure the body contour and induce possible visceral fat loss.

Gabriel Buendía Bordera  
Investigator

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