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(54) **AESTHETIC METHOD OF BIOLOGICAL STRUCTURE TREATMENT BY MAGNETIC FIELD**

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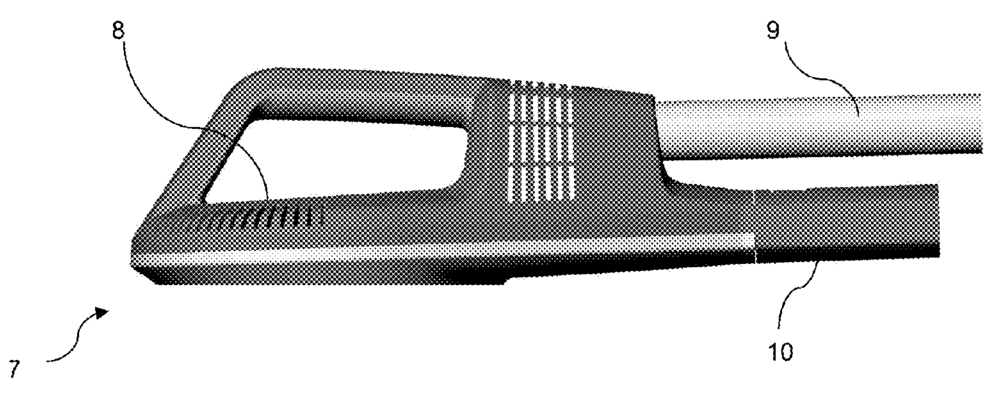
(57) **ABSTRACT**

In methods for treating a patient, a time varying magnetic field is applied to a patient's body and causes a muscle contraction. The time-varying magnetic field may be monophasic, biphasic, polyphasic and/or static. The method may reduce adipose tissue, improve metabolism, blood and/or lymph circulation. The method may use combinations of treatments to enhance the visual appearance of the patient.

21 Claims, 4 Drawing Sheets



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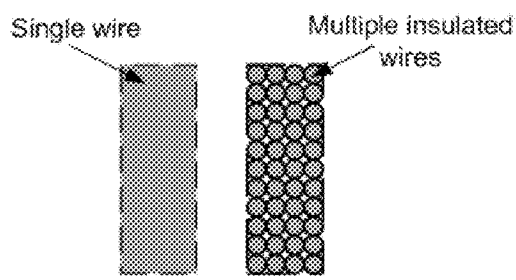

Figure 1

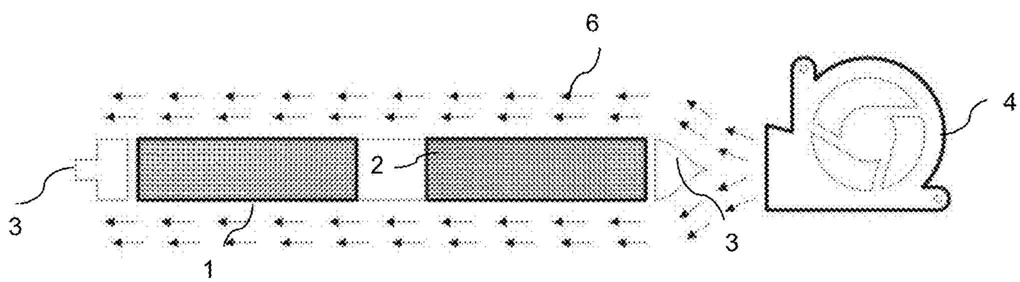

Figure 2

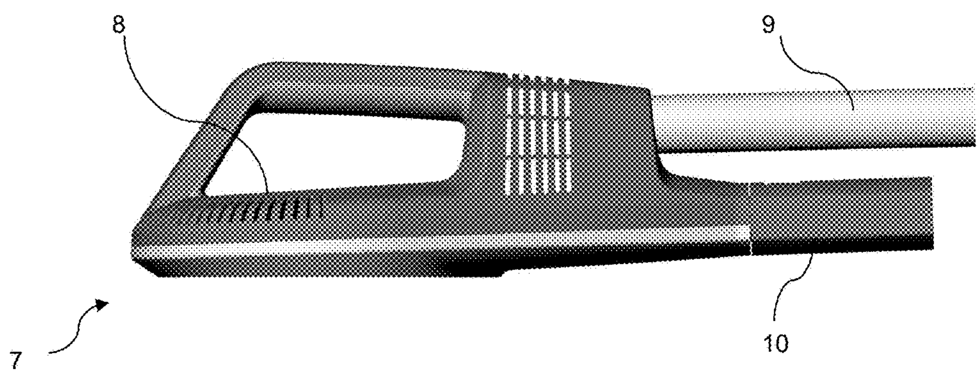

Figure 3

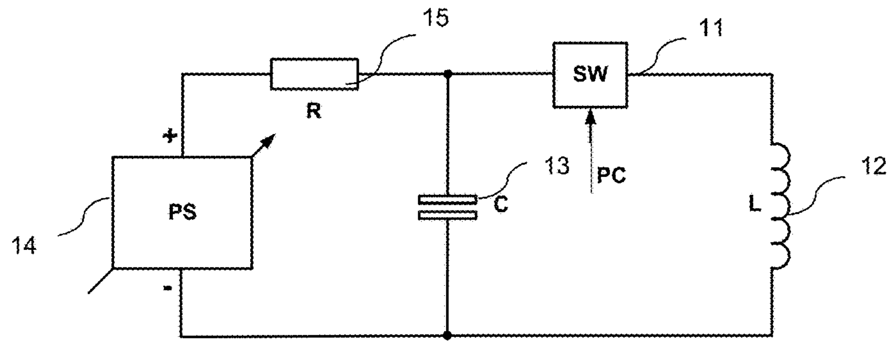

Figure 4A

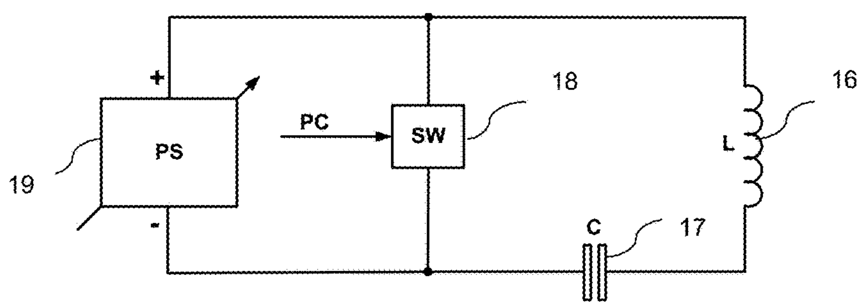

Figure 4B

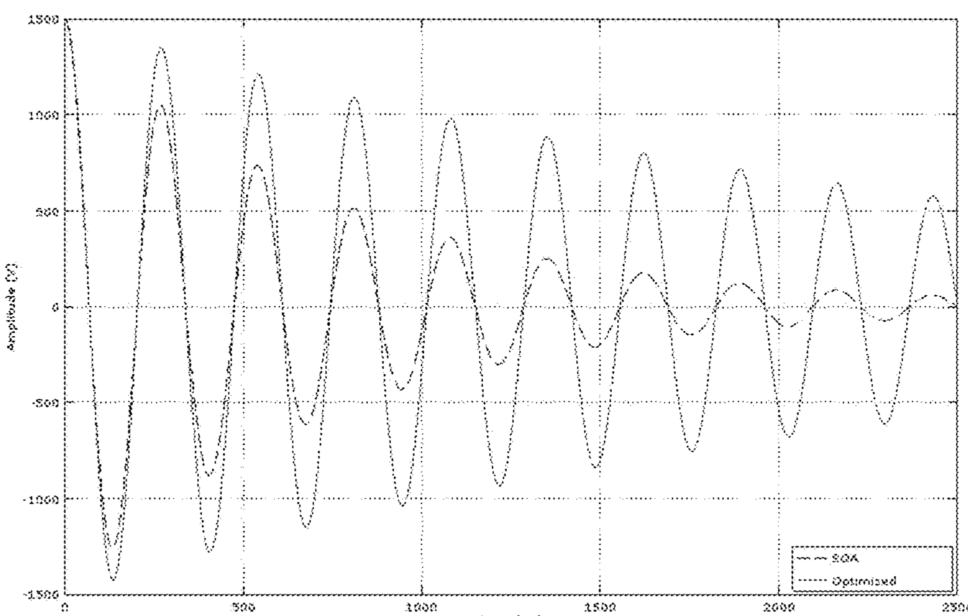

Figure 5

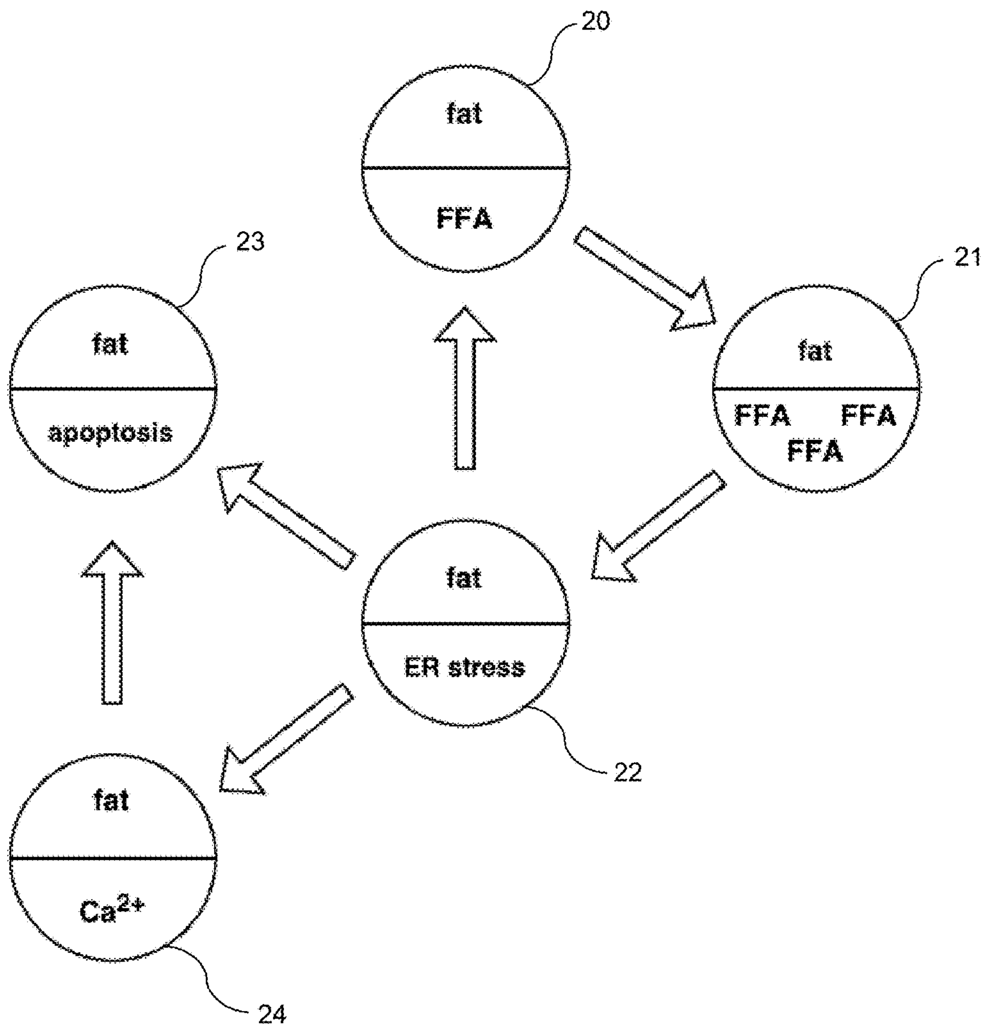
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Figure 6

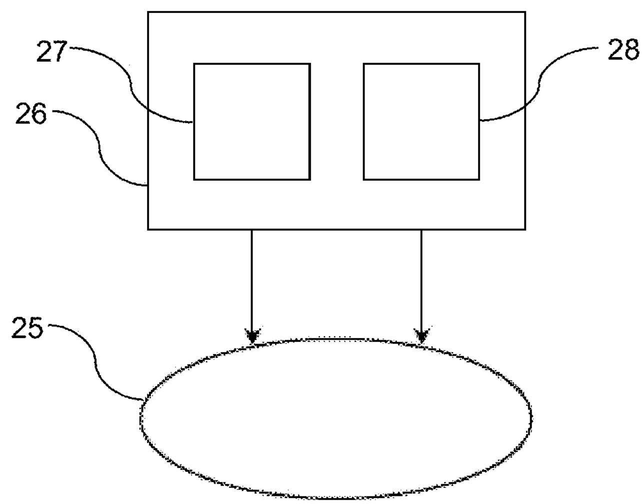

Figure 7A

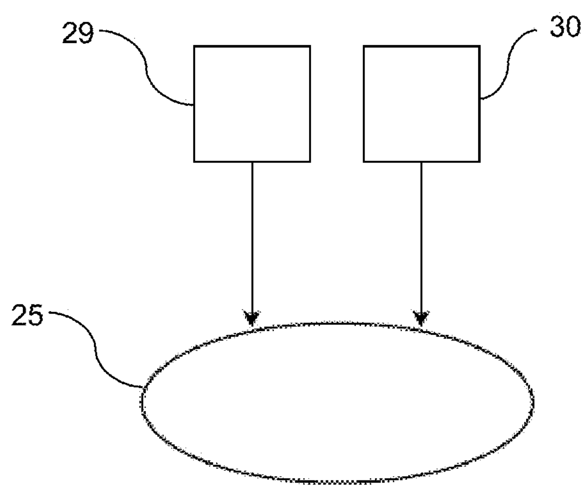

Figure 7B

AESTHETIC METHOD OF BIOLOGICAL STRUCTURE TREATMENT BY MAGNETIC FIELD

PRIORITY CLAIM

This application claims priority to U.S. Provisional Patent Application Nos. 62/357,679 filed Jul. 1, 2016, 62/440,905 filed Dec. 30, 2016, and 62/440,922 filed Dec. 30, 2016. These applications are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention generally relates to methods using the influence of magnetic and induced electric field on biological structure. The magnetic field is time-varying and high powered therefore the method is based on a value of magnetic flux density sufficient to induce at least partial muscle contraction.

BACKGROUND OF THE INVENTION

Aesthetic medicine includes all treatments resulting in enhancing a visual appearance and satisfaction of the patient. Patients want to minimize all imperfections including body shape and effects of natural aging. Indeed, patients request quick, non-invasive procedures providing satisfactory results with minimal risks.

The most common methods used for non-invasive aesthetic applications are based on application of mechanical waves, e.g. ultrasound or shock wave therapy; or electromagnetic waves, e.g. radiofrequency treatment or light treatment, such as intense pulsed light or laser treatment. The effect of mechanical waves on tissue is based especially on cavitation, vibration and/or heat inducing effects. The effect of applications using electromagnetic waves is based especially on heat production in the biological structure.

Skin tissue is composed of three basic elements: epidermis, dermis and hypodermis or so called subcutis. The outer and also the thinnest layer of skin is the epidermis. The dermis consists of collagen, elastic tissue and reticular fibers. The hypodermis is the lowest layer of the skin and contains hair follicle roots, lymphatic vessels, collagen tissue, nerves and also fat forming a subcutaneous white adipose tissue (SWAT). The adipose cells create lobules which are bounded by connective tissue, fibrous septa (retinaculum cutis).

Another part of adipose tissue, so called visceral fat, is located in the peritoneal cavity and forms visceral white adipose tissue (VWAT) located between parietal peritoneum and visceral peritoneum, closely below muscle fibers adjoining the hypodermis layer.

Existing devices have low efficiency and they waste energy, which limits their use. Eddy currents induced within the coil create engineering challenges. Existing devices contain coils which are made of metallic strips, electric wires or hollow conductors. Since the therapy requires large currents, significant losses are caused by induced eddy currents within the coil. Eddy currents lead to production of unwanted heat and therefore there is need to sufficiently cool the coil. Also, the energy source must be protected during reverse polarity of resonance. This requires using protective circuits which consume significant amounts of energy.

Current magnetic aesthetic methods are limited in key parameters which are repetition rate and/or magnetic flux density. All known methods use low values of magnetic flux density and/or low repetition rates which does not allow satisfactory enhancement of visual appearance. As a result, new methods are needed to enhance the visual appearance of the patient.

The currently used aesthetic applications don't provide any treatment combining the effect of time-varying magnetic field treatment and conventional treatment, e.g. treatment by electromagnetic field such as radiofrequency treatment. The currently used radiofrequency treatment includes many adverse events such as non-homogenous thermal temperature, insufficient blood and/or lymph flow during and/or after the treatment. Additionally several adverse event such as panniculitis may occur after the treatment.

SUMMARY OF THE INVENTION

The present methods and devices as described below produce a time varying magnetic field for patient treatment which better optimizes energy use, increases the effectiveness of the treatments and provide a new treatment. The magnetic pulses may be generated in monophasic, biphasic or polyphasic regimes. In a first aspect, the device has one or more coils; a switch; an energy storage device and a connection to an energy source. The coil may be made of insulated wires with a conductor diameter less than 3 mm even more preferably less than 0.5 mm and most preferably less than 0.05 mm. Smaller diameter and individual insulation of the wires significantly reduces self-heating of the coil and therefore increase efficiency of magnetic stimulation device. The coil may be flexibly attached in a casing of device. The casing may comprise a blower or blowers which ensure cooling of the coil.

Using a plurality of magnetic field generating devices provides faster treatment. Large and/or different areas may be treated in shorter time. Using a plurality of applicators allows different areas and/or target biological structures to be stimulated at the same time. The movement of the at least one applicator may automatically follow a predetermined trajectory. Hence manual manipulation is not needed.

The present methods provide new aesthetic applications for focused remodeling of the patient's body. The coil of the magnetic stimulation device may be flexibly attached to casing of the device. The blower or blowers may be arranged to blow air on both sides of coil. Optionally, the coil may be a flat type coil.

The method of treating a biological structure uses a combination of non-invasive methods for enhancing human appearance. The invention utilizes electromagnetic field. Methods may be used for targeted remodeling of adipose tissue, focused treatment of cellulite, body contouring, skin tightening or skin rejuvenation. The invention relates to focused heating of the target tissue by electromagnetic waves, whereas the effect of focused heating of the target tissue is amplified by the effect of a magnetic treatment.

The magnetic treatment induces the muscle contraction at higher repetition rates and the contraction is stronger. Therefore the treatment is more efficient for reducing the number and/or volume of adipocytes and enhancing the visual appearance of the treated body region via targeted muscle contraction. Further the temperature homogeneity of is improved. Additionally, strong muscle contractions at higher repetition rates cause mechanical movement of all the layers in proximity of the contracted muscle. The methods therefore cause remodeling and/or neogenesis of the collagen and elastin fibers.

The methods enable new treatments by magnetic and/or electromagnetic field. The repetition rate of the magnetic field is in the range of 1 to 300 Hz with high magnetic flux density up to 7 Tesla (equivalent to 70000 Gauss). The frequency of the electromagnetic field is 13.56 or 40.68 or 27.12 MHz or 2.45 GHz.

Glossary

Conventional non-invasive and/or invasive aesthetic medicine treatment methods refer to aesthetic applications based on application of mechanical waves, e.g. acoustic wave, ultrasound or shock wave therapy; or electromagnetic waves, e.g. radiofrequency or diathermy treatment or light treatment, such as intense pulsed light or laser treatment; or mechanical stimulation, e.g. positive or negative pressure, rollerball, massage etc.; or thermal treatment, e.g. cryotherapy; or electrotherapy method; or mesotherapy method and or any combination thereof.

Thermal treatment refers to treatment by heating or cooling, e.g. a cryotherapy treatment.

Biological structure is at least one neuron, neuromuscular plate, muscle fiber, adipose cell or tissue, collagen, elastin, pigment or skin.

Remodeling target biological structure refers to reducing the number and/or volume of the adipocytes by apoptosis and/or necrosis, cellulite treatment, body shaping and/or contouring, muscle toning, skin tightening, collagen treatment, skin rejuvenation, wrinkle removing, reducing stretch-marks, breast lifting, lip enhancement, treatment of vascular or pigmented lesions of the skin or hair removing.

Body region includes muscle or muscle group, buttocks, saddlebags, love handles, abdomen, hips, thighs, arms, limb and/or any other tissue.

Muscle includes at least one of muscle fiber, muscle tissue or group, neuromuscular plate or nerve innervating the at least one muscle fiber.

Deep muscle refers to a muscle that is at least partly below superficial muscles and/or to the muscle that is covered by a thick layer of other tissue, e.g. mostly adipose tissue and/or the skin, with thickness 0.5, 1, 2, 3, 4, 5 or more centimeters.

Adipose tissue refers to at least one lipid rich cell, e.g. adipocyte.

Bolus refers to a layer of fluid material, e.g. water or fluid solution of ceramic particles, preferably enclosed in a flexible sac made of biocompatible material.

Impulse refers to a single magnetic stimulus.

Pulse refers to a period of treatment by a magnetic field of at least one magnetic stimulus and time duration of no stimulation, i.e. time duration between two impulses from rise/fall edge to next rise/fall edge.

Repetition rate refers to frequency of firing the pulses; it is derived from the time duration of a pulse.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross section view of a coil winding.

FIG. **2** is a cross-section of a magnetic applicator.

FIG. **3** is a side view of a casing of a magnetic applicator.

FIGS. **4**A and **4**B illustrate circuits for providing high power pulses to a stimulating coil.

FIG. **5** is a graph showing voltage drop in the energy storage device.

FIG. **6** is a diagram of a biological effect.

FIGS. **7**A and **7**B illustrate diagrams of a treatment device.

DETAILED DESCRIPTION

FIG. **1** illustrates a cross section of winding of a coil for a magnetic stimulation device. The coil may be constructed from litz-wire, wherein each wire is insulated separately. Each individual conductor is coated with non-conductive material so the coil constitutes multiple insulated wires. Unlike existing magnetic coil conductors, the present coil is not made of bare wire e.g. litz-wire without insulation, or conductive tapes, conductive strips, or copper pipe with hollow inductors. The insulation of wires separately is a substantial improvement, since this leads to a significant reduction of the induced eddy currents. Power loss due to eddy currents, per single wire, is described by Equation 1 below. The small diameter of wires significantly reduces self-heating of the coil and therefore increases efficiency of the present magnetic stimulation device.

$$P_{EDDY} = \frac{\pi^2 \cdot B_P^2 \cdot d^2 \cdot f^2}{6 \cdot k \cdot \rho \cdot D}, \qquad \text{Eq. 1}$$

where: P_{EDDY} is power loss per unit mass ($W \cdot kg^{-1}$); B_p is the peak of magnetic field (T); f is frequency (Hz); d is the thickness of the sheet or diameter of the wire (m); k is constant equal to 1 for a thin sheet and 2 for a thin wire; ρ is the resistivity of material (Ω·m); D is the density of material ($kg \cdot m^3$).

The individual insulation of each wire reduces eddy currents. The individually insulated wires may be wound either one by one or in a bundle of individually insulated wires so as to form a coil, which will serve as a magnetic field generator. The coil provides an improvement in the efficiency of energy transfer in the LC resonant circuit and also reduces or eliminates unwanted thermal effects.

The coil may have a planar coil shape where the individually insulated wires may have cross-section wires with conductor diameter less than 3 mm even more preferably less than 0.5 mm and most preferably less than 0.05 mm. The wires are preferably made of materials with higher density and higher resistivity e.g. gold, platinum or copper. The diameters of the single wires should be minimal. On the other hand the total diameter should be maximal because of inverse proportion between the cross-section of all wires forming the coil and the electrical resistance. Therefore the ohmic part of the heat is then lower. Eq. 2 describes power loss of the coil:

$$P_R = \frac{\rho \cdot \frac{l}{S} \cdot I^2}{m} \qquad \text{Eq. 2}$$

Where: P_R is the power loss heat dissipation (W); ρ is the resistance (Ω·m); l is the length of wire (m); S is the surface area (m^2); I is the current (A) and m is 1 kg of wire material.

Total power loss is (Eq. 3):

$$P_{TOT} = P_{EDDY} + P_R, \qquad \text{Eq. 3}$$

Where: P_{TOT} is the total power losses ($W \cdot kg^{-1}$); P_{EDDY} is the power dissipation of eddy currents ($W \cdot kg^{-1}$); P_R is the power loss heat dissipation ($W \cdot kg^{-1}$).

Power losses and/or heat generation may be monitored and/or determined by the magnetic stimulation device based on determining the waveform of any operation parameter, e.g. voltage, electric current or magnetic flux density. The determined waveform is related with a reference and/or with the operation parameter measured in a different value of a characteristic quantity, e.g. time, frequency, amplitude or phase.

Dynamic forces produced by current pulses passing through the wires of the coil cause vibrations and unwanted noise. The individual insulated wires of the coil may be impregnated under pressure so as to eliminate air bubbles between the individual insulated wires. The space between wires can be filled with suitable material which causes unification, preservation and electric insulation of the system. Suitable rigid impregnation materials like resin, and elastic materials like PTE can be also used. With the coil provided as a solid mass, the vibrations and resonance caused by movements of the individual insulated wires are suppressed. Therefore noise is reduced.

The coil may be attached to the case of the applicator, such as a hand held applicator of the magnetic stimulation device; build-in applicator in e.g. chair, bed; or stand-alone applicator e.g. on mechanical fixture. The attachment may be provided by an elastic material e.g., silicone, gum; or other flexible manner. Connection with the coil of the applicator's case can be ensured by several points. The several fastening points ensure the connection of the coil to the casing by flexible material so that the main part of the coil and the main part of the casing of applicator are spaced apart. The spacing should be at least 0.1 mm so that air can easily flow. The gap between the coil and the casing can be used either for spontaneous or controlled cooling. The coil may optionally be connected to the case of the applicator by only one fastening point. The fastening points eliminate vibrations of wires which could be transferred to housing of the applicator and therefore reduce noise of the magnetic stimulation device.

FIG. **2** is a cross-section of the magnetic applicator which allows better flow on the lower and upper sides of the coil and thus more efficient heat dissipation. The magnetic stimulation device includes a coil **1**, the circuit wires **2** and the fastening points **3** for connection of the coil to the casing of the applicator (not shown). The fastening points **3** are preferably made of flexible material however the rigid material may be used as well. The fastening points **3** may be located on the outer circumferential side of the coil. However, alternatively it is possible to put these fastening points to a lower or upper side of the coil.

The fastening points **3** connect the coil to the case of the applicator in at least one point. The fastening points **3** maintain the coil and the main part of the case of the applicator spaced apart so that fluid (which may be air or any liquid) can flow between them. At least one blower **4** can be placed around the circumference of the coil, or perpendicular to the coil. The blower can be any known kind of device for directing the fluid e.g. outer air directed into the case of the applicator. This arrangement of the blower allows air to bypass the coil from upper and lower (patient's) sides. In still another embodiment the outer air can be cooled before directing into the case. The blower can have an inlet placed around the circumference of the coil for injecting air, to remove heat from the coil. A connecting tube (not shown) can ensure connection of the applicator **5** with the energy source and/or control unit of magnetic stimulation device. The connecting tube may also contain a conduit of the fluid.

The arrows **6** indicate the air flow through the applicator **5**. This arrangement of the blower allows the air to bypass the coil from upper and lower (patient's) side. Outlet may be preferably placed on upper side of the casing. By placing the blower around the circumference of the coil instead of on the top/below the coil, the blower **4** does not interfere with the magnetic flux peak and therefore its lifespan and reliability is increased.

FIG. **3** is an illustrative embodiment of a casing of the magnetic applicator. The overview drawing contains casing itself **7**, which might contain an outlet **8** preferably placed on upper side of the casing **7**. A connecting tube **9** may not only ensure connection of the applicator with the energy source and/or control unit of magnetic stimulation device, but also connection to a source of the fluid; however the conduit of the fluid **10** may also be connected separately.

In an alternative embodiment cooling may be provided by a member using thermoelectric effect, e.g. a Peltier cooler. Alternatively, cooling may be provided by Stirling engine cooling system.

FIG. **4**A and FIG. **4**B illustrate circuits for providing high power pulses to the stimulating coil. FIG. **4**A shows a circuit for providing high power magnetic pulses. FIG. **4**B shows a circuit for providing high power pulses.

The state of art magnetic stimulation device achieves magnetic flux density of a few tenths to several ones of Tesla (1 Tesla is equivalent to 10000 Gauss). To achieve this level of magnetic flux density, the energy source used generates sufficient voltage. This voltage can reach thousands of volts. In FIG. **4**A the circuits for providing high power pulses to the stimulating coil contain a series connection to the switch **11** and the coil **12**. The switch **11** and the coil **12** together are connected in parallel with an energy storage device **13**. The energy storage device **13** is charged by the energy source **14** and the energy storage device **13** then discharges through the switching device **11** to the coil **12**.

During second half-period of LC resonance, the polarity on the energy storage device **13** is reversed in comparison with the energy source **14**. In this second half-period, there is a conflict between energy source **14**, where voltage on positive and negative terminals is typically thousands of Volts. The energy storage device **13** is also charged to the positive and negative voltage generally to thousands of Volts. As a result, there is in the circuit, consequently, twice the voltage of the energy source **14**. Hence the energy source **14** and all parts connected in the circuit are designed for a high voltage load. Therefore, the protective resistors and/or protection circuitry **15** must be placed between energy source **14** and energy storage device **13**. Disadvantage of state of art solution is large amount of energy transformed to undesired heat in protective resistors and/or protection circuitry **15**.

FIG. **4**B shows a circuit for providing high power pulses for improved function of the magnet stimulation device. The coil **16** and an energy storage device **17** are connected in series and disposed in parallel to the switch **18**. The energy storage device **17** is charged through the coil **16**. To provide an energy pulse, controlled shorting of energy source **33** takes place through the switch **18**. In this way the high voltage load at the terminals of the energy source **19** during the second half-period of LC resonance associated with known devices is avoided. The voltage on the terminals of energy source **19** during second half-period of LC resonance is a voltage equal to the voltage drop on the switch **18**.

The switch **18** can be any kind of switch such as diode, MOSFET, JFET, IGBT, BJT, thyristor or their combination. Depending on the type of component the load of energy source **19** is reduced to a few Volts, e.g., 1-10 volts. Consequently, it is not necessary to protect the energy source **19** from a high voltage load, e.g., thousands of Volts. The use of protective resistors and/or protection circuits is reduced or eliminated. The present designs simplify the circuits used, increase efficiency of energy usage and provide higher safety.

The treatment by the magnetic stimulation device may be in different operation modes. One operation mode may generate a plurality of impulses at one time within the pulse. Another operation mode may generate a plurality of the impulses at different times within the pulse. Both operation modes may be combined.

In an example, a magnetic stimulation device includes at least one energy source, N energy storage devices, N magnetic field generating devices, and 2×N switching devices, wherein N is a positive integer greater than 1. The at least one energy storage device may be selectively charged by the energy source by selectively switching the switching devices and the impulses may be selectively generated by selectively switching the switching devices.

The magnetic stimulation device may include a plurality of applicators. The applicator includes at least one magnetic field generating device which may be movable. The benefit of this embodiment is that the movement and/or positioning of the plurality of the applicators may be independent. Hence, different parts of the patient's body may be treated simultaneously. Therefore, the total treatment time is reduced and patient's downwtimes are reduced as well. The movement of the at least one applicator may be automatic so that manual manipulation may not be needed. The movement of the at least one applicator may follow a predetermined trajectory or it may be random. In an alternative embodiment the movement of the plurality of applicators may be synchronized.

The plurality of applicators may be positioned with respect to each other in one plane; in at least two mutually tilted planes defined by convex or concave angles, or perpendicular to each other; or in at least two parallel planes. The angles of the planes may be adjusted by an operator following the patient's needs. In an alternative embodiment the patient may be positioned in the intersection of the magnetic fields generated by the plurality of magnetic field generating devices.

FIG. **5** shows an exponential voltage drop in the energy storage device. Energy savings during time-varying magnetic therapy may be characterized by reduced voltage drop in the energy storage device between the first, second and subsequent maximums of the resonant oscillation. The magnitude of the individual voltage oscillations is exponentially dampened up to establishing the energy balance. This allows increasing the maximum possible frequency/repetition rate of magnetic pulses, since the frequency/repetition rate is dependent on the speed with which it is possible to recharge the energy storage device. Since the energy storage device is recharged by the amount of energy loss during the previous pulse, it is possible to increase the frequency/repetition rate of the device up to hundreds of magnetic pulses per second without the need to increase the input power. The voltage drop between any of the successive amplitudes is not higher than 21%, even more preferably not higher than 14% and most preferably not higher than 7%.

The device can be used for treatment/successive treatments in continual, interrupted or various duty cycle regime. The duty cycle may be higher than 10%, which means interrupted regime with the ratio up to 1 active to 9 passive time units. The ratio may possibly change during the therapy. The device enables operation defined by the peak to peak magnetic flux density on the coil surface at least 3 T, more preferably at least 2.25 T, most preferably at least 1.5 T at repetition rates above 50 Hz, more preferably at repetition rates above 60 Hz, even more preferably at repetition rates above 70, most preferably at repetition rates above 80 Hz with treatment/successive treatments lasting several seconds or longer, for example, for at least 5, 10, 30, 60, 120 or 240 seconds, or longer. The total power consumption is below 1.3 kW and the width of pulses is in the range of hundreds of μs.

The device enables achieving repetition rates above 100 Hz, more preferably repetition rates above 150 Hz, most preferably repetition rates above 200 Hz with the magnetic flux density providing a therapeutic effect on neurons and/or muscle fibers and/or endocrine cells (e.g. at least partial muscle contraction, action potential in cell). Based on achievement of repetition rates in order of few hundreds the device also enables assembling the magnetic pulses into the various shapes (e.g. triangular, rectangular, exponential), with the shape widths from 6 ms to several seconds or longer.

Alternatively the magnetic field generating device may generate a static magnetic field. The magnetic field generating device generating the static magnetic field may be e.g. a permanent magnet or electromagnet. The coil may be powered by a power source, a transformer and/or an energy storage device. The magnetic field may be applied as time-varying magnetic field by movement of the magnetic field generating device. Alternatively the magnetic field generating device may be switched on and off.

According to the invention a current value of an operation parameter, e.g. voltage, electric current or magnetic flux density, may be determined by measuring via a suitable sensor or by deriving from a value of voltage source, e.g. an energy storage device or power source. The currently determined operation parameter is processed by a mathematic and/or signal processing method.

The currently measured voltage waveform and the calibration curve are related using a mathematic and/or signal processing method. Based on the relation at least one threshold may be established. The at least one threshold may correspond to the correctness of the stimulation and/or notify operator of the magnetic stimulation device about an unintended event. The unintended event may refer to detection of a metal object e.g. metal jewelry such as ring or bracelet, or a prosthetic device such as an endoprosthesis or surgical nail within the proximity of the magnetic stimulation device; or to detection of a hardware error of the magnetic stimulation device, e.g. error of the switching device such as a thyristor. Based on the evaluation of any unintended event the treatment may be disabled and/or the notification for the operator may be generated by the magnetic stimulation device in a human perceptible form, e.g. by mechanical and/or electromagnetic means, such as audibly perceptible notification (e.g. beep) or visually perceptible notification (flashing light, color change etc.).

According to another aspect of the application, the magnetic stimulation device may disable the treatment in the case that the temperature determined by the calculation algorithm exceeds the maximal temperature. In this case the magnetic stimulation device may suggest at least one maximal value of treatment parameter. Based on the predicted temperature of the magnetic stimulation device the calculation algorithm may determine at least one value of treatment parameter to not exceed the maximal temperature of the magnetic stimulation device during the treatment. Based on the operator's preferences the value of the treatment parameter may be automatically adjusted by the magnetic stimulation device or it may be suggested to the operator in human perceptible form such as audibly perceptible notification (e.g. beep) and/or visually perceptible notification (e.g. flashing light, color change etc.). In an exemplary application the suggested treatment parameter may be a maximal achievable value of magnetic flux density which can be sufficiently cooled by the cooling system. However, any other treatment parameter may be suggested to the operator.

During last few decades patient have not only wanted to be in good health, they have also wanted to look well, i.e. to be well shaped, without any unattractive fat and to have a young appearance, without wrinkles, stretchmarks or sagging breasts. This has resulted in a progressive evolution of invasive aesthetic methods such as surgical removing of fat and remodeling the human body by invasive and potentially dangerous methods, e.g. liposuction or inserting implants into human body. The side effects of invasive methods may be scars, swelling or bruising. The side effects resulted in the rapid progress in non-invasive method, e.g. lipolysis or removing skin imperfections. One example of the last few years may is rapid increase of patients' demand for enhancing the visual appearance of buttocks. This has resulted in a higher percentage of these operations by plastic surgeons.

Electric current may be induced in the treated biological structure during pulsed magnetic treatment. Due to the high value of magnetic flux density the biological structure may be targeted and treated more specifically. A distribution of magnetic field is uniform in the biological structure. Particles (e.g. atoms, ions, molecules etc.) in the biological structures are influenced by the magnetic field and permeability of a cell membrane may also increase.

Due to increased permeability of the cell membrane, the pulsed magnetic treatment may induce following effects: at least partial muscle contraction; reduction of adipose tissue—volume and/or number of the adipose cells; neogenesis and/or remodeling of collagen and/or elastin fibers. Further magnetic treatment may improve circulation of blood and/or lymph and improve local and/or adipose tissue metabolism.

Motor-threshold stimulus is stimulation by magnetic flux density which induces sufficient current flow in the target biological structure at a level to begin to cause at least partial muscle contraction.

With the present methods, factors for enhancing visual appearance of the body include: treatment of major muscle, e.g. gluteus maximus; treatment of deep muscle which may be enabled by high value of magnetic flux density; non-contact application of magnetic flux density, it may be applied even through clothing; stronger muscle contraction due to higher value of magnetic flux density; higher-quality of muscle targeting; treatment may not be influenced by small movements during treatment; treatment time duration may be shortened due to high value of magnetic flux density and/or higher repetition rate; no delays may occur.

It is to be understood that the method is not limited to the particular applications and that the method may be practiced or carried out in various ways.

Present method may be applied for enhancing the visual appearance of body parts including or proximate to major muscle structures. Further the method may be applicable for enhancing the visual appearance of patients with high value of BMI. A patient with BMI of at least 18, preferably at least 25, more preferably at least 30, most preferably at least 35 or more may be preferably treated by the recited methods. The thickness of patient's SWAT and/or VWAT may be at least 0.1, 0.5, 10, 15, 25, 50, 75, 100 or more. The patient may be preferably healthy without any life-threatening conditions such as circulatory system disease, e.g. deep vein thrombosis. The present method is not limited to the application of the treatment to major muscle. Muscles other than major muscles may be treated as well.

The applicator of magnetic treatment may be placed proximate to the patient's body. As used here, proximate to includes both contactless and in actual contact with the skin of the patient. The muscles may be selectively treated and the magnetic flux density may be adjusted following the patient's feeling or needs. The treatment time may be shortened due to selective treatment of the correct muscles. Additionally, due to the high value of magnetic flux density, the muscle may be treated more effectively. Further, the treatment may be non-invasive or even preferably contactless due to the high value of magnetic flux density. The patient may be treated without removing clothing, reducing patient discomfort. Additionally, following the high efficiency of the muscle contraction the collagen and/or elastin fibers above the muscle structure may be remodeled, hence the visual appearance may be enhanced.

The position of the patient may correspond to treated biological structure and/or body region. The patient may be treated in seated position. Alternatively, the patient may be treated in lying position, e.g. in supine position. Treatment in lateral recumbent position may be also applicable. Patient may be in prone position as well.

In the preferred application the treatment method may be applied to body regions prone to cellulite and/or prone to adipose accumulation, such as thighs, saddlebags, buttocks, abdomen, region of love handles, region of bra fat or arm. The adipose accumulation may be influenced by number and/or volume of adipose cells.

The magnetic treatment of the biological structure may have various applications for enhancing visual appearance of the contour of a body region. High density magnetic field reaching such values which may be used for: adipose tissue reduction, wherein the adipose tissue reduction may be achieved by reduction of number and/or volume of adipose cells; muscle toning, wherein the muscle appearance enhancement may be achieved by adipose tissue reduction with no muscle bulking; muscle shaping, wherein the muscle appearance enhancement may be achieved by adipose tissue reduction and/or muscle bulking; body contouring, wherein the silhouette appearance enhancement may be achieved by adipose tissue reduction with no muscle bulking; body shaping, wherein the silhouette appearance enhancement may be achieved by adipose tissue reduction and/or muscle bulking; skin tightening, wherein the skin appearance enhancement may be achieved by obtaining smoother and younger appearance, including wrinkles reduction; cellulite treatment, wherein the appearance enhancement may be achieved by adipose tissue reduction, muscle contraction and/or elastic fibers neogenesis; circumferential reduction, wherein the reduction may be achieved by adipose tissue reduction and/or the muscle bulking; breast enhancement, wherein the appearance enhancement effect may be achieved by elevation or shape modification; lip enhancement, wherein the lip appearance enhancement may be achieved by obtaining fuller and firmer appearance. The body region may be reduced in overall size. Further aesthetic effects may be achieved, e.g. connective tissue improvement, fat disruption, muscle volumization, muscle forming, muscle toning, muscle remodeling, contouring, sculpting or body sculpting.

In the methods described, the magnetic stimulation device may or may not include a magnetic core. The magnetic stimulation device may be cooled by fluid, e.g. by air, water or oil. Total power consumption of the magnetic stimulation device may be below 1.3 kW. The power of the magnetic stimulation device may be at least 150, 250 or 500 W to generate a magnetic flux density sufficient to induce at least muscle contraction. A magnetic stimulation device as described in the U.S. patent application Ser. No. 14/789,156 or U.S. patent application Ser. No. 14/789,658, incorporated herein by reference, may be used.

The applicator for magnetic treatment may be placed proximate to the patient's body. The magnetic flux density may be applied into the target biological structure. Electric current may be induced and treat the neuromuscular plate and/or the nerve innervating the at least one muscle fiber. The treatment may cause at least a partial muscle contraction.

Furthermore, the present invention discloses the advanced approaches in aesthetic applications, e.g. for cellulite treatment and/or body shaping. Combined methods of treatment by electromagnetic field and treatment by magnetic field are used. The electromagnetic field may include treatment by radiofrequency, infrared or optical waves. The magnetic treatment may be provided by permanent magnets, electromagnetic devices generating a static magnetic field or time-varying magnetic devices. In the preferred application the treatment by a pulsed magnetic field and radiofrequency treatment may be combined. However the application is not limited by the recited combination so the combined method may include magnetic treatment and any treatment by electromagnetic field, e.g. light treatment, IR treatment or treatment by radiofrequency waves, e.g. microwaves, short waves or long waves. The magnetic treatment may also be provided with thermal treatment, e.g. heating and/or cooling.

The transmatch and generator control unit **14** receives information from the operator via the control unit and regulates the operation of the HF generator **11** and the transmatch **12**. The transmatch transmits HF to a balun transformer **13**, which converts unbalanced impedance to balanced impedance. This processed signal goes to two capacitive applicators **6**, which may be positioned 0.5 cm or higher above the surface of the skin or applied on dielectric or insulating, non-conductive material which is in contact with the skin surface.

A device described in U.S. patent application Ser. No. 14/278,756 incorporated herein by reference may be used for application of the present methods. The device may exclude the balun transformer, or the balun transformer may be included in transmatch. The possible methods of treatment by combined methods are described below.

Magnetic treatment in combination with radiofrequency treatment may be applied by two independent treatment devices, e.g. one device for treating the biological structure by radiofrequency waves and second device for treating the biological structure by magnetic field. Both devices may have a separate applicator for treating the biological structure, or one applicator may be used by at least two devices, i.e. the applicator may be modular for a plurality of devices.

The device may include at least one HF frequency generator for providing energy for radiofrequency treatment and for providing energy for magnetic treatment. In an alternative embodiment, the device may include at least one HF frequency generator for providing energy for radiofrequency treatment and at least one other independent frequency generator for providing energy for magnetic treatment. The device may include plurality of applicators for providing separate radiofrequency or magnetic treatments to the patient.

In alternative embodiment the applicator may provide a combination of radiofrequency and magnetic treatment. In one embodiment, the applicator may include at least one radiofrequency electrode for providing radiofrequency treatment and at least one magnetic field generating device, e.g. a coil, for providing magnetic treatment. In another embodiment, the applicator may include at least one electrode for providing radiofrequency treatment and at least one magnetic field generating device providing magnetic treatment, wherein the at least one RF source provides energy for both at least one electrode and at least one magnetic field generating device.

In still another embodiment the at least one RF source may provide the energy for the at least one magnetic field generating device providing magnetic treatment wherein the at least one magnetic field generating device may be used as the at least one electrode. The essence is the far different stimulation frequencies which are used for RF treatment and magnetic treatment. The magnetic field generating device in the high frequency field is similar to the electrode. This enables the magnetic field generating device to be the electrode for radiofrequency treatment. In the preferred embodiment a flat coil may be used as the electrode.

The frequencies for the radiofrequency treatment may be in the range of ones of MHz to hundreds of GHz, more preferably in the range of 13 MHz to 3 GHz, most preferably around 13.56 or 40.68 or 27.12 MHz or 2.45 GHz. The term "around" should be interpreted as in the range of 5% of the recited value. The impulse frequencies for the magnetic treatment may be in the range of hundreds of Hz to hundreds of kHz, more preferably in the range of ones of kHz to tens of kHz, most preferably up to 10 kHz. However the repetition rate of the magnetic impulses may reach up to 700 Hz, more preferably up to 500 Hz, most preferably in the range of 1 to 300 Hz, e.g. at least 1, 5, 20, 30, 50, 100, 140 or 180 Hz. The magnetic flux density of the magnetic treatment may be at least 0.1, 0.8, 1, 1.5, 2, 2.4 or up to 7 Tesla on the coil surface (equivalent to 70000 Gauss). The treatment/successive treatments may last several seconds, e.g. at least 5, 10, 30, 60, 120 or 240 seconds, or longer, e.g. at least 20, 30, 45, 60 minutes. The impulse duration may be in the range of 3 μs to 10 ms or more, or alternatively 3 μs to 3 ms or alternatively 3 μs to 1 ms. The impulse duration may be e.g. 3, 10, 50, 200, 300, 400, 500, 625, 1000, 2000 or 3000 μs. The duty cycle of the stimulation may be at least 1:50, more preferably at least 1:40, even more preferably at least 1:20, most preferably at least 1:8 or up to 1:4. The magnetic stimulation device may emit no radiation.

A derivative of the magnetic flux density is defined by Equation 4.

$$\frac{dB}{dt}, \qquad \text{Eq. 4}$$

where: dB is magnetic flux density derivative [T]; dt is time derivative [s].

The maximal value of the magnetic flux density derivative may be up to 5 MT/s, preferably in the ranges of 0.3 to 800 kT/s, 0.5 to 400 kT/s, 1 to 300 kT/s, 1.5 to 250 kT/s, 2 to 200 kT/s, 2.5 to 150 kT/s. In exemplary applications the maximal value of the magnetic flux density derivative may be at least 0.3, 0.5, 1, 2.5, 3.2, 5, 8, 10, 17, 30 or 60 kT/s. The value of magnetic flux density derivative may correspond to induced current within the tissue.

The magnetic flux density derivative may be determined within the entire period of the magnetic signal and/or in any segment of the magnetic signal.

Alternatively the treatment device may include no deep muscle diathermy device for heating the target biological structure. The treatment preferably may include no electrode which may enable heating the biological structure in contact mode.

Cellulite is an effect of skin change resulting in orange peel appearance. The cause of the cellulite is orientation of collagen fibers in so called "fibrous" septae. The fibrous septae contract and harden over time creating a dimple effect. Additionally, blood and lymphatic vessels lack circulation due to the contraction and hardening of the septae. The lymph flow may be blocked resulting in swelling. Another cause of cellulite may be adipose cells protruding to dermis. Cellulite may be treated by the recited methods.

One application of time-varying magnetic field for enhancing the visual appearance of body region may be treatment of a muscle by magnetic flux density for reducing the cellulite. The magnetic flux density may be delivered through the skin to the neuromuscular plate and/or nerve innervating at least one muscle fiber. The electric current may be induced in the target biological structure causing at least partial muscle contraction. The at least partial muscle contraction may cause the movement of the skin and all the biological structures subtending epidermis. Additionally, the at least partial muscle contraction may improve blood circulation by itself, or via the movement of the muscle in the vicinity including fibrous septae. Additionally, blood and/or lymph circulation may be improved in the layers subtending epidermis since the muscle contraction may move the fibrous septae. Also local and/or adipose tissue metabolism may be improved.

The lymph flow may be improved by at least partial muscle contraction which may provide effect similar to manual massage. The improved lymph flow may improve local metabolism and/or immune system. The improved lymph flow may contribute to purer lymph due to faster delivery of the lymph to the lymph nodes where the lymph may be cleared.

The present method may provide a massage effect via the treatment which may be caused by the at least partial muscle contraction. Therefore the massage effect may be achieved by contactless methods instead of manual massage techniques or soft tissue techniques. The massage effect may improve lymph circulation.

In another aspect, improvement of functionality and/or the appearance of the muscle may be achieved with results similar to body exercise. The results may be achieved by application of high magnetic flux density to the body region and inducing at least partial muscle contraction. Higher values of magnetic flux density applied may result in a stronger muscle contraction. The patient may feel firmer and tighter.

With the present method muscle contractions induced by the applied magnetic flux density may help to tone the muscle providing a more attractive appearance. As the muscle structure is treated by time-varying magnetic field the entire limb may be moved due to the high power of the magnetic treatment. Nevertheless, the method is not limited to the applications to the limbs and the method is able to treat any muscle, e.g. gluteus maximus or any muscle/deep muscle to induce body contouring and/or body shaping effect and fat burn. Additionally, shortened and/or flabby muscles may be stretched. The physical fitness of the patient may be improved as well.

The magnetic field may treat various body regions, e.g. thighs, buttocks, hips, abdomen or arms. The muscles may be shaped to enhance visual appearance of the treated body region. The body part may obtain enhanced visual appearance of its contour.

The magnetic field may treat at least one muscle of lower limb, particularly the parts which are prone to cellulite such as thighs or saddlebags. The time-varying magnetic field may induce at least partial muscle contraction in different muscle and/or muscle group. Following the position and/or orientation of the magnetic field generating device the anterior, posterior and/or medial compartment of the thigh may be treated. The anterior compartment includes sartorius muscle, rectus femoris muscle, vastus lateralis muscle, vastus intermedius muscle, vastus medialis muscle. Posterior compartment includes biceps femoris muscle, semitendinosus muscle and semimembranosus muscle. Medial compartment includes pectineus muscle, external obturator muscle, gracilis muscle, adductor longus muscle, adductor brevis muscle and adductor magnus muscle.

The treatment may cause circumferential reduction of thighs. Further the muscle may obtain enhanced visual appearance, thigh may be well-shaped. Thigh contour may be enhanced as well.

The at least one surrounding body region may be treated as well, e.g. buttocks.

The applicator may be placed within proximity of the patient's treated area. The applicator may be fixed to the patient. Alternatively the correct position may be provided by a mechanical arm and/or adjustable applicator. The applicator may be made of adhesive and/or high friction material at least on contact surface with the patient.

The magnetic field may be generated with a low repetition rate such as 1 Hz for a predetermined period of time, e.g. 30 seconds, sufficient for setting the applicator to a correct position where the treatment is most effective. During the period the magnetic flux density may be adjusted following the patient's needs to induce muscle contraction sufficiently strong and comfortable for the patient.

The treatment may start a treatment protocol. The treatment protocol may include a set of predetermined treatment sequences of predetermined repetition rates applied for predetermined time periods. The sequences may be repeated and/or adjusted following the patient's need. The sequence may include a repetition rate in the range of 1 to 100 Hz, preferably in the range of 2 to 90 Hz, more preferably in the range of 5 to 50 Hz, most preferably in the range of 10 to 45 Hz. The sequences may last at least 30, 45, 60, 90, 120 or up to 300 seconds.

Alternatively the treatment may include the only the treatment protocol without applying the magnetic field of low repetition rate. The correct position of the applicator and/or adjusting the magnetic flux density may be adjusted during the first sequence of the treatment protocol.

In one application, the treatment may induce the same effect as muscle exercising of buttocks. During the treatment of buttocks the magnetic field may be targeted to treat of muscles shaping the buttocks, e.g. tensor fasciae latae muscle or at least one of gluteal muscles: maximus, medius or minimus. In one preferred application all three gluteal muscles may be treated. Further other muscles may be treated, e.g. abdominal muscles, spinal muscles and/or thoracic muscles. By the complex treatment and muscle contraction in the body region the treated muscles may be strengthened, toned, the cellulite may be reduced and dimples may be removed. Buttocks and even the patient's figure may be enhanced in visual shape appearance and may become more attractive. Buttocks become well-shaped, round, firm, well-trained, toned, smoother, tight and lifted. The complex treatment may reduce hips, make perfect round and lifted buttocks, increasing the self-confidence of the patient

The treatment may be more efficient than standard workout in fitness since the fitness machines strengthen only the isolated muscles. The results may be achieved in very short-time periods with minimal time of treatment. Without being limited, it is believed that the exercising of the gluteus medius may reduce the volume of the buttocks; exercising of the gluteus maximus may shape and/or lift the buttocks; exercising of the gluteus minimus may lift the buttocks.

In the preferred application the magnetic treatment may be combined with other treatment methods using different approaches, e.g. conventional non-invasive treatments. The combined treatment may be applied to the surroundings tissues around buttocks to reduce the cellulite around the buttocks and enhance the shape of the enhanced appearance of the buttocks. The surrounding tissues may be represented by e.g. abdomen, love handles, thighs or saddle bags.

The magnetic field may treat at least one muscle responsible for silhouette of the body. The time-varying magnetic field may induce at least partial muscle contraction in different muscle and/or muscle group responsible for silhouette in the region of abdomen, love handles and/or bra fat. Following the position and/or orientation of the magnetic field generating device rectus abdominis muscle may be treated. Alternatively latissimus dorsi muscle, abdominal internal oblique muscle, abdominal external oblique muscle, transverse abdominal muscle and/or pyramidalis muscle may be treated by the time-varying magnetic field.

The treatment may cause circumferential reduction in the region of belly, hips and/or love handles. Alternatively the treatment may tighten at least one of these body parts. Further the muscles may obtain enhanced visual appearance, belly may be well-shaped. Repetitive application may even reach in a six-pack look. The at least one surrounding body region may be treated as well, e.g. buttocks.

The magnetic field may treat at least one muscle of upper limb, particularly the parts which may be prone to cellulite such as arm. The time-varying magnetic field may induce at least partial muscle contraction. Following the position and/or orientation of the magnetic field generating device the at least partial muscle contraction may occur in biceps brachii muscle, brachialis muscle, coracobrachialis muscle and/or triceps brachii muscle.

The treatment may cause circumferential reduction of the arm. Further the muscle may obtain enhanced visual appearance, arm may be well-shaped. Arm contour may be enhanced as well.

The at least partial muscle contraction may be more efficient for adipose tissue metabolism as the value of magnetic flux density increases since the muscle contraction may be stronger. The higher magnetic flux density may treat the higher number of muscle fibers contraction and the more adipose tissue may be reduced. Therefore the visual appearance of regions prone to cellulite may be enhanced.

Treatment by time-varying magnetic field may induce lipolysis. Adipose tissue may be reduced by decreasing the number and/or volume of adipose cells. Promoted adipose cell metabolism may increase as the value of magnetic flux density increases. The treatment may release free fatty acids (FFA) from at least one adipose cell. The increased concentration of FFA may influence a homeostasis of the adipose cell. A disruption of the homeostasis may cause a dysfunction of the adipose cell. The dysfunction may be followed by stress for endoplasmic reticulum (ER stress). ER stress may cause additional lipolysis and/or apoptosis of the at least one adipose cell.

Furthermore, ER stress may cause increase of intracellular calcium ions (Ca2+) which may promote an apoptotic process and may continue into controlled cell death of the adipose cell. The apoptosis may be induced by Ca-dependent effectors, e.g. calpain or caspase-12. Endogenous ligands or pharmacological agents, such as vitamin D, may induce prolonged cytosolic calcium increase. Vitamin D may influence release of Ca2+ from endoplasmic reticulum. Hence the effect of treatment may be enhanced by application of vitamin D and/or Ca2+ prior, during and/or after the treatment. The most significant effect may be achieved by application of both, Ca2+ and vitamin D, prior the treatment to provide all factors influencing adipose cell apoptosis.

Alternatively, increased level of Ca2+ may induce autophagy within adipose cell as well. Autophagy is self-eating process of cellular organelles to produce energy and it may proceed into cell death. Autophagy may be induced by ER stress or it may be induced via Ca2+ signaling.

FIG. **6** illustrates pathways which may induce apoptosis of the at least one adipose cell. FFA may accumulate in the at least one adipose cell (**20**). The magnetic field may induce lipolysis (**21**), i.e. a release of FFA from adipose tissue. Accumulated FFA may reach a threshold when adipose cell is unable to utilize FFA. A dysfunction of the adipose cell may occur. The adipose cell may react on the dysfunction by ER stress (**22**). ER stress may induce lipolysis hence additional release of FFA may occur (**20**). ER stress may cause apoptosis of the adipose cell (**23**). Furthermore, the ER stress may release Ca2+ (**24**) which may contribute the apoptosis (**23**).

The effect of the treatment by magnetic field for adipose tissue reduction may be influenced by various biological processes and/or pathways as recited above. The processes and/or pathways may be synergic hence the adipose tissue reduction may be accelerated and/or more efficient.

The method may cause the circumferential reduction i.e. a reduction of the size of the treated body region. The method may be mostly indicated for the regions with cellulite, particularly for thighs, buttocks, saddlebags, love handles, abdomen, hips and/or arms. However, the indication is not limited to the mentioned regions and the method may be used for treatment of any other body region.

Furthermore, the method may change BMI index of the patient. In a preferred application the BMI of the patient may be reduced. Alternatively, the BMI of the patient may increase.

Heating/Cooling

The magnetic field may be combined with application of heat and/or cold. The body region may be heated/cooled. The target biological structures may be selectively treated due to different tolerance of various biological structures to heating/cooling. Applying of heat/cold may improve metabolism of the biological structure, alternatively a reduction of the biological structure may occur.

Various biological structures have a different tolerance to heating/cooling. Hence target biological structures may be remodeled, e.g. adipose cells may be selectively reduced. The cells different from adipose cells such as epidermal cells, are not reduced by the heating/cooling. The selective reduction of adipose cell may be caused by e.g. crystallization within adipose cells. The heating/cooling of the adipose cell may reduce the number and/or volume of adipose cells by lipolysis, apoptosis and/or necrosis.

Cooling

Although the following exemplary treatment describes applying cold to the patient, the treatment method is not limited to the exemplary application. The method may include heating the patient instead of cooling the patient.

The cooling may be provided in a contact, indirect contact and/or non-contact manner. Contact cooling may be provided by a cooling element placed to the proximity of the treated body region, e.g. a thermally conductive material such as metal, gel or ice may be used. Indirect contact may be provided by a flow of cooling media within a layer of flexible and/or rigid material, e.g. cooling media such as glycerol, saline or water solution may be used. The cooling element may include a plurality of passages which the cooling media may flow in. Non-contact cooling may be provided by radiant cooling. Alternatively cooling media may be applied directly on the body region. The cooling media used for non-contact heating/cooling may be preferably a fluid, e.g. a gas or liquid. The gas may be applied in form of a spray, e.g. cold air, $CO2$ or $N2$ may be used. The cooling media may be at a predetermined temperature which may be controlled by the device to induce selective treatment of the target biological structure.

In an exemplary application the adipose cells may be selectively treated by cooling. A cooling media may be applied to the body region. A reduction of adipose cell may be induced by cooling the adipose cell. The cells different from adipose cells are not reduced by the cooling.

Temperature Ranges

The temperature of the cooling media and/or element may be less than the temperature of the patient's body. The temperature of cooling media may be at least −196° C. The temperature of the cooling element may be preferably in the range of 40 to −40° C., more preferably in the range of 20 to −20° C., even more preferably in the range of 10 to −15° C. or in the range of 5 to −10° C. A temperature of the adipose cells may be above a freezing point of water to prevent a reduction of cells including water. The temperature of the adipose cells may be preferably in the range of 37 to −10° C., more preferably in the range of 20 to −4° C., even more preferably in the range of 15 to −2° C. or around 4° C. The temperature of epidermis may be at least −40, −20, −10, 15, 20, 35° C., more preferably the temperature of epidermis may be in the range of around 5 to −5° C. The term around may be interpreted to mean in the range of 10% of the particular value.

Alternatively the body may be heated by application of various treatment methods, e.g. radiofrequency, diathermy or optical waves. The temperature in the target tissue may be up to 80° C., more preferably in the range of 37 to 60° C., even more preferably in the range of 39 to 50° C., most preferably in the range of 42 to 47° C. The temperature may be adjusted based on the intended use, e.g. adipose tissue reduction or collagen production.

The temperature of adipose cells may vary during the treatment. The temperature of the adipose cells may oscillate around a predetermined temperature. The temperature of the adipose cells may also follow a temperature profile in a predefined temperature range. The temperature and/or the temperature range may be adjusted following the patient's needs.

Cycles

Alternatively the adipose cells may be heated prior, during and/or after cooling. The term "heat prior" refers to preheating the adipose cells before cooling treatment. The term "heat during" refers to cyclically changing periods of cooling and heating the adipose cells during the treatment. The treatment may also include passive periods between heating and/or cooling. The term "passive period" refers to applying neither heating nor cooling. The term "heat after" refers to applying heat after the cooling treatment. The periods of heating/cooling and/or passive periods may be adjusted following by the patient's need.

Treatment Duration

The cooling may be applied for at least 10 seconds. Time duration of cooling the body region may be in the range of 1 to 240 minutes, more preferably in the range of 5 to 120 minutes, even more preferably 10 to 60 minutes, most preferably up to 30 minutes.

The cooling element and/or media may be applied continuously and/or in pulses. Continuous application may be used for a cooling element and/or media at a temperature above 0° C. Pulsed mode may be used for application of fluids below 0° C. The cooling may be provided cyclically for short periods in order of milliseconds, e.g. $N2$ may be applied cyclically to prevent damage to epidermis/dermis. The cooling element and/or media may be applied preferably non-invasively, e.g. by topical application. Alternatively the cooling element and/or media may be applied subcutaneously, e.g. injected.

Adjustable Applicator

The cooling element may correspond with the body region. The cooling element may be adjustable in shape to fit the body region. The cooling element may be made of flexible material to be modified in shape to follow the shape and/or contour of the body region. A fitting of the cooling element may provide homogenous treatment and/or temperature distribution. Further the heat exchange may be optimized at the contacted surface.

Pressure

A treatment may induce a thermal gradient in the body region, i.e. the shallow layer of the skin such as epidermis and/or dermis may have a lower temperature than the deeper layer such as adipose tissue. The effect of cooling may be improved by limiting and/or eliminating dermal blood flow. The dermal blood flow may be limited by applying vasoconstrictive medicine, preferably topically administered.

Positive

The dermal blood flow may also be limited and/or eliminated by applying a pressure. The pressure greater than systolic blood pressure may be used for pushing the blood out of the dermal and/or subcutaneous veins. The deeper adipose cells may be cooled and/or the cooling of the adipose cells to the temperature sufficient to reducing the adipose cells may be reached in shorter time period. Furthermore appropriate contact of the cooling element may be provided by the pressure in case of contact treatment.

Negative

The treatment effect may also be enhanced by applying negative pressure to the skin below the applicator, e.g. a convex cooling element may be used. The skin may be pulled towards the inner surface of the cooling element. Hence the contact may be enabled by applying negative pressure. Alternatively, the folded tissue may be pinched by two or more cooling elements and the cooling may be applied to the tissue, particularly to adipose cells. Further the skin may be stretched and a thickness of the skin may decrease. Skin thickness decrease may promote improved heat transfer to/from adipose cells.

Miscellaneous

The cooling may be applied with application mechanical treatment such as acoustic, ultrasound, and/or shockwave treatment to enable more homogenous treatment effect. The adipose cells reduction may also be promoted by physical movement of the body region by e.g. massaging, or vibrations. The pressure applied to the body region may vary to improve the results.

Protocols

An apoptotic index may increase after cooling the body region. The apoptotic index refers to a percentage of apoptotic cells in specimen. The apoptotic index may increase due to cooling up to ten times greater value compared with the value prior the cooling.

Based on the apoptotic index a treatment combining various methods may be designed as a tailor-made solution following the patient's need. The cooling may be applied to the body region of the patient prior, during and/or after applying a magnetic field to the patient.

Pain Relief

A pain relieving medicament may be provided during the treatment if the patient is more sensitive to decreased temperature. A topical application may be preferred. The pain relief effect may be provided by a magnetic field of repetition rate at least 100 Hz, more preferably 120 Hz, even more preferably at least 140 Hz or at least 180 Hz. The pain relieving effect may be provided before, during or after the treatment.

Precooling

Cooling the body region prior to applying the magnetic field may influence a metabolism of adipose cells. Alternatively, the cooling of the adipose cells may induce apoptosis, lipolysis, autophagy and/or disruption of the adipose cells. A release of FFA from adipose cells may induce ER stress as recited above. The application of the magnetic field may cause at least partial muscle contraction reducing the adipose cells. Furthermore the released FFA from adipose cells influenced by cooling may be used as energy source for muscle work. Hence the cooling may be followed by treating a patient by magnetic field inducing at least partial muscle contraction. Due to the combined effect of cooling and magnetic treatment the adipose cells may be reduced in number and/or volume. Moreover the muscles may be shaped, tightened, strengthened and/or the volume of the muscle may increase. Additionally, the cellulite appearance may be reduced due to muscle work.

The magnetic treatment may provide a massage effect. Hence blood and/or lymph flow may be improved. Additionally frozen tissue may be relaxed.

The combined magnetic treatment may be applied immediately after cooling, more preferably around 1 to 24 hours after cooling, e.g. 1, 2, 8 or 20 hours after cooling. The combined treatment may be applied periodically. Alternatively, the treatment by cooling and/or magnetic field may be applied separately, e.g. treatments may alternate in appropriate periods. The period may last from 12 hours to 1 month, more preferably from 1 day to 2 weeks, most preferably from 3 days to 1 week.

In an exemplary application of the treatment method a patient's body region may be cooled by a cooling element for e.g. at least 20 minutes up to 1 hour. After stopping the cooling the body region may be treated by magnetic field for e.g. 15 to 45 minutes.

Cooling

Cooling the body region may be applied simultaneously while the body region is treated by magnetic field within one treatment.

The magnetic cooling may be provided to the patient while the patient is being treated by magnetic field.

Alternatively, cooling may alternate with treatment by magnetic field, i.e. the magnetic field is applied when cooling is not provided to the patient or vice versa. Periods of alternating cooling and magnetic treatment may vary.

The magnetic field may be preferably applied in burst mode. Each burst contains train of magnetic impulses and a period of no magnetic treatment. The train may include a plurality of magnetic impulses. A number of magnetic impulses may vary in the range of at least 1 to 10000 impulses, more preferably in the range of at least 10 to 1000 impulses. The time duration of the train and/or the period of no magnetic treatment may vary in order of milliseconds to order of seconds, e.g. in the range of 100 milliseconds to 100 seconds, more preferably in the range of 1 to 30 seconds, most preferably in the range of 5 to 15 seconds.

In one exemplary application the body region may be cooled for a period of e.g. at least 5 minutes. After stopping the cooling the body region may be treated by a magnetic field for a period of e.g. at least 5 minutes. After stopping the magnetic treatment the body region may be cooled.

Post Cooling

The cooling may also be applied after magnetic treatment. The treatment by magnetic field may provide stimulation, pain relief and/or a myorelaxation effect for the treated body area before cooling. The cooling applied with pressure may be better accepted by the adipose tissue when the muscle below the adipose cells is relaxed. Alternatively the magnetic treatment may provide a temporary pain relief effect hence a patient suffering from a lower pain threshold, e.g. cool sensitivity, may be treated.

In an exemplary application the body region may be treated by a magnetic field for a period of e.g. at least 15, 20 or 30 minutes. After stopping the magnetic treatment the body region may be cooled.

The cooling may be applied immediately after magnetic treatment, more preferably around 1 to 24 hours after magnetic treatment, e.g. 1, 2, 8 or 20 hours after magnetic treatment. The combined treatment may be applied periodically.

In an exemplary application of the treatment method a patient's body region may be treated by magnetic field for e.g. at least 20 minutes up to 1 hour. After stopping the magnetic treatment the body region may be treated by cooling for e.g. 15 to 45 minutes.

In the previously described exemplary treatment methods the cooling of the patient may be replaced by heating the patient.

FIGS. **7**A and **7**B illustrate an application of the treatment by a device providing heating/cooling to the body region of the patient **25**. FIG. **7**A illustrates a treatment device **26** including a connection to power source, a magnetic field generating device **27** and means for providing heating/cooling **28**, e.g. RF source or cooling element. FIG. **7**B illustrates alternative treatment applied by two separate treatment devices, i.e. by a device providing magnetic treatment **29** and a device providing heating/cooling **30**.

All the recited combined treatment methods may be provided by at least one applicator. The applicator may provide cooling and magnetic treatment. Alternatively one applicator may provide cooling and second applicator may provide magnetic treatment.

The target structure may be treated by combined methods which may be used for remodeling the adipose tissue, body shaping and/or contouring, muscle toning, skin tightening, skin rejuvenation, wrinkle removing, reducing stretchmarks, breast lifting, lip enhancement or treatment of cellulite in general by application of electromagnetic radiation to target structure to selectively heat the target tissue to remove and/or remodel adipose tissue from the target tissue. The second approach is to transmit a magnetic treatment to the target structure, inducing at least partial muscle contraction within the target structure to remodel the adipose tissue by natural adipose tissue catabolism. Adipose tissue catabolism may be caused by apoptosis or necrosis of the adipocytes. The muscle contraction caused by induced eddy current is the same as a natural contraction. The adipose tissue may be reduced in natural way. Additionally, the muscle may be shredded in a natural way. Therefore the effect resulting in body shaping and/or contouring may be significantly improved.

The combination of the recited method may improve currently used applications in various aspects and the effect of the treatments may be significantly enhanced. The application of a radiofrequency electromagnetic field may be combined with application of a magnetic field applied before, simultaneously or after the radiofrequency treatment. The application of a magnetic field may induce many benefits for radiofrequency treatment, such as applications inducing at least partial muscle contraction, myorelaxation effect or analgesic effect. The perfusion or metabolism may be improved as well.

The at least partial muscle contraction may induce enhanced effects on adipose tissue reduction by catabolism of the adipose tissue and burning energy from adipose tissue. The total adipose tissue reduction effect may be enhanced by radiofrequency treatment.

Additionally, the at least partial muscle contraction may improve a blood flow and/or perfusion in the treated body region. The improved blood flow may be caused by activation of muscle pump and/or by the muscle necessity of more oxygen due to the at least partial contraction. The blood flow may increase rapidly and it may last temporarily, preferably up to 1 hour, more preferably up to 45 minutes, most preferably up to 30 minutes. Due to increased blood flow and/or local perfusion, the risk of overheated muscle may be limited or even eliminated. Further the homogeneity of the thermal field induced by thermal effect of radiofrequency treatment may be significantly enhanced and/or the temperatures may be well-balanced/compensated in the target body region. Still another benefit may be prevention of creation any hot spot caused by steep thermal gradient.

Due to improved blood flow, perfusion and/or lymph flow the metabolism may be improved. Additionally, the effect of radiofrequency treatment may be enhanced by improved metabolism, e.g. cellulite treatment, body shaping and/or contouring, skin tightening or skin rejuvenation. Further benefit may be reducing or eliminating the risk of panniculitis or local skin inflammation since any clustering of the treated adipocytes may be prevented by the improved metabolism. The improved blood and/or lymph flow may contribute the removing of the adipocytes. The removing of the adipocytes may be promoted by higher number of cells phagocytosing the adipocytes as well. Synergic effects of magnetic and RF treatment may significantly improve metabolism. Therefore the possibility of adverse event occurrence may be limited and treatment results induced by the present invention may be reached in shorter time period.

Further the at least partial muscle contraction may improve the movement of lymphatic vessel and the lymph flow may be improved.

In the preferred application the RF and/or magnetic field may be modulated. In the most preferred application both treatments are modulated. The magnetic treatment may be modulated in the magnetic flux density domain, repetition rate domain, or impulse duration domain, to provide different treatment effects and to prevent adaptation of the target biological structure. The radiofrequency treatment may be modulated in the frequency domain, intensity domain and/or time domain to reach the most complexity and/or efficiency of the target treated biological structure. The modulation in the time domain may be changing the active and passive periods of stimulation, e.g. the radiofrequency treatment may include period with no stimulation, i.e. the radiofrequency treatment may be not continual but the treatment may be provided in pulses. The periods of no stimulation may vary and may be adjusted by the operator. Due to modulation during the treatment, different target biological structures may be treated in the different depth.

The application may be contact or in the preferred application the treatment may be applied contactless. Contactless application may avoid all biocompatibility factors which may occur during contact treatment. In the most preferred application the treatment may be provided by self-operated device. Hence the applicator and/or magnetic field generating device need not be guided by the operator. The applicator may be fixed at a sufficient distance from the patient's skin enabling safe treatment for the patient. Self-operated treatment may be provided by a hand-held applicator or the applicator may be fixed to stand-alone device. The self-operated treatment may be also enabled using various types of sensors in communication with the device for monitoring the treatment and/or the patient. The at least one sensor may be e.g. reactive sensor, electrochemical sensor, biosensor, biochemical sensor, temperature sensor, sorption sensor, pH sensor, voltage sensor, sensor for measuring distance of applicator from the patient surface and/or from the treated area, position sensor, motion detector, photo sensor, camera, sound detector, current sensor, sensor for measuring of specific human/animal tissue and/or any suitable sensors measuring biological parameters and/or combination thereof such as sensor for measuring dermal tensile forces, sensor for measuring the activity of the muscle, muscle contraction forces, tissue impedance or skin elasticity.

Further the homogeneity of the treatment may be improved by several approaches. A first approach may be represented by a moveable applicator providing the dynamic treatment to a large target area. The dynamic treatment may improve the homogeneity of applied treatment energy and additionally due to large area the effect is uniform and/or well balanced. Static positioning of the applicator may be used as well. Another approach of improving homogeneity may be represented by using a bolus. The bolus may provide improved transmittance of the electromagnetic energy to the treated biological structures. Additionally, the bolus may prevent occurrence of hot spots within the treated area; the bolus may provide constant temperature to the target treated surface area; or the bolus may increase the homogeneity of the radiofrequency waves application by providing a homogenous medium for electromagnetic waves propagation not being influenced by the interface of the target treated area and an air. The bolus may profile the electromagnetic field to enhance the effect of the treatment. In still another approach an air gap may be between the applicator and the patient.

The treatment by magnetic and/or electromagnetic field may be in continuous or discrete mode. In one application the magnetic treatment may be applied in continual mode with no pauses and the electromagnetic treatment may be applied in pulsed mode to provide improved adipose tissue reduction caused by natural process and by the increased temperature. In another application the electromagnetic treatment may be applied continuously with no pauses and the magnetic treatment may be applied in pulsed mode to provide improved thermal reduction of adipose tissue and by improved metabolism due to improved blood flow. Both modes may be combined in various treatment sequences.

In the preferred application the treatment may be started at the moment when the target biological structure reaches the predetermined temperature. The temperature in the target tissue may be up to 80° C., more preferably in the range of 37 to 60° C., even more preferably in the range of 40 to 45°

C. The temperature may be adjusted based on the intended use, e.g. adipose tissue reduction, collagen production or muscle contraction. In an alternative application the intended use may be coagulation and/or ablation. The temperature in the target biological structure may be measured by invasive method, e.g. using an invasive probe; or by contact method, e.g. using thermocouple sensor; or by contactless method, e.g. using infrared sensor or camera. The temperature of the target biological structure may be determined by a mathematic method. The sensor for measuring the temperature in the target biological structure may be attached to the applicator.

A benefit of the application of magnetic treatment and electromagnetic treatment may be causing an analgesic effect of the application and providing a possibility of treating a patient with higher sensitivity for thermal effects induced by electromagnetic treatment, i.e. patients with any predisposition inducing increased thermal sensitivity. The analgesic effect may be induced by magnetic treatment by suitable repetition rates and it may be induced immediately during the magnetic treatment. The analgesic effect may last up to several hours after magnetic treatment. The magnetic flux density of the magnetic treatment may preferably reach at least motor-threshold intensity inducing at least partial muscle contraction therefore the homogeneity of the thermal field may be significantly enhanced.

Another benefit of application the magnetic treatment may be causing a myorelaxation effect. The magnetic treatment may be applied on spastic muscle structures to relieve the hypertonus of the muscle and improving the blood and/or lymph flow. Therefore relieving the hypertoned muscle may contribute to the analgesic effect and contribute to the acceptability of the treatment by the patient.

The blood and/or lymph flow may be limited in the spastic muscles and the metabolism may be limited as well, meaning that the risk of clustering the treated target structures may be higher and possible adverse events may occur. The recited risks may be eliminated by the used of magnetic treatment.

In one aspect of the invention, the treatment by magnetic field may be applied to the target structure before the radiofrequency treatment to prepare the target structure for following treatment by radiofrequency field. The effect of magnetic treatment may be to induce at least partial muscle contraction or to treat a muscle structure to increase a muscular tonus of the target structure. Both effects may provide a massage effect for the structure within the proximity of the target structure hence the blood and/or lymph circulation may be improved to promote local metabolism. The temperature may be locally increased by the improved blood flow and the target structure may accept the following radiofrequency treatment at significantly higher quality. Additionally, the collagen and/or elastin fibers may be remodeled or restored and/or its neogenesis may be improved to provide a younger, smoother, firmer and enhanced skin appearance.

Additionally, previous application may improve acceptability of the electromagnetic field by increasing the temperature of the skin and the transmittance of the electromagnetic field may be improved due to less value of skin impedance. Further the radiofrequency may penetrate deeper target structures relative to treatment without a preceding magnetic treatment of the target structure and/or area.

Another benefit may be releasing the adipose tissue in the muscle by muscle contraction and/or by temperature increase causing better liquidity of adipose tissue. Still another benefit of the at least partial muscle contraction may be mechanical breaking large adipose tissue bulks into smaller bulks which may be easier metabolized and/or the smaller adipose tissue bulks may be removed faster by the lymphatic and/or blood flow. Due to improved metabolism and/or circulation the cellulite may be treated in a short time and the visual effect on skin appearance may be significantly enhanced.

In another aspect of the invention, the treatment by magnetic field may be applied to the target structure simultaneously with the radiofrequency treatment to improve effects of the electromagnetic treatment inducing heat in the target structure.

The simultaneous application of magnetic treatment and radiofrequency treatment may be in two modes: a first mode may generate the magnetic impulses while radiofrequency treatment is active or another mode may generate radiofrequency treatment while the magnetic treatment is not in an active stimulation period, i.e. the period of magnetic treatment and radiofrequency treatment alternates. Both modes amplify the resulting effect of the treatment. Therefore the results may be achieved in significantly shorter time than the same results achieved by separate applications of the radio frequency and magnetic treatments.

The simultaneous method of magnetic treatment and radiofrequency treatment of the target tissue may increase the peak magnetic component of the entire treatment resulting in improved heating of the target structure including containing higher water volume, e.g. skin. Due to increased temperature of skin, the production and/or remodeling of collagen and/or elastin fibers may be improved and the skin may be provided with a younger, smoother, firmer and enhanced appearance. The effect of overheating the muscle may be reduced by the improved blood flow.

In still another aspect of the invention, the treatment by magnetic field may be applied to the target structure after the treatment by electromagnetic field to enhance and/or contribute to the effects of radiofrequency treatment by influencing the target structure by magnetic field.

The magnetic field may treat the target structure to cause at least partial muscle contraction proximate to the target structure to improve blood flow and provide homogenous temperature distribution at high quality after creating a temperature distribution at lower quality by radiofrequency treatment.

All of the methods may be provided by the above recited technical solutions. The above mentioned methods may be used separately or in any combination.

The method may cause the circumferential reduction i.e. a reduction of the size of the treated body region. The method may be mostly indicated for the regions with cellulite, especially for buttocks, saddlebags, love handles, abdomen, hips, thighs or arms. However, the indication is not limited to the mentioned regions and the method may be used for treatment of any other body region.

The at least one applicator may include at least one magnetic field generating device. The plurality of magnetic field generating devices may be positioned in isolated locations of the at least one applicator. Alternatively, the magnetic field generating devices may be positioned next to each other, in an array or matrix, in a pattern or in randomized locations of the at least applicator.

The magnetic field generating devices may be positioned and/or moved in the at least one applicator in one plane; in at least two mutually tilted planes defined by a convex or concave angle, or perpendicular to each other; or in at least two parallel planes with the at least one magnetic field generating device in each parallel plane. The movement of the at least one magnetic field generating device may be translational and/or rotational, constant or accelerated. The movement may follow a predetermined, random or predefined trajectory, such as a pattern, array or matrix. The movement of the at least one applicator may be handled in similar manner as the movement of the at least one magnetic field generating device. The angles of the planes and/or the movement of the at least one magnetic field generating device may be adjusted by an operator following the patient's needs. The positioning may be provided by mechanical holder, enabling tilting, distancing and positioning magnetic field generating device in various planes. In an alternative embodiment the patient may be positioned in the intersection of the magnetic fields generated by the plurality of magnetic field generating devices. In the preferred application the at least one applicator may be movable and the movement may be circular.

The plurality of magnetic field generating devices may be positioned within one applicator having form of mechanical holder. The shape of the applicator having form of mechanical holder may be adjustable, e.g. the applicator may include at least one moveable part. In a preferred embodiment the applicator having form of mechanical holder may provide spatial arrangement of the energy delivery elements in one axis, two axes or three axes and/or provide tilting and/or rotation. The applicator having form of mechanical holder may provide fixation of the at least one magnetic field generating device in one position. The moveable parts may be connected by sliding mechanism and/or by a joint mechanism. An exemplary embodiment of such an applicator may be found in U.S. Pat. No. 9,468,774, incorporated herein by reference. The applicator may be adjustable following the body region and/or biological structure.

The static position of the at least one applicator may be provided by a positioning member. The positioning member may be e.g. an arm or an adjustable flexible belt. The positioning member may include a buckle for adjusting the length of the belt. The applicator may be placed within predefined locations of the belt. Alternatively the applicator may be shaped to be moveable along the positioning member, e.g. the shape of the applicator may be preferably concave, e.g. V-shaped or U-shaped. The positioning member may be inserted itself into the concavity of the applicator. The position of the applicator may be adjusted by limited movement along the positioning member because the positioning member may be used as guiding member. However, the applicator may not be fixed to a particular static position. The position of the applicator may be dynamically adjusted during the treatment following the patient's needs. The position of the applicator may be adjusted manually by the operator, or automatically by the treatment device. In one exemplary embodiment a plurality of applicators may be used for treating larger body regions, e.g. buttocks, abdomen or thigh.

The present methods may also induce muscle contraction to reduce effect of skin laxity. Skin laxity may be caused by e.g. aging process or increasing number and/or volume of adipose cells which pulls down the skin by gravity, rapid weight loss or skin stretching during the pregnancy. The muscles may be treated by the induced electric current to contract. Repetitive contractions may cause the muscles to obtain the tonus and flexibility. Therefore the skin appearance may be enhanced by treating the flabby muscles. The effect of skin tightening may be achieved. The method also may promote the collagen and elastin fibers in the layers subtending the epidermis hence the skin may obtain enhanced visual appearance. The method may be widely applied but not limited to application to the regions of neck, breasts, arms or abdomen. The method may provide the smoother and younger appearance of the skin to the patient.

Similar methods of the muscle structure treatment by time-varying magnetic field for inducing the at least partial muscle contraction may be used for treatment of wrinkles as well. Wrinkles are results of extrinsic and intrinsic factors. Nowadays, wrinkles are considered to be negative effect of natural aging process which decreases the production of collagen and elastin fibers and weakens the skin which becomes thinner. As the muscle treatment by the magnetic flux density may induce at least partial muscle contraction, the collagen and elastin fibers neogenesis may be improved. Additionally, the muscles subtending the treated region may be toned and the skin may obtain a younger and enhanced visual appearance. Therefore, the effect of skin tightening may be achieved.

Wrinkles may be prevented or reduced by practicing facial exercises which may cause a massage effect to the facial tissues, improving blood and lymph circulation. Additionally, the facial muscles may be relaxed and toned after the exercise. A similar effect as facial exercise may be achieved by non-invasive and/or contactless method of treating the facial muscles by magnetic flux density. Further additional advantage of the present method may be the improvement of restoration of the collagen and elastin fibers, more effective toning and strengthening of the facial muscles.

The present methods may improve the neogenesis and remodeling of collagen fibers in the lips to reach a full, plump and firmer appearance. The magnetic flux density may be applied to the lips by an applicator. Therefore the lips may become fuller and firmer without any need of invasive method such as injection of the synthetic fillers, permanent makeup or the facial implants. The present method may promote the remodeling and/or neogenesis of collagen fibers in a natural way. Additionally, the collagen is natural substance of the human body which may provide the elasticity to the structure.

The present methods may be used for enhancing the visual appearance of breasts. Cooper's ligament may be treated, improved and/or firmed by the at least partial muscle contraction. The treatment may induce the elevation of the breast tissue. Additionally, the breast tissue may be treated to be modified in a shape, wherein the shape includes the size and/or the contour of the breast tissue. Therefore the visual appearance may be enhanced and breasts may be more attractive for the patient. The present method may be a non-invasive alternative for current aesthetic surgery method for the treatment of sagging breast tissue. The present method may provide a patient a method of breast visual appearance enhancement without surgery. Therefore the method lacks post-surgery complications such as scars, postoperative pain or long recovery period. Various treatment protocols may be used.

Following the recited methods the treatment may be but is not limited to continuous, pulsed, randomized or burst. The impulse may be but not limited to monophasic, polyphasic, biphasic and/or static magnetic field. In the preferred application the magnetic impulse may be in biphasic regime, i.e. it is consisted of two phases, preferably positive and negative.

In the preferred application of the present method the trains of pulses, called bursts are used.

Repetition rate and/or magnetic flux density may vary during the treatment protocol. Further the treatment may include several periods of different repetition rates, therefore the modulation may be in repetition rate domain. The treatment may include several periods of different magnetic flux densities, therefore the modulation may be in magnetic flux density domain. Alternatively the treatment may include different impulse durations, therefor the modulation may be in impulse duration domain. In yet another approach the treatment may be modulated by any combinations thereof.

Various envelopes and/or waveforms, e.g. pulse, sinusoidal, rectangular, square, triangular, saw-tooth, trapezoidal, exponential etc. for the purpose of muscle treatment may also be used, and are not limited to recited shapes.

The values of magnetic flux density and repetition rate are cited in several preferred applications since the perception of the treatment is subjective. Nevertheless, the magnetic flux density and repetition rates are not limited by the recited values. A person skilled in the physical therapy is able to repeat and apply the treatment methods adjusting the magnetic flux density and/or repetition rate following the patient's sensitivity or needs.

The present method is not limited to be used independently. For enhancing the result the method may be used in combination with other conventional non-invasive and/or invasive aesthetic treatment method.

All the recited methods may be applied to a patient in a non-invasive and/or contactless way. Therefore the present methods provide an effective alternative approach of enhancing the visual appearance with no need of invasive treatment or surgery. Further, the visual results are appreciable after several treatments. Additionally, the results include not only the visual appearance enhancement but even the improvement of the muscle structures, hence the patient feels firmer and tighter. The muscle structures become toned with no need of any diet or spending time by exercising in fitness.

The patient may feel firmer and/or tighter. The skin may be also tighter. Additionally, adipose tissue reduction may occur. Furthermore, cellulite may be reduced as well.

Thus, novel systems and methods have been described. Various changes and substitutions may of course be made without departing from the spirit and scope of the invention. The invention, therefore, should not be limited, except by the following claims and their equivalents.

The following U.S. patent applications are incorporated herein by reference: Ser. Nos. 14/873,110; 14/926,365; 14/951,093; 15/073,318; 15/099,274; 15/151,012; 15/178,455; 15/396,073; 15/446,951; 15/404,384 and 15/473,390.

Thus, novel apparatus and methods have been shown and described. Various changes and substitutions may of course be made without departing from the spirit and scope of the invention. The invention, therefore, should not be limited, except by the following claims and their equivalents.

The invention claimed is:

1. A method for treating a patient, comprising:
- positioning a first applicator having a first magnetic field generating device disposed within it, the first applicator being in contact with a body region of the patient;
- positioning a second applicator having a second magnetic field generating device disposed within it, the second applicator being in contact with the body region of the patient;
- securing each applicator at the body region of the patient in mutually tilted planes defined by an angle via a belt;
- charging a first energy storage device;
- charging a second energy storage device;
- discharging energy from the first energy storage device to the first magnetic field generating device to generate a first time-varying magnetic field;
- discharging energy from the second energy storage device to the second magnetic field generating device to generate a second time-varying magnetic field;
- simultaneously applying each of the time-varying magnetic fields to a muscle of the patient in the body region in order to contract the muscle; and
- cooling adipose cells in the patient to a temperature in a range of 15° C. to −2° C.

2. The method of claim 1, wherein the first and second time-varying magnetic fields each have a magnetic flux density in a range of 0.5 T and up to 7 T, a repetition rate in a range of 1 Hz to 700 Hz, an impulse duration in a range of 3μs to 10000 μs, and a maximal value of a magnetic flux derivative in a range of 2.5 kT/s to 150 kT/s, and wherein the body region comprises the patient's buttocks or abdomen.

3. The method of claim 1, further comprising cooling the first magnetic field generating device with a cooling media.

4. The method of claim 1, further comprising measuring with a sensor one or more of a voltage, a current, a phase shift, a magnetic flux density, or a temperature; and
- adjusting the first time-varying magnetic field in response to the measurement.

5. The method of claim 1, further comprising determining an unintended event has occurred based on measurements from a sensor, wherein the unintended event comprises a hardware error or a metal object being within proximity of the first or second applicator.

6. The method of claim 1, wherein the belt is flexible.

7. A method of toning or firming a patient's muscles using a treatment device, comprising:
- placing an applicator in contact with a body region of the patient, wherein the applicator houses a magnetic field generation device, and wherein the body region comprises one or more of thighs, buttocks, or abdomen;
- using a belt to maintain the applicator's position within the body region;
- charging an energy storage device via an energy source;
- discharging energy from the energy storage device to the magnetic field generating device, such that a time-varying magnetic field is generated, the time-varying magnetic field comprising magnetic pulses;
- applying bursts of the magnetic pulses to muscle fibers, neuromuscular plates, or nerves innervating the muscle fibers, each burst comprising a first duration wherein a plurality of subsequent magnetic pulses are generated in a trapezoidal envelope, and a second duration wherein no magnetic pulses are generated, wherein the treatment duty cycle of the bursts is at least 10% in order to achieve toning or firming of the body region of the patient, wherein the time-varying magnetic field comprises a magnetic flux density between 0.1 T and 7 T, a repetition rate between 1 Hz and 700 Hz, an impulse duration between 3 μs and 10000 μs, and a maximal value of a magnetic flux derivative between 2.5 kT/s and 150 kT/s.

8. The method of claim 7, wherein the belt further comprising comprises a buckle.

9. The method of claim 7, further comprising determining an unintended event has occurred in response to a signal from a sensor measuring one or more of voltage, current, phase shift, or magnetic flux density of a hardware component.

10. The method of claim 7, further comprising evaluating a signal from a hardware component of the treatment device

and providing at least one maximal treatment parameter comprising one or more of magnetic flux density, repetition rate, or impulse duration to an operator in response to one or more treatment parameters set by the operator.

11. The method of claim **7**, further comprising applying radiofrequency waves to the body region, wherein the magnetic field generating device generates both the time-varying magnetic field and the radiofrequency waves.

12. A treatment device for toning at least one muscle of a patient using a time-varying magnetic field, the treatment device comprising:

an applicator configured to be held in contact with a body region of the patient with a belt, the applicator housing a magnetic field generating device within a casing;

an energy storage device;

means for discharging energy from the energy storage device to the magnetic field generating device such that impulses of the time-varying magnetic field are generated, the time- varying magnetic field having a biphasic shape with a repetition rate in between 1 Hz and 700 Hz, an impulse duration between 3 μs to 10000 μs, and a maximal value of a magnetic flux derivative between 2.5 kT/s to 150 kT/s; and

means for cooling the magnetic field generating device by a fluid cooling media,

wherein the belt is configured to aid in positioning the applicator in order to apply the time-varying magnetic field with at least motor-threshold magnetic flux density to a peripheral neural system innervating the at least one muscle of the patient in order to repetitively contract the at least one muscle within the body region such that the at least one muscle is toned, the body region comprising one of buttocks or abdomen.

13. The device of claim **12**, further comprising:

a high-frequency generator;

a balun transformer; and

means for converting an unbalanced radiofrequency signal to a balanced radiofrequency signal in order to generate radiofrequency waves, wherein the radiofrequency waves are configured to be applied to the body region.

14. The device of claim **13**, further comprising a transmatch; and

means for matching the impedance of the radiofrequency signal.

15. The device of claim **12**, further comprising:

a sensor configured to measure one or more of voltage, current, phase shift, magnetic flux density, or temperature of a hardware component of the device;

means for evaluating a signal from the sensor; and

means for providing at least one maximal treatment parameter comprising one or more of magnetic flux density, repetition rate, and impulse duration to an operator such that the magnetic field generating device does not overheat, wherein the at least one maximal treatment parameter is based in part on at least another treatment parameter set by the operator.

16. The device of claim **12**, further comprising a sensor, wherein the device is configured to use a signal from the sensor in order to determine an unintended event including a hardware error or a metal object within proximity of the device and the device is configured to disable generating the time-varying magnetic field in the case of determining the unintended event.

17. The device of claim **16**, further comprising a second applicator housing a second magnetic field generating device, wherein a first time-varying magnetic field generated by the first magnetic field generating device and a second time-varying magnetic field generated by the second magnetic field generating device is based in part on the signal from the sensor.

18. A treatment device for toning muscles of a patient using time-varying magnetic fields, the treatment device comprising:

a first applicator configured to be coupled to a body region of the patient, wherein the first applicator houses a first magnetic field generation device, and wherein the body region comprises one or more of thighs, buttocks, or abdomen;

a second applicator configured to be coupled to the body region of the patient, wherein the second applicator houses a second magnetic field generation device;

a first energy storage device configured to be charged by an energy source;

a second energy storage device configured to be charged by the energy source;

means for discharging energy from the first energy storage device to the first magnetic field generating device and discharging energy from the second energy storage device to the second magnetic field generating device, respectively, such that a first time-varying magnetic field and a second time-varying magnetic field is generated, each of the time-varying magnetic fields comprising magnetic pulses,

wherein the device is configured to apply bursts of the magnetic pulses to muscle fibers, neuromuscular plates, or nerves innervating the muscle fibers, each burst comprising a first duration wherein a plurality of subsequent magnetic pulses are generated and a second duration wherein no magnetic pulses are generated, wherein the treatment duty cycle of the bursts is at least 10%, wherein the time-varying magnetic fields each comprise a magnetic flux density between 0.1 T and 7 T, a repetition rate between 1 Hz and 700 Hz, an impulse duration between 3 μs and 10000 μs, and a maximal value of a magnetic flux derivative between 2.5 kT/s and 150 kT/s.

19. The device of claim **18**, further comprising means for determining an unintended event has occurred in response to a signal from a sensor measuring one or more of voltage, current, phase shift, or magnetic flux density of a hardware component.

20. The device of claim **18**, further comprising means for evaluating a signal from a hardware component of the treatment device and for providing at least one maximal treatment parameter comprising one or more of magnetic flux density, repetition rate, and impulse duration to an operator in response to one or more treatment parameters set by the operator.

21. The device of claim **18**, wherein each of the magnetic field generating devices are configured to generate radiofrequency waves configured to be applied to the body region.

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