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(54) **METHODS AND SYSTEMS FOR SUBCUTANEOUS TREATMENTS**

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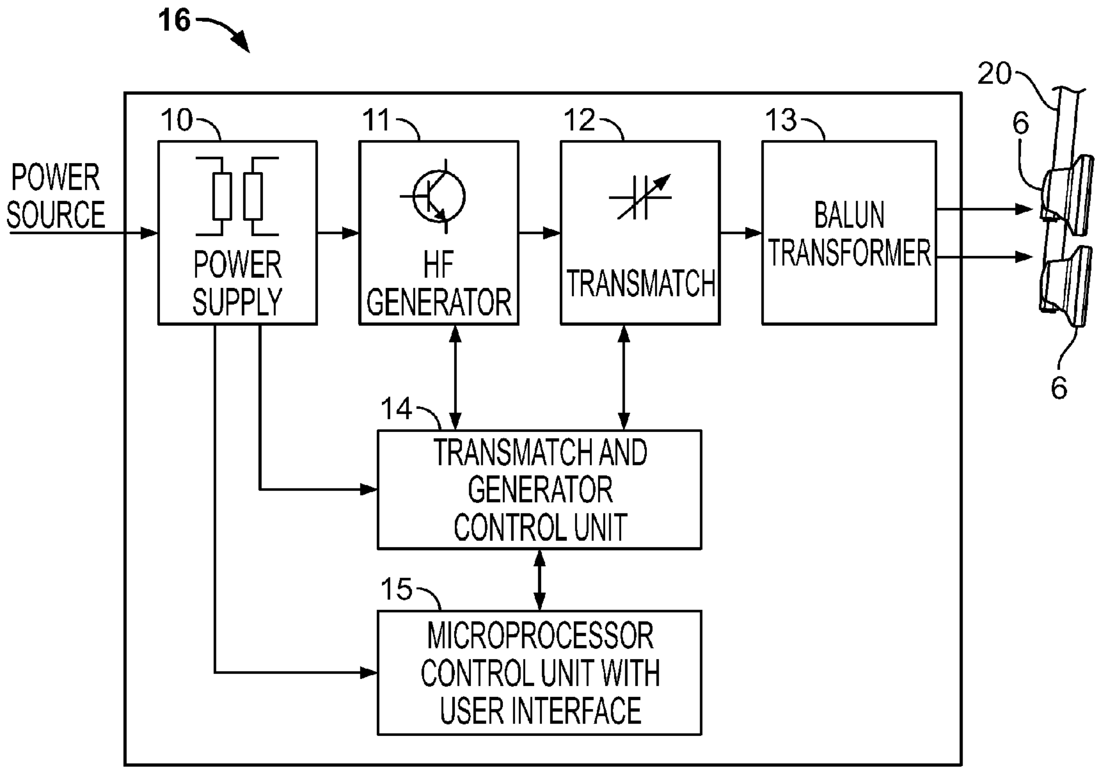
(57) **ABSTRACT**

Methods for focused remodeling and downsizing the volume of subcutaneous lipid-rich cells, body contouring, and tightening skin tissue, using controlled heating of the targeted areas on the body. The electromagnetic energy heats the subcutaneous tissues which provides the desired effect. The electromagnetic energy is applied via an applicator without continuously moving the applicator. A spacer of insulating or dielectric material may be provided between the applicator and the skin.



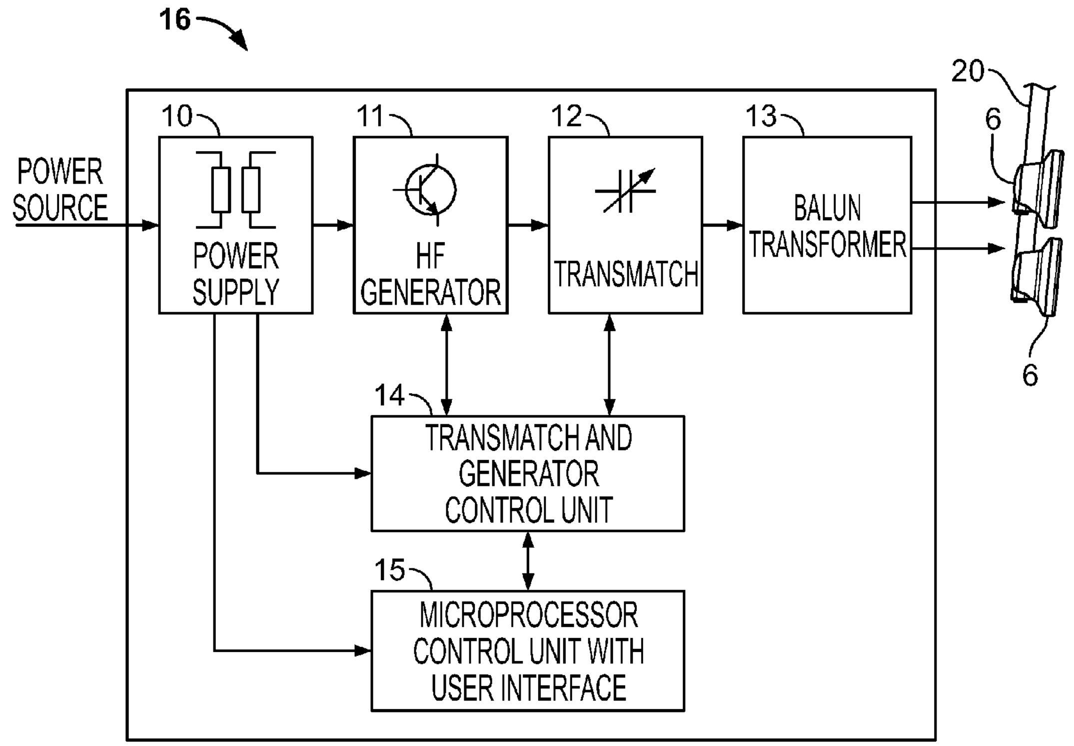
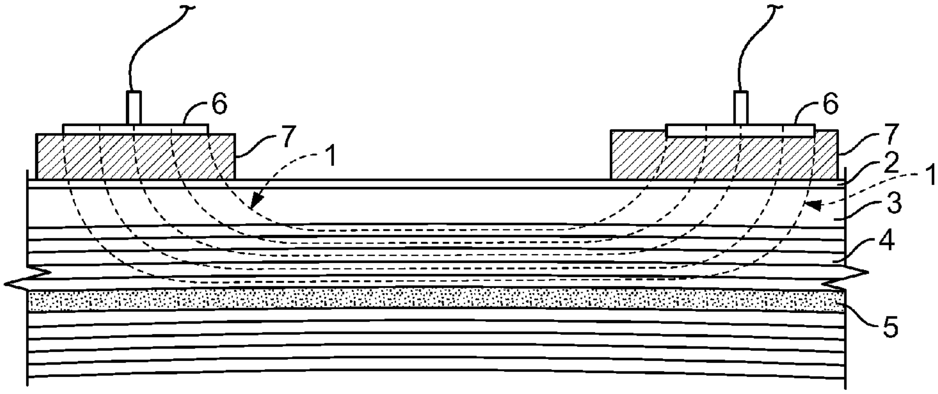

16
POWER
SOURCE
10
POWER
SUPPLY
11
HF
GENERATOR
12
TRANSMATCH
13
BALUN
TRANSFORMER
20
6
6
14
TRANSMATCH AND
GENERATOR
CONTROL UNIT
15
MICROPROCESSOR
CONTROL UNIT WITH
USER INTERFACE

FIG. 1


6
7
1
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2
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4
5

FIG. 2

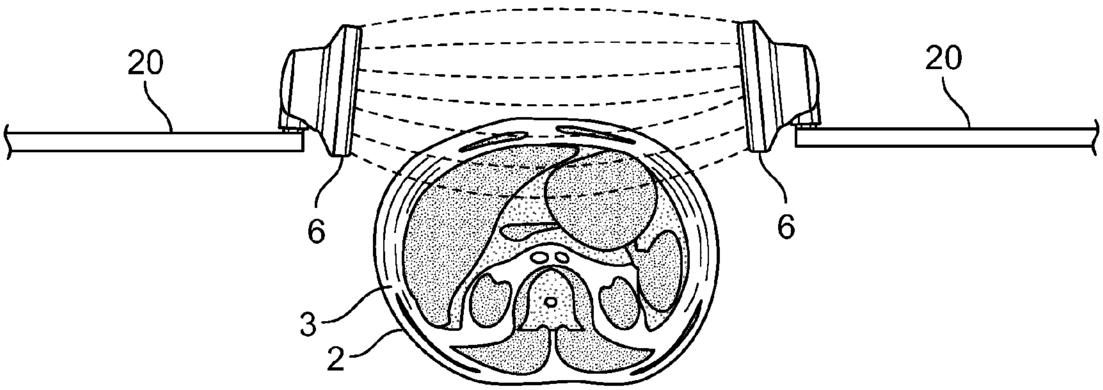

FIG. 3

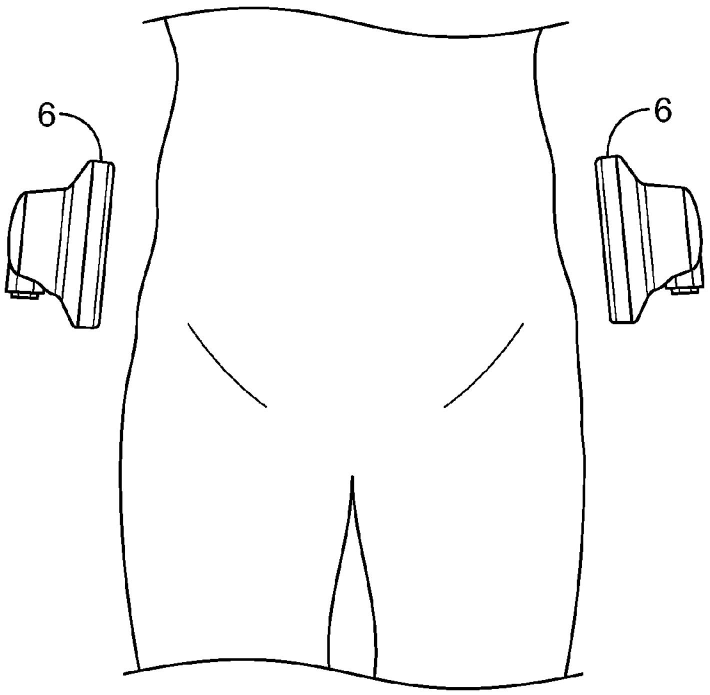

FIG. 4

METHODS AND SYSTEMS FOR SUBCUTANEOUS TREATMENTS

FIELD OF THE INVENTION

[0001] The field of the invention is non-invasive, non-traumatic focused remodeling and downsizing subcutaneous lipid-rich cells, body contouring and skin tightening. In particular, the invention relates to controlled heating of the targeted areas on the human body using electromagnetic waves without a need for continuous movement of an applicator or electrode.

BACKGROUND OF THE INVENTION

[0002] Human skin is composed of three basic elements: the epidermis, the dermis and the hypodermis or so called subcutis. The dermis consists of collagen, elastic tissue and reticular fibers. The hypodermis is the lowest layer of skin and contains hair follicle roots, lymphatic vessels, collagen tissue, nerves and also subcutaneous fat forming an adipose fat tissue. Adipose fat tissue is formed by aggregation of fat cells containing stored lipid (fat). Most fat tissue accumulations result from lipids (fat) primarily from food, when energy intake derived from food exceeds daily energy needs. This may result in an increase in fat cell size or fat cell number or both. Mature fat cells are very large, ranging up to 120 microns in diameter and containing as much as 95% lipid (fat) by volume. The subcutaneous adipose tissue layer may be thin (about 1 cm or less) or in humans of slight or moderate body type.

[0003] Excess adipose tissue may be perceived as aesthetically undesirable. Dieting and exercise may result in reduction of adipose tissue and weight loss. However, for most people, the reduction in adipose tissue volume occurs rather unpredictably from all anatomical areas. This can leave the areas intended for reduction, for example, the abdomen, largely unaffected, even after significant body weight loss. Various invasive and non-invasive methods have been developed to remove unwanted subcutaneous fat from specific areas of the body.

[0004] The main invasive method is surgical-assisted liposuction, where selected volumes of subcutaneous fat are mechanically aspirated out from the patient at desired anatomical sites of the body. However, liposuction procedures are invasive and can be painful and traumatic, with many undesirable side effects and risks. Lipodissolve is another invasive procedure involving a series of drug injections intended to dissolve and permanently remove small pockets of fat from various parts of the body. It also is known as mesotherapy, lipozap, lipotherapy, or injection lipolysis. Lipodissolve also has many disadvantages and risks, to the extent that various medical associations have issued health warnings against using it.

[0005] The non-invasive methods concentrate on the acceleration of the lipolysis as the natural process of the fat reduction. This can be achieved in several ways. One of them is application of pharmaceuticals accelerating the lipolysis. However, when applied topically they tend only to affect the outermost layers of the skin, rarely penetrating to the subdermal vascular plexus. Another method uses radio frequency or ultrasound energy focused on adipose tissue to cause cell destruction and death. These methods tend to damage the dead cellular and other debris. Non-invasive heating techniques have also been used. These involve heating the adipose fat tissue to about 40° C. or higher via direct contact with a heating element. These non-invasive methods have certain disadvantages as well, and have been used with varying degrees of success.

[0006] Accordingly, there is need for improved methods and systems for subcutaneous treatments.

SUMMARY OF THE INVENTION

[0007] New methods have now been invented. A method for treating subcutaneous tissue includes positioning one or more applicators adjacent to the skin of a patient, without a need for continuously moving the applicator. The applicator may be positioned so that it does not touch the skin. Electromagnetic energy is transmitted from the applicators into the subcutaneous tissue. The subcutaneous tissue is heated via the electromagnetic energy. The subcutaneous tissue may be remodeled. The volume of lipid-rich cells in the subcutaneous tissue may be reduced via the heating.

[0008] The electromagnetic waves may be applied in a pulsed mode or in a continuous mode. The skin may optionally be actively cooled, without contacting the skin. This method may also be used for tightening the skin and for remodeling collagen tissue in the subcutaneous tissue. The applicator may be spaced apart from the skin of the patient. There is no need to continuously move the applicator. One or more applicators may be supported on fixtures or holders, rather than hand-held. Exclusive and continuous attention to the treatment by an experienced user of the system may not necessarily be required.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. **1** is a schematic diagram of a system for controlled deep heating of sub dermal tissues.

[0010] FIG. **2** is a schematic view of a trans-regional course of electromagnetic field;

[0011] FIGS. **3** and **4** are schematic examples of positioning of electrodes shown in FIG. **1**.

DETAILED DESCRIPTION

[0012] Methods and apparatus for focused remodeling and downsizing the volume of subcutaneous lipid-rich cells, body contouring and tightening skin tissue, without contact with the skin, have now been invented. Prior art methods generally require direct contact of an applicator onto the skin. This in turn typically also requires use of active skin cooling elements. Direct skin contact can also raise bio-compatibility issues with the applicator material and further requires high sanitary standards, since the applicators are used for treatment of different patients. With the prior art methods, the practitioner must also continuously move the applicator, to reduce the risk of burning the patient.

[0013] These disadvantages are overcome by transmitting electromagnetic energy into the sub subcutaneous tissue, without physical contact with the patient, and without a need for continuous movement of the applicator. The step and repeat movements of the applicator over a grid pattern on the patient's skin is obviated. With the applicator applying heating over a larger area, constant movement of the applicator is not needed. The applicator may remain in a stationery posi-

Contactless application enables simultaneous treatment of large areas of human body. It also avoids the need for artificial cooling of the skin. In the present contactless methods, the skin may be sufficiently cooled passively by circulating air. Optionally, the skin may be cooled via a stream of chilled or room temperature air. The present methods also do not require use of cooling fluids and gels. This reduces costs and increases patient comfort.

[0014] In one aspect, the present methods work on the principle of selective deep heating of the human tissue containing low volume of water, such as adipose tissue. Radiant energy may be provided to the sub dermal tissue by one or more capacitive electrodes generating an electromagnetic field. Selective heating in the dermis occurs due to dielectric losses. An inductive electrode may alternatively be used.

[0015] In a continuous application mode, the electromagnetic field is applied continuously, which provides a maximum amount of heating. Using a pulse mode, the heat is local and typically limited to about 400 W. With the pulse mode, a high frequency field is applied in short intervals (typically (50-2000 μs) and at various pulse frequencies (typically 50 to 1500 Hz or pulses per second). The maximum Output during the continuous method is typically limited to 200 W.

[0016] The increase of the temperature in the dermal and the sub dermal tissues also affects the triple-helix structure of collagen fibers contained in such tissues. This may result in remodeling and rejuvenation of collagen, increase of skin density and dermal thickening based on neocollagenesis. Skin tightening may also be achieved.

[0017] Remodeling and reducing the volume of subcutaneous lipid-rich cells, and skin tightening in the targeted areas, can change the overall appearance of the body, for use in body contouring and body reshaping.

[0018] Electromagnetic energy is provided through the skin to the underlying sub dermal tissue, without contacting the skin. The radiant energy is converted into heat in the sub dermal tissue. The radiant energy enables focused heating of the subcutaneous adipose tissue and sub dermal collagen tissue, leading to accelerating lipolysis. At the same time the triple-helix structure of collagen fibers may result in remodeling and/or rejuvenation of collagen, increase of skin density and dermal thickening based on neocollagenesis. Subcutaneous lipid-rich cells may be remodeled and/or reduced in volume, contouring and tightening skin tissue.

[0019] Referring now to FIG. **1**, a system **16** applies electromagnetic energy through a skin layer, such as the epidermis, and to the underlying sub dermal tissue, and underlying collagen tissue, causing acceleration of lipolysis and collagen remodeling. The system may include 6 blocks. The power supply **10** is connected to a power source. An HF generator (high frequency generator) **11** and a transmatch and generator control unit **14**, and a microprocessor control unit with user interface **15**, are connected to the power supply **10**. The HF generator **11** may generate an electromagnetic field at 13.56 or 40.68 or 27.12 MHz, or 2.45 GHz, or optionally at other frequencies as well. The 13.56, 27.12 and 40.68 MHz and 2.45 GHz frequencies avoid creating radio interference, as these frequencies are exclusively assigned as free frequencies.

[0020] The microprocessor control unit with user interface **15** provides communication between the transmatch and gen-

[0021] 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 approximately 2-3 cm above the surface of the skin or applied on dielectric material which is in contact with the skin surface.

[0022] FIG. **2** is a schematic representation of a heat distribution under the skin. One or more applicators **6** create an electromagnetic field. This electromagnetic field crosses through the skin **2**, subcutaneous fat **3** and muscle **4** or the bone **5**. Capacitive applicators **6** provide deep heating, which heats selectively only structures with low volume of water. A spacer **7** of a dielectric or non electrically conductive material, such as a towel, gauze pad, foam pad, cloth pad, etc. may be placed on the skin, with the applicator then placed on top of the spacer **7**.

[0023] A selective heating process is observed in the dermis **3** due to dielectric losses. Dielectric loss is created as part of an AC electromagnetic field power is converted to heat in the dielectric. During this process, polar molecules rotate, and their movement produces the thermal energy. Skin and muscle are largely not affected by electromagnetic field **1** as they contain water and the blood circulation provides for cooling. Bone **5** gets little if any heating because the applicators **6** are positioned to create a field only on the upper structures. The lipid cells of the adipose tissue contain less water than the surrounding tissue and are therefore heated at higher level than the surrounding tissue.

[0024] FIGS. **3** and **4** are schematic examples of positioning of the applicators or electrodes **6** providing radiant energy through the skin **2** to subcutaneous fat **3**. The electrodes are positioned approximately 2-3 cm above the surface of the skin or placed onto a spacer **7** which is in contact with the skin surface, as shown in FIG. **2**. The spacer **7**, if used, may correspondingly be 0.5 to 1 cm thick. The applicator **6** may be temporarily fixed in position relative to the patient, if desired, for example on a mechanical fixture or holder **20**. The fixture **20** may be a rigid bracket, a flexible gooseneck arm, an adjustable position arm, etc. Two or more applicators may be supported on a single fixture **20** or on separate fixtures.

[0025] It is not necessary in each instance for the applicator to be continuously moving during the procedure. This makes the procedure easier to perform, since user need not constantly keep moving the applicator over the patient's skin. Consequently, the user can accordingly simultaneously attend to other needs of a patient. The applicator **6** may have a relatively large surface area, so that the field **1** is distributed more widely through the subcutaneous tissue. For example, the applicator may have a surface area of at least about 15, 30, 50, 75, 100 or 150 cm^2.

[0026] Methods may include one or more of the following steps: positioning a spacer in between the applicator and the skin of the patient; transmitting electromagnetic energy in the range of 13.553-13.567 or 26.957-27.83 or 40.66-40.70 MHz or 2.4-2.5 GHz from the applicator into the subcutaneous tissue; and placing or holding the applicator in a fixed position relative to the tissue for at least 60 seconds; optionally with the applicator not touching the skin of the patient. If two or more applicators are used, the applicators may be positioned

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