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METHOD AND APPARATUS FOR TREATMENT OF SKIN USING RF AND ULTRASOUND ENERGIES

FIELD OF THE INVENTION

The invention relates to non-invasive treatments of human tissue and more specifically to such treatments of skin.

BACKGROUND OF THE INVENTION

5 Skin rejuvenation is a medical aesthetic treatment in which energy is applied to selected areas of the skin surface and/or to subcutaneous layers of the skin in order to achieve an improvement in the appearance of the treated skin. The most popular form of skin rejuvenation is the application of an amount of energy to the skin to heat target tissue to temperatures sufficiently above normal body temperature to induce desired
10 effects in the tissue. The effects may be tissue damage, coagulation, ablation, destruction and necrosis. The specific effects achieved depend on the tissue, the temperature, and the period of time the tissue is maintained at the high temperature. This treatment improves the appearance of the skin by tightening the skin and reducing wrinkles, and by promoting regeneration in the skin layers and subcutaneous tissue.

15 Non-invasive delivery of energy to internal tissues has been done by directing electromagnetic energy or ultrasound energy to the skin surface. Electromagnetic radiation from a broad range of wavelengths has been used for heating the skin, including optical radiation, frequencies above 30GHz, frequencies between 300MHz to 30GHz, and radio frequency (RF) energy. Typical RF frequencies used for skin
20 treatment are between 100kHz and 10MHz. The technology, propagation through the body, interactions with the skin, and the effects on tissues are different for each part of the spectrum. Simultaneous application of optical energy and RF energy has also been used to treat skin.

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US Patent No. 5,405,368 discloses the use of flash lamps for skin treatment. US Patent No. 5,964,749 describes a method and apparatus for treating skin which includes applying pulsed light to the skin to heat the skin in order to effect shrinking of collagen within the skin, thereby restoring the elasticity of the collagen and of the skin.

5 The epidermis and outer layers of the skin may be protected by cooling with a transparent substance, such as ice or gel, applied to the skin surface. The temperature distribution within the skin is controlled by controlling the delay between the time the coolant is applied, and the time the light is applied, by controlling the pulse duration, applying multiple pulses, filtering the light and controlling the radiation spectrum.

10 Preferably, the spectrum includes light having a wavelength in the range of 600-1200 nm. The pulsed light may be incoherent, such as that produced by a flashlamp, or coherent, such as that produced by a laser, and may be directed to the skin using a flexible or rigid light guide. US Patent Nos. 6,662,054 and 6,889,090 disclose the application of RF energy for subcutaneous treatment. US Patent No. 6,702,808

15 discloses a combination of light and RF energy for skin treatment. US Patent No. 5,871,524, describes application of radiant energy through the skin to an underlying subcutaneous layer or deeper soft tissue layers.

The main limitation on non-invasive skin treatment is the ability to transfer the energy through the outer layers of the skin and concentrating it to the required level in

20 the target tissue, with minimal collateral damage to the surrounding tissue, including the tissue through which the energy must pass on its way to the target tissue. The solutions are based either on selective cooling or focusing of radiation. Focusing is possible when the wavelengths are sufficiently short, for example with optical radiation, millimeter and sub-millimeter waves, and high frequency ultrasound. Optical radiation is scattered

25 inside the skin, so it is difficult to focus efficiently. Laser light is preferred in order to enable better focusing. US Patent No. 5,786,924 discloses a laser system for skin treatment. Published U.S. Patent Application No. 10/888356 to De Benedictis et al., having the publication number 2005/0049582, discloses using one or more light sources to generate microscopic treatment zones in skin in a predetermined pattern. The

30 advantage of this approach is that the damaged tissue is localized to small volumes surrounded by healthy tissue, so that skin regeneration is faster.

High intensity focused ultrasound (HIFU) technology for non-invasive skin treatment is disclosed, for example, in US Patent Nos. 6,325,769 and 6,595,934. The

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last patent discloses the application of an array of focused ultrasound transducers, which generates an array of lesions in the skin or subcutaneous layers, with advantages similar to those disclosed in the above mentioned US Patent Application Publication 2005/0049582 but with minimal damage to the outer skin layer due to the focusing of the radiation. The resolution of the focusing of electromagnetic energy is limited by diffraction laws to about half of the wavelength. For less than a 0.5 mm focal dimension, a wavelength shorter than 1 mm is required. Although the application of electromagnetic energy at sub-millimeter wavelengths may have several advantages, generating sub-millimeter radiation is impractical for skin treatment due to its high cost.

10 In RF applications, voltages and currents can be induced in body tissues by applying electrodes to the skin surface, which do not propagate as waves but rather fall into the quasi-static regime of the Maxwell equations. RF applications for non-invasive skin treatment are disclosed, for example, in US Patent Nos. 6,662,054, 6,889,090, 5,871,524. Typical RF frequencies used are between 100kHz and 10MHz. At these frequencies, the wavelength, which is between 3000 m and 30 m is much larger than any relevant dimension of the treated tissue. An AC current is induced in the skin by the applied AC voltage, generally obeying Ohm's law. RF technology is relatively simple and inexpensive, and very effective in transferring energy to a tissue. However it is difficult to localize it to a specific tissue layer. One method to generate selectivity is by cooling the skin surface, thereby creating a temperature gradient from the outside to the internal layers. Such a method is disclosed in US Patent No. 5,871,524.

SUMMARY OF THE INVENTION

The present invention provides a method and an apparatus for non-invasive treatment of skin and subcutaneous layers. In accordance with the invention, acoustic energy at ultrasound wavelengths is directed to the skin surface. The ultrasound energy is focused onto one or more tissue volumes referred to herein as "*focal volumes*" in the skin or subcutaneous layer, below the skin surface. This provides a heating of the tissue at the focal volumes of the ultrasound energy. RF energy is also applied to the skin. According to preferred embodiments of the present invention, the ultrasound energy is preferably applied first and the RF current is then guided into the focal volumes preheated by the ultrasound energy. Without wishing to be bound by a particular theory, it is believed that this guiding effect is based on the temperature dependence of RF

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conductivity on temperature. In the temperature range of 20-90° C, and for RF frequencies between 100 kHz and 100 MHz, there is a positive slope of tissue electrical conductivity versus temperature (see for example, "*Physical Properties of Tissue*", by Francis A. Duck, Academic Press Ltd., 1990, p.200). This positive slope generates a
5 positive feedback effect, in which the preheated volumes have higher RF conductivity, therefore the RF current and energy deposition is higher in the preheated volumes which further raises the higher temperature of the focal volumes, which increases the conductivity even further.

In one preferred embodiment of the invention, for each pair of RF electrodes
10 applied to the skin surface, at least one focused ultrasound source is applied between the electrodes. In another preferred embodiment, a single focal volume of the ultrasound source is created extending between the RF electrodes, to produce a guiding channel for the RF current.

Preferred frequencies of the RF energy are between 100kHz and 100MHz, and
15 more preferred between 100kHz and 10MHz. Preferred ultrasound frequencies are between 500kHz and 50MHz, more preferred between 1MHz to 20MHz.

According to preferred embodiments, the apparatus of the invention preferably includes cooling means to lower the initial temperature of the treated area prior to the application of the energy sources, and/or to lower the temperature of the treated area as
20 treatment proceeds. This leads to a larger temperature gradient between focal volumes to be heated and the remainder of the treated area. This allows heating of the focal volumes while avoiding excessively high temperatures in the tissues surrounding the focal volumes, which might damage the tissue there. Optionally, the apparatus may comprise cooling for the ultrasound transducer, in addition to or in place of the cooling
25 means for lowering the temperature of the treated area.

The RF and ultrasound energy are preferably applied for a short time duration, preferably as a pulse or a train of pulses (or several pulses), in order to reduce loss of heat from the focal volumes by conduction or convection. Application times for the ultrasound energy are preferably between 1 msec and 10 sec, more preferably between
30 10 msec and 1 sec.

According to other preferred embodiments of the present invention, application of the RF energy preferably follows application of the ultrasound energy although optionally the ultrasound and RF applications may be made in a reverse order or

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alternatively the ultrasound and RF may optionally be applied with some overlap or even substantially simultaneously. The RF energy is preferably applied for times between 10 msec and 1 sec.

The temperature generated at the focal volumes by the energy sources and the
5 time of heating are selected so that adequate heating of the focal volumes is obtained, while heating of surrounding tissues is minimal. The focal volumes are preferably heated to a temperature from about 50 ° C to about 90° C. At the lower end of this temperature range, tens of seconds may be needed to obtain a substantial effect and at the higher end of the range, sub-second heating may be sufficient. Damage to
10 surrounding tissues might occur at temperatures close to and above 44° C when the heating times are long, (e.g. tens of minutes). A temperature of 44° C is also known as the threshold temperature for human pain perception. A more preferred time range, for the treatment is about few seconds or less, to prevent substantial heat flow from the focal volumes during the treatment. For that time range the preferred temperature range
15 for effecting damage to the selected tissue is from about 44 ° C to about 70 ° C, more preferably from about 60 ° C to about 70° C.

Thus according to preferred embodiments of the present invention, there is provided a system for treating skin comprising:

one or more ultrasound transducers adapted to focus ultrasound energy at
20 one or more focal volumes in the skin;
one or more pairs of RF electrodes adapted to deliver RF energy to the one or more focal volumes.

According to other preferred embodiments of the present invention, there is provided a method for treating skin comprising:

25 heating the skin to a first temperature at one or more focal volumes in the skin; and
heating the one or more focal regions to a second temperature, the second temperature being higher than the first temperature;
wherein said heating of the skin to said first and second temperatures
30 comprises focusing ultrasound energy at the one or more focal volumes and generating an RF current in a region of the skin containing the one or more focal regions.

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BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

5 **Fig. 1** shows a system for treating skin in accordance with one embodiment of the invention;

Fig. 2 shows an exemplary embodiment of an applicator for use in the system of Fig. 1;

Fig. 3 shows another exemplary embodiment of an applicator for use in the
10 system of Fig. 1; and

Fig. 4 shows a third exemplary embodiment of an applicator for use in the system of Fig. 1.

DETAILED DESCRIPTION OF THE INVENTION

15 It should be noted that the figures are all schematic, such that the actual physical implementation of the system and/or apparatus according to the present invention, and/or such features as the focal zone, may appear different than that shown in the figures.

 Fig. 1 shows a system for applying ultrasound and RF energies to skin tissue in
20 accordance with preferred embodiments of the present invention. An applicator **3**, to be described in detail below, contains one or more pairs of RF electrodes and one or more ultrasound transducers. The applicator **3** is adapted to be applied to the skin of an individual **5** in a region of skin to be treated. The applicator **3** is connected to a control unit **1** via a cable **2**. The control unit **1** includes a power source **8**. The power source **8**
25 is connected to an RF generator **15** that is connected to the RF electrodes in the applicator **3** via wires in the cable **2**. The power source **8** is also connected to an ultrasound driver **6**. The driver **6** is connected to the transducers via wires in the cable **2**. The control unit preferably contains a refrigeration unit **13** that optionally and preferably cools a fluid such as ethanol or water for cooling the applicator **3**. The
30 cooled fluid preferably flows from the refrigeration unit **13** to the applicator via a first tube in the cable **2**, and flows from the applicator **3** back to the refrigeration unit via a second tube in the cable **2**. The control unit **1** contains a processor **9** for monitoring and

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controlling various functions of the device. The control unit **1** has an input device such as a keypad **10** that allows an operator to input to the processor **9** selected values of parameters of the treatment, such as the frequency, pulse duration and intensity of the RF energy or the duration and intensity of the ultrasound energy or the depth of the focal volume below the skin surface. According to preferred embodiments, the processor may be configured to activate the ultrasound transducer for a first predetermined amount of time and then to apply an RF voltage to the RF electrodes for a second predetermined amount of time, although optionally the order may be reversed or the RF energy may overlap the ultrasound transducer activity. The RF energy may be delivered to the skin surface before termination of the ultrasound energy, or the ultrasound energy may persist during at least part of the time that the RF energy is applied. The processor **9** may also monitor the electrical impedance between the electrodes in the applicator **3**, and determine the temperature distribution in the vicinity of the target. The processor may also determine the parameters of the treatment based upon the impedance measurements.

Fig. 2 shows the applicator **3** in greater detail in accordance with one exemplary embodiment of the invention. The applicator **3** is shown in Fig. 2 applied to a skin surface **11**. Layer **10** is the epidermis, **12** is the dermis and **14** is the subcutaneous tissue. The applicator **3** includes a pair of RF electrodes **21** and **22** that are connected to the RF generator (not shown, see Figure 1) via wires **17** in the cable **2**. The applicator **3** also includes an ultrasound transducer **24** that is located in the applicator **3** and is connected to the driver (not shown, see Figure 1) via wires **19** in the cable **2** so as to focus ultrasound radiation at one or more focal volumes **30** in the dermis **12**. According to preferred embodiments, the applicator **3** contains a cooling coil that conducts a coolant from the refrigeration unit (not shown, see Figure 1) via a first tube **20a** in the cable **3** to the skin surface **11** and from the skin surface **11** back to the refrigeration unit (not shown, see Figure 1) via a second tube **20b** in the cable **3**.

In accordance with an exemplary but preferred embodiment of a method of the present invention, the applicator **3** is applied to the skin surface **11**. Preferably, an ultrasound liquid gel is applied between the ultrasound transducer **24** and the skin surface **11** to facilitate acoustical matching and good energy transfer, and a conductive liquid or gel **111** is applied between the RF electrodes **21** and **22** and the skin surface **11** to reduce contact resistance. Ultrasonic radiation from the transducer **24** is focused at

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the one or more focal volumes **30** located in the dermis layer **12**. The ultrasound energy raises the temperature at the focal volumes above that of tissue volumes **31** surrounding the focal volumes. The normal dermal temperature is typically around 34° C, and with the ultrasound heating of the focal volumes **30**, the temperature of the focal volumes rises. The slope of the electrical conductivity versus temperature is about 2-3° C. Thus, if the selected zone is heated by ultrasound to 10° C above the normal dermal temperature, the electrical conductivity of the zone rises by 20-30%. An RF voltage is then applied from the RF generator (not shown, see Figure 1) to the electrodes **21** and **22**, so that an RF current **32** flows between electrodes **21**, **22**, through the tissue layers **10**, **12**, **14**, with more current flowing through the pre-heated focal volume **30** due to its higher conductivity. The preferred spacing between the RF electrodes **21** and **22** is 0.2 cm to 2 cm, and more preferably, 0.5 cm to 1 cm. With a spacing of 1 cm between the electrodes, a typical voltage of 20 to 1000 Vrms, and more preferably 50 to 200 Vrms may be used. Lower voltages are required with smaller electrode spacing. For RF frequencies between 100kHz and 100MHz, the electromagnetic wavelength is much larger than the inter-electrode spacing. Also, the typical skin conductivity at these frequencies is about 0.5S/m (see for example, S. Gabriel, R.W. Lau, and C. Gabriel, Phys. Med. Biol. vol 41 (1996), pp 2251-2269). For 10MHz and 0.5S/m the electromagnetic skin depth is 22cm, much larger than the thickness of the human skin layer which is less than one centimeter. Under these conditions the current distribution is almost identical to the static solution obtained by Ohm's Law, $\mathbf{J} = \sigma \mathbf{E}$, where $\mathbf{J}$ is the current density and $\mathbf{E}$ is the electric field vector. The power delivered to a unit volume of tissue by the current is $\mathbf{J} \cdot \mathbf{E} = \sigma E^2$. The rate of increase of temperature increase is proportional to the power, and thus proportional to the conductivity, a positive feedback effect is generated since the conductivity increases with temperature.

The ultrasound transducer **24** may generate a single elongated focal zone **30**, extending between the RF electrodes as shown in Fig. 2.

Fig. 3 shows another exemplary embodiment of the applicator **3**. The embodiment of Fig. 3 has elements in common with the embodiment of Fig. 2, and similar elements are indicated by the same reference numeral in Figs. 2 and 3, without further comment. In the embodiment of Fig. 3, the applicator includes three ultrasound transducers **43** (shown as transducers **43a**, **43b** and **43c**) that generate three spaced about focal volumes **33** (shown as focal volumes **33a**, **33b** and **33c**, respectively). Each

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ultrasound transducer **43a**, **43b** and **43c** is connected to a driver or drivers (not shown; see Figure 1) through wires **19**, shown as wires **19a**, **19b** and **19c** respectively. This illustration of three transducers **43** is by way of example only, without intention to be limiting in any way, and the applicator **3** may include any number of spaced apart
5 ultrasound transducers **43**, generating an equal number of focal volumes **33**. The ultrasound transducers **43** have focal volumes **33** in the dermal layer **12**. Heating of these focal volumes by the ultrasound energy heats the tissue to be treated which thus forms a guide channel for the RF energy, which further heats the tissue to the desired temperature. In this embodiment, a single pair of RF electrodes preferably provides RF
10 energy to all of the focal volumes **33** (in the section shown in Fig. 3, only a single RF electrode **21** is visible, although in this exemplary but preferred embodiment applicator **3** includes a second RF electrode that is not visible in this section). It should be noted that preferably a conductive liquid or gel is again applied between the RF electrodes and the skin surface **11** to reduce contact resistance, as in Figure 2, but is not shown.

15 In another exemplary embodiment of the applicator, as shown in Fig. 4, each ultrasound transducer **44** is located between a respective pair of RF electrodes **28**, **29**. Figure 4 does not include all features of the applicator for the sake of clarity only and without intention of being limiting in any way; features of the applicator that are not shown may optionally and preferably be implemented as for Figures 1-3. As an
20 illustrative example only and without wishing to be limiting in any way, the applicator is shown as comprising three ultrasound transducers **44** (shown as transducers **44a**, **44b** and **44c**), each of which is located between a respective pair of RF electrodes **28**, **29** (shown as RF electrodes **28a**, **28b** and **28c**, and **29a**, **29b** and **29c**, respectively). The plurality of ultrasound transducers can be driven altogether by a single power supply, or
25 each one driven independently. This also applies to the RF electrodes. A single pair of electrodes driven by a single RF power supply, or a plurality of RF electrode pairs, each pair being driven independently. Each ultrasound transducer **44** and its respective RF electrodes **28**, **29** are preferably matched in two respects: a. Space matching – the electric field generated by the RF electrode should cover the focal volume of the
30 ultrasound transducer. b. Time matching between the application of the ultrasound energy and application of the RF energy, namely, starting with application of the ultrasound energy to the focal volumes and immediately follow with the application of RF energy to the skin.

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The focal volume, in the direction normal to the skin surface, is preferably continued within the deeper layer of the epidermis, the dermis layer and part of the subcutaneous layer, so that the skin surface is not damaged, that is, between 0.2 mm and 5 mm deep, more preferably, between 0.2 mm to 2 mm. The lateral width of the focal zone may be 0.05 mm to 1 mm, more preferably from 0.1 mm to 0.3 mm. The lateral spacing between focal volumes is preferably between 0.3 mm to 3 mm, more preferably from 0.5 mm to 1 mm. In the longitudinal direction, which is that of the guiding channel between the RF electrodes, the length of the focal volumes may be 1 mm to 20 mm, more preferred 3 mm to 10 mm.

10 While Fig. 4 shows cylindrical ultrasound transducers having cylindrical focal volumes, other geometries are possible. An ellipsoidal focal zone may be generated with a hemispherical transducer or with flat a transducer and an acoustical lens. For this focal geometry, a plurality of RF electrodes can be applied, with a 1-dimensional or 2-dimensional structure of interlacing RF electrodes and ultrasound transducers.

15 According to other preferred embodiments of the present invention, the ultrasound transducer is optionally and preferably cooled by a cooling unit, which may optionally comprise any cooling mechanism or mechanisms that are known in the art and which could easily be constructed and/or selected by one of ordinary skill in the art, including but not limited to, a heat sink, a TEC (thermoelectric cooler) and/or other cooler (such as a cooler featuring a chilled liquid, including but not limited to water, 20 ethanol, oil or a combination thereof). The heat sink itself may optionally be air cooled, but alternatively and preferably is cooled by a liquid such as water for example. The heat sink may optionally be purchased from various commercial suppliers, such as ThermaFlo Inc., (Newbury Park, California, USA) by way of example only and without 25 intending to be limiting. The TEC may optionally be purchased from various commercial suppliers, such as Marlow Industries, Inc. (Dallas, TX, USA) by way of example only and without intending to be limiting.

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CLAIMS:

1. A system for treating skin comprising:
 - (a) one or more ultrasound transducers adapted to focus ultrasound energy at one or more focal volumes in the skin;
 - 5 (b) one or more pairs of RF electrodes adapted to deliver RF energy to the one or more focal volumes.
2. The system according to Claim 1 further comprising a processor configured to:
 - (a) activate the one or more ultrasound transducers for a first
10 predetermined amount of time and
 - (b) apply an RF voltage to the RF electrodes for a second predetermined amount of time.
3. The system of claim 2, wherein said first predetermined period of time occurs before said second predetermined period of time.
- 15 4. The system of claim 2, wherein said first and second predetermined periods of time overlap at least partially.
5. The system of claim 4, wherein said first and second predetermined periods of time occur substantially simultaneously.
6. The system according to Claim 2 further comprising an input device for
20 inputting one or more parameters of the treatment of the processor.
7. The system according to Claim 6 wherein the one or more parameters are selected from a frequency of the RF voltage, an intensity of the RF voltage, a duration of the RF energy, an intensity of the ultrasound region, a depth below the skin surface of the focal regions.
- 25 8. The system according to Claim 7 wherein the RF energy is between 100 KHz and 100 MHz.
9. The system according to Claim 7 wherein the ultrasound energy has a frequency between 500 KHz and 50 MHz.
10. The system according to Claim 2 wherein the processor is configured to
30 apply RF energy in a train of one or more pulses.
11. The system according to Claim 2 wherein the processor is configured to apply an RF voltage to the RF electrodes for an amount of time between 1 sec and 10 sec.

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12. The system according to Claim 2 wherein the processor is configured to activate the ultrasound transducer for an amount of time between 1 sec and 10 sec.
- 5 13. The system according to Claim 1 wherein the ultrasound transducer is configured to focus ultrasound energy to one or more focal volumes located in a dermis layer of the skin.
14. The system according to Claim 1 further comprising a cooling system for cooling the skin surface.
- 10 15. The system according to Claim 1 further comprising an applicator adapted to be applied to the skin surface, the application containing the ultrasound transducer and the RF electrodes.
16. The system according to Claim 15 wherein at least one pair of RF electrodes and at least one ultrasound transducer are contained in an applicator in which at least one ultrasound transducer is located between a pair of RF electrodes.
- 15 17. The system according to Claim 1 wherein one or more of the focal volumes are located between 0.2 mm and 5 mm below the skin surface.
18. The system according to Claim 17 wherein one or more of the focal volumes are located between 0.2 mm to 2 mm below the skin surface.
- 20 19. The system according to Claim 1 wherein the lateral width of one or more of the focal zones is between 0.05 mm to 1 mm.
20. The system according to Claim 19 wherein the lateral width of one or more of the focal zones is between 0.1 mm to 0.3 mm.
21. The system according to Claim 1 wherein the lateral spacing between focal volumes is between 0.3 mm to 3 mm.
- 25 22. The system according to Claim 21 wherein the lateral spacing between focal volumes is between 0.5 mm to 1 mm.
23. The system according to Claim 1 wherein the length of the focal volumes between the RF electrodes is between 1 mm to 20 mm.
- 30 24. The system according to Claim 23 wherein the length of the focal volumes between the RF electrodes is between 3 mm to 10 mm.
25. A method for treating skin comprising:
- (a) heating the skin to a first temperature at one or more focal areas in the skin; and

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- (b) heating the one or more focal areas to a second temperature, the second temperature being higher than the first temperature;
wherein said heating the skin to said first temperature and to said second temperature comprises focusing ultrasound energy at one or more focal volumes and generating an RF current in a region of the skin containing one or more focal regions.
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26. The method of claim 25, wherein said heating the skin to said first temperature comprises focusing ultrasound energy at one or more focal volumes, and said heating the skin to said second temperature comprises generating said RF current to said region of the skin containing one or more focal regions.
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27. The method according to Claim 25 wherein the second temperature is from about 44°C to about 70°C.
28. The method according to Claim 25 wherein the RF current has a frequency between 100 KHz and 100 MHz.
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29. The method according to Claim 25 wherein the ultrasound energy has a frequency between 500 KHz and 50 MHz.
30. The method according to Claim 25 wherein the RF energy is applied in a train of one or more pulses.
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31. The method according to Claim 25 wherein the RF current is generated for an amount of time between 10msec and 10 sec.
32. The method according to Claim 25 wherein the ultrasound energy is focused on the one or more focal regions for an amount of time between 10 msec and 10 sec.
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33. The method according to Claim 25 wherein the one or more focal regions are located in a dermal region of the skin.
34. The method according to Claim 25 further comprising cooling the skin surface.
35. The method according to Claim 25 wherein one or more of the focal volumes are located between 0.2 mm and 5 mm below the skin surface.
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36. The method according to Claim 35 wherein one or more of the focal volumes are located between 0.2 mm to 2 mm below the skin surface.

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37. The method according to Claim 25 wherein the lateral width of one or more of the focal zones is between 0.05 mm to 1 mm.
38. The method according to Claim 37 wherein the lateral width of one or more of the focal zones is between 0.1 mm to 0.3 mm.
- 5 39. The method according to Claim 25 wherein the lateral spacing between focal volumes is between 0.3 mm to 3 mm.
40. The method according to Claim 39 wherein the lateral spacing between focal volumes is between 0.5 mm to 1 mm.
41. The method according to Claim 25 wherein the length of the focal volumes
10 between the RF electrodes is between 1 mm to 20 mm.
42. The method according to Claim 41 wherein the length of the focal volumes between the RF electrodes is between 3 mm to 10 mm.