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Physics Procedia 70 (2015) 1148 – 1151

Physics Procedia

2015 International Congress on Ultrasonics, 2015 ICU Metz

New Combinational Method for Noninvasive Treatments of Superficial Tissues for Body Aesthetics Applications

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Abstract

The paper introduces an innovative combinational treatment method based on ultrasonic standing waves (USW) technology for noninvasive surgical, therapeutic, lypolitic or cosmetic treatment of tissues including subcutaneous adipose tissue, cellulite or skin on arbitrary body part of patient. The method is based on simultaneous or successive applying of constructively interfering physically and biologically sensed influences: USW, ultrasonic shear waves, radio-frequency (RF) heating, and vacuum massage. The paper provides basic physical principles of USW as well as critical comparison of USW and HIFU methods. The results of finite-elements and finite- difference modeling of USW transducer design and nodal pattern structure in tissue are presented. Biological effects of USW-tissue interaction and synergetic aspects of USW and RF combination are explored. Combinational treatment transducer designs and original in-vitro experiments on tissues are described.

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Peer-review under responsibility of the Scientific Committee of ICU 2015

Keywords: combinational treatment, ultrasonic standing waves, radio-frequency heating, vacuum massage, body aesthetics.

1. Introduction

Systems and methods for performing a surgical, therapeutic or aesthetic medical procedure in target tissues of patient's body by using HIFU are well known in the art (Hill *et al.*, 2004). The HIFU systems are used particular for body aesthetic therapy by adipose tissue lysis (Rybyanets, 2010). The main disadvantage of HIFU application for treatment of large volumes of tissue is small treated volume in lateral direction. Other drawback of conventional HIFU treatments of tissue is a restricted number of body areas suitable for treatment because of low fat thickness, complex body shapes, and close proximity of bones or vital organs elsewhere in the body.

Therefore the need exists for new methods and devices aimed at treatment of large volumes of tissue, as for

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Peer-review under responsibility of the Scientific Committee of ICU 2015
doi:10.1016/j.phpro.2015.08.246

example in the case of removing significant amounts of adipose tissue from arbitrary body parts. The need also exists for devices and methods for treating the skin and subcutaneous adipose tissue region using ultrasound energy, wherein the ultrasound energy is applied in a more efficient, safe and effective manner (Rybyanets *et al.*, 2010).

Recently, an ultrasonic standing waves (USW) method and device were proposed (Sarvazyan *et al.*, 2009; Rybyanets, 2012) as alternative to HIFU, for noninvasive or minimally-invasive lypolitic, therapeutic or cosmetic treatment of large volumes of tissues including subcutaneous adipose or skin tissue on any desired body areas of patient. The method uses an ultrasonic resonator arranged to generate an ultrasound standing wave field at various resonance frequencies in the target tissue temporarily positioned within that resonator. Dynamics of temperature changes in the tissue under the action of a standing ultrasound wave, which is important for optimizing tissue treatment regimes, were evaluated theoretically and proved experimentally in (Sarvazyan *et al.*, 2009).

In this paper, an innovative combinational treatment method based on ultrasonic standing waves (USW) technology for noninvasive surgical, therapeutic, lypolitic or cosmetic treatment of tissues including subcutaneous adipose tissue, cellulite or skin on arbitrary body part of patient is introduced.

2. Method and Apparatus

The method is based on simultaneous or successive applying of constructively interfering physically and biologically sensed influences: USW, ultrasonic shear waves, radio frequency (RF) heating, and vacuum massage. Unlike all existing HIFU and non-focused systems, ultrasound energy in USW directed parallel to the body surface and fully localized in treated body region. Resulting USW efficiency is comparable with HIFU at huge increase of treated tissue volume. Continuous cyclic changes of the nodal pattern of USW with proper repetition rates corresponding to a specific resonant or relaxation times of living cells or tissue components provide effective dynamical influence of USW on tissues. Synergetic combination of USW with RF therapeutic heating and vacuum massage lowering cavitation threshold and intensifying a blood flow and clearance of disrupted cell debris along with inherent treatment process control and diagnostic possibilities offers a great future for the technology.

The therapeutic head is designed for vacuum suction of the target tissue and comprises: a suction cup; a cylindrical piezoelement generating cylindrical standing waves in the tissue portion retained inside the cup; a plunger compressing tissue and providing acoustic contact between piezoelement and tissue; and a metal RF electrodes disposed on the plunger and outer edge of the cup (Figure 1).

a b c

Fig. 1. Therapeutic head for combinational treatment comprising vacuum cup (a) cylindrical piezoelement (b) and RF electrodes (c).

The cylindrical piezoelement and RF electrodes are powered by the power generator providing formation of the cylindrical USW and RF field on the same resonant frequencies in the target tissue. A cylindrical standing wave is formed in the tissue at each resonance frequency defining a particular nodal pattern associated with that particular frequency. Each different resonance frequency defines a different nodal pattern at different location throughout the tissue consisting of a plurality of pressure nodes and antinodes separated by an acoustic half-wavelength distance. The tissue located in the ultrasonic standing wave field is affected by it with either one or both of thermal or non-thermal mechanisms (cavitational and various mechanical effects). Both mechanisms are most effective in the region of ultrasound pressure antinodes, which is the region of the pressure amplitude maxima. At these points distributed throughout the tissue according to the particular nodal pattern, two effects are most pronounced. First, at

the minimum (most negative) acoustic pressure, the probability of forming cavitational microbubbles is the highest. Secondly, the generation of heat is maximal at the acoustic pressure amplitude maxima.

Synchronous (at the same frequency) excitation of RF field and USW will lead to multi-resonant movements of ions and additional RF heating. Physically, the origin of tissue heating by RF is due to ion movements and vibrations as well as orientation and rotations of polar molecules (dipoles) like in dielectrics and electrolytes [ ].

The combinational treatment using USW and RF is non-trivial, because only in the developed transducer configurations RF and USW fields coincide spatially and are superimposed synchronously to provide new biological and physical effects. The synergetic combinations of the USW and RF are further intensified by the vacuum massage providing real combinational tissue treatment.

3. Feasibility Test of Combinational Treatment Method and Apparatus Prototype

Figure 2 shows apparatus prototypes for combinational treatment of superficial tissues.

Fig. 2. Apparatus prototypes for combinational treatment comprising electronic block and therapeutic head.

Ex-vivo experiments (safety and efficiency issue) were made on bovine liver at a standard protocol:

- generator - 2 channel with additional cooling of power boards;
- RF channel - electric power up to 30 W max, frequency 900 kHz;
- ultrasound channel - electric power up to 30 W max, frequency 900 kHz;
- excitation - CW, bursts 1/2,1/5;
- vacuum - constant, 730 mmHg
- protocol - RF alone, USW alone, RF+ USW;
- treatment time - 60 sec;
- tissue - fresh bovine liver.

Some of the results of combinational treatments are shown on Fig. 3. It is easy to see from Figure 3, that USW produce minimal fractional thermal tissue modifications at used powers and treatment times. Increase in ultrasound power leads to piezoelement and therapeutic head heating and can lead to “skin” burning at longer exposition times. RF alone produce thermal tissue modifications at long exposition times under central plunger RF electrode only with a strong “skin” burning. Combination of RF and USW leads to a strong tissue thermal modifications at minimal exposition times. Increase in exposition times leads to a “skin“ burning by RF and piezoelement heating. The preliminary experiments on volunteers are shown that used in the test RF and USW powers and expositions times are not acceptable for in-vivo treatments (expositions of RF, USW and RF+USW at used protocol lead to strong pain during first 5-10 sec and skin burnings). For personal home-used cosmetic devices the influence levels (vacuum, RF and USW) leading to pain or visible skin and tissue damages are unacceptable. At any regimes and kind of use the device can’t do harm to a patient (safety is superior to efficacy). So, the following treatment protocol can be recommended for next in-vivo experiments:

- vacuum - pulsating, 730-750 mmHg;
- RF power 15-30W burst mode 1/10;
- USW 15-30W burst mode 1/10;

- treatment mode – continuous movement of therapeutic head along the body;
- transducer design aspects: external cooling is desirable for pain and burning prevention (Peltier-element).

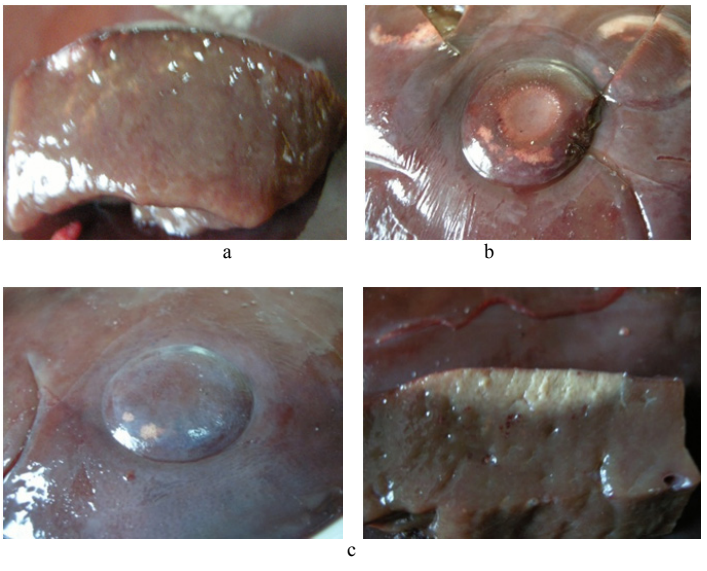

Fig. 3. Thermal lesions in bovine liver generated by USW alone (a), RF alone (b) and USW + RF (c).

4. Conclusion

The results of *ex-vivo* tissue experiments prove the efficacy, safety, and selectivity of the developed combinational treatment method and apparatus design. Synergetic combination of USW with RF therapeutic heating and vacuum massage lowering cavitation threshold and intensifying a blood flow and clearance of disrupted cell debris along with inherent treatment process control and diagnostic possibilities offers a great future for the technology. The main advantages of the developed method are: arbitrary body part treatment, bigger treated tissue area, reduced treatment time, high selectivity and safety, continuous process and tissue condition control, variety of applications (fat reduction, cellulite treatment, skin tightening and rejuvenation, wrinkle and scar removal, cancer hyperthermia, acnes, blackheads and hair removal, local surgical treatments (lypoma), ultrasonically assisted drugs delivery etc.).

Acknowledgements

Work supported by the RSF grant no. 15-12-00023.

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