

NOVEL PHASE CONTROLLED MULTI SOURCE RADIOFREQUENCY TECHNOLOGY FOR TARGETED VOLUMETRIC THERMAL THERAPY OF SKIN.

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INTRODUCTION

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The cause of lax skin is the decrease in quantity and function of dermal and sub dermal collagen. These physiologic deterioration leads to skin laxity and wrinkles.[1] The delivery of heat to the dermis can be achieved by a few different technologies .Since optical energy is limited in its ability to penetrate deep tissue, novel technological efforts in the last few years were targeted towards radiofrequency energy. [2]

RF affects skin by emitting high-frequency radio waves that mimic the thermal effects of lasers and intense pulsed light sources. RF is similar to optical energy in that it interacts with the tissue to produce a thermal change. Unlike lasers, however, which induce heat by selectively targeting particular chromophores, nonablative RF devices generate heat as a result of tissue resistance to the movement of electrons within the RF field.

The delivery of RF energy is thought to induce dermal heating to the critical temperature of 55-65 deg Celsius, causing collagen to shrink and allowing wound healing with a subsequent contraction. In the skin, RF radiation provokes significant thermal effects at a particular depth based on the electrode configuration.

Current RF systems use two basic mechanisms of heating. In the Monopolar (or Unipolar) RF devices, a single electrode emits energy onto the skin. The current is dispersed in tissue and is either flowing towards a receiving pad attached to the patient [3], or is grounded through the body to the treatment table (no pad) [4]. In order to achieve enough heat at the desired target depth, high energies are needed which have to be combined with potent epidermal cooling to prevent epidermal damage.

ABSTRACT

The demand for a non-invasive treatment for tightening of aging and lax skin is increasing in the recent years. As the demand for invasive aesthetic surgical intervention is decreasing the demand for non invasive treatment of wrinkles and lax skin is rising sharply. Similarly, non-surgical body contouring to treat skin laxity resulting from aging, weight loss or multiple pregnancies is becoming the target for energy- based treatment.

Since the available light- based technology exhibit limited penetration into the deeper layers of the skin, radiofrequency is increasingly used as means for skin tightening. Existing RF technologies has shown some promising results but have some significant limitations such as uncontrolled energy flow and pain in the monopolar devices, and insufficient penetration when using the current bipolar technologies. Addressing the challenge of current RF technologies we developed a novel proprietary RF technology that controls the interaction between multiple RF sources to deliver contained energy to selected deeper layers of the skin with decreased heating of the skin surface.

In the bipolar configuration, the current flows between 2 electrodes. Although maximal penetration is considered to be equal to half the distance between the electrodes, most of the thermal effect is concentrated very superficially along the shortest path between the 2 electrodes. [5]

The EndyMed 3DEEP™ technology overcomes these limitations by using an array of several electrodes and manipulating the phase of current flowing between each pair of electrodes. The multiple electrical fields created repel each other, leading to the ideal combination of energy directed to a deeper skin layer. Since all emitted energy is contained in

the target area, the same deep thermal effect can be achieved with considerably lower energies as compared to Monopolar systems. The repelling forces between adjacent electromagnetic fields drive energy vertically into the target tissue, reducing the amount of energy flowing through skin surface and alleviating the need for cooling. To further control the energy delivered into the tissue, the EndyMed 3DEEP™ system performs frequent intermittent measurements of skin impedance and automatically corrects system output to achieve the requested output power (W). The comparison between the different RF modalities is schematically represented in Figure 1.

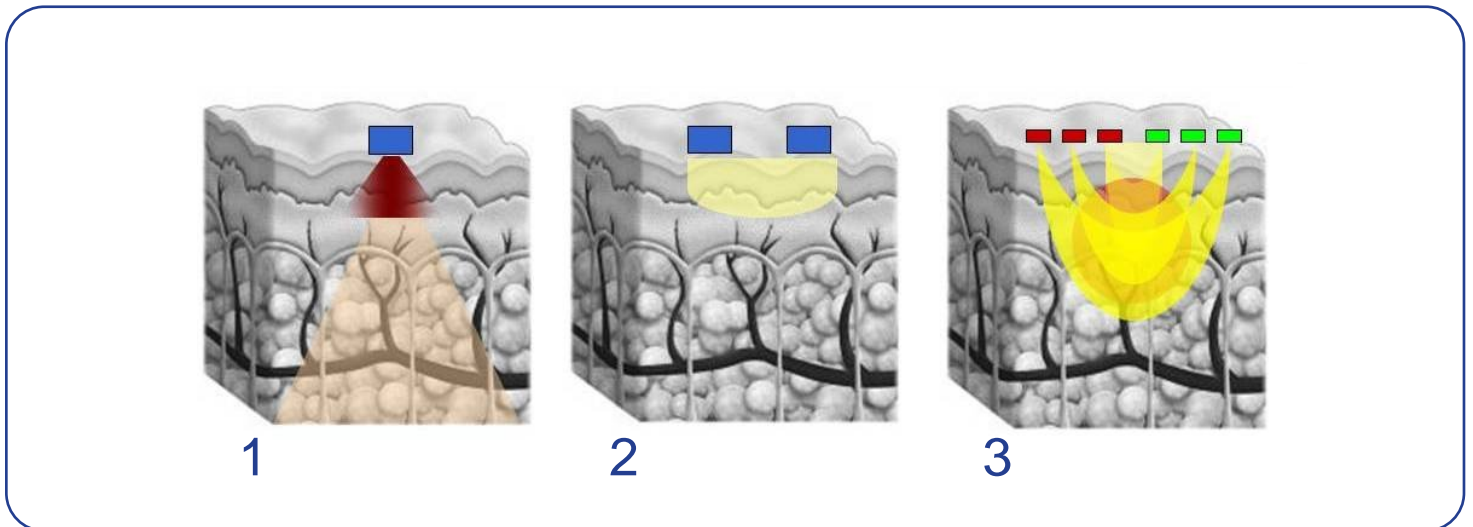


Figure 1: RF technology comparison: (1) Mono-polar (Unipolar) configuration, energy is dispersed through the skin to the whole body, requiring intensive contact cooling to prevent epidermal damage (blue electrodes); (2) Bipolar configuration, energy flows superficially between the electrodes, cooling is needed to prevent overheating of the epidermis in the contact areas; (3) 3DEEP™ configuration with phase-controlled electrodes (green/red electrodes denote electrical polarity) with energy deposited in the dermis and hypodermis. Since most energy is focused into the dermis and hypodermis, no cooling is needed.

MATERIALS AND METHODS

In order to test the thermal profile of energy delivery into tissue, ex vivo chicken breast tissue and ex vivo human skin (from abdominoplasty patients) were used. The temperature profile was measured using a thermal camera (FLIR, ThermoCAM SC 640).

Ex vivo chicken breast, stationary

Chicken breast was used to compare the thermal profile achieved using a bipolar configuration to that obtained by the 3DEEP™ - 2 RF phased controlled RF sources. Both experiments used 300W for 1 second (2 x150W, for the 3DEEP configuration).

Ex vivo chicken breast and ex vivo human skin, transitional

For this study, the large multisource 3DEEP™ Body Contouring handpiece was used (treatment contact area was 4cm x 3cm). RF energy was applied through constant movement of the handpiece over the treatment area. A built-in mechanism based on proprietary technology halts energy emission if the treatment handpiece is not in motion or if surface contact is not optimal.

A thin layer of clear ultrasound gel (Aquarius 101, TAB kozmetikai KFT. Hungary) was applied over

the treatment area. The treatment handpiece was swiped on the treatment area in a circular movement, for consecutive 30 sec time periods.

RESULTS

Ex vivo chicken breast, stationary

To test the difference in the thermal profile of RF delivery 2 experimental setups were compared: Standard bipolar configuration, 300W , 1 second exposure, and 3DEEP™ configuration - 2 phased controlled RF sources (150Wx2 , 1 second exposure).

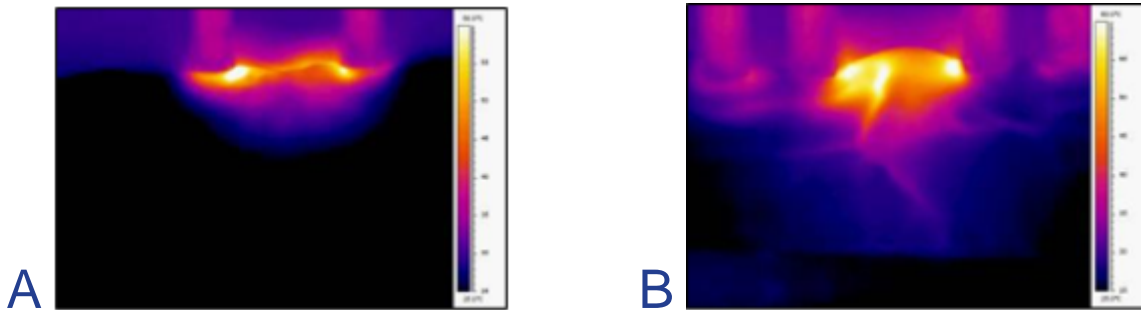
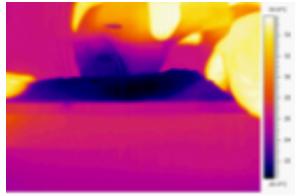


Figure 2: Thermal images show the significant advantage of the 3DEEP™ technology (B) in heat penetration into the skin, compared to standard bipolar RF configuration (A) delivering the same energy. In addition, thermal imaging shows superficial horizontal spread of energy with the bipolar configuration while the 3DEEP configuration produces a more vertical flow of heat, with minimal heating of the surface.

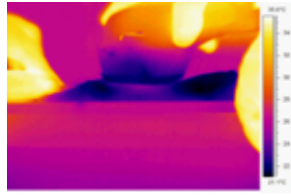
Ex vivo chicken breast, transitional

The aim of this simulation was to show the process of gradual heating of tissue, while treatment handpiece is sweeping the treatment area in circular movement. A 10cmx10cm area was examined. The

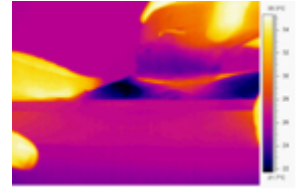
gradual heating of tissue was found to create a temperature gradient of 15°C at 0.4 cm depth and a 10°C gradient at 0.8 cm depth after 180 seconds exposure (Power 35W). (Figure 2)



Time = 0 sec
T=20°C @ 4 mm depth



Time = 60 sec
T=27°C @ 4 mm depth
T=24°C @ 8 mm depth



Time = 180 sec
T=35°C @ 4 mm depth
T=30°C @ 8 mm depth

Figure 3: Simulation of tissue heating using chicken breast tissue. Thermal image produced using FLIR SC 640 (ThermaCAM) camera. Note gradual heating reaching 15°C difference at 0.4 cm depth and 10°C difference at 0.8 cm depth after 180 sec. Please note also that the temperature of tissue surface (in image 3) is lower than the temperature at deeper tissue (no cooling).

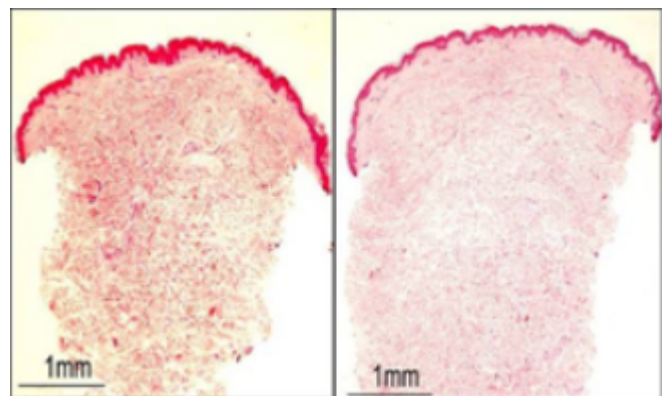
Ex vivo human skin, transitional

Ex vivo human skin was treated by EndyMed1000, at 50W, 6 passes of 30 sec.

Punch biopsies were taken from treated skin

immediately after treatment and were stained with Hematoxylin&Eosin (H&E). Thermal effect to collagen fibers was noted up to a depth of 4 mm (Fig 3).

Figure 4: Ex vivo human skin was treated by EndyMed1000, 50W, 6 passes of 30 sec. Punch biopsy 3mm, H&E staining.



CONCLUSIONS



The novel phase controlled multisource RF system (EndyMed1000, EndyMed Cesarea, Israel) described in this study was shown in a series of laboratory tests to provide advantages over current RF technologies. Monopolar and Unipolar RF technologies are based on one contact point to the skin and uncontrolled flow from the contact point through the body to a second electrode under the body (monopolar) or to through the area of least resistance (Unipolar). The tested EndyMed technology solves the safety concerns of the monopolar RF technologies by the a controlled delivery of energy that is completely contained in a cube of tissue beneath the treatment handpiece .

Moreover, by using multiple sources of RF in a phased array configuration, a significantly more efficient energy delivery is achieved. The energy reaches deeper skin layers, and at the same time significantly less superficial heating is produced. Thus the treatment can carries higher efficacy and safety.

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