

ORIGINAL ARTICLE

Non-invasive therapy of wrinkles and lax skin using a novel multisource phase-controlled radio frequency system

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Abstract

The last few years have shown an increased demand for non-invasive skin tightening to improve body contour. Since light (lasers or intense pulsed light sources) has a limited ability to penetrate deep into the tissue, radio frequency (RF) modalities were introduced for the reduction of lax skin to achieve skin tightening and body circumference reduction. This study presents the use of the novel 3DEEP™ technology for body contouring. 3DEEP is a next generation RF technology that provides targeted heating to deeper skin layers without pain or other local or systemic side effects associated with the use of the earlier generation RF systems available today. The study included 30 treatment areas on 23 healthy volunteers at two sites. The treatment protocol included four weekly and two bi-weekly ($n=6$) treatments on different body areas. Results were evaluated by standardized photography and by circumference measurements at the treatment area, and were compared to changes in body weight. Significant improvement could be observed in wrinkles and skin laxity, and in the appearance of stretch marks and cellulite. Some changes appeared as early as after a single treatment. Circumference changes of up to 4.3 cm were measured.

Key words: Lasers and light sources, radio frequency

Introduction

Patient demand for non-surgical, non-invasive, and no-downtime skin tightening and body contouring treatments has grown dramatically over the past decade as new treatments and technologies have been introduced.

A major cause of skin wrinkles, skin laxity and cellulite is the reduction in the quantity and quality of collagen fibers in the dermis and hypodermis. Until recent years, the options available to treat skin laxity to attain a tight body contour were limited to surgery. Non-invasive, vacuum and massage-based treatments offer only partial and short-term benefits as the improvement is only temporary. On the other hand, the effects of dermal heating are well recognized to include immediate effects on collagen structure (1,2), with stimulation of neocollagenesis (2). The effect of these changes to the collagen results in contouring and tightening of the body and face. Although systems combining massage with infrared (IR) or bipolar radio frequency (RF) heating enhance

the results of vacuum and massage systems, the heat penetration into deep dermal and sub-dermal layers is not sufficient for longer-term effective collagen tightening and remodeling (3).

On the other hand, an important characteristic of RF energy, which is creating a positive response in the medical aesthetic space, is its heating performance, independent of skin pigmentation. The first systems using bipolar RF have shown some benefit, but have been limited by the superficial flow of energy between the two bipolar electrodes (4). Other systems using a monopolar (or unipolar) RF setting employ a single electrode allowing energy to flow beyond the target area. In addition, energy scattering in a monopolar and unipolar configuration demands delivery of large amounts of energy into the tissue, resulting in possible pain and other local and systemic safety concerns.

The EndyMed 3DEEP™ technology overcomes these drawbacks by using an array of several RF sources, controlling the phase of current flowing

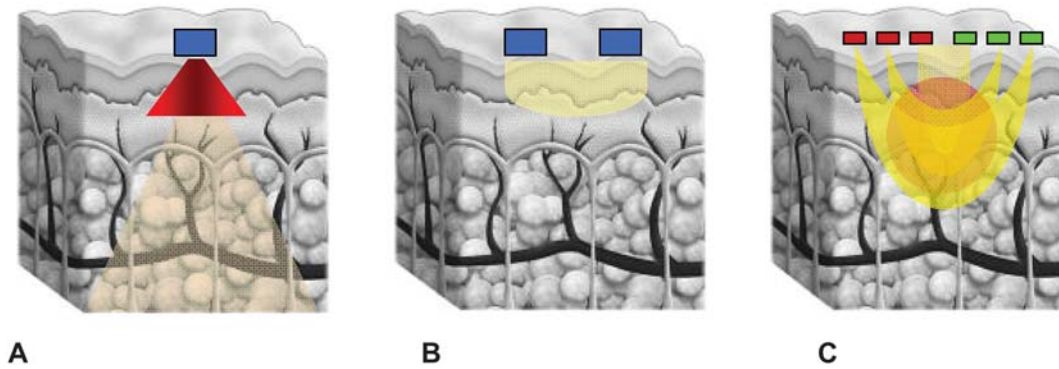


Figure 1. RF technology comparison. (A) Monopolar (unipolar) configuration: energy is dispersed through the skin to the whole body, requiring intensive contact cooling to prevent epidermal damage (blue electrodes). (B) Bipolar configuration, energy flows superficially between the electrodes, cooling is needed to prevent overheating of the epidermis in the contact areas. (C) 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.

between each pair of RF sources. Since adjacent electrodes possess an identical polarity, no current is created between these electrodes on the skin surface. The multiple deep electrical fields created repel each other, leading to precise delivery of energy directed and fully contained to the dermal and hypodermal targets (Figure 1).

The EndyMed technology provides the ability to deliver constant power, customized in real time to the individual patient skin impedance. The ability to adjust treatment parameters according to the patient's skin characteristics improves the predictability of results. Unique contact motion and temperature sensors built into the treatment handpiece allow optimal safety.

Materials and methods

We tested the 3DEEP technology ex vivo, followed by clinical trials.

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: two phase-controlled RF sources. Both experiments used 300 W for 1 second (2×150 W, for the 3DEEP configuration).

The temperature profile was measured using a thermal camera (FLIR, ThermaCAM SC 640).

Ex-vivo modeling of 3DEEP technology in duck skin

To treat lax skin and cellulite, the thermal energy must reach the collagen located in the dermis and in the peri-lobular connective tissue in sub-dermal layer. An ex vivo model of skin with the underlying sub-dermal fat was used to study the flow of energy through dermis (mostly collagen) and hypodermis (fat and collagen). For this purpose, fresh duck skin (including fat) was treated by a lab system using 3DEEP technology.

Prior to the experiment, the skin was brought to room temperature (approximately 20°C). The duck tissue was stained with aniline blue – a water soluble acid dye component of Mallory's triple stain used for staining connective tissue fibers within glands and muscles. The spatial heat distribution was recorded by IR camera (FLIR).

Device, subjects and clinical protocol

Treatment was performed using the EndyMed PRO 3DEEP body contouring system (EndyMed Medical, Caesarea, Israel). For this study, the large multisource EndyMed PRO 3DEEP body contouring

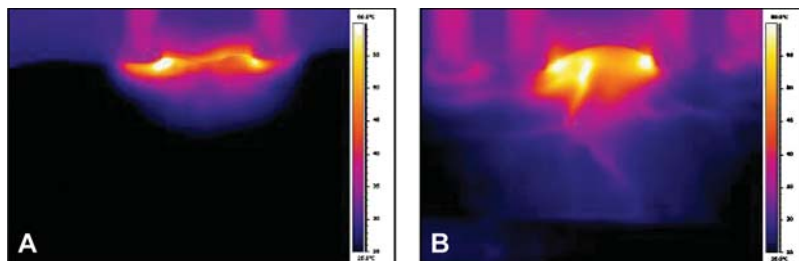


Figure 2. Thermal images show the significant advantage of the 3DEEP™ technology (B) in heat penetration into the skin compared with standard bipolar RF configuration (A) delivering the same energy. In addition, thermal imaging shows a superficial horizontal spread of energy with the bipolar configuration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

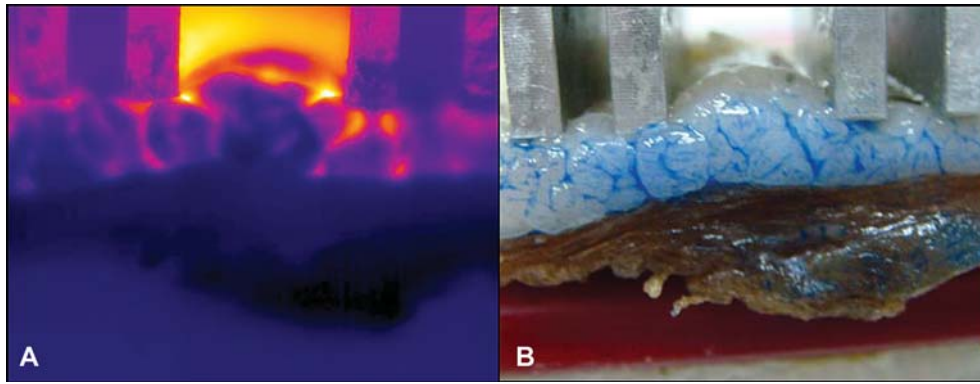


Figure 3. (A) Thermal profile of duck skin using the 3DEEP™ technology. The figure shows the electrodes, the skin surface and the heat distribution. Note the depth of penetration and the hot areas along the collagen fibers. Note also that no heat is created between the outer pair of electrodes. (B) This shows the same tissue previously stained with aniline blue for collagen. It can be seen that the heating pattern follows closely the distribution of collagen fibers between the fat lobules. Note the gray upper skin and the white fat tissue.

handpiece was used (power range 0–65 W, treatment contact area 4×3 cm). The treatment area was divided into 10×10-cm squares; the number of squares being dependent on the size of the treatment area and was typically three to four squares on the abdomen and two to three squares on each thigh. A built-in proprietary safety feature of the system stops energy emission if the treatment handpiece is not in motion or if surface contact is not optimal.

A total of 23 patients (22 female, one male), age range 20–60 years (median 47 years), were recruited to the study. Since some patients were treated for more than one area, the total treatment zones reported in this study is 30, distributed between abdomen – 20 patients; and thighs – 10 patients. A subgroup of 10 female patients, age range 27–55 years (median 45.5), were additionally examined for changes in the circumference of the treatment area. Patients in this group were treated for abdomen (nine) and thighs (six); some patients were treated in more than one area.

The treatment protocol included six treatments: four weekly treatments and two additional treatments at 2-week intervals (total 8 weeks). Clinical targets were: therapy of lax skin, stretch marks, body contouring, and improvement in the appearance of cellulite.

The treatment area was divided into squares of 10×10 cm. Each treatment was started by using system presets for the specific area (30 W for abdomen and thighs). A thin layer of clear ultrasound gel (Aquarius 101; TAB kozmetikai KFT, Hungary) was spread over the treatment area. The treatment handpiece covered the treatment area in a circular movement for the duration of the pulse (30 seconds). Skin

temperature was measured after each pulse, using an external IR thermometer (TES 1326S; TES Electrical Electronic Corp., Taiwan). When the skin temperature reached 39°C, six additional passes were administered, maintaining this temperature for an additional 3 minutes. The system is equipped with two automatic safety features that stop RF emission if the handpiece is not in full contact with the skin, and if the movement of the handpiece over the treatment area is below the allowed threshold.

All patients were photographed at every treatment session, before and immediately after treatment, at a standard distance and illumination. In addition, patients were postured at constant angles relative to the camera: eight positions for thigh treatment (every 45°) and five positions (only front) – for abdomen. The overall change was graded on a scale of 0–4, where 0 denoted no visual effect, 1 = mild (less than 20%) change; 2 = moderate (less than 50%) change; 3 = significant (up to 80%) change; 4 = extensive (more than 80%) change.

For the circumference analysis, measurements were recorded at each visit, and were compared to the weight of the patients and to the circumference of a reference area (above the knee). All circumference measurements were taken using a standardized measurement methodology.

Safety of the treatment was evaluated by careful monitoring of all possible adverse events and by patient subjective grading of pain during every treatment.

All patients graded their satisfaction rate 1 week after completion of the study using a specially designed questionnaire. Patient satisfaction was graded 1–4, where 1 = dissatisfied and 4 = highly satisfied.

Table I. Summary of treatment results as graded from analysis of patients' photographs and from patient satisfaction questionnaires.

Treatment area	Overall change score					Average patient satisfaction	
	0	1	2	3	4		Average
Abdomen (n=21)	0	0	2	10	9	3.5	2.8
Thighs (n=10)	0	2	1	1	4	2.3	3.0
Overall						3.1	2.8

Results

Ex vivo chicken breast study (Figure 2)

To test the difference in the thermal profile of RF delivery two experimental setups were compared: standard bipolar configuration (300 W, 1-second exposure);

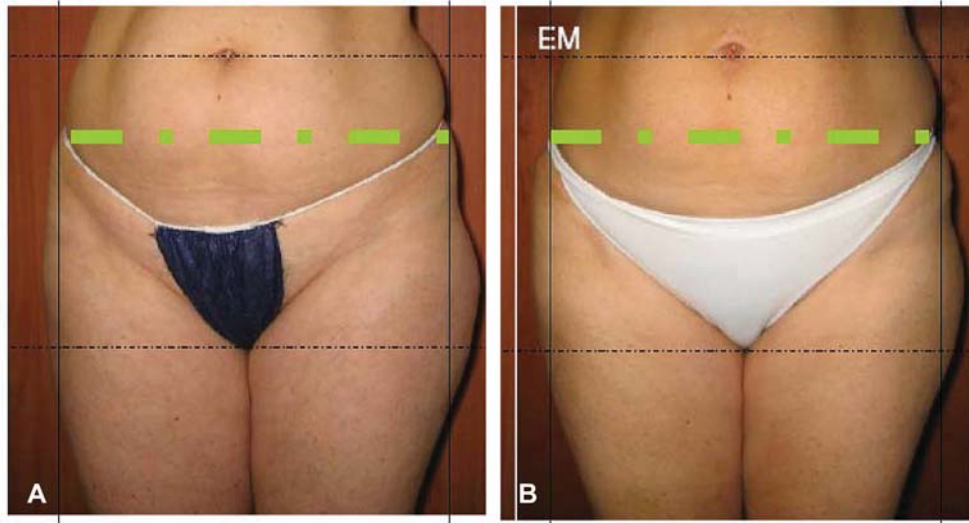


Figure 4. Female, 47 years old. (A) Before treatment; (B) after 6 treatments: there is evidence of a significant improvement in body contour with skin tightening and circumference reduction (4.3 cm).

and 3DEEP configuration, two phased-controlled RF sources (150 W \times 2, 1-second exposure).

Thermal images show the significant advantage of the 3DEEPTM technology (B) in heat penetration into the skin compared with standard bipolar RF configuration (A) delivering the same energy. In addition, thermal imaging shows a 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 duck skin study (Figure 3)

Modeling the tissue selectivity of 3DEEP technology in duck skin. (A) Thermal profile of duck skin using the 3DEEPTM technology. The figure shows the electrodes, the skin surface and the heat distribution. Note the depth of penetration and the hot areas along the collagen fibers. Note also that no heat is created between the outer pair of electrodes. (B) This shows the same tissue previously stained with aniline blue for collagen. It can be seen that the heating pattern follows closely the distribution of collagen fibers between the fat lobules. Note the gray upper skin and the white fat tissue.

Multicenter clinical study

No adverse events were recorded. All patients had transient erythema in the treatment area, which resolved within 10–15 minutes. All patients reported the treatment as comfortable (no pain).

The overall success rate was evaluated by comparison of patients' photographs, by patient satisfaction (as analyzed from the satisfaction questionnaires), and by measuring changes in the circumference of the treatment area. The scores are summarized in Table I.

It is important to note that for many of the patients the results could be observed after two to three treatments, and for some of them even after a single treatment.

Some typical photographic results are shown in Figures 2–4.

The photographs show body contouring in the abdomen area, with improvement of skin texture, improvement of lax skin resulting from multiple pregnancies and/or massive weight loss, and improvement in the appearance of cellulite.

A second parameter evaluated in the study was the circumference of the treated area. The circum-

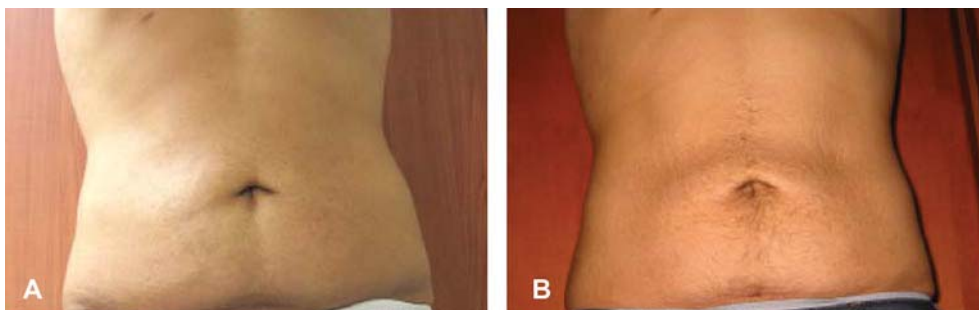


Figure 5. Male, 21 years old. (A) Before treatment; (B) after four treatments: there is evidence of a significant improvement in body (love handles) contour with skin tightening and circumference reduction.

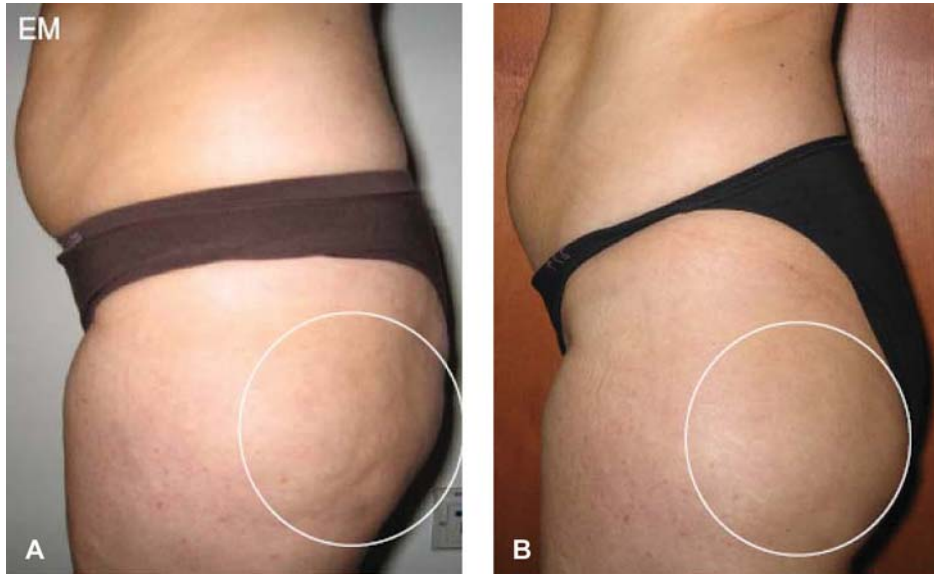


Figure 6. (A) Before treatment; (B) after six treatments: there is evidence of a significant reduction in the appearance of cellulite.

ference analysis was performed on a subgroup of 10 patients (15 treatment regions). The reduction in circumference after six treatments was compared to the weight change of the patients at the time of evaluation. The weight served as the control, to

prove that circumference changes were not necessarily a result of weight loss. The results are presented in Figures 4, 5, and 6.

The average circumference reduction in the abdomen area was 2.3 cm, with an average weight

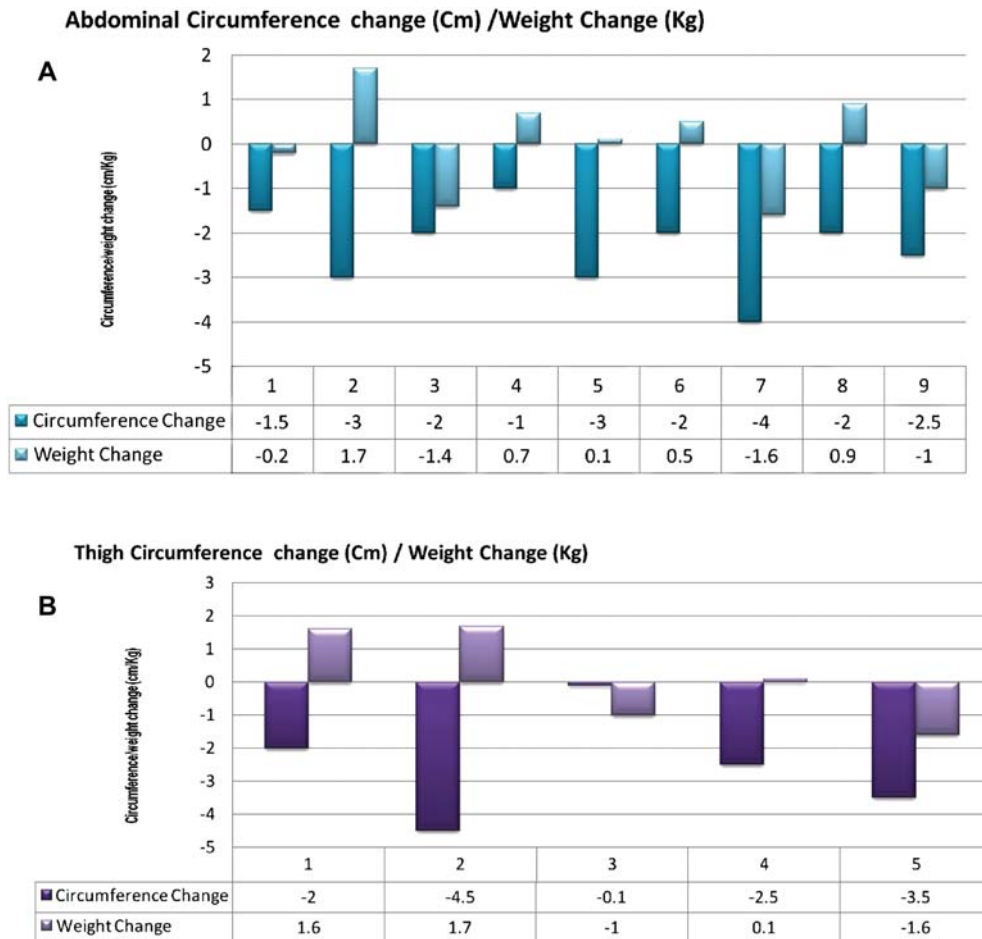


Figure 7. (A) Circumference changes versus weight for treatment of the abdomen; (B) circumference changes versus weight for treatment of the thighs.

decrease of 0.03 kg (Figure 7A). The average circumference reduction in the thighs was 2.52 cm, with the corresponding weight increase of 0.16 kg (Figure 7B). The results prove that the EndyMed 1000 treatment has a significant body contouring effect.

Discussion

The cause of lax skin is the decrease in quantity and function of dermal and sub-dermal collagen. This physiologic deterioration leads to skin laxity and wrinkles (5).

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 RF energy (6).

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, non-ablative 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°C, 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 (7), or is grounded through the body to the treatment table (no pad) (8). 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.

In the bipolar configuration, the current flows between two 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 two electrodes (4).

Conclusion

The novel EndyMed 3DEEP phase-controlled multisource RF system described in this study was shown to be effective in the improvement of skin laxity and cellulite appearance and for the improvement of body contours in abdominal and thigh areas. All patients monitored for circumference changes showed a reduction in the circumference of the treated area, which was unrelated to weight changes. The novel technology implemented in the EndyMed system has proven to be efficient while providing pain-free, totally safe treatment for the specified indications. The unique safety features implemented in the design of the system assure both exact energy delivery customized in real-time to individual patient skin impedance and fool-proof safety preventing user mishandling.

Declaration of interest: Harth - equity in EndyMed Ltd, Gottfried - employed by Endymed Ltd.

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