Body Contouring And Circumference Reduction

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Abstract

The last few years has shown an increased demand for non-invasive skin tightening to affect body contour. Since light (lasers or intense pulsed light sources) have limited ability to penetrate deep in the tissue, radiofrequency 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 at deeper skin layers without pain or other local or systemic side effects associated with the use of 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, skin laxity, in the appearance of stretch marks, and in the appearance of cellulite. Some changes appeared as early as after a single treatment. Circumference changes up to 4.3 cm were measured.

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 for 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 [2,3] with stimulation of neocollagenesis [3]. 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 radiofrequency (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 [1].

On the other hand, an important characteristic of radiofrequency 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 2 bipolar electrodes [4]. Other systems using monopolar (or unipolar) RF setting employ a single electrode allowing energy to flow uncontrolled through the entire body. Since energy spreads beyond the target area, the use of this type of system is frequently associated with pain and other local and systemic safety concerns.

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

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 predictability of results. Unique contact motion and temperature sensors built into the treatment handpiece allow optimal safety.

MATERIALS AND METHODS

We first tested the 3DEEP™ technology ex vivo, followed in clinical trials.

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. 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, ThermaCAM SC 640).

PATIENT DISTRIBUTION AND CLINICAL PROTOCOL

23 patients (22 female, one male), age range 20-60, median 47, 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, median 45.5, were additionally examined for changes in the circumference of the treatment area. Patients in this group were treated for abdomen (9), and thighs (6); some patients were treated in more than one area.

Treatment protocol included 6 treatments: Four weekly treatments and two additional treatments at two week intervals (total 8 weeks). Clinical targets were: therapy of lax skin, stretch marks, body contouring, and improvement in the appearance of cellulite.

All patients were photographed at every treatment session, before and immediately after treatment, at standard distance and illumination. In addition, patients were postured at constant angles relative to the camera: 8 positions for thighs treatment (every 45°) and 5 positions (only front) – for abdomen. 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 one week after completion of the study, using a specially designed questionnaire. Patient satisfaction was graded 1-4, where 1 is dissatisfied and 4 – highly satisfied.

TREATMENT SYSTEM

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 handpiece was used (power range 0-65W, treatment contact area 4cmX3cm). The treatment area was divided into 10cmx10 cm squares; the number of squares dependent on the size of the treatment area and was typically 3-4 squares on the abdomen and 2-3 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.

TREATMENT PROTOCOL

The treatment area was divided into squares of 10x10 cm. Each treatment was started by using system presets for the specific area (30W for abdomen and thighs). A thin layer of clear ultrasound gel (Aquarius 101, TAB cozmetikai 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 sec). 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.

RESULTS

Modeling the tissue selectivity of 3DEEP technology in duck skin.

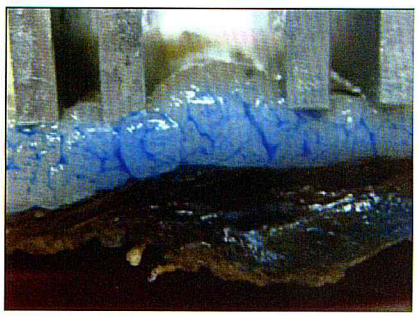

Figure 1: [A] Thermal profile of duck skin using the 3DEEP technology. The figure shows the electrodes, the skin surface and the heat distribution. Note depth of penetration and the hot areas along the collagen fibers. Note also that no heat is created between the outer pair of electrodes; [B] Shows the same tissue previously stained with Aniline Blue for collagen. One can observe 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.

CLINICAL EVALUATION

All patients recruited to the study finished the treatment protocol.

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

Efficacy: The overall success rate, as evaluated by comparison of patient's photographs and by patient satisfaction and by measuring changes in the circumference of the treatment area.

The scores of success as determined from analysis of photographs and the satisfaction rate of the patients as analyzed from the satisfaction questionnaires are summarized in

Table 1.

Table 1. Summary of treatment results as graded from analysis of patients' photographs and from patient satisfaction questionnaire.

Table 1.

Treatment Area	Overall Change Score						Average Patient Satisfaction
	0	1	2	3	4	Average	
Abdomen (n=20)	0	0	2	10	9	3.5	2.8
Thighs (n=10)	0	2	1	1	4	2.3	3.0

*Two patients of the Thigh group were not evaluated due to reasons unrelated to the evaluation.

It is important to note that for many of the patients results could be observed after 2-3 treatments, and for some of them even after a single treatment.

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

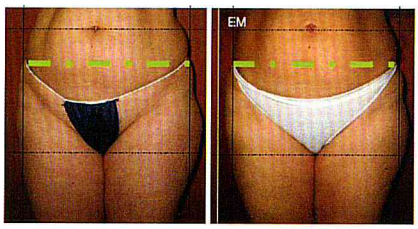

Figure 2: Female 47 years old. [Lt] Before treatment. [Rt] After 6 treatments; there is evidence of significant improvement in body contour with skin tightening and circumference reduction (4.3cm).

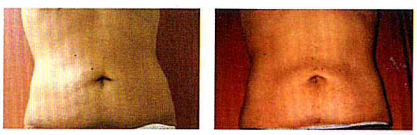

Figure 3: Male 21 years old. [Lt] Before treatment. [Rt] After 4 treatments; there is evidence of significant improvement in body (love handles) contour with skin tightening and circumference reduction.

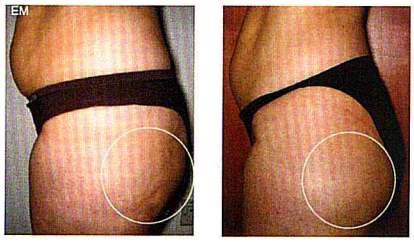

Figure 4: [Lt] Before treatment. [Rt] After 6 treatments; there is evidence of significant reduction in the appearance of Cellulite.

The photos 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 circumference analysis was performed on a subgroup of 10 patients (15 treatment regions). The reduction in circumference after 6 treatments was compared to weight change of the patients at the time of evaluation. The weight served as control, to prove that circumference changes were not necessarily a result of weight loss. The results are presented in Figure 5.

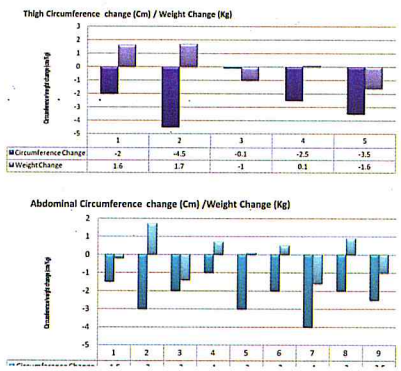

Figure 5: Circumference changes vs. weight for treatment of abdomen (A) and thighs (B).

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

0.03Kg. The average circumference reduction in the thighs was 2.52 cm with the corresponding weight increase of 0.16Kg. The results prove that the EndyMed 1000 treatment has a significant body contouring effect.

CONCLUSIONS

The novel EndyMed 3DEEP™ phase controlled multisource RF system described in this study was shown to be effective in improvement of skin laxity and cellulite appearance and for improvement of body contour in abdominal and thigh area. All patients monitored for circumference changes have shown reduction in the circumference of the treated area, which was unrelated to weight changes. The novel technology implemented in the Imagine 3Deep ™ 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 full proof safety preventing user mishandling.

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