EFFECTIVE AND SAFE TREATMENT OF FACE, ARMS AND NECK, WRINKLES, RHYTIDES AND SKIN LAXITY USING A MULTISOURCE PHASE CONTROLLED RADIOFREQUENCY DEVICES

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INTRODUCTION

The effects of dermal heating are widely accepted to include the modification of collagen structure and stimulation of new collagen production. These changes can help improving the appearance of fine rhytides or skin that has begun to lose its elasticity. Dermal heating may be achieved either directly via ablative laser skin resurfacing, or indirectly through the intact epidermis via a process often referred to as 'non-ablative skin resurfacing' or 'sub-surface resurfacing'. The 1320nm Nd:YAG laser was the first device developed specifically for non-invasive dermal heating and it has proven to be highly useful in the treatment of acne scars, depressed scars, and fine wrinkles. This type and other infrared lasers of its kind, primarily exert a relatively superficial effect. Although this laser can be effective at treating fine wrinkles and shallow acne scars, it does not produce deep dermal tissue tightening or lifting effects. To achieve more dramatic skin-tightening, deeper heating is required.

Electrical energy can be advantageous for deep dermal heating as, compared with light energy, the movement of electrons is not impeded by tissue proteins. RF energy heats tissue by creating electric fields between two electrodes causing molecules to rotate or move millions of times per second to create heat. Resistance varies with the nature of the tissue,(skin versus fat, for example), temperature, and water content.

The first systems implementing bipolar (two electrodes) RF have shown some limited benefit due to the superficial flow of energy between the bipolar electrodes [4]. Other systems that implement monopolar (or unipolar) RF configuration use a single electrode, which allows the energy to flow uncontrolled through the body. In this case, the energy spreads beyond the target area, and as such, the use of this type of system is frequently associated with pain and other local and systemic safety concerns.

ABSTRACT

The effects of dermal heating are widely recognized to include the modification of collagen structure and stimulation of neocollagenesis. These changes can help improve the appearance of fine rhytides or skin that has begun to lose its elasticity. Since laser or other light sources have limited ability to penetrate the depth of the skin, radiofrequency (RF) devices are a first choice for treatment of wrinkles and lax skin. In this study, we tested the efficacy and safety of a novel multisource phase controlled, RF device that delivers energy to the depth of the skin with significantly decreased risk. Eighteen patients completed the course of the treatment protocol. A total of 20 areas were treated: face (n=15 - 75%); abdomen (n=2 - 10%); arms (n=2-10%); and neck (n=1- 5%). For our purposes, we only analyze here the results relating to the face and neck. In our study, the improvement in the wrinkle appearance was reported in 85-90% of the patients as judged by picture analysis by blinded reviewers. Computerized surface and contour analysis of the photographic results revealed significant improvement of skin texture, and in jaw line and chin contours. No unexpected adverse effects were detected or reported.
The EndyMed 3DEEP™ technology overcomes these drawbacks by implementing an array of several RF sources, controlling the phase of current flowing between each pair. 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 3DEEP™ technology provides the ability to deliver constant power customized in real-time to the individual patient's skin impedance, improving the predictability of results. Unique contact motion and temperature sensors integrated into the treatment hand piece allow optimal safety.

**MATERIALS AND METHODS**

We examined the treatment results of 18 patients treated for wrinkles in two clinical centers.

All 18 patients, all women, ages 39-71 years (average 52.4±10.34), were enrolled in the study after meeting all inclusion/exclusion criteria and providing signed Informed Consent Forms. The patients' skin wrinkles were classified according to Fitzpatrick Wrinkle Scale (2). (Table 1) A total of 4 body areas were treated - face, abdomen, arms and neck; where the face was the most requested area for treatment (75%). Patients received three to eight treatments (average 4.8±1.32 treatments), spaced at intervals of one to two weeks. Follow-up was carried out from one to five months after treatment.

Prior to the RF treatment, the treated areas was assessed visually as to skin relevant parameters and photographed in a standardized method using high-resolution digital photography. This permitted comparison and assessment of wrinkle appearance improvement following treatment. Photographs were taken prior to each treatment.

<table>
<thead>
<tr>
<th>Scale</th>
<th>Wrinkling Grade</th>
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<tbody>
<tr>
<td>I</td>
<td>Fine wrinkles</td>
</tr>
<tr>
<td>II</td>
<td>Fine to moderate depth wrinkles, moderate number of lines</td>
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<tr>
<td>III</td>
<td>Fine to deep wrinkles, numerous lines with or without redundant skin folds</td>
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*Table 1. Fitzpatrick wrinkle scale.*

The treatment area was cleaned thoroughly with soap and water. The skin surface was dried prior to the treatment. Based on the patient's skin type and area of treatment, the physician adjusted the pulse power (W). All patients had six passes of 30 sec each on each treatment zone (approximately 10cm x 10cm).

The study's efficacy endpoint was considered by pre-treatment photographs that were assessed and graded by two physicians blinded to the study and the patients. Assessment of treatment efficacy was performed using the Fitzpatrick wrinkle scale. Any wrinkle score improvement (downgrade score) following treatment, relatively to pre treatment wrinkle score, was considered a success.

The safety of the procedure was also evaluated by monitoring the occurrence of potential procedure related side effects. Patients were asked to evaluate the degree of pain during treatment. Immediately following the treatment the treated area was visually assessed for skin responses, including edema, erythema, hypopigmentation, hyperpigmentation, and textural changes.

**RESULTS**

All 18 patients completed the course of the treatment protocol. A total of 20 areas were treated: Face (n=15 - 75%); abdomen (n=2 - 10%); arms (n=2- 10%); and neck (n=1- 5%).

No unexpected adverse side effects were detected or reported. In some patients, post treatment erythema
(hyperemia) was detected which was resolved within 10 to 30 minutes. No patients experienced burns, skin breakdown, or scarring. None of the patients has reported pain during the study.

All patients (100%) were very satisfied from treatment results. The following sets of before and after photographs (Figures 1-4) illustrate the significant beneficial effect achieved with this multisource phase controlled radiofrequency system.

**Figure 1:** Female XX years old. [Lt] Before treatment. [Rt] After 6 treatments; there is evidenced a significant anti-wrinkles effect. Notice improvement under the chin and jaw line contours, including a lifting effect and texture improvement. Below is a texture image analysis, performed by ImageJ (National Institute of Health, USA).

**Figure 2:** Female XX years old. [Lt] Before treatment. [Rt] After 6 treatments; significant anti-wrinkle effect, and improvement under the chin and jaw line contours, lifting effect and texture improvement. Below is a texture image analysis, (ImageJ National Institute of Health, USA).
Photographic analysis of pre-and post treatment of the digital images was conducted by two blinded Board certified dermatologists. Analysis revealed improvement (downgrade of at list 1 score according to the Fitzpatrick scale) in 18 of the 20 treated areas (90%), according to the first reviewer, and 17 out of 20 treated areas (85%) according to the second reviewer. Statistical comparison of the pre-and-post treatment Fitzpatrick scores was conducted (using paired TTest) for each reviewer.

Score differences (pre and post treatment) was found to be statistically significant (p<0.05) for both reviewers indicating treatment efficacy. Furthermore, no statistical significance were found (p>0.05) while comparing the Fitzpatrick scores given by the two reviewers pre treatment, and post treatment, indicating that the two blinded reviewers were in agreement regarding wrinkles assessment, pre and post treatment. Figure 5 represents averages (± STDV) of Fitzpatrick scores given by the two reviewers pre-and-post treatment.
The data reported in our study demonstrate that this RF device offers a safe and effective noninvasive technique to improve the appearance of age-related rhytides and lax skin. The clinical results of nonablative RF anti wrinkle effects were first reported in the periorbital area (3). In this multicenter study, Fitzpatrick and his colleagues demonstrated clinical improvement in periorbital rhytides in 80% of subjects. In contrast, in 24 patients who underwent a single RF treatment to improve the upper third of the face, only 36% of the patients' self-assessment reported improvement (4).

In our study, the improvement in the wrinkle appearance was reported in 85 and 90% respectively, of the patients by blinded reviewers.

In a similar study it has been reported that the use of a RF device was associated with significant pain, and in a small but significant number of cases subcutaneous fat atrophy developed (5). No subcutaneous fat atrophy was noted in our patients. In our study, all treatments were performed without any anesthesia, and yet were regarded by all patients as pain-free. In fact, no patients considered the procedure intolerable at any session.

The results of this study clearly indicate that this innovative RF system offers a non invasive, effective, safe and virtually painless wrinkle reduction treatment.

In conclusion, the data reported in this study support the effectiveness of the Imagine™ Computerized Radiofrequency System in the treatment of wrinkles.

REFERENCES


