

Non Ablative Skin Tightening and Wrinkle Reduction Treatment with the Reaction™ System

A Three Month Follow-Up Study & Evaluation

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ABSTRACT: The following study evaluates the Reaction™ system's efficacy for skin tightening and wrinkle reduction treatments. Sixteen healthy female patients, between 37 to 66 years of age, with moderate to severe wrinkles and/or lax, sagging skin were enrolled in this study. Patients were treated with the Reaction™ system, which is based on CORE™ technology and emits Radio Frequency (RF) energy at three different frequencies: 0.8MHz, 1.7MHz and 2.45MHz as well as a multi-channel mode that combines all three frequencies together. Participants underwent 3 treatment sessions at 3 week intervals. Results show moderate to significant improvement in 81% of the patients. The study demonstrates the Reaction™ system to be safe and effective for wrinkle reduction and skin tightening treatments.

Introduction

Collagen is a major structural protein in the body which comprises 75% of our skin; two major types are Type I and Type III. Collagen molecules are produced by fibroblast cells located in the dermis, which synthesize three polypeptide chains wound together in a tight triple helix. With age, the amount of collagen decreases and by the age of 60, this amount is significantly reduced and is manifested by moderate to severe wrinkles⁽¹⁾.

RF is a form of electromagnetic energy, commonly used for many decades in surgery for hemostasis and tissue ablation treatments. In recent years, the application has been applied in the aesthetic medicine field and is known today as Selective Electro-thermolysis.

There are two typical configurations used to deliver RF energy: monopolar and bipolar:

- Monopolar RF energy is delivered to the tissue from a single electrode. RF current passes through the patient to a large grounding electrode located on the other side of the body. High current RF density is generated only close to the emitting electrode and density disperses as distance from the electrode grows (like an antenna). Therefore, heat and clinical effect are limited to the proximity of the electrode to the treatment area.
- Bipolar RF energy is generated using two electrodes while both are in contact with the treatment area. RF current passes between these two electrodes, allowing the practitioner to specifically target different penetration depths by manipulating RF frequency. Thermal and clinical effects take place in the tissue between these electrodes.

The disadvantage of a monopolar system lies in its unpredictable behavior and potential side effects. As the RF current passes through the body towards the grounding electrode it may cause damage to surrounding tissue. Alternatively, the bipolar configuration utilizes controlled RF thereby reducing the chance of any damage to surrounding tissue.

When RF at frequencies of 0.3-10 MHz is applied to the skin, it produces electromagnetic fields, causing the oscillation of molecules within the tissue. This molecular motion generates heat resulting in two phenomenon:

1. Breakdown of the intermolecular collagen cross-links which results in immediate, improved elasticity to the connective tissue for firmer skin⁽¹⁾.
2. Gene expression, particularly of collagen Type I and Type III, is enhanced, resulting in skin remodeling which continues for several weeks following treatment⁽²⁾.

Collagen production continues for 3-5 weeks post treatment where final expression is evident. Thus, RF is an attractive source of energy for a range of dermatological and aesthetic applications^{(3) (4)}.

Materials and Methods

CORE™ Technology

The Reaction™ system is based on bipolar technology and emits RF energy at three different frequencies: 0.8MHz, 1.7MHz and 2.45MHz in addition to a multi-channel mode that combines all three frequencies together (Figure 1).

Reaction™'s Skin Tightening applicator is indicated for the treatment of mild to moderate wrinkles and lax sagging skin. The Skin Tightening applicator utilizes RF energy of up to 125J/cm³ with a pulse duration of up to 200msec. The specially designed applicator also includes an integral cooling mechanism that cools the electrodes to 6°C.

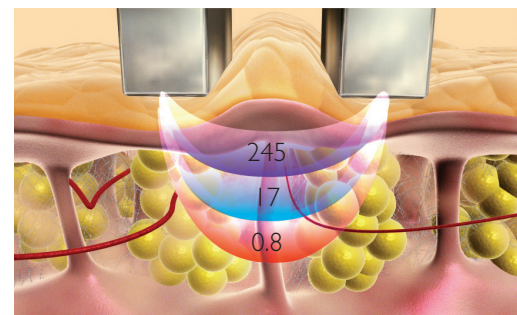


Figure 1: CORE™ Technology

Participants and Treatment Protocols

Sixteen healthy, female patients ranging from 37 to 66 years of age, with moderate to severe wrinkles or/and lax, sagging skin were treated using the Reaction™ system. All of the patients underwent 3 treatment sessions at three week intervals. The patients who underwent treatment in the facial area were treated on both sides of the face, while those who underwent treatment on body areas, such as the abdomen, were treated only on the right side of the body. The average duration of each treatment session was 25 minutes.

Treatments were executed according to Viora's treatment protocol which combines the various treatment modes and frequencies. Patients were called for follow up visits at one month and three months following completion of the treatment course to monitor and evaluate final results.

Analysis and Score

Pictures of the patients were taken in a standardized method using high resolution digital photography (Canon, Power Shot, SD880 IS) at baseline, prior to each treatment and at each of the two follow-up visits. Photographs which were taken at the second follow up visit were analyzed by 3 objective analysts who scored the improvements compared to baseline, according to the following scale:

- 0** - No improvement (<25%)
- 1** - Mild improvement (25-50%)
- 2** - Moderate improvement (51-75%)
- 3** - Significant improvement (>75%)

In addition, the appointed analysts compared photographs from the first and second follow-up visits to monitor any significant withdrawals in results.

Patients' satisfaction scores were obtained post third treatment session and at each follow up visit according to the following scale:

- 0** - Not satisfied
- 1** - Partially satisfied
- 2** - Satisfied
- 3** - Very satisfied

Results

All the patients enrolled in the study successfully completed the course of treatments. The mean RF energy density was $68 \pm 9 \text{ J/cm}^3$ in the abdomen area and $34 \pm 7 \text{ J/cm}^3$ in the facial area.

For treatments of skin laxity in the abdomen, a moderate improvement (51-75%) was recorded in 3 of the patients and a significant improvement (>75%) was recorded in two patients. In treatment of the jowls, a moderate improvement (51-75%) was recorded in 2 of the patients and a significant improvement (>75%) was recorded in one patient. In treatment of the cheeks, a moderate improvement (51-75%) was recorded in 3 of the patients and a significant improvement (>75%) was recorded in 2 of the patients.

In total, 50% of the patients demonstrated moderate improvement and 31% of the patients demonstrated a significant improvement (see Figure 2).

According to the satisfaction scale completed by the patients, 57% were satisfied with the results, 25% were very satisfied and only 18% were partially satisfied.

When evaluations were taken at both follow up visits (post 1 and 3 months) and compared to baseline, results were sustained and no significant withdrawal was recorded.

No adverse effects were reported, except for mild and transient erythema.

- (<25%) No Improvement
- (25-50%) Mild Improvement
- (51-75%) Moderate Improvement
- (>75%) Significant Improvement

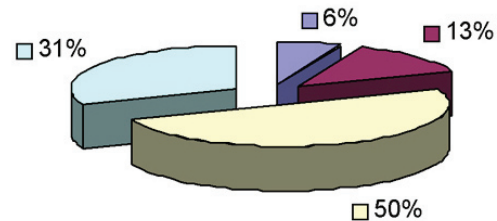
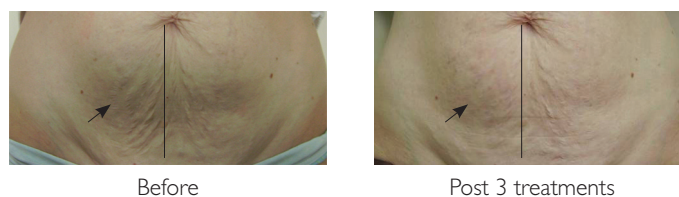


Figure 2: Improvement rate at second follow up (post 3 months of treatments completion).



Discussion

The results obtained in this study demonstrate significant improvement in the appearance of wrinkles and remarkable skin tightening. This study confirms the Reaction™ system treatment to be an effective and safe procedure for improvement in the appearance of wrinkles and lax skin.

The availability of different frequencies of CORE™ technology allows the practitioner to target different tissue depths, focusing energy in the dermis where fibroblast cells are located, ultimately inducing the production of Type I and Type III collagen.

Of the patients who participated in this study, 81% showed moderate to significant improvement in the appearance of lax, sagging skin. The evaluation of skin texture and appearance showed an ongoing improvement after the treatment course and at the first follow-up visit, indicating positive latent results consistent with collagen build up with time. Moreover, evaluations indicate that results were sustained over time and no significant withdrawal was recorded in any of the patients. Furthermore, patients' scores of satisfaction were consistent with the results, with 82% of the patients scoring 'satisfied' and higher.

With the exception of transient mild erythema, no adverse effects were reported during the entire study period.

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