

Reaction™ CORE™ Technology for Cellulite and Body Shaping Treatments

A six month clinical study and evaluation

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ABSTRACT: The aim of the study was to evaluate the safety and effectiveness of the Reaction™ CORE™ (Channeling Optimized RF Energy) technology for cellulite treatment of buttocks, abdomen and thigh areas in female patients. Twenty four healthy, non-obese females (<29 BMI) ranging from 24 to 63 years of age, with a cellulite grade equal to or greater than 2 participated in the study. An overall average improvement of 55% was recorded. Side effects were recorded and monitored and found to be transient and non significant. The findings in this study show clinical results to be superior to those previously reported with RF aesthetic systems, possibly due to the capability of CORE™ technology to target different skin tissue depths through the use of three specific radio frequency modes.

Introduction

Cellulite is a term used to describe a dimpled skin phenomenon normally appearing on the thighs and buttocks. Research shows that at least 85% of post-pubertal women have some degree of cellulite¹. The basic pathophysiology of cellulite has not been clearly identified but appears to be related to hormonal factors that regulate the different connective tissue anatomy of superficial fat and dermis in females and males².

In vivo & *in vitro* studies have demonstrated that women have an irregular and discontinuous connective tissue structure immediately below the dermis, but this same layer of connective tissue is smooth and continuous in men³. The study also indicates that in affected individuals, tissue structure irregularity appears to be worse than in unaffected individuals.

An additional contributing factor to the appearance of cellulite relates to inter-cellular edema, which has been linked to inefficient lymphatic drainage³. A number of techniques have been demonstrated to provide temporary reduction in edema. The first approach, historically, was deep tissue massage, a procedure that is executed manually. Tissue massage aims to reduce the edema by vasodilation with subsequent improvement in local blood and lymphatic circulation⁴. In addition, suction massage has been suggested to have a direct effect on the elasticity of the connective tissue septae in the dermis and subdermal fat⁵.

Deep tissue heating has also been identified as a treatment component for cellulite. This mechanism increases the metabolic rate of adipocytes in the superficial fat layer and reduces the volume of fat cells¹.

Radiofrequency (RF) energy is a form of electromagnetic energy. When applied to tissues, it produces electromagnetic fields, causing the oscillation of molecules within the tissues, which results in the generation of heat. This heat effect has been extensively used in surgery for hemostasis and tissue ablation (electro-surgery), but more recently it has been applied for the treatment of cellulite as well as for various other aesthetic applications such as tightening of lax skin, elimination of wrinkles and rhytid, all of which occur as a result of the stimulation of fibroblast cells that produce pro-collagen. Moreover the combination of vacuum massage and RF energy have been shown to assist in the reduction of thigh and buttocks circumference.

Radiofrequency can be applied to tissue by using either two points on the tip of a probe (bipolar) or between a single electrode tip and a grounding plate (monopolar). Since bipolar energy is more localized, less energy is required to achieve the same heating effect⁶.

Numerous clinical studies have demonstrated that the combination of tissue massage with deep tissue heating using RF-based technology is highly efficient in improving the appearance of cellulite.

The Reaction™ System

The Reaction™ system utilizes unique CORE™ technology that combines vacuum massage with RF energy. The system enables vacuum intensities up to 500 mbars for the application of tissue massage, along with bipolar radiofrequency (RF) power of up to 50 Watts, delivered at three distinct

frequencies or a combination of all three frequencies using the multi-channel mode. Each frequency optimizes the thermal effect at different tissue depths, dependent also on the skin condition (dry or oily), the impedance of the skin and the intensity level of the vacuum.

In *In-vivo* studies conducted by Viora on CORE™ technology, thermal images of the heating effects on porcine skin were recorded to investigate the different penetration depths of the available frequencies. RF penetration depths were found to range from a minimum of 3.5mm to a maximum of 18.6mm (Fig. 1) allowing a wide range of treatment parameters with optimal clinical efficacy.

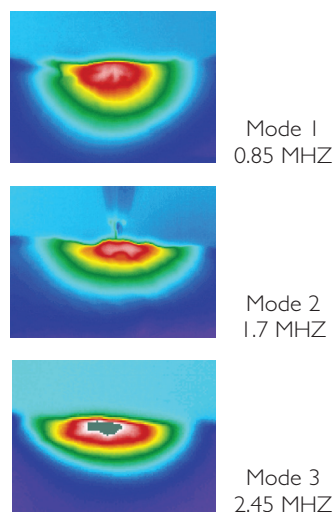


Fig 1: The RF penetration depth with different frequencies were investigated *in vivo* on porcine

Materials and Methods

Twenty-seven healthy females aged 24 to 63, with a Body Mass Index (BMI) lower than 29 participated in the study. Inclusion criteria consisted of the presence of moderate bilateral cellulite, equal to or higher than 2 (see Table 1) in the abdomen, thighs and buttocks. Participants were not allowed to diet or induce any weight fluctuations above 2 Kg, throughout the entire study period. All subjects underwent 8 treatment sessions at 1 week intervals. Three of the participants dropped out of the study for personal reasons that do not relate to this particular study.

Treatments were administered according to Viora's treatment protocol which combines the various treatment programs and frequencies. Photographs were taken in 3 phases: (1) at baseline - prior to the first treatment (2) during the treatment course - after the fourth treatment session (3) at the end of the treatment course - one week after the eighth treatment, at each of the three monthly follow-up visits and one session six months after the last treatment session. Circumference measurements of thighs, buttocks and abdomen were taken by independent evaluators and not by the treating practitioner to avoid partiality.

Analysis was performed at baseline, prior to the fourth treatment and at each follow-up visits, according to the following methods:

1. Clinical photographic assessment
2. Circumferential measurements
3. Participants' satisfaction assessment

Three independent evaluators were asked to complete two separate surveys. The first survey was to rate cellulite grade of random photographs using the following scale:

Cellulite Grade:

- 0 - No dimpling, smooth skin
- 1 - Few small, shallow dimples
- 2 - Moderate dimpling
- 3 - Large number of visible dimples over the area
- 4 - Severe dimpling (cottage cheese appearance)

Table 1: Cellulite Grade Scale

The second survey required the evaluators to rate the improvement in the appearance of cellulite, by comparing photographs taken at baseline with those taken at the third follow-up visit, using the following grading scale:

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

Table 2: Improvement Scale

Circumference was measured by the independent evaluators according to a standardized measurement method.

Additionally, the investigators were asked to record and immediately report any adverse or unexpected effects.

Participants' satisfaction scores were obtained at each of the three monthly follow-up visits, using the following scale:

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

Table 3: Satisfaction Scale

Results

twenty-four of the participants enrolled in the study successfully completed the full course of treatments, and returned for the first follow-up visit. Therefore final results of the study were evaluated at the first follow-up visit.

An overall average improvement of 55% (average of 2.26 according to improvement scale) in the appearance of cellulite was recorded for all participants. In 79% (19/24) of the participants, the cellulite improvement scores ranged from 2 (moderate improvement) to 3 (significant improvement). Only one subject showed an improvement score less than 1.

At baseline, the mean cellulite grade of all subjects was 2.56, with 75% of the subjects (18/24) demonstrating a 2-3 cellulite grade and 25% of the subjects (6/24) demonstrating a cellulite grade of 3-4.

Evaluations taken at the first follow-up visit clearly show an overall reduction in cellulite appearance with a mean cellulite grade of 1.38. Final results at the end of the study show that 91.6% (22/24) of the participants demonstrated a cellulite grade of 1-2 and only 8.4% (2/24) show a cellulite grade of 2-3.

The most significant improvement (>75%) was recorded in subjects who initially demonstrated a cellulite grade of 2-3.

The mean circumference taken at baseline compared to the mean circumference taken at the first follow-up visit showed an average reduction of 3.31 cm in the buttocks, 2.94 cm in thighs and 2.14 cm in the abdomen. Over 83% of the subjects (20/24) showed various degrees of circumferential reduction while no increase in circumference was reported during the entire study. At six-months follow-up visit a slight withdrawal was observed.

According to the satisfaction questionnaire completed by the participants, 20.8% (5/25) were very satisfied with the results, 62.5% (15/24) were satisfied and only 17% (4/24) were partially satisfied.

Side effects were minimal and transient, consisting of erythema lasting for an average of one hour, edema and slight bruising observed in only 3 subjects. No other adverse effects were observed or reported during the treatment sessions or the follow-up period.

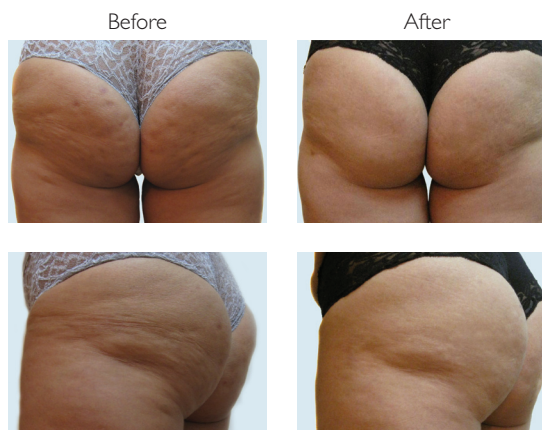


Fig. 2: 49 years old female with cellulite grade 3 showing significant improvement at the 1st follow up visit.

Summary

Results of this study show an overall average improvement of 55% in the appearance of cellulite. These results suggest that CORE™ technology, utilizing different frequencies and targeting tissue at different depths, is particularly advantageous in the treatment of cellulite and circumferential reduction.

According to participants' assessment of results, all participants indicated satisfactory results from the treatment course. There was no record of any dissatisfaction by any of the participants.

It is noteworthy to mention that no withdrawals occurred throughout the study period as well as during the three month follow-up visits, indicating consistency of CORE™ clinical results. However a slight withdrawal was recorded at six month follow-up visit, suggest maintenance every 3-4 months.

Additionally, both investigators and participants reported visible and significant improvement in skin laxity and texture in the treatment area. Investigators postulated this desired effect to be related to the different frequencies and specifically to Mode 3 (2.45 MHz which targets the epidermis and dermis). This may be a subject for future research.

Based on the results of this study, the Reaction™ system with CORE™ technology was found to be a safe and highly effective modality for the treatment of cellulite and body shaping especially in the thighs and buttocks areas.

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