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.

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 visit, 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 2-2.33.

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.

### 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.