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ORIGINAL ARTICLE

Observational Study

Multi-channeling optimized radiofrequency energy: A new age in well-established radiofrequency technology

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Institutional review board statement: The study performed according good clinical practice requirement.

Informed consent statement: All study participants provided informed written consent prior to study enrollment.

Conflict-of-interest statement: Both authors, both authors are employees in Viora Company that manufactures the RF system used in the study. However, both authors did not receive any additional financial or other benefit/interest due to this study or publication. All data provided in the study is original and not modified.

Data sharing statement: Technical appendix, statistical code, and dataset available from the corresponding author at inna@vioramed.com. Participants gave informed consent for data sharing.

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Abstract

AIM

To evaluate the safety and efficacy of Viora's new multi-polar radiofrequency (RF) handpiece.

METHODS

A group of twelve volunteers (11 females and 1 male) participated in the current study, ranging in age from 23-70 years with Fitzpatrick skin type Ⅱ-Ⅴ. The inclusion criteria for the enrollment were no contraindications for the treatment, body mass index (BMI) < 35 and local fat accumulation or cellulite formation. A total of 19 treatment areas were treated in the study: 9 abdomen, 2 abdomen plus flanks, 2 arms and 6 thighs. The treatment performed with new multi-polar RF handpiece (V-FORM) with 4 levels of RF power (up to 50 W), 4 levels of vacuum pressure intensity (up to 500 mbar) and 4 operational modes (0.8, 1.7 and 2.45 MHz). Circumferential reduction and cellulite reduction treatments were performed once a week (7 ± 1 d) for a treatment series of 3-8 sessions. The clinical assessment of the treatment outcomes included skin moisture level, skin impedance, body temperature, circumferential measurements, clinical photographic assessment and BMI.

RESULTS

Ten of twelve patients completed the treatment course. No side effects were recorded during the study. The skin responded with slight erythema and sometimes edema, which is considered a positive end-point. All patients maintained a stable weight during the

entire period of the study. No patient underwent any treatments or took medications for fat volume reduction during the study. A moderate positive correlation was found between the patient's age and BMI (correlation coefficient 0.54). The initial body temperature increased in average to 34.0 ℃ from 31.9 ℃, the initial skin moisture level increased to an average 40.98% from 38.9% and the initial skin impedance decreased by 3.8%-35.9% by the end of the treatment course. The pre-heating time for all body areas ranged between 1-6 min with negative correlation to the body's end-point temperature (correlation coefficient -0.31). All patients responded to the treatment and showed some degree of circumferential reduction (up to 15 cm), on at least one of two-three measured points.

CONCLUSION

According to clinical data collected in this study, the new V-FORM handpiece represents an effective treatment with 100% response rate, with the safest treatment profile.

Key words: Radiofrequency; Vacuum; Body contouring; Circumferential reduction; Cellulite

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Core tip: The significant change in circumferential measurements post-V-FORM treatments can be contributed not only to volume reduction due to improved metabolic rate and enhanced natural lipolysis, but also to edema reduction due to vacuum pressure integrated in the handpiece. Moreover, this technology enables the control of radiofrequency depth penetration which allows finishing the treatments with a skin tightening effect using higher radiofrequency frequencies (1.7 and 2.45 MHz).

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INTRODUCTION

Local fat accumulation and cellulite formulation are two main symptoms related to the reduced metabolic rate in the tissue and rigid connective tissue. Non-invasive procedures based on different modalities such as high intensity focused ultrasound energy (HIFU), radiofrequency (RF), infrared light (IR), cryolipolysis, low-level laser therapy (LLLT), cavitation ultrasound, *etc.*[1-9], in their principle indicated to induce natural lipolysis and reduce fat volume. Technologies that aimed to heat the adipose tissue mainly focused on improving the blood microcirculation to improve the metabolic rate in the impact tissue. In several RF-based systems the thermal heat is combined with vacuum to produce mechanical pressure[3-7,10]. The addition of mechanical pressure enhances the improvement of blood microcirculation and stimulates lymphatic drainage.

The distribution of RF's electrical current mainly depends on the geometry of the device's electrodes. In the esthetic market, two typical configurations are used: Monopolar and bipolar. The major difference between these two configurations is in the way the RF current is controlled and directed at the target tissue[11]. The main advantage of a bipolar configuration is the controlled distribution of RF current inside the tissue, which is limited by distance between the two electrodes. Recently in the esthetic market new terms have sprouted up, such as multi-polar, tri-polar, octi-polar, *etc*. In this concept, the multi-polar RF is an engineering modification of a bi-polar configuration, where more than one pair of bi-polar electrodes exists in the handpiece[10]. The main advantage of a multi-polar handpiece is the ability to cover a much larger treatment area in one pulse, which in most cases leads to faster heating of the treated tissue and its ability to deliver homogeneous distribution of the heat.

The aim of this clinical study was to evaluate the safety and efficacy of Viora's new multi-polar RF handpiece (V-FORM) based on channeling optimized RF energy (CORE), Viora's proprietary technology[10].

MATERIALS AND METHODS

Case study group

A group of twelve volunteers (11 females and 1 male) participated in the current study, ranging in age from 23-70 years (average 43.7, SD ± 14.1) with Fitzpatrick skin type Ⅱ-Ⅴ. The inclusion criteria for the enrollment were no contraindications for RF treatment, body mass index (BMI) < 35 and local fat accumulation or cellulite formation. A total of 19 treatment areas were treated in the study: 9 abdomen, 2 abdomen plus flanks, 2 arms and 6 thighs (Table 1).

The initial body weight range of the patients was 57.3-78.7 kg (average 67.64, SD ± 7.56) with a height range between 150-180 cm (average 163.8 cm, SD ± 7.88) and a calculated BMI of 22-31 kg/m^2 (average 25.4, SD ± 2.2). Six patients were in the range of normal "healthy weight" (BMI 18.5-25 kg/m^2), five patients were in the "overweight" category (BMI 25-30 kg/m^2) and one patient was in the "obese class I" (moderately obese) category (BMI 30-35 kg/m^2) (Table 1).

Handpiece description

The new multi-polar RF handpiece (V-FORM) utilizes Viora's proprietary CORE technology with vacuum[10], which represents the Multi-CORE technology. V-FORM handpiece has 4 levels of RF power (up to 50W), 4 levels of vacuum pressure intensity (up to 500 mbar) and 4 operational modes (Mode Ⅰ-Ⅳ) with three RF frequencies: 0.8, 1.7 and 2.45 MHz and additional

Table 1 Case study patient details

Patient ID	Treatment area	Age	BMI	Number of treatments
VF-001	Thighs, abdomen plus flanks	28	23	6
VF-002	Abdomen	33	22	7
VF-003	Abdomen	44	26	6
VF-004	Abdomen	56	26	8
VF-005	Abdomen	31	26	Dropped from the study
VF-006	Abdomen	40	26	3
VF-007	Abdomen and thighs	23	25	Dropped from the study
VF-008	Arms and abdomen	70	31	8
VF-009	Thighs	34	25	3
VF-010	Abdomen plus flanks	61	27	5
VF-011	Abdomen	47	24	2
VF-012	Thighs	57	23	3
Average		43.7	25.4	5.1
SD (±)		14.1	2.2	2.1

BMI: Body mass index.

operation mode which includes all three RF frequencies. The V-FORM handpiece incorporates integrated IR thermometer, continuous impedance measurement system and interchangeable applicators in different sizes.

Treatment regimen

Circumferential reduction and cellulite reduction treatments were performed once a week (7 ± 1 d) for a treatment series of 3-8 sessions. Each treatment area was treated for 15-20 min, according to the treatment area's size. The treatments were performed according to Viora's standard protocol.

Clinical assessment

The clinical assessment of the treatment outcomes included several measurements and tools: The skin moisture level measured with a digital moisture monitor (Skin Testing Checker, Hautpflege-Konzepte aus Erfahrung) before the treatment and immediately post treatment. The measurement was performed on the same spot of the body, after the glycerin was applied. According to the digital moisture monitor indicator, values < 30% indicate extremely dehydrated skin, values between 31%-36% indicate dehydrated skin, values of 34%-47% indicated normal skin and values > 48% indicated excellent hydration; a skin impedance measurement was conducted according to Ohm's law, in which the impedance was derived from the peak voltage detected during the "test pulse" of the V-FORM handpiece after the electrodes came in touch with the skin. This measurement was performed in a separate test, on 10 randomly chosen treatment areas before the treatment and immediately post treatment on the same spot of the body, after the glycerin is applied; body temperature was measured *via* an integrated IR thermometer, at three times points: Before, during and immediately post treatment; circumferential measurements were performed using the same tape measure tool at the same points on the treated area. Two-three measurement points with 5 cm distance in between were taken for each treatment area at three times: before, middle of course and four weeks after the last treatment. The circumferential change (in cm) was calculated as the following: Circumference (cm) recorded in the baseline meeting, minus circumference (cm) recorded four weeks after the last session; BMI was calculated according to standard guidelines, where weight in kg (kilograms) is divided by height in square meter. The body height and weight were measured according to a standardized protocol where patients are requested to stand without shoes and heavy outer garments for the measurement[12]. The calculation of BMI conducted during the enrollment meeting and four weeks after the last treatment; clinical photographic assessments were recorded twice: (1) during enrollment meeting-(before the first treatment); and (2) four weeks after the last treatment; finally, the treating personnel were asked to record and immediately report any adverse event or unexpected side-effect.

Statistical analysis

For statistical analysis all tests were performed using Microsoft Excel 2010. In total, ten patients were included in the statistical analysis since two patients didn't complete the treatment course. Descriptive analysis was performed on the treated group and the number of valid cases for each test, minimum and maximum values, mean and standard deviation (SD), correlations between two values (CORREL) and percentage were calculated.

RESULTS

Ten of twelve patients completed the treatment course. No side effects were recorded during the study. The skin responded with slight erythema and sometimes edema, which is considered a positive end-point.

All patients maintained a stable weight (weight fluctuations were limited to -0.4 and + 0.6 kg) during the entire period of the study. No patient underwent any treatments or took medications for fat volume reduction during the study.

A moderate positive correlation was found between the patient's age and BMI (correlation coefficient 0.54).

The pre-heating time for all body areas ranged between 1-6 min (average 2.26 min) with a low negative correlation to the body's end-point temperature (correlation coefficient -0.31).

The initial body temperature (temperature before the treatment) ranged between 31 ℃-35 ℃ as the baseline (average 31.9 ℃) and increased to 32 ℃-36 ℃ (average 34.0 ℃) by the end of the treatment course.

The initial skin moisture level (detected before the treatment) ranged between 28.5%-49.0% as the baseline (average 38.9%) and increased to 31%-50% (average 40.98%) by the end of the treatment course (these values are not related to the skin impedance test described in Table 2). The skin moisture level measured at the end of each treatment ranged between 28.6%-65.0% (average 47.2%) which represents a 0.4%-31.4% change in the

Table 2 Skin impedance change post treatment (correlated to skin moisture level)

Patient ID	Treatment area	Skin moisture level (%)			Impedance (Ω)		
		Initial	End	Change (%)	Initial	End	Change (%)
VF-001	Abdomen	38.9	48.4	20	156.4	123.5	21.0
VF-002	Abdomen	32.0	54.2	41	201.9	188.0	6.9
VF-003	Abdomen	39.6	46.1	14	139.1	114.6	17.6
VF-004	Abdomen	38.5	46.7	18	147.7	94.6	35.9
VF-005	Abdomen	38.9	48.4	20	143.9	97.0	32.6
VF-006	Abdomen	41.6	48.3	14	144.0	132.0	8.3
VF-007	Abdomen	38.9	48.4	20	144.2	104.2	27.7
VF-008	Abdomen	36.3	47.0	23	104.8	95.7	8.6
VF-009	Thigh	37.2	46.6	20	216.5	179.3	17.2
VF-010	Abdomen	40.0	56.3	29	114.3	110.0	3.8
Average		38.2	49.0	21.7	151.3	123.9	18.0
SD (±)		2.5	3.2	7.6	32.7	32.1	10.7

Table 3 All measurement points of circumferential reduction per treatment area, number of treatments and body mass index (each line represents a separate measurement point)

Area	Circumference measurement		Circumferential reduction (cm)	Circumferential reduction (%)	Number of treatments	BMI (kg/m^2)
	Baseline (cm)	4 wk post last treatment (cm)				
Thighs	63	62.5	0.5	0.8	6	23
	58	58	0	0		
	64	63.5	0.5	0.8		
	56	56	0	0		
	56.7	54.2	2.5	4.6	3	25
	52.5	51.4	1.1	2.1		
	40.4	39	1.4	3.6	3	23
	40	39.4	0.6	1.5		
Abdomen	94	90	4	4.4	6	23
	71.5	71	0.5	0.7		
	92	90	2	2.2	4	27
	96	94	2	2.1		
	87	85	2	2.4		
	92	90.5	1.5	1.7	6	26
	93	95	-2	-2.1		
	87	86.5	0.5	0.6		
	83	82	1	1.2	8	26
	91	87	4	4.6		
	101	95	6	6.3		
	112	100	12	12	5	31
	104	104	0	0		
	112	97	15	15.5	8	31
	104	96	8	8.3		
	92	89	3	3.4	5	27
	96	92.5	3.5	3.8		
	87	84	3	3.6		
Arms	38	37	1	2.7	4	31
	36	34	2	5.9		
	38	35	3	8.6	8	31
	36	38	-2	-5.3		
	35	34	1	2.9	4	31
	35	36	-1	-2.8		
	35	33.2	1.8	5.4	8	31
	35	34	1	2.9		

BMI: Body mass index.

moisture level post-treatment (average 9.23% change).

A test that aimed to evaluate the change in skin impedance was performed separately on ten randomly chosen treatment areas (Table 2). The initial skin impedance (detected before treatment) ranged between 104.8-216.5 Ω in the baseline (average 151.3 Ω, SD ± 32.7) and decreased by 3.8%-35.9% (average 18%) by the end of the treatment, which represents a 4.4-53.1 Ω change in the impedance post-treatment.

A moderate negative correlation was found between

the changes in the skin's moisture level and skin impedance (correlation coefficient -0.5) with similar coefficient between initial values of impedance and skin moisture level (Table 2). This founding was expected, since blood and parts of the body with high water concentration have lower electrical resistance[10].

All patients (10 of 10) responded to the treatment and showed some degree of circumferential reduction, on at least one of two-three measured points. The measured circumferential reduction of all 36 measurement points ranged from -2 cm (gained circumference) to 15 cm, with an average reduction of 2.78 cm (SD ± 3.38) (Table 3). From a total 36 measurement points, only three measurement points did not show any change in the circumference, (0 cm) and three showed an increase in circumference (negative values in Table 3). Thighs showed the lowest percentage of circumferential reduction (1.68%), followed by the abdomen (4.28%) and arms (4.74%). A negligible positive correlation was found between the percentage of circumferential reduction and number of treatments (correlation coefficient 0.21). However, a low positive correlation was found between a percentage of circumferential reduction and BMI (correlation coefficient 0.44).

DISCUSSION

In this study, 100 percent of patients responded to the V-FORM treatment with at least a 0.6% circumferential reduction on one of the measurement points, indicating that RF treatment has influence on all types of patients. No correlation between the circumferential reduction and the number of treatments (correlation coefficient 0.21) may indicate that treatment response is based on individual characteristics of the patient such as metabolic rate, age and BMI. The positive correlation between circumferential reduction and BMI (correlation coefficient 0.44) supports this conclusion. Interestingly, the high BMI values (above 30 kg/m^2) were mostly considered as exclusion criteria for RF-based treatments. In this study, the positive value of correlation between circumferential reduction and BMI indicates that the higher the patient's initial BMI, the higher percentage of circumference reduction we can achieve. Moreover, the patient with the highest BMI in this study (BMI 31 kg/m^2) was also the most responsive to the treatment, with the highest circumferential measurement values and percentages (15.5% and 8.3%, Figure 1). These findings may suggest the multi-polar RF together with CORE technology may represent a non-invasive solution for high BMI patients. However, in order to establish a more accurate recommendation, additional study with a bigger cohort size, with BMI 30-35 needs to be conducted. The moderate positive correlation between the patient's age and BMI was also expected due to the fact that the metabolic rate of the body reduces with age, which leads to higher values of BMI. The positive correlation between age and BMI was also showed in several unrelated studies[13,14].

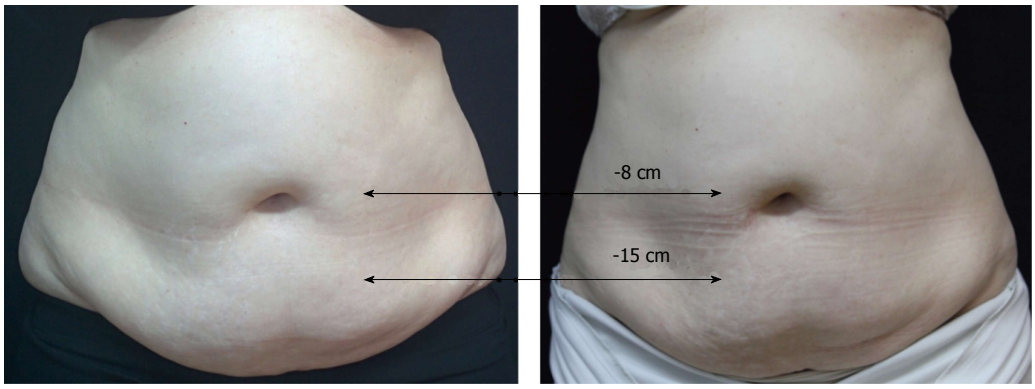
Since in this study, all patients had maintained a stable weight, the circumferential reduction can by directly related to the treatment itself. Contrary to fat destruction techniques, such laser lipolysis, liposuction, cavitation ultrasound, *etc*., the RF-based treatment aimed to increase the metabolic rate and enhance natural lipolysis of the fat cells without hypodermal distraction[10]. The assessment of improvement in blood circulation can be evaluated *via* the changes in initial body temperature, skin moisture level and skin's impedance. In this study, the increase in initial body temperature from an average of 31.9 ℃ to an average of 34.0 ℃ by the end of the treatment course indicates improvement in the local blood microcirculation. This data is further supported by an increase in the initial skin moisture level (from an average of 38.9%-40.98%) and even more by an 18% change in the skin impedance. The negative correlation between skin moisture level and skin impedance (correlation coefficient -0.5) indicates that low water concentration contributes to the skin resistance as showed by high values of impedance. This finding is expected, since blood, and parts of the body with high blood content, have the highest electrical conductivity. The 0.4%-31.4% change (average 9.23%) in the moisture level post-treatment is additional supporting point to prove improved blood circulation. The change in the skin's moisture level at the end of the treatment course compared to the initial level recorded in the first treatment (average change of 40.98%) indicates a long term influence on the extracellular matrix achieved *via* fibroblast stimulation. This finding stands together with previously published data on the influence of RF and, in particular, CORE technology, on the dermal tissue[10].

In addition, the significant change in circumferential measurements post-V-FORM treatments can be contributed not only to fat volume reduction due to improved metabolic rate and enhanced natural lipolysis, but also to edema reduction due to vacuum pressure integrated in the handpiece. Moreover, the Multi-CORE technology enables the control of RF depth penetration which allows finishing the treatments with a skin tightening effect using higher RF frequencies, at 1.7 and 2.45 MHz.

Thighs showed the lowest percentage of circumferential reduction with only 1.68% (compared to abdomen and arms with 4.28% and 4.74%, respectively). This can be explained by the fact that patients who participated in the study for thigh treatments exhibited cellulite appearance and not local fat accumulation (Figure 2).

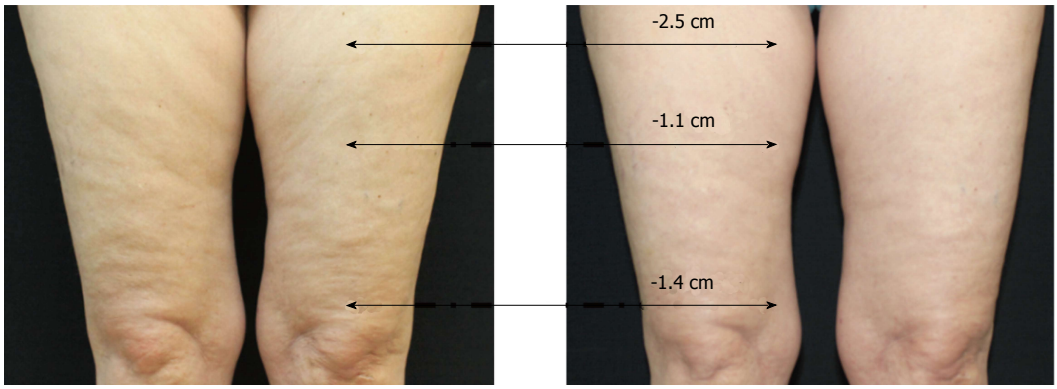
The design of the V-FORM handpiece includes multiple electrodes (multi-polar RF) enables the coverage of big treatment areas in a very short time (the time needed to increase the body temperature to 39 ℃-42 ℃ measured an average 2.26 min pre-heating time). The negative correlation between pre-heating time and the body's end-point temperature related to the fact that patients with higher skin conductivity can be heated much faster and to higher end-point temperatures.

During the entire study no adverse effects were recorded. This can be attributed to the fact that the



Before 4 wk after 8 treatments

Figure 1 A 70-year-old female (body mass index 31) before and 4 wk after 8 treatment sessions (after), with 15 and 8 cm circumferential reduction (according to 2 measurement abdomen points).



Before 4 wk after 3 treatments

Figure 2 A 57-year-old female (body mass index 31) before and 4 wk after 3 treatment sessions with 2.5, 1.1 and 1.4 cm circumferential reduction (according to 3 measurement points). Reduction of cellulite grade 3 to grade 2.

V-FORM handpiece monitors the skin impedance during the entire pulse and controls the RF energy current release accordingly. The design of the applicator itself contributes to an even vacuum spread over the tissue which dramatically reduces the chance to cause hematomas. Multiple electrodes contribute to the homogeneous heat spread over the tissue without hot-spots, which increase patients' tolerance to the treatments and also reduces the appearance of side effects. In addition, as expected, all skin types (Ⅰ-Ⅴ) that were included in the study reacted to the treatment regardless of the skin phototypes, as RF energy has similar behavior in all Fitzpatrick skin types.

In conclusion, according to clinical data collected in this study, the new V-FORM handpiece represents without any doubt an effective treatment with 100% response rate, with the safest treatment profile.

COMMENTS

Background

Local fat accumulation and cellulite formulation are two main symptoms related to the reduced metabolic rate in the tissue and rigid connective tissue. Invasive fat removal procedures are usually too expensive, with long downtime and complication. Therefore non-invasive procedure commonly used. Technologies that aimed to heat the adipose tissue mainly focused on improving the blood microcirculation to improve the metabolic rate in the impact tissue. The main difference between these different technologies is the magnitude of change.

Research frontiers

In the recent years most of the studies in the field of non-invasive body contouring treatments concentrating on the ability to reduce fat volume with significant circumferential reduction achieved *via* several treatment without pain, complications and downtime.

Innovations and breakthroughs

This is a first published study conducted with multi-polar radiofrequency (RF) handpiece (V-FORM) which based on channeling optimized RF energy (CORE) technology. For the authors' knowledge, it was also the first study that examined the correlation between initial body temperature, moisture level, skin impedance and circumferential reduction.

Applications

The data in this study suggested that treatment with multi-polar RF based on CORE technology can achieve high percentage of circumferential reduction also among patient with BMI higher then 30, which was common limitation for most of RF based treatments.

Terminology

Multi-polar RF configuration is a system that has more than two typical bi-polar electrodes. In such configuration, each pair of electrodes acts as bi-polar RF, but more than one pair is available making the heating procedure faster and homogeneous.

Peer-review

It is an interesting and well written review. The paper describes a new technique of way to Dermatology. This is an interesting paper regarding the use of radiofrequency technology, with regards to safety and efficacy. Overall, the study methodology was adequate, and the results were significant.

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