Journal of Cosmetics, Dermatological Sciences and Applications, 2021, 11, 279-292
https://www.scirp.org/journal/jcdsa
ISSN Online: 2161-4512
ISSN Print: 2161-4105

Retrospective Analysis of Treatment Results by Non-Invasive Radiofrequency (RF) Device with Standard and High Voltage RF Electrical Pulses Coupled with Suction for Fat Reduction and Cellulite Improvement

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How to cite this paper: Hellman, J. and Mulholland, R.S. (2021) Retrospective Analysis of Treatment Results by Non-Invasive Radiofrequency (RF) Device with Standard and High Voltage RF Electrical Pulses Coupled with Suction for Fat Reduction and Cellulite Improvement. *Journal of Cosmetics, Dermatological Sciences and Applications*, **11**, 279-292.
https://doi.org/10.4236/jcdsa.2021.114023

Received: August 31, 2021
Accepted: November 5, 2021
Published: November 8, 2021

Abstract

Introduction: The growing demand for non-surgical, non-invasive procedures for fat and circumference reduction and for cellulite treatments has led to the development of various energy-based technologies. Bi-polar radiofrequency (RF) technology combined with additional technologies, such as vacuum, massage or infrared (IR) light is widely used in various body contouring treatments in the medical aesthetic market. The current study is based on a retrospective efficacy analysis of an RF device, combining two RF modalities, coupled with suction. **Methods:** Representative treatment outcomes, documented in photographs taken at baseline and post-treatment were gathered from several clinics. Photos of the various treatment areas were evaluated by independent evaluators for cellulite and contour improvement. **Results:** Before and after photographs were gathered from 31 patients treated in different clinics. Analysis was carried out on different body areas such as thighs, abdomen, back, buttocks and arms and analyzed by two independent evaluators. Scoring was performed according to the Global Aesthetic Improvement Scale (GAIS) scale and indicated an overall improvement in the contour of all treated body areas. In cellulite cases, improved appearance according to the cellulite grading scale was noted. **Conclusion:** This retrospective analysis supports the device's efficacy for fat and circumferences reduction and cellulite improvement. The device's unique specifications contribute to treatment safety and efficacy which is highly tolerable by the patients.

Keywords

Noninvasive Radiofrequency, RF, Fat Reduction, Adipocytes Apoptosis, Adipose Tissue, Fat Reduction, Cellulite Improvement, Electroporation

1. Introduction

Non-invasive body contouring technologies to treat fat and cellulite deposits are widely used in the medical aesthetics market. The growing demand for non-surgical, non-invasive procedures for fat and circumference reduction and for cellulite treatments has led to the development of various energy-based technologies.

During the last decade of the 20th century, these technologies were based on non-thermal mechanical rollers and suction, enhancing lymphatic drainage. Various combinations of thermal-based devices emerged, such as lasers, radio-frequency (RF), infrared (IR) or cryo-based energies along with or without suction or other types of mechanical massage [1].

Optical energy, IR or RF-based systems, with or without suction or rollers, were reported to emit thermal energy to the upper-fat layers, enhancing adipocytes metabolism, including lipolysis [2] [3].

Adipose tissue is spread throughout the body, comprising 15% - 25% of body weight and serving as the body energy reservoir. Energy is stored in the adipocytes as triglycerides in fat lobules. The fat lobules are separated by rigid fibrotic septae comprised mainly of collagen fibers. Volume extension of the adipocytes caused by excess triglycerides is nearly unlimited and may cause focal fat accumulation. The rigidity of the septa around the fat lobules may force the excess fat to bulge into the softer dermis and become apparent on the skin surface, presenting as cellulite. Cellulite presents a cosmetic issue mainly in females, due to the positioning of the septae [4] [5].

Natural lipolysis is causing disintegration of the triglycerides into its components—free glycerol and triglycerides, using the emitted energy. Noninvasive energy-based devices decrease the adipocyte volume by enhancing the natural rate of lipolysis. Excess glycerol and triglycerides are metabolized, but adipocytes stay intact and may refill and enlarge with stored triglycerides [1].

Additionally, non-invasive energy-based devices may affect the dermal cells and fibers and may induce neo-callogenesis, as well as fibroblast regeneration. This leads to a tightening effect on the skin and some improvement in cellulite. RF devices, being able to penetrate as deep as 5 - 25 mm into the subcutis, have a better effect on skin tightening than other energy sources. Direct effect on the adipose tissue is possible when the vacuum is involved, allowing the energy to penetrate deeper [1] [2] [3].

The RF-based system with the BodyFX and MiniFX handpieces has, in addition to enhancing lipolysis and tightening the skin, the ability to destroy some

adipocytes. The objective of the current article is to evaluate retrospectively the effect of the BodyFX and MiniFX handpieces for the improvement in the appearance of cellulite, circumference reduction and body contouring.

2. Materials and Methods

2.1. Device and Technology

The InMode BodyFX and MiniFX handpieces (InMode Ltd., Israel) are based on RF technology combined with vacuum. The BodyFX is designed for large body areas, while the MiniFX is a smaller applicator developed for the submentum, jowl and smaller body areas like arms and localized areas of cellulite. The handpieces comprise a vacuum chamber, 2 RF electrodes and a temperature sensor. The device specifications are frequency of 1 MHz, RF energy of 10 - 50 W for BodyFX and 10 - 25 W for MiniFX, and simultaneous controlled vacuum. The vacuum chamber is applied to the skin surface and comes into complete contact with the skin for optimal heating. The RF electrodes are located in the vacuum chamber and deliver RF to the treated tissue. A temperature sensor is located in the distal end of the vacuum chamber for skin surface temperature measurement.

The BodyFX and MiniFX handpieces are shown in Figure 1.

The RF technology of the BodyFX and MiniFX combines the following suction-coupled energy sources:

• Uniform standard-voltage RF pulses, using high frequency oscillatory electrical current at 1 M cycles per second (1 MHz). The outcome is heating of the dermis and underlying superficial fat layers accompanied by real-time temperature monitoring of skin surface, by an integrated IR thermometer. A cut-off temperature measurement mechanism, predetermined by the user, ensures a limited safe temperature that prevents overheating. At the same time, this safety feature enables a prolonged therapeutic temperature to yield effective outcomes.

Figure 1. MiniFX (Left) and BodyFX (Right) handpieces.

• High-peak power pulses with high voltage (HV) RF, emitted during ultra-short duration pulses are applied to the skin surface, reaching the dermis and subcutaneous fat. These RF pulses are designed to affect selectively large cells like adipocytes and cause irreversible electroporation in their cell membrane. The outcome is a natural delayed gradual process of apoptosis, leading eventually to adipocytes cell death. Immunological staining with apoptosis markers indicated ~20% of fat cells exposed to this HV, ultrashort RF pulses to presented electroporation leading to apoptosis [5] [6] [7].

The handpiece applies negative pressure to the soft tissue of the area to be treated, drawing the skin and subcutaneous tissue up to 1 cm into the cavity. Standard bipolar RF is passed between the two electrodes and through the adipose tissue and skin, resulting in stimulatory tissue heating.

The unique RF pulse design contributes to BodyFX and MiniFX efficacy. Standard RF at low voltage creates a transient physiological effect of fat cells shrinkage, as well as collagen tightening. In addition, HV RF pulses of high peak-power enforce the effect by leading to some adipocytes cell death by apoptosis with long-term results.

BodyFX and MiniFX technology include some features which optimize treatment safety.

The cut-off temperature as set by the user, up to an upper limit of the temperature of 43˚C, is constantly maintained, and when reached, RF delivery is automatically disabled. An integrated temperature sensor inside the vacuum chamber of the handpiece renders the treatment very safe.

The measured temperature is shown during the treatment on the screen, thus giving a real time feedback contribution to treatment safety and efficacy.

In addition, there is a vacuum level monitoring and RF is disabled when vacuum is below the predetermined level.

2.2. Treatment Procedure

BodyFX and MiniFX treatment contraindications include pacemaker or internal defibrillator, other implanted metallic or electronic devices, permanent metal or silicone implants in the treated area, current or history of cancer, pre-malignant conditions, cardiac disorders and any severe concurrent disease, pregnancy or lactating, impaired immune system, current or history of diseases stimulated by heat, uncontrolled diabetes, active skin condition in the treatment area, skin disorders, any treatment or surgery performed within 3 months prior to treatment, and any therapies or medications used as determined by the study physician. These exclusion criteria are similar to other RF devices.

The recommended number of treatment sessions by BodyFX and MiniFX may vary from 4 - 8 sessions once a week. The number of treatment sessions depended on the individual patient. RF treatment parameters were usually 30 - 40 W in the case of BodyFX and 10 - 20 W when MiniFX was used in smaller and curved treatment areas or for more superficial effect. Pulse width was 1 - 4

seconds according to skin sensitivity. Treatment was typically concluded when the results were satisfactory to the patient or according to the physician's discretion. One session every 3 - 6 months, or as needed, was recommended as it might help in maintaining treatment results.

The current article is based on a retrospective analysis of 31 patients treated with the BodyFX and MiniFX handpieces in several clinics that agreed to share their results. The teams in these clinics are trained and experienced with the BodyFX/MiniFX treatment technology and guidelines.

2.3. Efficacy and Safety Evaluation

Treatment efficacy was based on analysis of photographs of the treated areas that were taken at standard conditions at baseline and following the treatments.

Photos of the various treatment areas were evaluated for efficacy by qualified independent evaluators for cellulite and contour improvement. Safety was evaluated during and after each treatment. Adverse events, if any, were asked to be documented and followed to determine resolution time.

All gathered photos were graded by two qualified independent evaluators for overall area appearance improvement. Scoring was based on the Global Aesthetic Improvement Scale (GAIS) below (Table 1).

The before and after photos of the cellulite cases were evaluated according to the cellulite grading scale below (Table 2).

3. Results

Representative photographs gathered from several clinics demonstrate the BodyFX and MiniFX treatment effects. The photos of 31 subjects of which 27 were treated with the BodyFX and 4 with MiniFX were taken at baseline and at follow-up time points. BodyFX treatment areas included 13 cases of abdominal fat, 5 cases of back fat, 8 cases of cellulite in thighs and buttocks and one case of arms. MiniFX treatment areas included 1 case of buttocks focal fat deposit and 3 cases of submental area. Treatment procedures were conducted according to instructions in the BodyFX and MiniFX Operator Manual. Treatment parameters, as well as the number of treatment sessions were adjusted individually. This retrospective summary showed an improved appearance of cellulite, fat deposits and body contour. No significant adverse events were reported. Informed consent was received by all patients to include their photos.

Table 3 summarizes the evaluators GAIS scoring results.

The two evaluators assessed all photos as 1 - 3 scores (Very much improved, much improved and improved, respectively), using the GAIS scale. No cases were graded as no change or worse.

Table 4 summarizes the evaluators' cellulite scoring results.

Both evaluators observed improvements in cellulite grades in all cases apart from 1 case that evaluator 2 didn't noticed improvement in cellulite. In most of the cases the improvement was by 1 grade. In few cases improvement of 2 scores was noticed.

Figures 2-4 show representative cases of treatment results with BodyFX.

Figure 5 and Figure 6 demonstrate representative results of MiniFX on the submental area.

Figures 7-11 illustrate the improvement in the appearance of cellulite.

No significant or unexpected adverse events were reported by the t patients.

Table 1. Global Aesthetic Improvement Scale (GAIS).

Score	Improvement
1	Very much improved
2	Much improved
3	Improved
4	No change
5	Worse

Table 2. Cellulite grading scale.

Grade 0—None	Smooth surface of skin
Grade 1—Mild	Stippling of the skin, compared to orange peel skin, without deep pits of large nodules.
Grade 2—Moderate	Mild to moderate sized nodule formation with occasional superficial pits.
Grade 3—Severe	Very deep and numerous pits and large, visibly elevated nodules

Table 3. Evaluators' scores according to GAIS scale.

Patient No.	Treatment area	Evaluator 1	Evaluator 2	Patient No.	Treatment area	Evaluator 1	Evaluator 2
1	Abdomen	1	1	16	Back	2	2
2	Abdomen	2	3	17	Back	3	2
3	Abdomen	1	2	18	Back	2	3
4	Abdomen	1	2	19	Thigh/Buttocks	2	3
5	Abdomen	3	3	20	Thigh/Buttocks	2	3
6	Abdomen	2	2	21	Thigh/Buttocks	3	3
7	Abdomen	3	3	22	Thigh/Buttocks	3	3
8	Abdomen	3	2	23	Thigh/Buttocks	1	1
9	Abdomen	3	2	24	Thigh/Buttocks	3	3
10	Abdomen	3	3	25	Thigh/Buttocks	2	2
11	Abdomen	2	3	26	Thigh/Buttocks	3	3
12	Abdomen	3	2	27	Arm	2	3
13	Abdomen	3	2	28	Buttocks-focal	3	3
14	Back	2	3	29	Under chin	3	2
15	Back	3	1	30	Under chin	3	2
				31	Under chin	2	2

Table 4. Evaluators' cellulite scoring.

Patient No.	Treatment area	Evaluator 1 Before	Evaluator 1 After	Evaluator 2 Before	Evaluator 2 After
19	Thigh/Buttocks	2	1	2	1
20	Thigh/Buttocks	2	1	2	2
21	Thigh/Buttocks	2	1	2	1
22	Thigh/Buttocks	2	1	2	1
23	Thigh/Buttocks	3	1	3	2
24	Thigh/Buttocks	1	0	2	1
25	Thigh/Buttocks	2	0	2	1
26	Thigh/Buttocks	2	1	2	1

Figure 2. Patient #4—BodyFX Results after 6 Sessions. Photos courtesy of Dr. Jacobson/The Collagen Bar.

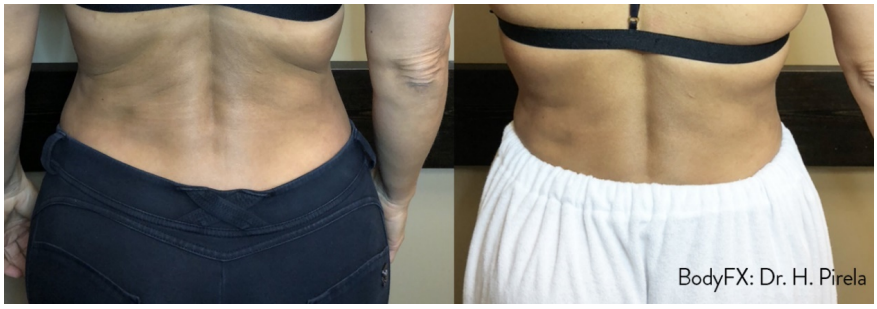


Figure 3. Patient #17—BodyFX Results after 6 Sessions. Photos courtesy of Dr. H. Pirela.

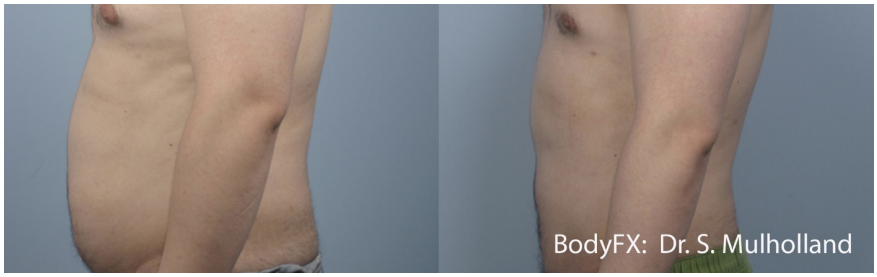


Figure 4. Patient #6—BodyFX results after 8 sessions. Photos courtesy of Dr. S. Mulholland.

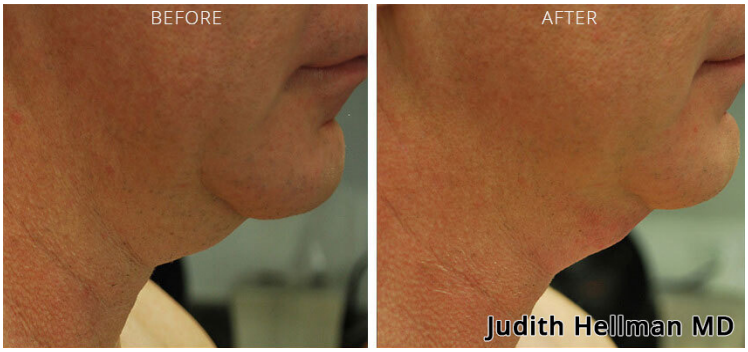


Figure 5. Patient #30—MiniFX results after 4 treatments. Photos courtesy of Dr. J. Hellman.

Figure 6. Patient #31—MiniFX results after 4 treatments. Photos courtesy of Dr. J. Hellman.

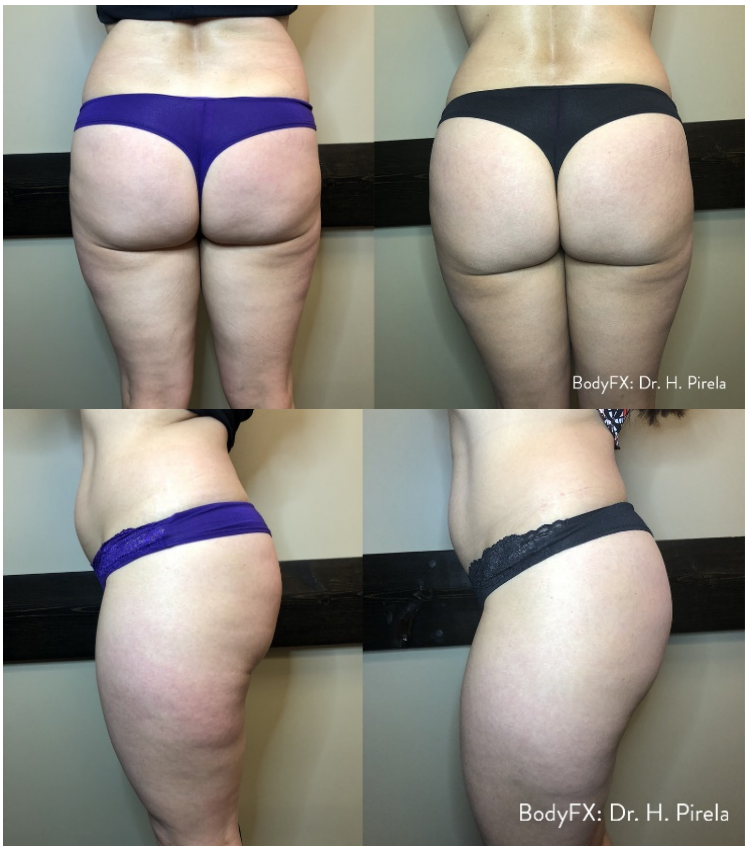


Figure 7. Patient #26—Illustrates improvement in cellulite appearance. Photos courtesy of Dr. H. Pirela.

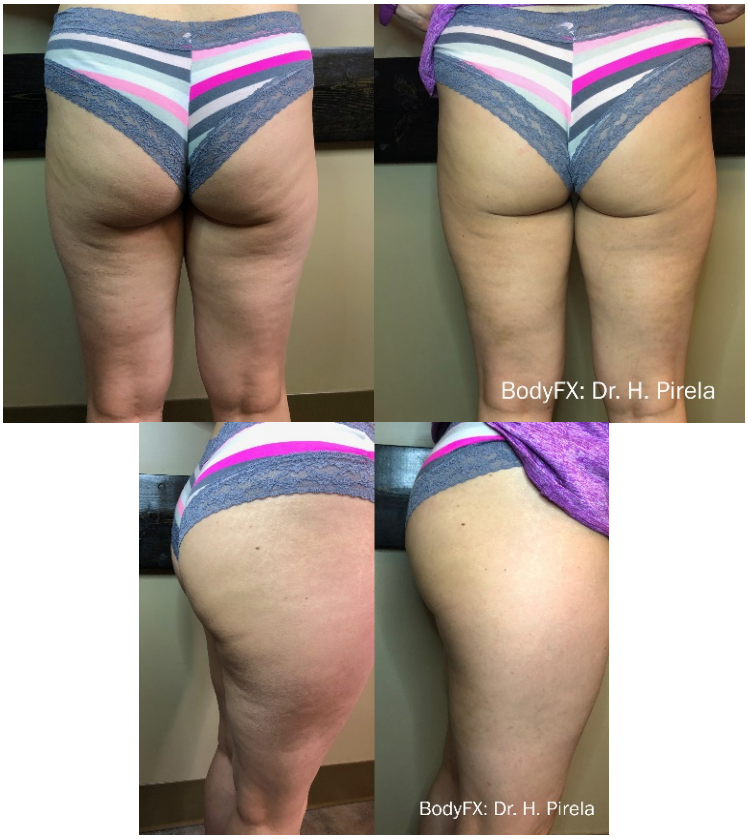


Figure 8. Patient #21—Illustrates improvement in cellulite appearance. Photos courtesy of Dr H. Pirela.

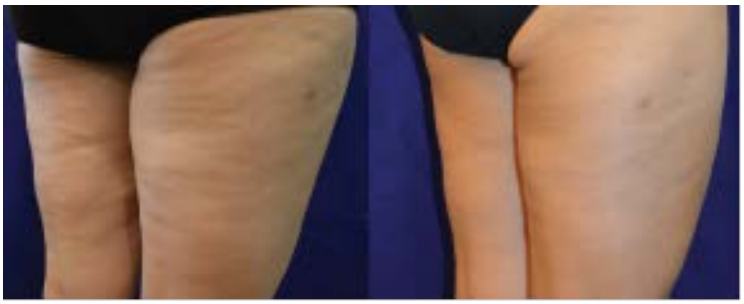
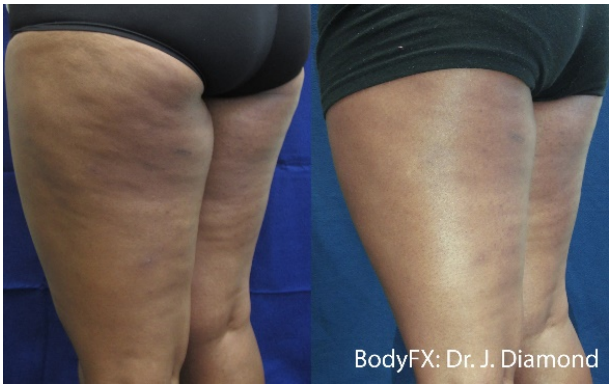


Figure 9. Patient #22—Illustrates improvement in cellulite appearance. Photos courtesy of Dr. J. Diamond.



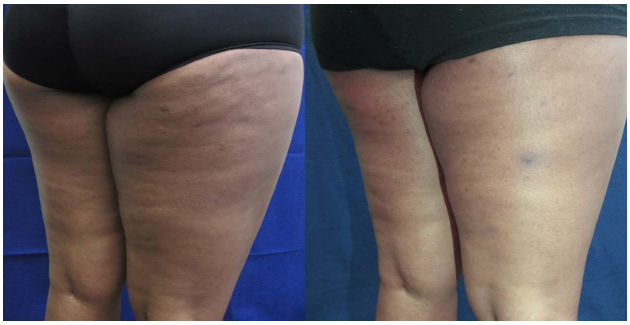


Figure 10. Patient #22—Illustrates improvement in the appearance of cellulite on upper back thighs. Photos courtesy of Dr. J. Diamond.

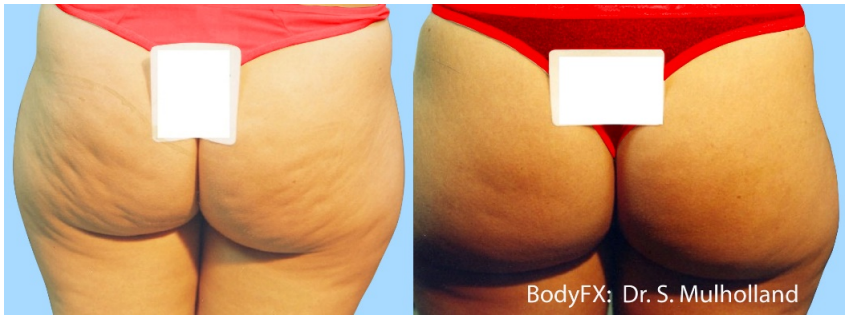


Figure 11. Patient #25—Illustrates improvement in the appearance of cellulite on buttocks and posterior thighs. Photos courtesy of Dr. S. Mulholland.

4. Discussion

Non-invasive body contouring using RF-based technologies is widely used in the medical aesthetics market. Clinical studies have been conducted evaluating similar technologies as well as the BodyFX handpiece, establishing the safety and efficacy of the RF-based modalities for body treatments.

Numerous studies were conducted with the VelaSmooth and the VelaShape systems (Syneron Medical Ltd., Israel) that use combined energies—bipolar RF, IR light, and mechanical massage by vacuum. In a two-center study [2], 35 female subjects with cellulite and/or skin irregularities on the medial thighs received 8 to 16 VelaSmooth treatments twice weekly. 100% of all patients showed some level of improvement in skin texture and cellulite and some reduction in thigh circumference after 8 weeks of treatment. Maximal circumference reduction was >2 inches, with a mean reduction of 0.8". Minimal complications associated with treatment were documented. This preliminary study indicated that the VelaSmooth system with its 3 technologies is effective in cellulite treatment, skin texture and circumference reduction.

Two studies evaluating the VelaShape device further confirmed the safety and efficacy of the technology for fat treatment in various body areas [8] [9]. Brightman *et al.* [8] treated subjects of most skin types (I - V) on the upper arms, abdomen and flanks. Significant arm circumference reduction was noted after 5 treatments (0.6 cm at 3-month follow-ups). Significant abdominal circumference reduction achieved at third treatment was 1.25 cm mean loss that further im-

proved to 1.43 and 1.82 cm at 1- and 3-month follow-ups. This study showed that treatment with VelaShape can cause a significant sustainable reduction in the circumference of arms and abdomen.

Adatto *et al.* [9] studied the high-power RF version of VelaShape device. Adipose tissue and circumference reduction, as well as skin tightening of abdomen/flank, buttocks, or thighs, were investigated. Thirty-five patients received 6 weekly treatments in a few body areas and were followed up to 3 months post-last treatment. A gradual decline in patient circumferences from baseline to post six treatments was demonstrated and correlated with measurements of adipose tissue volume and skin firmness/elasticity, using diagnostic ultrasound and cutometer, respectively. Fat layer thickness showed a 29% mean reduction between baseline and the 1-month follow-up. Mean circumference reduction of abdomen/flanks, buttocks, and thighs from baseline to the 3-month follow-up was 1.4, 0.5, and 1.2 cm, respectively. Study conclusions were that the combined technologies work synergistically, whereby the vacuum enables deeper fat layer treatment and IR heating primes the tissue for RF by reducing the electrical resistance for better results.

Another device that combines bi-polar RF with mechanical pressure is the Reaction (Viora Inc., USA) [10]. Twenty-two Asian patients (Fitzpatrick skin types III-V) received 6 sessions of consecutive abdomen contouring treatment. The system technology allows RF heating at 3 depths by 3 different RF frequencies: 0.8, 1.7 and 2.45 MHz or a combination of three frequencies in a single pulse. No side effects were recorded. Statistic Circumference change was apparent. The study established the safety of RF combined with mechanical manipulation treatment for dark Asian skin.

Previously published BodyFX articles demonstrated the safety and efficacy of the technology [1] [5] [6] [7].

The first BodyFX article published in 2012 [1], presented clinical and histological circumference and cellulite improvement of 25 patients. The abdominal and flank areas received 6 weekly sessions and patients were followed up for 3 months. Three patients who were scheduled for future abdominoplasty surgery had biopsies taken at 72 hours and 14 days following their initial RF treatment. The mean circumferential reduction was 3.58 cm with no non-responders. The mean cellulite score improved 2 sub-grades according to Nurnberger-Muller scale. The mean pit depth reduction was 70% of 4.1 mm, as measured by the Vectra 3D imaging device. The death of some fat cells by the treatment was revealed by histological analysis of the biopsies. No adverse events were recorded. The study conclusion was that the BodyFX treatment is a safe and effective treatment for the non-invasive management of both focal fat excess and cellulite. Standard and ultra-short RF pulses appear to result in a short-term and long-term response, respectively.

Another study evaluated 21 subjects who underwent BodyFX treatment of their abdominal fat for 6 weekly treatment sessions [5]. Three subjects, abdominoplasty candidates, were treated with the same protocol, but on one abdominal

side only prior to abdominoplasty. Biopsies were taken from the RF-treated and controlled untreated sides during abdominoplasty and cultured. Dermal thickness, measurements of adipocyte size and shape, rate of apoptosis and collagen production, were determined. Statistically significant clinical improvements ($P < 0.05$) were noticed at 3-month follow-up visits. They included 113.4 - 110.7 cm reduction in abdominal circumference, 40.5 - 38.5 mm reduction of subcutaneous adipose tissue thickness (measured by ultrasound), 32.2 - 30.7 kg reduction in adipose tissue weight and overall patient weight also decreased. Histological findings showed adipocytes decreased size and withered shape, with increased levels of apoptosis; increased collagen synthesis, and reorganization of the dermis. Only minor, transient and expected side effects, such as bruises, were reported. It was concluded that the BodyFX treatment protocol used was safe and effective clinically by reducing abdominal circumference and reducing subcutaneous fat layer thickness.

Two publications by D. Duncan present her clinical experience with the BodyFX and MiniFX with findings supported by Scanning Electron Microscope (SEM) images [6] [7]. Twenty female patients were treated by the BodyFX device and changes in fat thickness and volume were measured [6]. Measurements included weight, body mass index, ultrasonic transcutaneous fat thickness, and 2D and 3D Vectra photos, indicating the circumferential and volumetric change. Results of ultrasound demonstrated a mean transcutaneous thickness reduction of ~40% after 1 and 3 months. Vectra circumference measurements showed a mean abdominal circumference reduction of 2.3 cm. Mean abdominal volume loss was 202.4 and 428.5 cc at 1 and 3 months post-treatment, respectively. Permanent cell destruction caused by irreversible electroporation has been confirmed by scanning electron microscopy (SEM).

In a study evaluating the treatment protocol [7] the author performed 2 or 3 "mega-sessions" of longer duration of each treatment and compared the outcome to 8 ordinary weekly sessions. The mega-sessions included 3-depth levels, 40 min each, whereas the ordinary sessions were a monolayer of 20 min for 8 weekly sessions. The outcome of volume and patient assessment showed similar results with the 2 or 3 mega-sessions when compared with the traditional protocol of 8 shorter weekly sessions.

In the research, SEM was used to photograph serial biopsy samples taken at different time points following treatment by the BodyFX device. The treatment effect on adipocytes was followed over a period of 8 weeks. SEM photos demonstrated the serial effects of electroporation on adipocytes. Two weeks post two treatments, the adipocytes cell membrane exhibited small cracks. After 4 weeks, post four treatments with BodyFX, the cell wall revealed indentations, representing the electroporation effect. At 8 weeks post the final (eighth) RF treatment, some adipocytes lost significant amounts of cytosol. Lipid droplets extruding through the pores of the affected adipocyte were seen. Study conclusion regarding the mechanism of fat reduction was that the cell response, seen at 8 weeks after BodyFX treatment, is part of a pyroptotic process that combines apoptosis and ne-

crosis. During apoptosis, the cell membrane remains intact and when the cell eventually dies, the metabolized fat droplets egress through cracks in the cell membrane. During the necrotic process, there is early lysis of the cell wall, with a sudden release of the cytosol and a strong inflammatory response. The author hypnotized that both processes of necrosis and apoptosis take place.

The above BodyFX and similar devices published articles indicate that despite the complexity of fat reduction, the treatment of various body areas on a variety of patients' characteristics, like skin type, gender or age, is safe and effective.

The design of the BodyFX and MiniFX handpieces in terms of the use of RF along with vacuum, the RF pulse which is optimized for fat reduction and real-time temperature monitoring, takes advantage of the wide experience collected from similar devices for fat-related indications.

Based on the clinical experience gathered with the BodyFX and with similar non-invasive devices, it is concluded that the BodyFX and MiniFX handpieces are safe and effective as other commercially available devices, using similar technologies and similar treatment parameters for the same indications.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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