

Megasessions: Efficacy of Fewer, Longer Treatment Sessions for Fat Reduction in Noninvasive Body Contouring Using a Radiofrequency Based Device

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ABSTRACT

While the field of noninvasive body contouring is booming, many patients still note a lesser result than they might achieve with a single session of liposuction or dermolipectomy. The duration of a noninvasive fat reduction treatment series can be daunting. Patients have questioned the worth of these procedures when the expected benefit is modest and the time they devote to the project is significant.

An eight-patient mini-study was performed to see if two or three “megasessions” could be substituted for eight weekly sessions of bipolar radiofrequency based fat reduction treatments. Patients were randomized into a two session or three session group by drawing straws. The device used was the BodyFX bipolar RF device by InMode. This device employs a suction coupled vacuum that heats a section of skin and soft tissue in the treatment region and delivers a high voltage pulse. Each patient was treated for 2 hours per session, using the Body FX, more superficial Mini FX, and the Deep FX device in an effort to treat on a multilevel basis. Preoperative 2D and 3D Vectra photos were taken, and were repeated at 1 month and 3 months post-treatment. Volumetric analysis and patient assessment showed similar results with a two or three treatment “megasession” protocol when compared with the traditional protocol of eight weekly sessions. While the cohort number was not statistically significant, the photographs and measurements are compelling enough to warrant further investigation into this treatment protocol.

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INTRODUCTION

While ASAPS statistics show that liposuction continues to be the most popular aesthetic surgical procedure in the US,¹ the field of nonsurgical fat reduction is rapidly expanding.^{2,3} However, devices that initially were designed for a single treatment are now being utilized as a multi-treatment regime in order to optimize results.^{4,5} Patients shopping for the best nonsurgical treatment evaluate cost, down time, clinical efficacy, and the duration and number of office visits needed to achieve their fat reduction and contour correction goals.⁶ In a strongly consumer driven market, it is important to consider safety and clinical efficacy as well as patient satisfaction. In order to achieve more subcutaneous fat reduction in fewer treatment sessions, taking a look at the physics and mechanism of action of radiofrequency on adipose tissue can offer a method to optimize outcome. With bipolar radiofrequency devices, the focal depth of the RF heating and high voltage pulses is determined by the distance between the bipolar RF electrodes on the treatment handpiece.⁷ Because of this factor, a calculated depth of penetration of energy into the adipose layer can be derived for each differently sized radiofrequency based handpiece. In contrast, many alternative noninvasive devices focus at a single depth of treatment,^{8,9} and repeat treatments are, in effect, retreating the same area. By changing the field of treatment to a multiple depth target, more tissue volume should be able

to be effectively treated during a single session than with a single level focus. The premise of this pilot study was that a longer duration of treatment time per session combined with a targeted multilevel approach could achieve results similar to that of a standard longer treatment regime.

MATERIALS AND METHODS

For this study, the Inmode Body FX radiofrequency based device was utilized for treatment of periumbilical abdominal adiposity in eight consecutive patients. Patients were required to be nonpregnant and not breast feeding. All patients were women between the ages of 35 and 63. None had a BMI greater than 30. All patients were weighed at each timepoint; scale weight was not allowed to vary more than 5 pounds from inception in order to control that variable. 2D and 3D Vectra photographs were taken before treatment, and at one month and three months after treatment cessation. The 3D Vectra photos were posture and breathing cycle controlled.

Circumference measurements were digitally calculated at point zero (level of the umbilicus), and at intervals 20 mm above and below the umbilicus. The volume of the 20 mm cylindrical segments was calculated, and the additive volume was assessed at each timepoint in order to measure interval change.

Three different handpieces designed to treat superficial fat, midlevel fat, and deep suprafascial fat were employed during the treatment megasessions. The standard BodyFX treatment regime in the past included eight weekly patient treatment sessions using only the midlevel handpiece for a treatment time of 40 minutes on tissue in the periumbilical abdominal region. The revised protocol included the use of three different handpieces targeting various tissue depths: deep, midlevel, and superficial. Each handpiece was deployed for a duration of 40 minutes on tissue in the periumbilical abdominal region. Other than this change, the standard treatment protocol was observed. The In-mode BodyFX device was utilized. The periumbilical abdomen was divided into four 10 x 15 cm treatment quadrants. Each region was heated for ten minutes using a 43 degree C maximum temperature using a stamping technique, with a 50% overlap. High voltage pulses (HVPs) accompanied the moving external radiofrequency heating in order to produce poroptosis of the adipocytes induced by irreversible electroporation.¹⁰ The Deep FX handpiece was used first, the midlevel Body FX handpiece second, and the MinFX superficial handpiece was used last. Treatment interval was three to four weeks. No postcare was needed following treatments.

RESULTS

All patients agreed that a visible reduction in fat was achieved. Serial 2D and 3D Vectra photographs confirm this assessment. As with previous studies (11, 12), there was little to no clinically perceived difference until one month following the final treatment session (Figure 1). This correlates to changes seen on scanning electron microscopy biopsies taken immediately post-treatment, at one month post-treatment, and at three months post-treatment (Figure 2).

No expected sequelae of RF treatment such as bruising, mild to moderate swelling, or purpura were noted. No complications such as an arc burn, hematoma, infection, or skin abrasion was noted.

A subset of two patients' Vectra measurements was independently evaluated by a Canfield technician. Patient A, age 46, underwent two megasession treatments performed 4 weeks apart. Interestingly, her Vectra measurements showed a slight increase in volume at one month post-treatment despite no weight gain. At three months post-treatment, her calculated volumetric change was -535 cc over baseline (Table 1). Patient B, age 50, underwent three megasession treatments performed four weeks apart. Her volumetric change showed a steady decrease as seen at three timepoints. Her calculated volumetric loss at three months was 412 cc. In a previously conducted 20 patient prospective trial using the eight weekly treatments with a single depth handpiece protocol, the mean volumetric fat loss was 428 cc at three months post-treatment. Figure 3a shows a patient before and after eight treatment sessions; 3b depicts a similar patient before and after two treatment sessions with a

longer treatment time and multilevel approach. Figure 4 shows Vectra images of patient A before and three months following treatment cessation. Figure 5 shows comparison photos of patient A before treatment and 3 months following two treatment sessions, and patient B, before and after treatment with 3 megasessions of the BodyFX device.

DISCUSSION

Current noninvasive fat reduction trends include shorter treatment times, lower cost per treatment, and a wider array of energy types than were available three years ago.^{13,14} While claims of efficacy abound, there are also citations of decreasing efficacy with repeat treatments in the same area on the same patient.^{15,16} Logically, thermal-based energy sources would generate more of a result with more time on tissue, not less. Our study premise, that by treating a patient at multiple levels within the adipose layer, a more profound change might occur with fewer treatments, is a corollary of the time on tissue premise. If a larger thickness of fat could be treated before an inflammatory collagen response is generated, there would be less physical shielding of the fat by that collagen ingrowth that occurs at 1-3 months post-treatment. If two long treatment sessions were performed within 3-4 weeks of each other (before documented peak of collagen generation), the optimum amount of susceptible fat might be reached with thermal energy.

Devices such as Ultrashape, based on ultrasonic cavitation, target a layer of adipose tissue 1.5 cm below the skin's surface.¹⁷ Gross anatomic photographs of the tissue response show focal fat loss with scar formation at the treatment level. A second treatment, again focused at 1.5 cm deep, would re-target the initial treatment region, hitting scar tissue instead of mostly fat. While changes in the depth of fat as measured by ultrasound are seen with most FDA approved nonsurgical fat reduction devices,^{18,19} the percent of measured fat reduction varies widely.²⁰ To optimize outcome and minimize treatment session number, the entire thickness of the adipose layer ideally should be treated when optimal fat thickness reduction is the desired goal.

Limitations of this study include the small subject number and relatively short 3-month duration of follow-up. The measurement of only two patients' Vectra based volumetric changes is another shortcoming. This pilot study was performed to explore the possibility that the premise was worthy of further investigation. Despite these limitations, the pre- and post-treatment photographs and Vectra data are compelling. We recommend a prospective study with a larger patient cohort, longer follow-up time, and independent measurement of all patients' volumetric and surface contour data in order to view the data that then might be statistically significant.

CONCLUSION

A change in treatment protocol from eight weekly sessions to two or three megasessions shows promise in the quest for

more effective and less inconvenient nonsurgical abdominal fat reduction while using a bipolar radiofrequency based device. This thermally based treatment regimen was modified from a previous eight weekly treatment model using a single depth handpiece for a total of 40 minutes' treatment time on tissue. The new protocol utilized a "megasection" model in which three levels of tissue: deep, midlevel, and superficial—were treated for 40 minutes each. Instead of targeting only one level of adipose depth, a multilevel treatment was able to be achieved. Comparison of standardized before and after photographs and 3D Vectra volumetric analysis suggests that efficacy using either two or three treatment megasections can result in a measured volumetric fat loss of over 400 cc at three months following treatment cessation.

DISCLOSURES

The Inmode device was loaned to the author for the purpose of performing the study. Dr. Duncan is a consultant for Inmode.

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