Selective Non-contact Field Radiofrequency Extended Treatment Protocol: Evaluation of Safety and Efficacy

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ABSTRACT

Background and Objective: Currently there are many non-invasive radiofrequency (RF) devices on the market that are utilized in the field of aesthetic medicine. At this time, there is only one FDA cleared device on the market that emits RF energy using a non-contact delivery system for circumferential reduction by means of adipocyte disruption. Innovation of treatment protocols is an integral part of aesthetic device development. However, when protocol modifications are made it is important to look at the safety as well as the potential for improved efficacy before initiating change. The purpose of this study was to evaluate the safety and efficacy of a newly designed extended treatment protocol using an operator independent selective non-contact RF device for the improvement in the contour and circumferential reduction of the abdomen and flanks (love handles).

Methods: Twenty-five subjects enrolled in the IRB approved multi-center study to receive four weekly 45-minute RF treatments to the abdomen and love handles. Standardized digital photographs and circumference measurements were taken at baseline and at the 1- and 3-month follow-up visits. Biometric measurements including weight, hydration and body fat were obtained at baseline and each study visit. A subset of 4 subjects were randomly selected to undergo baseline serum lipid and liver-related blood tests with follow-up labs taken: 1 day post-treatment 1, 1 day post-treatment 4, and at the 1- and 3-month follow-up visits.

Results: Twenty-four subjects (22 female, 2 male), average age of 47.9 years (30-69 years), completed the study. The data of the twenty-four subjects revealed a statistically significant change in circumference $P<.001$ with an average decrease in circumference of 4.22cm at the 3-month follow-up visit. Lab values for the subset of 4 subjects remained relatively unchanged with only minor fluctuations noted in the serum lipid values in two of the subjects. Three independent evaluators viewed pre-treatment and 3-month post treatment photographs to determine which photo was the after photo. The evaluators were able to correctly identify the post treatment photos with an 88% accuracy rate. Treatments were well tolerated by all subjects. No study related adverse events were reported.

Conclusion: This study found that an extended treatment protocol using a selective RF device is a safe and effective method for the reduction of circumference and improved contouring of the abdomen and love handles.

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INTRODUCTION

A wide range of radiofrequency devices for nonsurgical aesthetic treatments is available on today's market. However, they differ significantly in application, treatment time, efficacy, and patient safety. RF devices are commonly used to treat skin laxity, wrinkle reduction, cellulite, and body contouring.[1] The demand for nonsurgical fat reduction has grown significantly over the past years. There are several fat reduction technologies on the market including lasers, high intensity focused ultrasounds, cryolipolysis, and radiofrequencies.[2]

The number of fat cells (adipocytes) is the major determinant of fat mass in adults. Even after marked weight loss, the number of fat cells remains constant and only adipocyte volume is changed.[3] Certain areas of the body tend to be more resistant in terms of volume reduction even with diet and exercise. A recent study showed that after 6 weeks of abdominal exercise training, there was no significant effect of abdominal exercises in reducing abdominal subcutaneous fat when compared to a control group in which no exercise was performed.[4] These findings support the widely held notion that abdominal fat is one of the "stubborn" areas and resistant to change.

The induction of apoptosis has proven to be a viable means to effectively and permanently reduce adipose tissue. Apoptosis is a process of natural cell elimination necessary for maintaining body homeostasis. During this process, dangerous and/or unnecessary cells are removed.[5,6] Apoptosis can be achieved when adipocytes are heated to a temperature range of 42-45C and this thermal threshold is maintained for a minimum of 15 minutes.[7,8] The device under investigation (BTL Vanquish, BTL Industries Inc., Boston, MA) is proven to cause apoptosis in adipocyte tissue induced by selective RF field generated heat.[9,10] The device is capable of reaching the desired treatment temperature (44-45C) in targeted subcutaneous adipose tissue within the first 15 minutes of the treatment and maintaining

therapeutic temperature for the remainder of the treatment.[11,12] The extended treatment protocol is expected to prolong the incidence of therapeutic temperature inside the adipocyte compartment resulting in a greater response of delayed adipocyte cell death.

"The induction of apoptosis has proven to be a viable means to effectively and permanently reduce adipose tissue."

METHODS

Study Design

A prospective, multi-center, IRB approved study was designed to evaluate the safety and efficacy of a newly designed extended treatment protocol using a non-contact RF device for the improvement in the contour and circumferential reduction of the abdomen and flanks (love handles).

A total of 24 subjects (22 females, 2 males) were enrolled. Age of participants ranged from 30 to 69 years with the average of 47.9. Average BMI at the start of the study was 23.9. The study participants were asked to maintain their current diet and exercise habits for the duration of the study. All subjects that met the inclusion/exclusion criteria were enrolled in the study. Inclusion criteria included the following: 18 years or older, visible fat to the abdomen and flanks, a BMI of 30 or less, and a stable weight. Exclusion criteria included the following: pregnancy/nursing or planning to become pregnant during the course of the study, surgical procedure in the treatment area in the past 6 months, invasive fat reduction procedure (eg, liposuction, abdominoplasty) in the treatment area in the past year, presence of active implants such as a pacemaker, defribrillator/cardioconverter and cochlear implant, and metal implants (excluding oral implants).

Every effort was made to standardize digital photography as well as circumference measurements.

Circumference measurements were taken at or proximal to the umbilicus, using a digital circumference measuring tape (by Healthometer®). A wall-mounted height rod (by Healthometer®) was used to standardize the location of the circumference measurement. Once the location of the measurement was determined, a nonpermanent skin-marking pen was used to confirm the location on the anterior abdomen, left and right flanks and back. The spring-loaded, digital measuring tape was then placed around the abdomen following the marked areas. The distance from the floor to the area being measured was observed on the height rod and recorded in the subjects' charts for subsequent measurements. Measurements were taken at baseline and at the 1- and 3-month follow-up visits. Additional biometric data such as weight, % hydration, and % body fat were obtained at baseline and each study visit using a standard home use impedance scale. Digital photographs were taken at baseline and at the 1- and 3-month follow-up visits. In order to produce quality images for reproducibility and assessment, the following variables were controlled: background, lighting, camera angle, camera distance, subject positioning, and undergarments.

A subset of 4 randomly selected subjects underwent baseline serum lipid tests: cholesterol; triglycerides; and VLDL, LDL and HDL cholesterol. As well as liver-related blood tests: AST; AST; alkaline phosphatase; total bilirubin; and albumin. Subjects were instructed to fast 12 hours prior to their blood draw. The blood tests were drawn via venipuncture at baseline, 1 day post-treatment 1, 1 day post-treatment 4, and at the 1- and 3-month follow-up visits.

Ethics

The protocol used in this study adhered to the Good Clinical Practice guidelines of the International Conference on Harmonization and was approved by an independent Institutional Review Board (U.S. IRB, Chesapeake IRB, Columbia, MD) Informed written consent was obtained from each subject prior to participation in any study-related activities.

Treatment Device

The selective RF device is a non-invasive aesthetic treatment cleared by the FDA for use as a noninvasive aesthetic treatment for reducing the circumference of the abdomen. The operator independent applicator consists of multiple poles that create a broad RF panel that covers the whole abdominal area including the love handles. The RF field emitted by each pole is independent of the other poles. These overlapping patterns ensure homogeneous coverage of the entire abdominal treatment area. (See Figure 1)

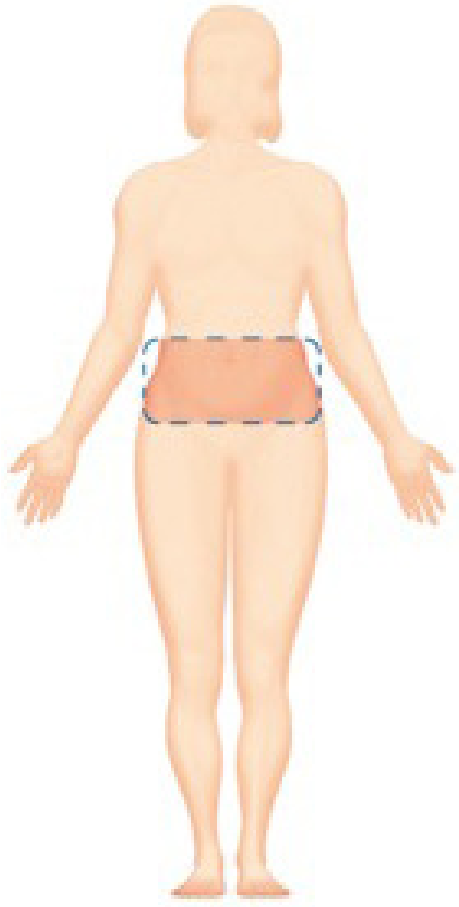
Treatment Protocol

Participants of the study underwent four 45-minute treatments of the abdominal area (abdomen and love handles) by the selective RF field device. Treatments were administered once a week (+/- 4 days). Subjects were positioned comfortably in the supine position. The applicator was placed approximately 1 cm from the subject's anterior abdomen and right and left flank area. Each treatment started with maximal power output setup (200 W) that was subsequently adjusted based on a tuning percentage and subject's subjective heat perception (4-point evaluation scale).

Method of Evaluating Safety and Efficacy

The efficacy of the extended treatment protocol was evaluated using standardized circumference measurements as well as standardized clinical before and after photographs.

FIGURE 1. Treatment applicator.



In order for the treatment to be considered efficacious there had to be a statistically significant reduction in circumference at 3-months post-final treatment. The statistical significance was analyzed using the pared sample T-test. Significance was defined as a value of $P< .05$. It is important to note that the study results are based on findings from 2 study locations. A third study location was excluded from the study and final analysis due to sub-optimal energy delivery of the study device.

Three independent evaluators, from two separate dermatology offices, all of which were unrelated to the study, viewed a series of before and after images. The evaluators were blinded to the order of the before and after photo status. Pre-treatment and post-treatment photos were randomized for side-by-side comparison. Correct identification of the series of photographs were considered successful if the after images were correctly identified at least 80% of the time.

The extended treatment protocol was deemed safe if there were no significant changes in the serum lipid and liver blood tests as well as no reports of serious adverse events.

RESULTS

The main objective of this study was to evaluate the efficacy and safety of extended treatment protocol for selective RF field device by means of circumferential measurements, clinical photographs, lipid and liver blood tests and reports of side effects. All 24 participating subjects received 4 complete treatments by selective RF field and completed the study. A group of 4 subjects also underwent lipid and liver blood tests.

Circumferential measurements taken at 1- and 3-month follow-up visits were compared against the baseline values showed average reduction of 3.6 and 4.2 cm, respectively. Paired sample T-test proved the results to be statistically significant with $P<.001$.

Independent reviewers successfully identified 88% of clinical photographs.

There were no clinically meaningful changes in the lipid profiles at any of the testing time points and the fluctuations seen were consistent with periodic fluctuations.[13] All liver related values remained stable throughout the study. These finding are consistent with a study performed by Klein et al using another fat disruptive technology.[14]

Subjects were also asked to report their subjective heat perception level based on a 4 point evaluation scale where 1 corresponds to no perception of heat and 4, intense heat. Subjects were asked their heat sensation at the 15th and 30th minutes of treatment. The average reported heat sensation was 2, corresponding to slight warming.

There were no statistically significant changes in weight or % body fat for the duration of the study, suggesting that the circumferential reduction occurred as a result of the treatment and not changes in body composition from modifications in diet and exercise habits.

During the course of the study, no study related adverse events were reported. Side effects were mild and transient, which included post treatment erythema, tissue warmth and tissue tenderness. Of the 96 treatments performed, 7 treatments resulted in tissue tenderness/inflammation that was self-limiting and resolved in 3-7 days. (Table 1, Figure 2)

DISCUSSION

The results of this study are consistent with a prior study involving 40 subjects.[15] The prior study had an overall higher average BMI. The combination of the studies demonstrate that the non-contact field RF device is effective in producing results in a wide range of patient body types. This current study is not without limitations. To meet the industry standard thresholds

TABLE 1.

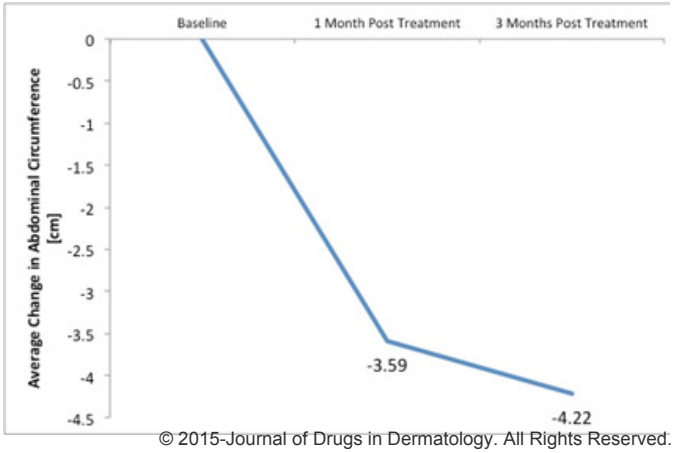
Demographics	
Sex, n (%)	
Female	22 (91.7)
Male	2 (8.3)
Age, y	
Mean (SD)	47.9 (11.2)
Median (range)	47 (30-69)
BMI	
Mean (SD) baseline	23.9 (2.1)
Mean (SD) 3 month f/u	23.6 (2.3)
Race, n (%)	
White	19 (79.1)
Black/African American	1 (4.2)
Other	4 (16.7)
Ethnicity, n (%)	
Non-Hispanic Latino	22 (91.7)
Hispanic/Latino	2 (8.3)

for reliability of our statistical tests, only nine subjects were required, so N=24 exceeded the threshold. However, having the third site would have given us additional data. Future studies using a higher level of evidence such as a randomized controlled trial (RCT) are warranted in the field of aesthetic medicine. In addition to an RCT, long-term follow-ups would provide important data in terms of longevity of results.

CONCLUSION

This study showed significant results without any confounding variables. The extended treatment protocol using selective field RF is capable of reducing abdominal circumference and improving the overall contour of the abdomen and love handles. Furthermore, these results can be achieved safely as assessed by means of lipid and liver blood tests and no reports of adverse events.

FIGURE 2. Circumferential reduction was statistically significant at 1 month and 3 months post treatment $P < .001$.



DISCLOSURES

Dr. Moradi is a board-certified facial plastic surgeon in private practice in Vista (San Diego County), California. Dr. Moradi serves as a consultant for Galderma, BTL, and Merz. He is a Principal Investigator for Merz, Galderma, and BTL. He did not receive compensation for this article. Dr. Palm is a Clinical Investigator and speaker for BTL.

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