

Evaluation of the Safety and Efficacy of a Non-contact Radiofrequency Device for the Improvement in Contour and Circumferential Reduction of the Inner and Outer Thigh

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ABSTRACT

Background and Objective: When evaluating self-image, research confirms that the main focus of dissatisfaction for the majority of women is the size and shape of their bodies, particularly their hips, waist and thighs. The appearance of a woman's thighs is often distanced from what she views as her ideal shape and size and is largely out of her control due to gender specific fat deposition. The issue of excessive subcutaneous fat deposits in the lateral thigh area is enhanced by the resistivity of local adipocytes to lipolysis. Subjects in this study underwent treatment of the bilateral inner and outer thighs using a non-contact field radiofrequency device (BTL Vanquish Flex Applicator, BTL Industries Inc., Boston, MA). The main objective of this study is to evaluate the safety and efficacy of the device for reducing the circumference of the inner and outer thighs as well as improving the overall contour of the treatment area.

Materials and Methods. A total of 30 female subjects age 32 to 59 (average 42.4) were enrolled in the study. After meeting the inclusion/exclusion criteria each subject received 4 weekly 30-minute bilateral thigh treatments (1 hour total treatment time). As the primary outcomes, circumferential reduction was measured and clinical before and after photographs were taken for assessment. Safety of the device was assessed by means of reported adverse events.

Results. All 30 subjects completed the entire treatment series and 1 month follow-up visit. The average reduction measured on both thighs was 3.86 cm with statistical significance $P < 0.05$. There was no significant change in weight for any of the subjects. During the course of the study two adverse events occurred, but were deemed unrelated to the treatment.

Conclusions. Based on the measurements obtained the device under investigation was considered safe and effective in terms of improved contour and circumferential reduction of inner and outer thighs.

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INTRODUCTION

Many women are very critical about the appearance of their bodies. Research confirms that the main focus of dissatisfaction for the majority of women is the size and shape of their hips, waist and thighs.¹ For women, subcutaneous fat deposits to these areas, specifically the lateral thighs (saddle bags), are more resistant to change, by traditional means of diet and exercise, than fat deposits in other areas of the body.² This phenomenon is characterized by a higher level of estrogen production in women, which influences an increased number of α -2 adrenergic receptors on the surface of adipocytes in women's hips and thighs. Presence of these α -2 adrenergic receptors inhibits the lipolytic process and has negative influence on subcutaneous fat reduction.³ The role of hormones in gender specific fat deposition, from an evolutionary perspective, played a major role in increasing the chances of reproductive success. However, in modern times, with ample access to food and thus ample ability to sustain weight gain, women no longer need to have large fat stores to draw upon during childbearing years.⁴ What was once an evolutionary necessity is now the bane of many women's existence. Since diet and exercise alone have

little impact, many seek surgery, such as traditional liposuction or non-invasive methods such as lasers, high intensity focused ultrasounds, cryolipolysis, and radiofrequencies.^{5,6}

The device used in this study, BTL Vanquish, has been cleared by the United States Food and Drug Administration (FDA) as a noninvasive aesthetic treatment for the reduction of abdominal circumference. The device emits radiofrequency energy (RF), which when introduced to biological matter generates friction or movement of the atoms and molecules in response to the tissue's resistance (impedance) to an electric field. Tissue such as adipose tissue has greater resistance to the electric field than skin and muscle, thus resulting in a greater thermal effect in the targeted tissue.⁷

Two recently published studies have shown that the biochemical mechanism of action of RF energy causes disruption of adipocyte cells via heat-induced apoptosis with subsequent cell collapse. This has been demonstrated in both the porcine and human model.^{8,9} In order to successfully induce apoptosis or

programmed cell death, it is necessary to reach and maintain temperatures within the adipose tissue in the range of 42-45°C for a minimum of 15 minutes.^{10,11} The study device has been shown to reach this thermal threshold within 15 minutes of treatment and maintain the temperature for the remainder of the treatment.^{12,13}

The main purpose of this study is to evaluate the safety and efficacy of a non-contact radiofrequency device for the improvement in contour and circumferential reduction of the inner and outer thighs.

MATERIALS AND METHODS

Study Design

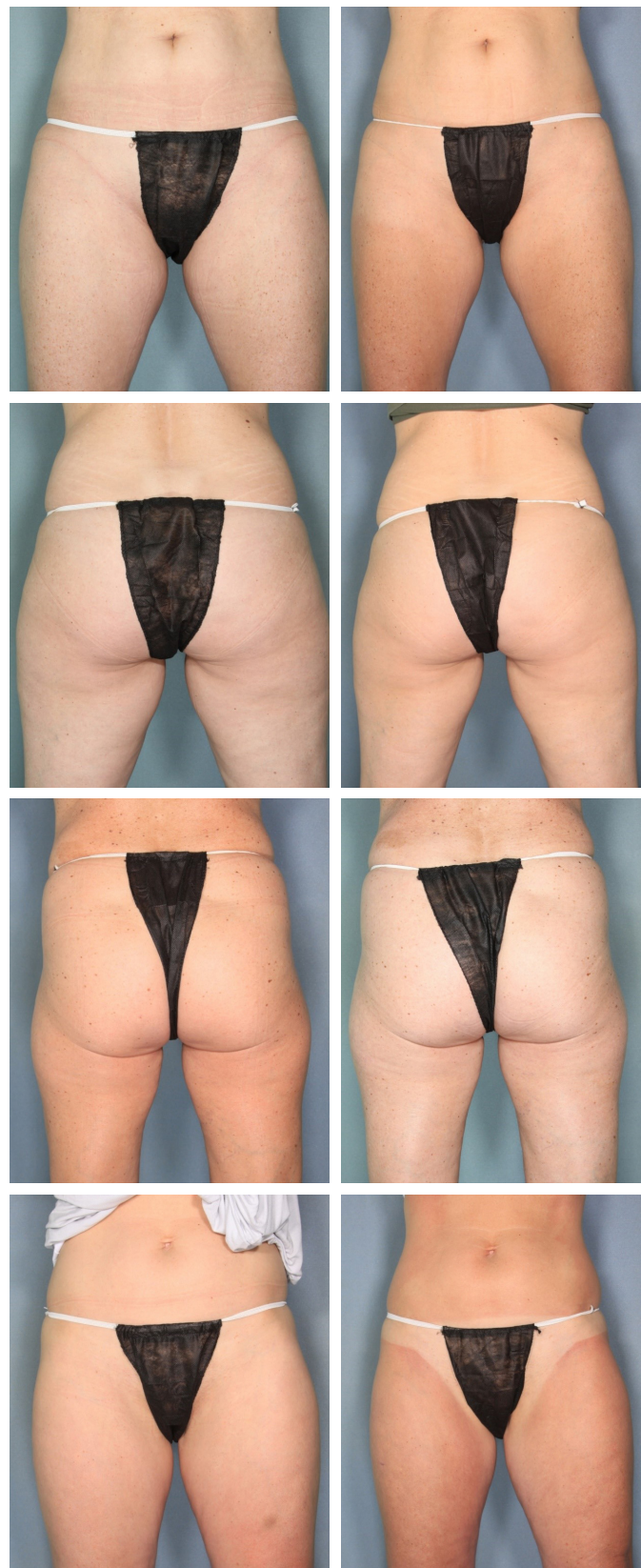
30 female subjects were enrolled in this multi-center, IRB approved study. Subject ages ranged from 32 to 59 with average of 42.4. Subjects were screened based on the following inclusion criteria: Female subjects > 18 years of age; subject has clearly visible fat to the inner and outer thighs with minimal to moderate cellulite severity according to Investigator assessment. More severe cellulite grades were deemed unsuitable for the study; stable weight for a minimum of one month prior to the study; willing to maintain their weight within 5 lbs and current dietary and lifestyle habits for the duration of the study; willing to sign the informed consent. Subjects were excluded based on the following criteria: BMI > 30; surgical procedure in the treatment area in the past year; pregnancy, lactating or planning a pregnancy during the study; subject who is unwilling or unable to comply with the requirements of the protocol; subject has any dermatological conditions or scars in the location of the treatment area that may interfere with the treatment evaluation; subject with metal implants (excluding oral implants), that may, in the Investigator's opinion, be a contraindication to treatment; subject with an active implant as a pacemaker, defibrillator/cardioconverter, cochlear implant.

Standardized digital photographs were taken at baseline and at the 1 month follow-up visit (+/- 10 days). Every effort was made to standardize the background, lighting, camera distance and angle as well as patient positioning. A photo positioning mat was used to ensure consistent distance between the subjects' legs for all photographs. Circumference measurements were taken at baseline and at the 1-month follow up visit (+/- 10 days). Measurements were taken proximal to the upper thigh just below the gluteal fold using a standard spring-loaded measuring tape. A wall mounted height rod (by Healthometer®) was used to standardize the location of the circumference measurements. Weight, and % Hydration was obtained at baseline and each study visit using a standard home use body impedance scale.

Treatment Protocol

Subjects received four (4) treatments 7 days apart (+/- 4 days) to their bilateral inner and outer thighs. The applicator enables

FIGURE 1. Baseline (left) and 1 Month F/U (right).



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the inner and outer thigh to be treated simultaneously in one 30-minute application for each thigh (1 hour total treatment time). The single bi-paneled applicator was placed over the inner and outer thigh. The distance from the applicator to the skin was approximately 1cm. A spacing tool was used to ensure proper distance.

Each treatment started with an output power of 80W. Power was then titrated up or down based on the percentage of tuning/absorption and the subject's report of heat sensation and comfort level. The clinician performed skin checks to assess tissue response.

Method of Evaluating Safety and Efficacy

The efficacy of the treatment for circumferential reduction was evaluated using standardized circumference measurements of the proximal thigh at the widest point below the gluteal fold. In order for the treatment to be considered efficacious there had to be a statistically significant reduction in circumference at 1 month post the final treatment. T-test of paired observations was performed to evaluate the statistical significance of obtained results with significance level $\alpha = 0.05$.

The thigh treatment protocol was deemed safe if there were no reports of study related adverse events.

"Tissue such as adipose tissue has greater resistance to the electric field than skin and muscle, thus resulting in a greater thermal effect in the targeted tissue."

RESULTS

The main goal of this study was to evaluate the efficacy and safety of a non-contact RF device for circumferential reduction of inner and outer thighs. All 30 subjects participating in the study completed all treatments and the 1 month follow-up visit.

As a result, the average circumference reduction measured on both thighs was 3.86 ± 3.5 with statistical significance $P = 0.00000173$ (< 0.05) as evaluated by the T-test. Secondary outcome measured data were weight and % hydration. Mean of body weight change of subjects was +0.22 kg. Change in % hydration was insignificant.

During the course of the study two adverse events were reported, but deemed unrelated to the study. Overall, only a mild to moderate heat sensation was reported. Side effects were transient and limited to mild erythema to the treatment area.

and tissue warmth lasting up to 30 minutes post treatment. The treatments were tolerated well by all study participants.

CONCLUSION

This study found that 4 thirty-minute treatments to the inner and outer thigh (saddle bag) area could produce statistically significant changes in circumference. The study device was also deemed safe as there were no reports of study related adverse events.

DISCLOSURES

Dr. McDaniel received research grants, equipment and consulting fees from BTL Aesthetics who sponsored this study.

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