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A novel selective RF applicator for reducing thigh circumference: a clinical evaluation

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ABSTRACT: The demand for noninvasive body contouring procedures continues to drive the development of new technology to treat areas on the body that are more resistant to diet and exercise. This study assesses the safety and efficacy of a novel selective RF applicator as a noninvasive, contactless method for reducing thigh circumference using a radiofrequency electric field (Vanquish Flex Applicator, BTL Industries Inc., Boston, MA). Forty-two female subjects were enrolled to undergo a treatment of their bilateral inner and outer thighs (saddle bags) once weekly for 4 weeks. Thigh circumference was measured at the baseline and 2 weeks after the fourth treatment. The primary objective was the evaluation of clinical outcomes of 40 treated subjects. Safety of the device was assessed based on adverse events reports during the course of the study. Forty subjects completed the study. After four treatments, the therapy group showed a statistically significant ($p < 0.001$) reduction in thigh circumference of 2.43 cm compared with an untreated control group of 10 patients, where no change was seen ($p = 0.297$). No treatment associated pain or discomfort was reported by the subjects. There were also no reports of adverse events. This study demonstrates that the contactless RF Applicator is safe, painless and effective for the circumferential reduction of the thighs.

KEYWORDS: body contouring, radiofrequency, subcutaneous tissue/panniculitis/lipodystrophy

Introduction

The demand for noninvasive fat reduction procedures will continue to grow due to the high demand for no pain, no downtime efficacious treatments. Available modalities vary in the utilized fat removal methods, treatment duration, and comfort. Commonly used modalities are RF, ultrasound, cryolipolysis, and lasers. Among these, RF is one of the most frequently used technologies. Its efficacy is supported by a wide range of studies and its principles are well known and studied. Although the results are not always comparable to conventional surgical methods, it offers a viable treatment option without the risks and cost of surgery.

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FIG. 1. Thigh applicator treatment setup. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

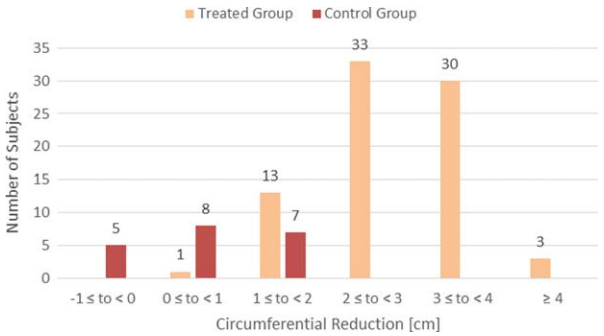

FIG. 2. Circumferential reductions among treated group and control group (includes both legs). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Most desired treatment areas include abdomen, flanks, and thighs. Adipose tissue metabolism varies from one region of the body to another. For example, the lipolytic process is generally slower in the thigh area than in the abdominal region. The process of lipolysis is inhibited through the presence of α-2 adrenergic receptors on the fat cells surface. Women, as a result of higher levels of estrogen, have more α-2 adrenergic receptors on the fat cells on their hips and thighs. Thus, these areas are one of the most critical by women in the sense of occurrence and reduction (1).

The device investigated by this study (Vanquish Flex Applicator, BTL Industries Inc., Boston, MA) utilizes RF electric fields to selectively heat the subcutaneous adipose tissue without direct contact with subject to induce natural process of programmed cellular death, known as the apoptosis. Unlike necrosis – sudden cellular death – apoptosis results in a minimal burden for the body. Still, apoptosis is a complicated process and its certain subprograms are not yet completely understood (2). Increased apoptotic activity inside the adipose tissue under treatment has been proved by a porcine model study (3).

The device is engineered to focus the energy mainly into the subcutaneous adipose tissue. Selectivity of the device is achieved through the specific impedance of adipose tissue. Surrounding tissues have lower impedance (dermis, epidermis, and muscles), therefore, they remain unaffected (3). The adipose tissue is dielectric with ability of inner polarization. It contains electric dipoles. Every time the electric field changes the polarity, dipoles rotate against its polarization. With a rapidly changing electric field, all dipoles oscillate. This oscillating movement results in heating of the tissue (3,4).

Materials and methods

Participants of the study were 52 healthy female subjects with age ranging from 22 to 53, resulting in average age of 38.9 ± 9.8. All selected subjects presented localized fat deposits on the inner and outer thighs. Throughout the duration of the study, all subjects were asked to maintain their current diet and lifestyle. Exclusion criteria included pregnancy, nursing, and active metal implants. Subjects' progress was evaluated both subjectively, based on clinical observation and evaluation of before and after photos, and objectively, by circumferential measurements taken at baseline and 2-weeks post final treatment.

Forty of 42 subjects, who underwent the treatment procedure, finished the study according to the protocol. Two subjects did not finish the study for reasons not associated with the study. Ten subjects served as an untreated control group. A contactless RF applicator was applied to the medial and lateral thigh covering the proximal to mid-thigh region (FIG. 1).

The treatment protocol was defined as four weekly sessions. Each session took 30 minutes for each leg. The initial output power was set at 80 W. Surface skin temperature varied between 40° and 42°C throughout the treatment as measured by a contactless infrared thermometer.

Output power was adjusted based on subjects' report of heat sensation using a four-point scale, as presented.

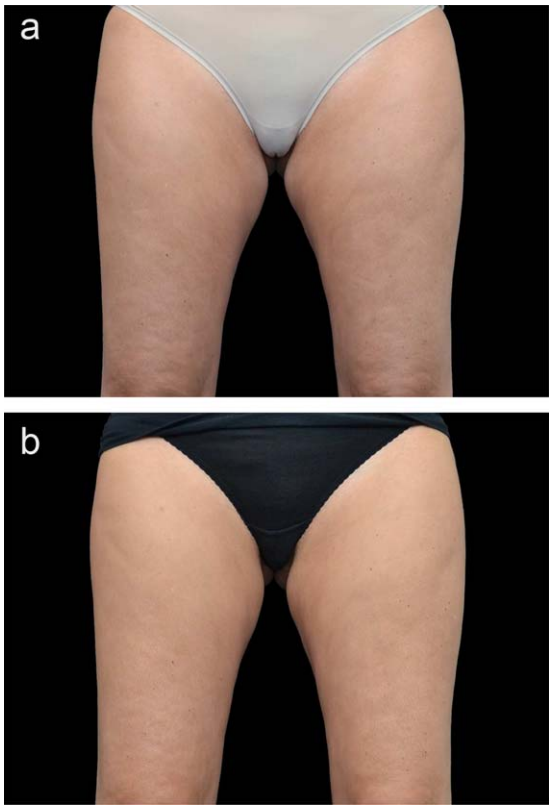

FIG. 3. Patient before (a) and after (b) treatment. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

FIG. 4. Patient before (a) and after (b) treatment. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

To evaluate the efficacy of the contactless RF applicator, thigh circumference was measured and photographs were taken prior to the first treatment and 2 weeks after the last treatment. The measurements were performed according to specific instructions to control potential variables to ensure reproducibility and accuracy. The subjects were instructed to stand with weight distributed equally on both their feet and with legs slightly apart using a body positioning mat. The measurements were taken at the widest point just below the gluteal fold. Clinical photographs were taken for documentation and evaluation purposes.

The resultant values of before and after treatment measurements were evaluated using Paired Sample *T*-test for means. Circumferential reduction was considered statistically significant with $p < 0.001$ (FIG. 2).

Results

The purpose of this study was to evaluate the efficacy and safety of a contactless RF applicator designed for thigh circumferential reduction.

Patients

Forty of 42 subjects participating in the study completed the entire treatment cycle as defined by the treatment protocol. Ten served as a control group without treatment.

Efficacy

Resulting from the measured before/after values, the average circumferential reductions reached 2.45 cm for the right thigh and 2.40 for the left thigh. Total average value was 2.43 cm (FIG. 2). Circumference categorization is in FIG. 2. The strong significance of the results was confirmed using Paired Sample *T*-test for means ($p < 0.001$).Our control group of 10 untreatd patients showed no significant change over the time (significance is $p = 0.297$). The mean circumferential reduction over this group was 0,2 on the right and 0,15 cm on the left side – in average 0,175 cm.

Safety

No pain or discomfort during the treatments was reported. There were no reports of adverse

events. The only side effect observed was mild erythema. The erythema resolved spontaneously within 30 minutes.

Figures 3 and 4 show sample before & after photos.

Conclusion

This study proves the investigated contactless selective RF (Vanquish) device can safely and effectively cause thigh circumferential reduction based on the circumference measurements and following statistical evaluation. Applied Paired Sample *T*-test proved strong statistical significance of the results ($p < 0.001$). In addition, the photographic evidence showed not only overall clinical improvement, but also a smooth, natural transition from the treated area to the non-treated area of the thigh (5).

This study warrants further investigation looking at possible continued improvement post 2 weeks and longevity of results.

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