A Clinical Evaluation of a Next Generation, Non-Invasive, Selective Radiofrequency, Hands-Free, Body-Shaping Device

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ABSTRACT

Objective: The aim of this study was to compare clinical outcomes of a noninvasive selective radiofrequency (RF) field device (BTL Vanquish ME™, BTL Industries Inc., Boston MA) with its predecessor (Vanquish™, BTL Industries Inc., Boston MA). The BTL Vanquish ME™ system has been thoroughly redesigned for more efficient, predictable and homogenous energy delivery to the targeted tissue.
Materials and Methods: In this multi-center study, 36 subjects with BMIs under 30 were randomly assigned to be treated in Group A (BTL Vanquish ME™) or Group B (Vanquish™) in order to obtain a side by side comparison of the devices' efficacies. Each subject received 4 weekly 45-minute treatments with the device determined by their group assignments. Measurements of subject's abdominal fat were taken prior to the first treatment and again four weeks after finishing the final treatment.
Results: The primary outcome was abdominal fat thickness reduction as measured by ultrasound one month following each subject's final treatment. Thirty four subjects completed the study. Two patients did not complete their treatments due to the reasons unrelated to the study (one from each group). Subjects in Group A treated with BTL Vanquish ME™ had an abdominal fat thickness reduction of 4.17 mm, or 29.46%, while subjects in Group B treated with Vanquish™ had an abdominal fat thickness reduction of only 2.72 mm, or 15.21%. The 4 weekly treatments with BTL Vanquish ME™ in Group A produced a 53% higher reduction (4.17 mm vs 2.72 mm) of abdominal fat layer thickness than those in Group B. The standard deviation of ultrasound measurements in Groups A and B were 1.42mm and 2.21mm, respectively.
Assuming a homogenous response across the entire treatment area, the volume of fat reduced was calculated by multiplying the average measured reduction in fat layer by the surface area of the treatment applicator (2100 cm2; 325.5 square inches). It was calculated that Group A patients lost an average of 0.876 liter (0.23 liquid gallon) of fat, while Group B patients lost 0.571 liter (0.15 liquid gallon) of fat.
Discussion and Conclusion: The mean difference between the tested groups was statistically significant proving better outcomes in the Vanquish ME™ than its predecessor. Furthermore, the reduction in standard deviation of fat reduction measurements in Group A vs Group B is evidence that the Vanquish ME™ provides more consistent performance.

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INTRODUCTION

Radiofrequency energy generates electric current which irradiates the targeted tissue. When this electric current meets resistance in the tissue, it produces heat. It is the heat generated which induces the desired changes in the body. This method has emerged as an effective, noninvasive, aesthetic treatment modality for body contouring and fat reduction.

The medical use of RF is based on an oscillating electrical field that forces collisions between charged molecules and ions, causing molecular friction, which is then transformed into heat. Selective RF technology allows for noninvasive and preferential heating of large volumes of subcutaneous adipose tissue. By choosing the electric field's conductivity and relative permittivity, it is possible to selectively achieve greater heating of fat. Under normal conditions, the orientation of dipoles in the adipose tissue is random. Polarization forces these dipoles to rotate and orientate in one direction. Dielectric polarization induces each electrical dipole to rotate against the polarization of the electrical field. With a rapidly alternating electromagnetic field, the electrical dipoles oscillate back and forth, creating molecular friction. This causes the fatty tissue to heat up, which is the principle mechanism of action of selective RF fields on fat.

The contactless selective radiofrequency device is designed to deliver noncontact transcutaneous selective RF, generate heat specifically in subcutaneous adipose tissue, and to induce adipocyte apoptosis with only minimal effect on skin and muscle. Muscle and skin have different conductivity and relative permittivity than fat; water in skin contributes to its low impedance while subcutaneous adipose tissue has high impedance. The applicator-generator circuitry is engineered to selectively deliver the energy to the adipose tissue layer. The contactless selective

radiofrequency system focuses energy specifically into the adipose tissue layer, while limiting the delivery to the dermis, epidermis, and muscles. A selective RF field applicator shapes the electro-magnetic field to optimize the penetration and maximize the treatment area. In addition, the applicator is equipped with Energy Flow Control™ (EFC™). EFC™ automatically tunes the tissue-applicator-generator circuitry to selectively deliver the energy to the adipose tissue layer while minimizing the risk of overheating in the skin, muscles, or internal organs.

This effect was demonstrated and substantiated by pathologic and histologic findings in an in vivo porcine model.[1] Pathological examination clearly demonstrated fat layer reduction in the treated area. Microscopic photographs of histology and TUNEL staining for apoptosis showed that the reduction was caused by the apoptotic phenomenon. Histologic evaluation revealed that the epidermis, dermis, and hair follicles were unaffected by the treatment, while adipocytes were significantly affected. Thermocouples used to monitor irradiated tissue temperature during the procedure showed that the adipose tissue was gradually heated up to the temperature of 46°C while the skin temperature reached only 42°C. These findings confirmed that non-contact selective RF was safe and effective for subcutaneous fat reduction in this porcine animal model. Laboratory, histological, or gross pathological analyses did not indicate any safety risks or side effects. These findings opened a path to contact-free selective RF use for the reduction of human adipose tissue in clinical practices. A human study was consistent with the results of the animal study in terms of temperature elevation in the irradiated adipose tissue and TUNEL staining for increase in apoptotic index in adipocytes 1 hour after a 45-minute, non-contact selective RF treatment.[5] Other published reports and studies further demonstrate the safety and efficacy of contactless selective RF treatment for abdominal fat reduction.[2-7]

Presently, both the BTL Vanquish™ and BTL Vanquish ME™ (BTL Industries Inc., Framingham, MA) are the only radiofrequency devices on the US aesthetic market that allow for non-contact, hands-free treatment of subcutaneous fat. They are multipolar radiofrequency devices that are designed and cleared for deep tissue heating for the purpose of achieving a circumferential reduction of the abdomen and thighs.

Recently, the Vanquish™ system was redesigned to improve its tuning circuit. This improvement, in combination with its newly designed applicator, enables homogenous energy delivery to the tissue in a more efficient and predictable way.

TABLE 1.

Composition of Subject Groups

Group A				Group B			
BTL VANQUISH ME™ Subjects	Initial BMI	Age	Sex	BTL VANQUISH™ Subjects	Initial BMI	Age	Sex
1	25	34	M	18	26	45	F
2	28	26	F	19	25	34	F
3	26	47	F	20	27	55	F
4	29	38	F	21	25	47	M
5	24	25	M	22	24	32	F
6	27	33	F	23	29	36	F
7	26	42	F	24	25	22	F
8	25	53	M	25	26	37	F
9	28	44	M	26	26	56	M
10	27	48	F	27	26	27	M
11	27	53	F	28	27	43	F
12	24	56	F	29	27	38	F
13	25	46	F	30	26	44	F
14	26	32	F	31	25	24	F
15	24	44	F	32	23	48	F
16	26	38	F	33	24	53	F
17	26	54	F	34	24	48	F
AVG	26.06				25.59		

TABLE 2.

Exclusionary Criteria
1. BMI > 30.
2. Surgical procedure in the treatment area in the past 6 months.
3. Invasive fat reduction procedure (e.g. liposuction, abdominoplasty) in the treatment area in the past year.
4. Concurrent therapy with any medication or device either topical or oral that might interfere with the study.
5. Not willing to maintain current dietary and lifestyle for the duration of the study period.
6. Pregnant, lactating or planning a pregnancy during the study.
7. Active systemic or local skin disease that may affect wound healing.
8. Dermatological conditions or scars in the location of the treatment area.
9. Metal implants (excluding oral implants).
10. Active implant such as pacemaker, defibrillator/cardio converter, cochlear implant.
11. Active, systemic autoimmune diseases.

This clinical study was conducted to evaluate how the improvements to BTL Vanquish ME™ impact efficacy and patient outcomes as compared to the BTL Vanquish™.

MATERIALS AND METHODS

Thirty-six subjects were randomly assigned for a series of treatments in one of two groups: Group A – BTL Vanquish ME™ or Group B - Vanquish™. The subjects in Group A had an average BMI of 26.06 and their ages ranged from 25 to 56 years old, while the subjects in Group B had an average BMI of 25.59 and an age range of 22 to 56 years old. Each group was predominantly female (Table 1). Exclusionary criteria included a BMI over 30 and previous fat reduction treatments on the abdomen in the past year (Table 2). Each subject received 4 weekly 45-minute treatments on their abdomen with the device determined by their group assignment. Subjects were instructed to maintain their usual diet and lifestyle throughout the duration of the study. Each subject's abdominal fat layer thickness was measured by ultrasound before beginning the study and 1 month after the last treatment. One subject in each group dropped out of the study during the treatment stage for reasons unrelated to study.

RESULTS

Analysis of the study groups showed no statistical difference in average abdominal fat layer thickness prior to the study [Group A 18.51±4.21 mm (range 11.6–24.7 mm) vs Group B 18.01±5.81 mm (range 13.0–30.4 mm)]. Thirty-four subjects completed the study, with two leaving it due to reasons unrelated to the study. There were no reports of serious adverse events or device malfunctions. Side effects were mild and transient and included post treatment erythema and tissue tenderness which resolved within an hour after the treatment.

FIGURE 1. Ultrasound Abdominal Fat Thickness Measurement in Patient Treated with BTL Vanquish ME™: (A) Before treatments; (B) 1-month post final treatment. (0.5 square inches). This assumes an homogenous response to treatment.

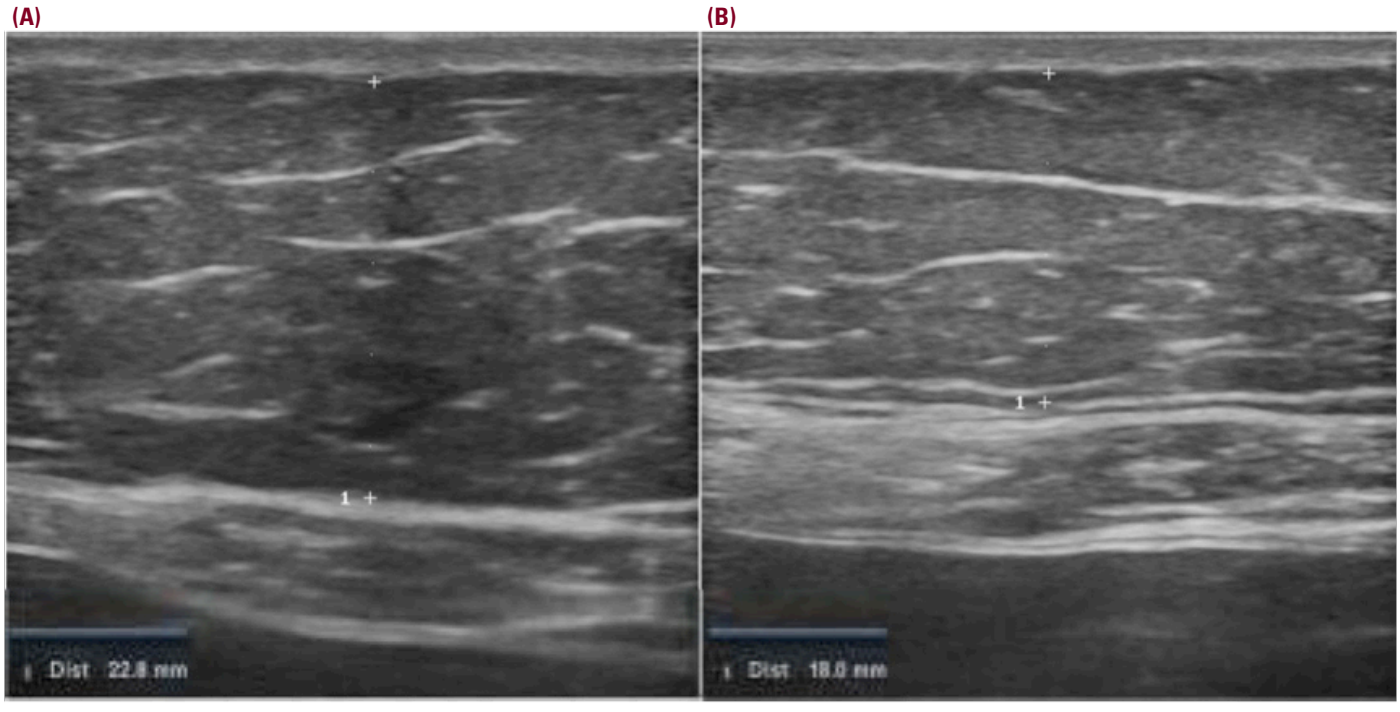

FIGURE 2. Ultrasound Abdominal Fat Thickness Measurement in Patient Treated with VanquishTM: (A) Before treatments; (B) 1-month post final treatment.

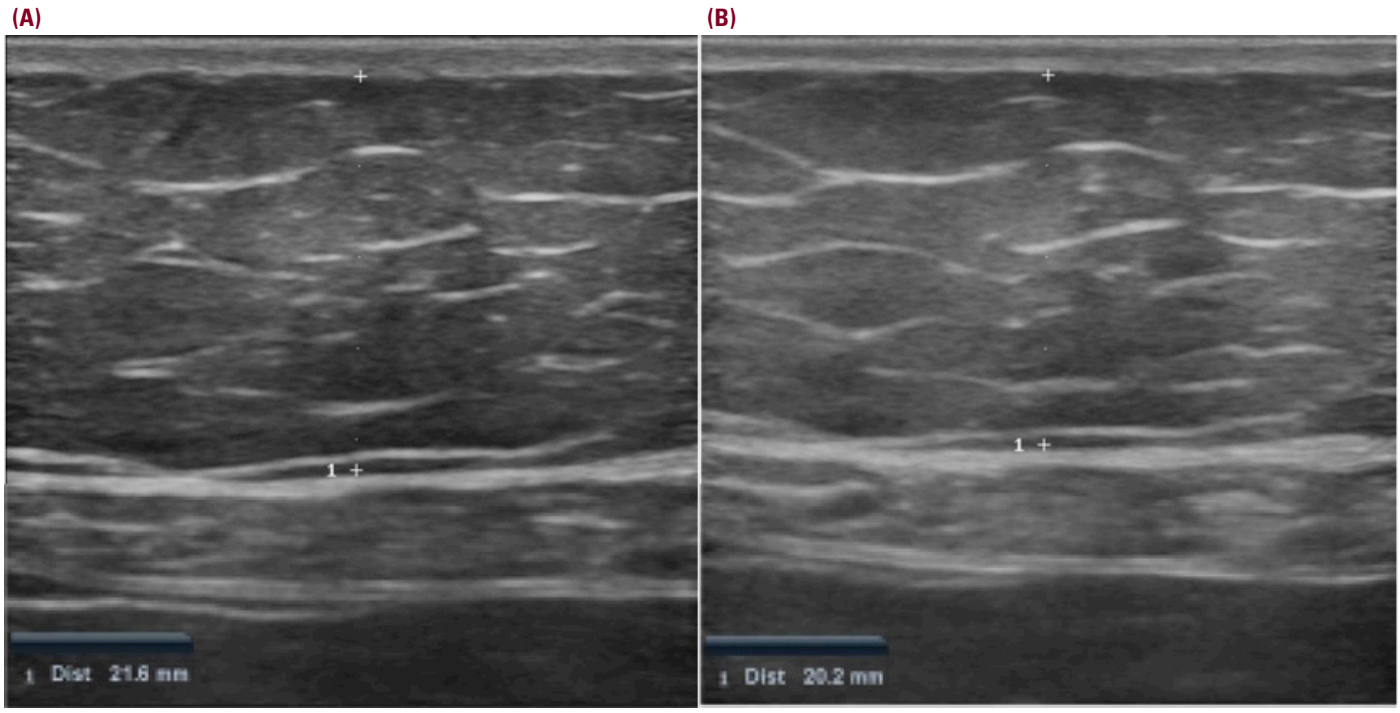

TABLE 3.

Composition of Subject Groups

GROUP A – BTL VANQUISH METM					GROUP B – VANQUISHTM				
Subject #	Ultrasound Measurement (mm)		Change		Subject #	Ultrasound Measurement (mm)		Change	
	Before Tx	After Tx	mm	%		Before Tx	After Tx	mm	%
1	11.6	9.2	2.4	20.69	18	21.6	20.2	1.4	6.48
2	15.9	12	3.9	32.5	19	19.6	18.2	1.4	7.14
3	20.1	15.8	4.3	27.22	20	13	9.8	3.2	24.62
4	23.3	16.7	6.6	39.52	21	13.9	10.9	3	21.58
5	12.7	9.6	3.1	32.29	22	14.6	12.9	1.7	11.64
6	15.3	10.5	4.8	45.71	23	30.4	20	10.4	34.21
7	16.2	12	4.2	35	24	15	10.8	4.2	28
8	14.1	10	4.1	41	25	12.9	10.6	2.3	17.83
9	24.7	18.1	6.6	36.46	26	27	23.1	3.9	14.44
10	17.9	12.2	5.7	46.72	27	25	23.3	1.7	6.8
11	20.3	15	5.3	35.33	28	14.6	11.4	3.2	21.92
12	19	14.8	4.2	28.38	29	11.9	9.9	2	16.81
13	14	11.6	2.4	20.69	30	20	17.7	2.3	11.5
14	22.8	18	4.8	21.05	31	25	23.7	1.3	5.2
15	24.6	22.4	2.2	8.94	32	14.6	13.9	0.7	4.79
16	22.3	18	4.3	19.28	33	13.2	12	1.2	9.09
17	19.9	17.9	2	10.05	34	13.9	11.6	2.3	16.55
Av±SD	18.51±4.21	14.34±3.81	4.17±1.42	29.46		18.01±5.82	15.29±5.15	2.72±2.21	15.21

Abdominal fat layer thickness reduction at 30 days post treatment 4 was the primary outcome measurement in the study as measured by ultrasound. Examples of fat layer thickness measurements are presented in Figure 1 (Group A, subject #1) and Figure 2 (Group B, subject #18). Every subject in the study showed a reduction in the abdominal fat layer thickness. Reduction ranged from 2.0 to 6.6 mm in Group A (BTL Vanquish ME™) and 0.7 to 10.4 mm in Group B (Vanquish™). The average reduction in abdominal fat thickness in Group A was 4.17±1.42 mm and in Group B was 2.72±2.21 mm, which equates to reductions of 29.5% and 15.2%, respectively (Table 3). The degree of change in the abdominal fat layer thickness between Group A and B was statistically significant (P<0.008).

Using the measured reduction in fat layer thickness and the treatment surface area of the applicator (2100 cm^2 or 325.5 square inches), a reduction of 0.876 liter (0.23 liquid gallon) and 0.571 liter (0.15 liquid gallon) of fat were calculated for Groups A and B, respectively. (Volume lost = fat layer thickness reduction x effective area or spot size of the applicator (2100 cm^2; 325).

DISCUSSION

The BTL Vanquish ME™ was engineered to have improved energy delivery to the targeted fat layer over the original Vanquish™ device. This improvement was proven to produce larger reductions in the targeted fat layer as shown by ultrasound images (Figure 1 and 2), with a statistically significant difference in the reduction of abdominal fat layer from an average of 2.72mm in the Vanquish™ to 4.17mm in the Vanquish ME™. This improved reduction seen after four weekly treatments can also be calculated to be a 0.876 liter loss versus 0.571 liter. Improved tissue targeting and clinical results are also shown by a smaller range of fat loss in Group A versus Group B (1.42 vs 2.21), indicating more consistent effects on the target tissue.

Patients with a higher BMI seeking fat reduction who prefer to avoid invasive procedures can successfully and safely be treated with Vanquish ME™. There were only transient minor side effects after treatments, and each subject showed a measured reduction in abdominal fat. The sizable applicator can easily cover the abdomen and flanks in a single application, allowing for a large reduction in volume of fat, rivaling invasive liposuction results.

DISCLOSURES

Dr. Melanie Palm is a paid speaker and clinical investigator for BTL Aesthetics. Dr. Peter Jenkin is a paid speaker for BTL Aesthetics.

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