

SAFETY AND EFFICACY OF A 1064NM DIODE LASER, PULSED ELECTROMAGNETIC FIELDS AND VACUUM ASSISTED MULTIPOLAR RADIOFREQUENCY FOR NON-INVASIVE FAT REDUCTION OF THE ABDOMEN AND FLANKS

KAROL A GUTOWSKI¹, ALISON KANG², SUZANNE L KILMER^{2,3} AND SONIA BATRA^{4,5}

¹PRIVATE PRACTICE, DIVISION OF PLASTIC SURGERY, UNIVERSITY OF CHICAGO, AND DIVISION OF PLASTIC SURGERY, UNIVERSITY OF ILLINOIS, CHICAGO, ILLINOIS

²LASER AND SKIN SURGERY CENTER OF NORTHERN CALIFORNIA, SACRAMENTO CALIFORNIA

³CLINICAL PROFESSOR, UNIVERSITY OF CALIFORNIA, DAVIS

⁴BATRA DERMATOLOGY, SANTA MONICA, CALIFORNIA

⁵DEPARTMENT OF DERMATOLOGY, USC KECK SCHOOL OF MEDICINE, LOS ANGELES, CALIFORNIA

SUMMARY

Device Description

The Venus Bliss™ is a medical device that is approved for non-invasive lipolysis in the abdomen and flanks in individuals with a Body Mass Index of 30 or less. The device includes four 1064nm diode laser applicators and has another applicator that combines multi-polar radiofrequency, pulsed electromagnetic field, and vacuum massage. During treatment, the four diode laser applicators are secured to the patient using a belt, specially designed for hands-free operation. Temperatures in targeted tissues are elevated and kept in the range of 42-47°C for around 21 minutes. The device is controlled through a user-friendly, pre-programmed console.

Clinical Evaluation

This white paper focuses on an open-label trial that was conducted with 28 participants (20 females, 8 males) seeking treatment for unwanted fat on their abdomen and flanks. Subjects underwent three treatments consisting of both the diode laser and body contouring applicator sessions at 8 weeks intervals (week 0, week 8 and week 16), and had one follow-up visit (24 weeks post last treatment). Patient satisfaction, average pain during the treatment, evaluator scoring of the before and after treatment images by three evaluators blinded to the treatment, and incidence of adverse events were recorded.

Safety Results

No unexpected adverse events were reported from use of the Venus Bliss™ device in this study. Reported immediate treatment effects were mild to moderate pain, 3 mild instances of nodules and 1 mild bruise were reported during entire duration of the study.

Efficacy Results

Photographic evaluation by three independent, blinded reviewers graded the subjects' baseline photos versus week 24 photos, with an average score of 1.1 (slight change) out of 3.0 (significant change). Additionally, treatment pain was low and tolerable, and subjects had high levels of satisfaction, with 70% reported being 'satisfied' or 'very satisfied' at 24-weeks post-treatment.



INTRODUCTION

Non-surgical fat reduction was the fourth most commonly performed aesthetic treatment (both surgical and non-surgical treatments), with 129,686 procedures performed in the USA, in 2019¹. Interest in non-surgical body contouring is still growing, as are the number of technologies that provide alternatives to surgery^{2,3}. Although liposuction remains the most commonly performed body contouring technique, international research company GlobalData predicts non-invasive and minimally invasive fat-reduction procedures to be a \$1.1 billion industry by 2022, as patients are prioritizing in-office treatments with minimal downtime, over surgical solutions⁴.

DIODE LASER APPLICATOR



The 1060nm diode laser is one such non-invasive technology for fat-reduction. The optical radiation at the wavelength of 1064nm is absorbed by water and lipids resulting in heating of the adipose tissue. The full treatment cycle of the Venus Bliss™ is 25 minutes, containing 4 minutes of building temperature to get the target tissue to the desired range of 42-47°C, then 21 minutes of exposure to maintain the temperature after the building temperature mode is complete. Heating of fat cells results in lipolysis and apoptosis (programmed cell death) of some of these cells. The damaged adipocytes are removed gradually by phagocytosis. In addition, melanin is minimally targeted at the 1060nm wavelength, so the device can be used in all skin types⁵.

(MP)² APPLICATOR



Radiofrequency (RF) energy heats the tissue and subcutaneous fat to trigger collagen remodeling in the dermis and a reduction in subcutaneous fat in the hypodermis⁶. A major cause of wrinkles, laxity and cellulite is the reduction in the quantity and quality of collagen in the dermis⁷. Radiofrequency thermal stimulation results in a micro-inflammatory stimulation of fibroblasts which in response produce new collagen and new elastin^{8,9}. This gives a smoother appearance to the skin and reduced circumference of the abdomen and flanks. Also, radiofrequency heats adipose tissue in the hypodermis, resulting in a thermal mediated stimulation and increased lipase mediated enzymatic degradation of triglycerides into free fatty acids and glycerol¹⁰. Pulsed electromagnetic fields (PEMF) increase the vascularity of the skin and create new pathways for blood flow as well as increases collagen and fibroblast production¹¹.

This increase in perfusion provides more oxygen to the skin and brings more nutrients to the tissue¹². The combination of both technologies in the Venus Bliss™ (MP)² applicator is to promote in fibroblast stimulation, collagen synthesis and contraction of elastin fibres, resulting in smoother and healthier-looking skin. To further increase the efficacy of the RF and PEMF technologies, a vacuum massage is applied to the surface of the skin tissue during treatment. The vacuum is used to massage deep tissues by creating mild to deep suction, thus improving the contact surface between electrodes and tissue.

Venus Bliss™

Venus Bliss™ is designed for non-invasive fat reduction and body contouring. The device is comprised of a console, four 1064 nm diode laser applicators (60 mm x 60 mm effective area each) and a multipolar applicator (MP)² with VariPulse™ technology combining RF, PEMF, and vacuum massage technologies in one applicator. Temperatures in targeted tissues are elevated and kept in the range of 42-47°C for around 21 minutes. A belt is included to allow the operator to secure the laser applicators on the lipolysis treatment area, allowing hands-free operation. The (MP)² is a handheld applicator and is used by the Venus Bliss operator.

CLINICAL TRIAL: FAT REDUCTION ON THE FLANKS & ABDOMEN

Objectives

The objectives of this study were to evaluate the safety and efficacy of using the 1064 nm diode laser for non-invasive fat reduction and improved appearance of the abdomen and flanks.

Methods

Twenty-eight (28) subjects seeking treatment for non-invasive fat reduction of the abdomen and flanks, with a body mass index score of less than 35 were recruited. The device is approved for patients with BMI less than 30, therefore some patients completed the treatment off-label. Participants completing the study consisted of 20 females and 8 males between the ages of 25 and 66 years. Each subject received 3 treatments at 8-week intervals of the diode laser, followed by the PEMF and vacuum massage assisted RF treatment. Investigators ensured at least 30 minutes passed between the diode and RF treatments to allow the skin adequate time to return to normal temperature. The diode laser power used was between 1.3 to 1.2 Watts/ cm² and the PEMF and vacuum massage assisted RF was between 75.0 to 73.9 Watts/ cm². Subjects returned for follow up at 24 weeks post treatments. Improvement in appearance of the abdomen and flanks was assessed by blinded evaluators using the baseline and 24-week follow-up photos. Fat reduction was rated as '0 = 'no change', 1 = slight change', '2 = moderate change' and '3 = significant change'. Patient satisfaction and overall pain level was evaluated at each treatment visit.

Results

Three blinded evaluators assessed images of the abdomen and flanks from baseline images pre-treatment compared to post-treatment images taken at 24 weeks post treatment. The graders reported a slight improvement in 58.2% of subjects, a moderate improvement in 23.6% of subjects and a significant improvement in 1.8% of subjects (**Figure 1**). Subjects had a high degree of satisfaction with their treatment, 70% reported being 'satisfied' or 'very satisfied' at 24-weeks post-treatment, 30% of subjects had 'no opinion'. Only 1 subject (5%) was dissatisfied with the outcome, while 5 subjects (25%) were neutral.

Immediately after each treatment, subject discomfort was assessed using an 11-point Wong Baker FACES Pain Scale (WBFS) on a scale from 0 (no pain) and 10 (worst pain imaginable)¹³. Subjects were not permitted to view their previous WBFS treatment scores. The WBFS was an average of 2.9 at Visit 1, 2.9 at Visit 2 and 2.7 at Visit 3. Pain on average peaked at around 5 minutes, but then consistently lessened over the treatment period (**Figure 2**). There were no unexpected adverse events. Four (4) subjects reported mild adverse events (palpable nodules and one bruise) during the study, all were mild in severity and resolved by study end. Ninety-five (95%) percent of subjects noticed improvement in their treatment areas at the final follow-up visit at 24-weeks. **Figure 3** shows before and after images of a subject in the study.

Figure 1. Percent of subjects experiencing slight, moderate, and significant fat reduction.

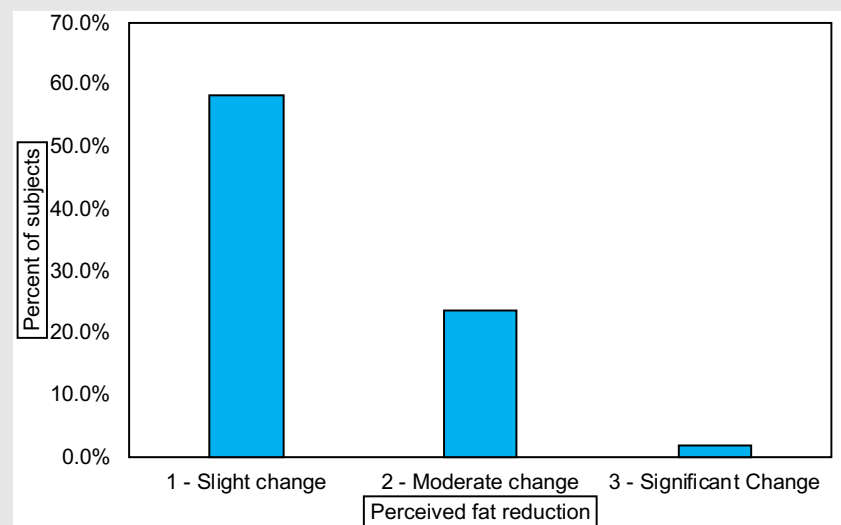


Figure 2. Pain related to the treatment, measured over time it takes to complete the treatment.

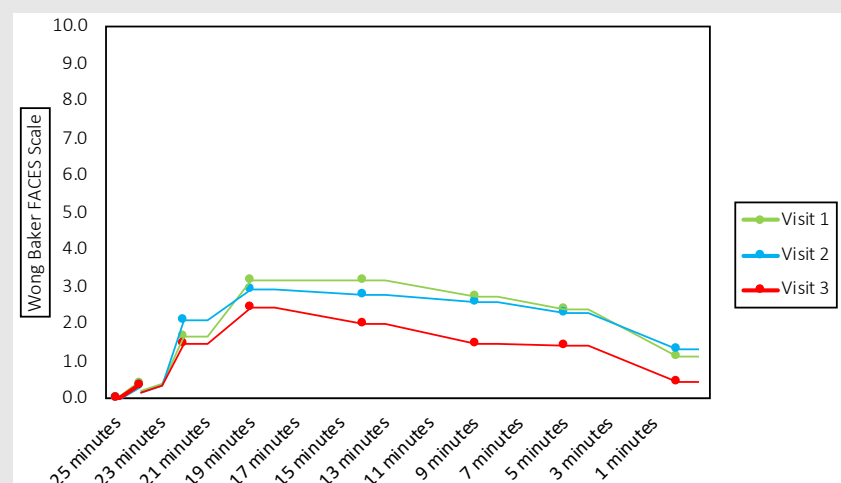
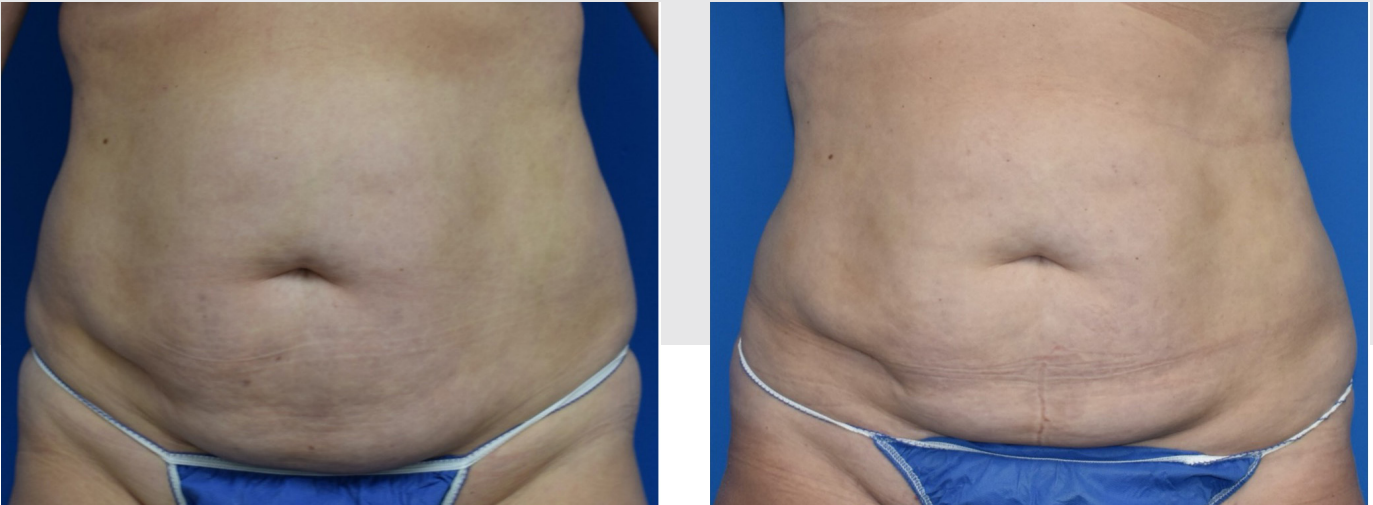


Figure 3. Baseline (week 0) and follow-up visit (24 weeks post treatment) images of a subject after three treatments with the Venus Bliss™.



CONCLUSIONS ON SAFETY & EFFICACY

This was an open-label, baseline-controlled, multi-centre, evaluator-blinded study using a 1064 nm diode laser in combination with PEMF, RF and vacuum massage for non-invasive fat reduction of the abdomen and flanks and body contouring in 28 subjects. After three treatments, results showed that fat around the abdomen and flanks was reduced in 83.6% of patients, based on blinded photography evaluations. Additionally, treatment pain was rated none to low, and subjects were satisfied with the treatment and the outcomes they achieved. This study demonstrates that the combination of diode laser, with the PEMF, RF and vacuum technologies can be used successfully for non-invasive body contouring. The combination of these technologies results in fat reduction, presumably as a result of collagen synthesis and contraction of elastin fibres as shown by Abraham & Ross, 2005¹⁴.

Furthermore, this study demonstrates that the Venus Bliss™ provides very promising results in two anatomical regions that can be a challenge to treat, without any unexpected adverse events. The device has no consumables, is cost-effective, and meets the patient needs with minimal overhead costs to the practice. The treatment is comfortable, effective, and there is no downtime. The Venus Bliss™ may be beneficial to any practice seeking to meet the needs of patients with an affordable, non-invasive solution. Laser lipolysis is an alternative to invasive treatments for fat reduction of the abdomen and flanks for patients looking to avoid downtime and risk of invasive treatments.

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