

Selective Radiofrequency Therapy as a Non-Invasive Approach for Contactless Body Contouring and Circumferential Reduction

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ABSTRACT

In this study, the efficacy of non-contact, selective radiofrequency (RF) were evaluated for body contouring as non-invasive fat and circumferential reduction of the abdomen. 40 healthy (36 female, 4 male) subjects showing significant volume of subcutaneous fat tissue on the abdomen and waistline were included. Once a week for 30 minutes, 4 sessions were performed. The applicator was placed on a supplied spacer covering the treatment area. Maximum power was 200W, which induced heat in the fat and connective tissue layer. The homogeneity of heat distribution and temperature of the skin surface were controlled. The circumferential reduction was measured at the baseline and after the last treatment. The photographs and adverse effects were recorded. Participants completed the self-evaluation questionnaires and rated their level of satisfaction. All subjects tolerated the treatments well. The only side effect was mild to moderate erythema. 35 subjects finished the protocol as planned and 5 subjects dropped off due to events not related to the study. 32 subjects had a 1-13 cm decrease in abdominal circumference and 3 subjects did not show significant response (0-1 cm). Most likely, a very thin fat layer was the reason for lack of response (the non-responding group was the thinnest patient group). No significant differences were found between men and women. The average decrease of 4.93cm was calculated as a result of circumferential reduction statistical evidence. This study demonstrates that the selective RF system designed for contactless deep tissue heating is a painless, safe, and effective treatment for non-surgical body contouring and circumferential fat reduction.

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INTRODUCTION

Excessive fat is not only cosmetic but also an overall health problem. People who exceed their ideal body weight by more than 20% have an increased risk of type 2 diabetes, mellitus, stroke, heart and liver disease, and orthopedic disorders, etc. Internationally, more than a billion people are overweight.¹

There are several fat reduction technologies on the market including lasers, high intensity focused ultrasounds, cryolipolysis, and radiofrequencies (RF).^{2,3,4}

Non-invasive body contouring procedures may have side effects and some procedures are very painful.

Radiofrequency technology was first applied to cosmetic dermatology at the beginning of 21st century for numerous indications.⁴ In aesthetic medicine, the use of RF as an energy source for selective thermolysis is a relatively new concept. The high efficiency of radiofrequency current for tissue heating has made it useful for various aesthetic applications. The dermal heating devices have recently emerged as an effective, non-invasive aesthetic treatment modality for skin tightening and fat reduction.

RF technology produces an electric current that generates heat through resistance in the dermis and subcutaneous tissue.⁵ The induced electric field results in greater heating of fat compared to heating of skin and muscle.⁶ Radiofrequency devices are able to achieve thermal damage with tissue penetration to the level of the dermis and subcutaneous layers without producing thermal burns.⁷

In a very recent animal study, a new model of fat reduction using high frequency RF has been successfully achieved in a porcine model. This non-contact high frequency broad RF field device proved to be safe and effective in subcutaneous fat reduction in the animal model, affecting induced apoptosis in the fat layers. This has very positive implications in the development of a contact-free device for reduction of human adipose tissue in clinical practice.⁸

In this study, we evaluated the effect of a selective RF system designed for contactless deep tissue thermal energy application (Vanquish™) on volunteers who have excessive abdominal fat.

Technology

The medical use of RF is based on an oscillating electrical current forcing collisions between charged molecules and ions, which are then transformed into heat. A dielectric, such as fat, is an insulator with the ability of inner polarization. Adipose tissue

contains electrical dipoles. The direction of dipoles is chaotic and polarization arranges dipoles in one direction. Dielectric polarization requires that every electrical dipole is rotated against the polarization of the electrical field. With a rapidly alternating electromagnetic field, all electrical dipoles oscillate.

This oscillating movement of dipoles leads to heating up of dipoles of fatty tissue, a principle mechanism of action of high frequency on fat. This study was designed to investigate an operator independent focused field system designed for contactless deep tissue thermal energy application. The applicator-generator circuitry is engineered to selectively deliver the energy to tissue layer with specific impedance, in this case the adipose tissue layer. This high-frequency system focuses energy specifically into the adipose tissue layer, while limiting the delivery to the dermis, epidermis, and muscles. A multipolar broad field applicator shapes the electro-magnetic field to optimize the penetration and maximize the treatment area. Using a patented Energy Flow Control (EFC) system this device automatically tunes the tissue-applicator-generator circuitry to selectively deliver the energy to the adipose tissue layer while minimizing the risk of overheating of the skin, muscles, or internal organs as is detailed below.

Temperature in subcutaneous tissue increases to 44-45°C. A phenomenon called apoptosis is observed at this temperature. Other structures such as skin and muscles have maximum temperature around 42°C. Fat reduction is based on the process of apoptosis, investigated in an animal porcine study.⁸

The Vanquish™ device made by BTL Industries (Prague, CR) uses so-called selective focused-field radiofrequency to overheat fat without even touching the patient's body. A selective RF applicator shapes the energy field to optimize the penetration and maximize the treatment area. It automatically tunes the tissue-applicator-generator circuitry to selectively deliver the energy to tissue layers with the specific impedance such as adipose tissue layers with minimizing the risk of overheating of the skin, muscles, or internal organs.⁹

MATERIALS AND METHODS

A prospective, non-randomized, clinical study for 40 healthy subjects (4 male, 36 female) with ages ranging from 18 to 68 years, showing significant subcutaneous fat tissue on the abdomen and love handles. The subjects were instructed to maintain their standard caloric intake and lifestyle during the course of the study.

Study Protocol

The treatment was performed according to the protocol recommended by the manufacturer. The patient laid underneath the device's ergonomically designed applicator positioned over the targeted area approximately 1cm above the skin using standard supplied spacer for distance standardizing delivering RF-based energy. The applicator was placed without contact above the treated area (Figures 1, 2). A maximum power of 200 watts was used with the intention to heat the target tissue to the therapeutic temperature. The energy dosage and applicator positioning was optimized according to the patient's feeling during the course of the session. The subjects were maintained with dosage level of heat sensation between Levels I-IV (Table 1). The skin temperature was selectively monitored over the treatment area via the "infrared thermal imager". The therapeutic temperature of 39–42.5°C was achieved after a few minutes and maintained throughout the treatment.

FIGURE 1. Application area.

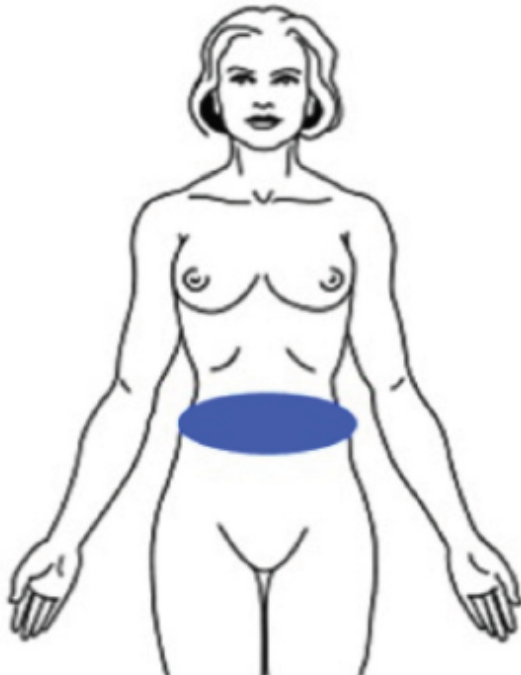


FIGURE 2. Device and method.

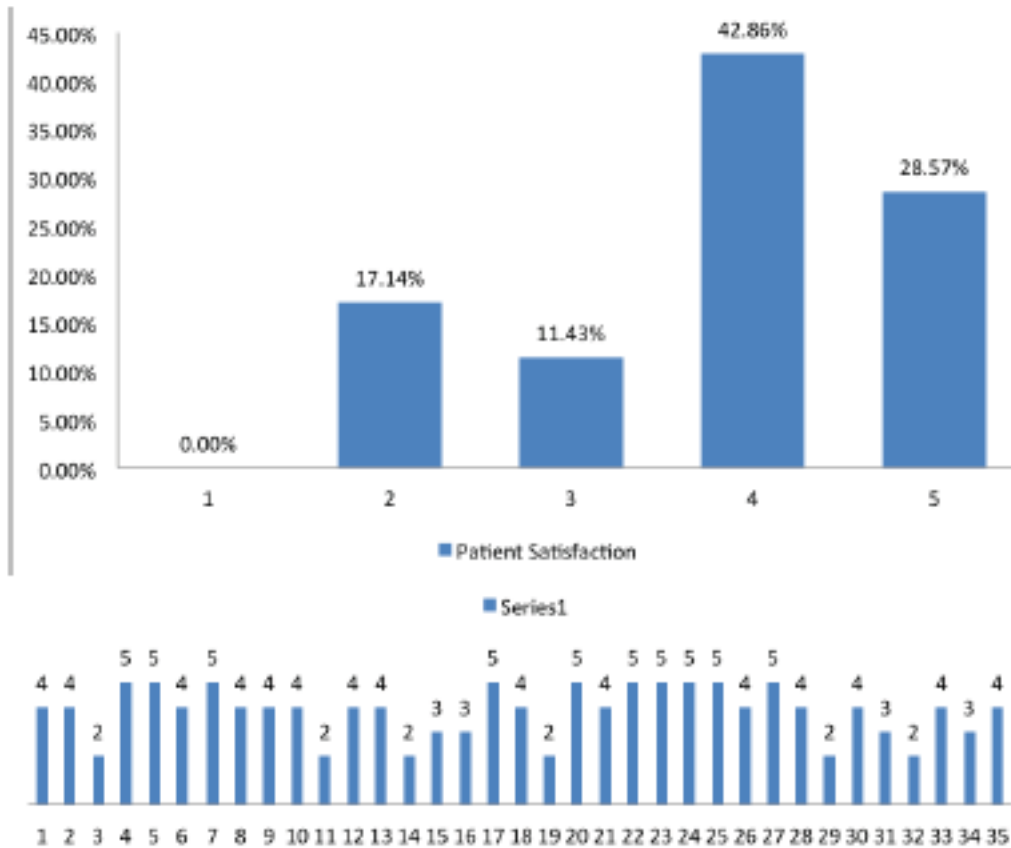


TABLE 1.

Dosage Levels of Heat Sensations

Dosage I	No perception of heat
Dosage II	Slight Warming
Dosage III	Pleasant Warming
Dosage IV	Strong Warming

FIGURE 3. Satisfaction results. 5-Very satisfied, 4-Satisfied, 3-Neither satisfied/nor dissatisfied, 2-Dissatisfied, and 1-Very dissatisfied.



The treatment provider was present during the entire session. The treated subject communicated the perception of heat and was asked for the level of warmth felt. The device was also equipped with an emergency pull thread, which remained in the subject's hand during the procedure.

The therapy consisted of one treatment administered weekly with the duration of 30 minutes each over a 4-week time period. Patients were advised to drink plenty of water before and after, which helps the body to eliminate the dead fat cells as well as maintain high metabolic turnover.

The circumferential reduction of abdomen and waistline was measured at the baseline and 1 month after the last treatment. Body Mass Index (BMI) and weight were recorded at the baseline and after the last treatment.

Adverse effects were also monitored. All participants completed the self-evaluation questionnaires after the last treatment rating their level of satisfaction on the following scale that represented the following groups: 5-Very satisfied, 4-Satisfied, 3-Neither satisfied nor dissatisfied, 2-Dissatisfied, and 1-Very dissatisfied.

The standardized digital photographs of the treatment area were taken.

All photographs were taken from anterior and lateral view with dark background. Body weight, water and fat percentage were recorded before and after each session. All subjects were asked to complete a self-evaluation form at the end of the therapy including the comfort rating based on the following scale: 1- Very comfortable, 2- Comfortable, 3- Uncomfortable, and 4- Intolerable.

RESULTS

Five of the subjects dropped out of the study due to non-study related issues. The statistical analysis was based on the results of 35 subjects who completed all treatment visits.

All subjects tolerated the treatment well. The only treatment side effect reported was mild to moderate erythema in the treatment area which resolved within up to 60 minutes. No adverse events occurred during this evaluation. All subjects found the treatment comfortable or very comfortable. They could resume normal activities immediately. 31 subjects (89%) found the treatment comfortable or very comfortable. The pain level evaluation showed that 90.5 % of subjects felt no pain.

After the last treatment, all participants completed the self-evaluation questionnaires and rated their level of satisfaction. 71% of subjects reported their feeling as satisfied (Figure 3).

Body circumference measurements of the abdomen/love handles were taken in the umbilicus area, 5cm above, and 5cm below, and the body parts were photographed.

An average circumferential decrease in the abdomen zone was 4.93 cm after 4th session. 5 subjects showed the reduction of 1 cm or less, 14 subjects 1-4 cm, 9 subjects 4-7 cm, 3 subjects 7-10 cm, 4 subjects showed over 10 cm reduction (Figure 10).

"This high-frequency system focuses energy specifically into the adipose tissue layer, while limiting the delivery to the dermis, epidermis, and muscles."

Thirty-two subjects had a decrease in abdominal circumference from 1cm up to 13cm. There were 3 non-responding subjects (included in group 0-1cm). It is possible they did not respond to treatment due to a thin subcutaneous fat layer (the non-responders represented the thinnest patient group). No significant differences were found between men and women.

Subjects maintained their weight during the study with average change in BMI (Body Mass Index) of -0.263 kg/m^2 .

Circumferential reduction results in all patients are listed, (Figure 11) along with each subject's corresponding BMI (Figure 12). The BMI/Circumferential Reduction Correlation graph (Figure 13) clearly indicates, for the majority of subjects, the best results are associated with subjects having a higher BMI.

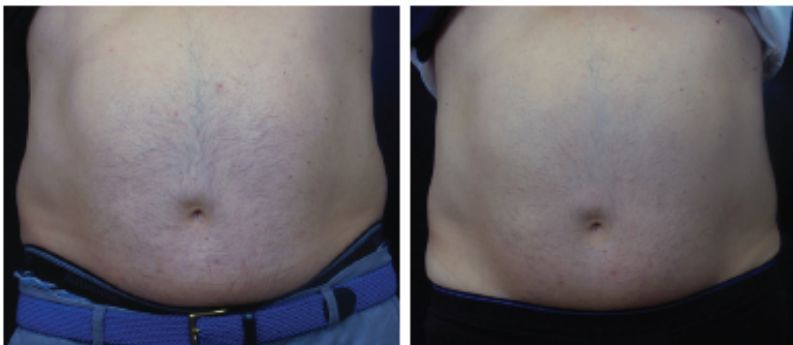
Mild changes of the body weight, water and fat percentage were observed, with no statistical significance. A significant body re-

FIGURE 4. Patient's anterior abdomen and lateral aspects photographs before and after.



Treatment	Before 1 st treatment	After 4 th treatment
Weight (kg)	79	77
BMI	26.09	25.43
Circumference (cm)	109	96

FIGURE 5. Patient's anterior abdomen and lateral aspects photographs before and after.



Treatment	Before 1 st treatment	After 4 th treatment
Weight (kg)	91	89.2
BMI	29.37	28.79
Circumference (cm)	113	106

shaping effect was observed on all responding cases. An objective improvement was in correlation with the patient satisfaction rate.

CONCLUSION

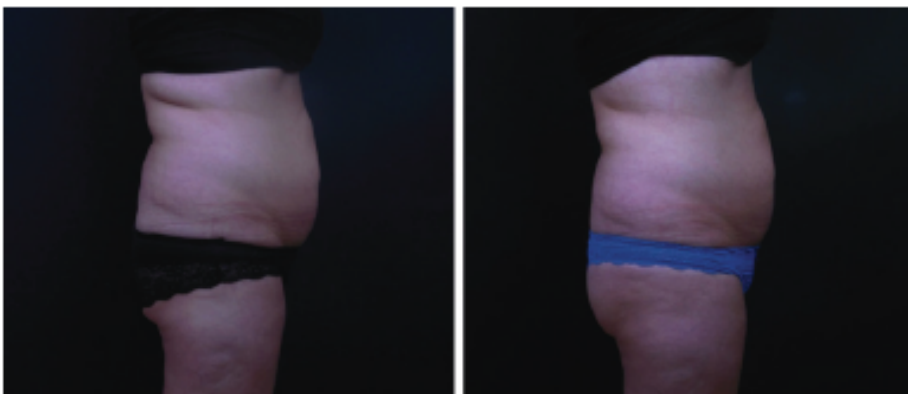
The removal of unwanted body fat using a non invasive technique is desirable to patients and physicians. Radiofrequency is a type of energy that changes the temperature of selected tissues. The Vanquish's™ applicator-generator- patient circuitry

FIGURE 6. Patients anterior abdomen and lateral aspects photographs before and after.



Treatment	Before 1 st treatment	After 4 th treatment
Weight (kg)	67.7	67
BMI	24.86	24.61
Circumference (cm)	84	77

FIGURE 7. Patients anterior abdomen and lateral aspects photographs before and after.



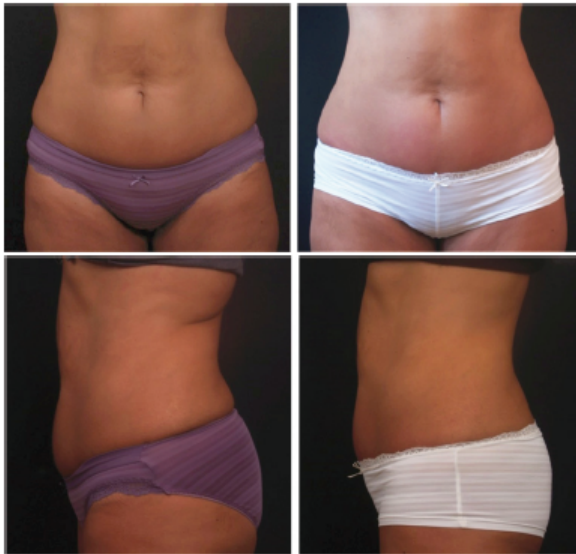
Treatment	Before 1 st treatment	After 4 th treatment
Weight (kg)	84	83.2
BMI	26.51	26.25
Circumference (cm)	110	103

delivers energy selectively to tissue layers with specific impedance; focusing the RF energy into fat layers, while restricting the delivery of high heat elsewhere.

A selective contactless RF technology field shapes the electromagnetic field to optimize penetration and delivery of the energy with no risk of overheating muscles or even internal organs.

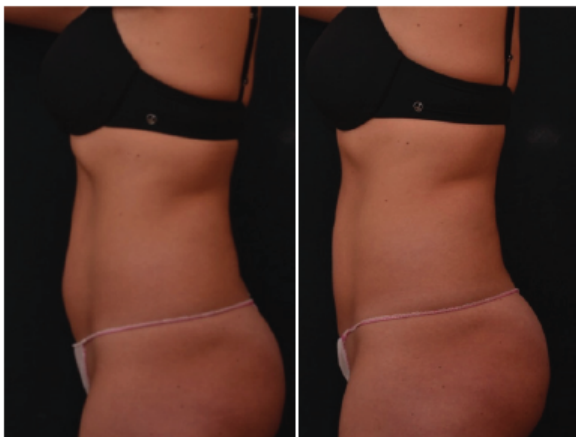
Weiss et al used the Vanquish™ RF applicator in their animal study. Three Vietnamese pigs were treated. Histological results showed marked reduction of adipocytes of the treated area, while epidermis, dermis and adnexal structures such as hair follicles were unaffected. Duplex ultrasound evaluation revealed reduction of fat layer. Authors discussed that this contact free device can be used for reduction of human adipose tissue as well. Temperature in subcutaneous tissue increases to 44-45°C. A phenomenon called apoptosis is observed at this temperatu-

FIGURE 8. Patients anterior abdomen and lateral aspects photographs before and after.



Treatment	Before 1 st treatment	After 4 th treatment
Weight (kg)	79.3	77.6
BMI	29.12	28.50
Circumference (cm)	101	93

FIGURE 9. Patients anterior abdomen and lateral aspects photographs before and after.



Treatment	Before 1 st treatment	After 4 th treatment
Weight (kg)	75	72.2
BMI	25.65	24.69
Circumference (cm)	93	90

FIGURE 10. Circumferential reduction categories.

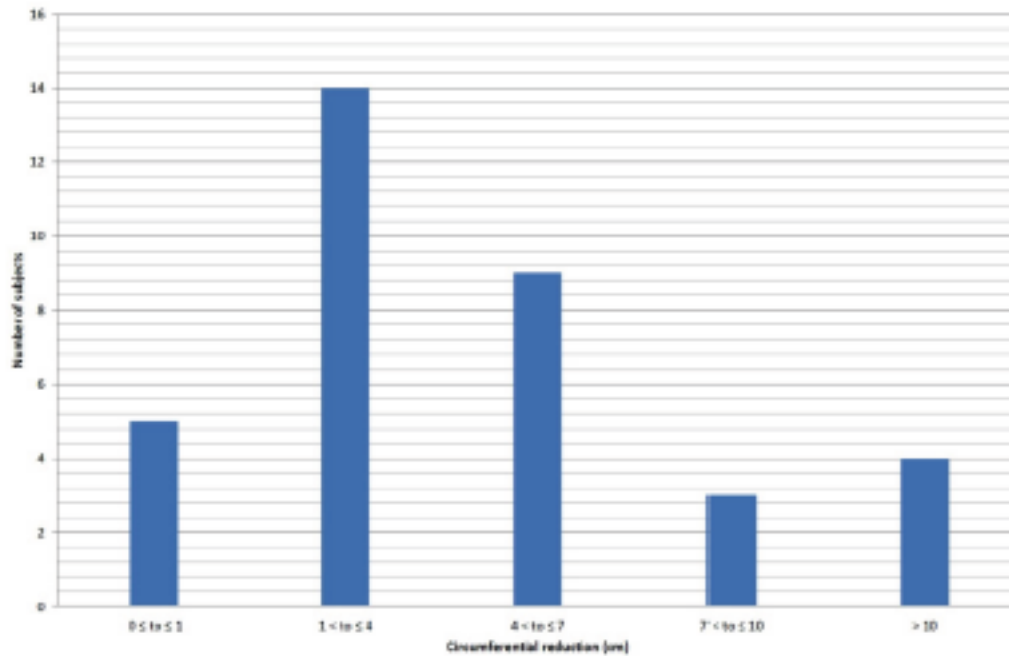
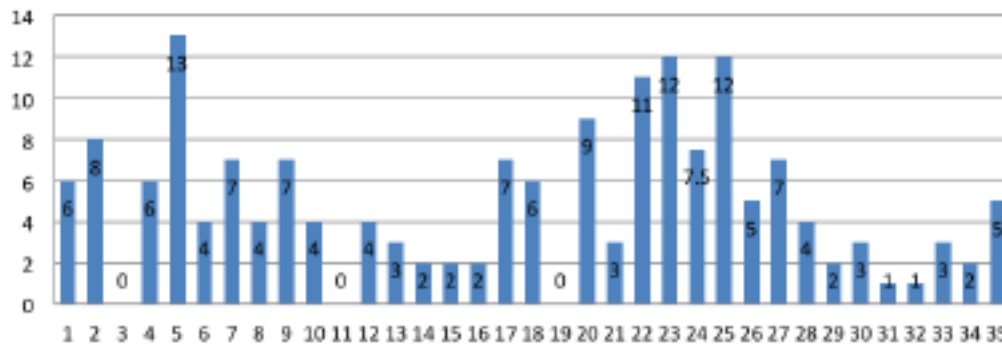


FIGURE 11. Circumferential reduction – all subjects.



re. Other structures such as skin and muscles have maximum temperature around 42°C. Fat reduction is based on the process of apoptosis, investigated in an animal porcine study.⁸

The aim of this clinical study was to prove the efficacy of the selective RF system for body contouring, fat volume, and circumferential reduction of the abdomen, love handles, and waistline. This clinical study, to the best of our knowledge, is the first assessment of non invasive, non-contact, selective RF system in an aesthetic application. The results of this evaluation indicate that the device is safe and effective for body contouring, fat, and circumferential reduction.

There was a mean reduction in circumference of 4.93cm throughout the study. Although the change is minor when compared to the invasive surgical procedure, the selective RF proved to be an effective treatment. Due to the non-invasive nature, patients require little or no recovery time, which makes the treatment an attractive alternative to surgical liposuction. Selective RF body contouring is an ideal procedure for patients who require moderate amounts of adipose tissue removal over time using single or multiple treatments or who otherwise would not be considered for large-volume liposuction procedures. Future clinical studies will provide insights into whether greater fat reduction can be achieved through various treatment algorithms, in conjunction with

FIGURE 12. BMI – all subjects.

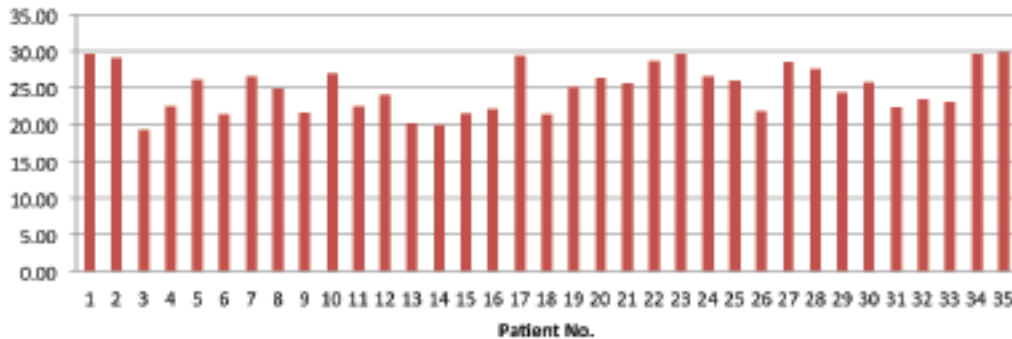
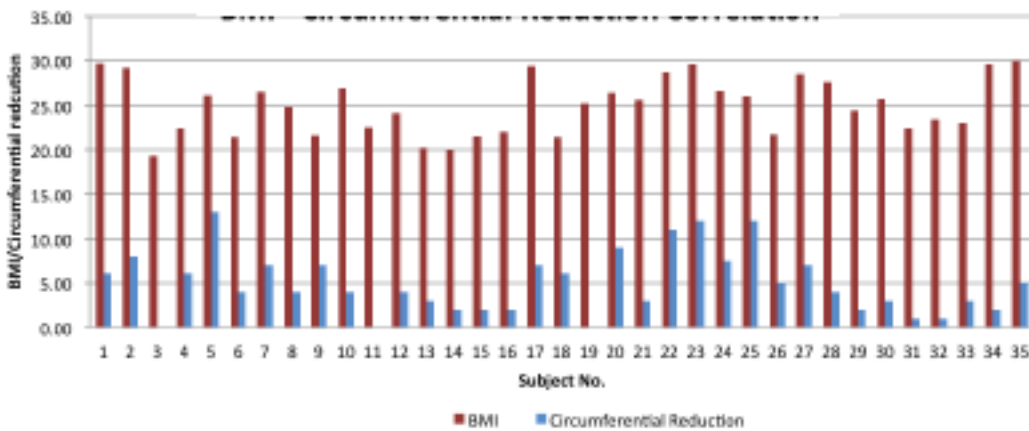


FIGURE 13. BMI – Circumferential reduction correlation.



weight loss strategies or other aesthetic technologies to treat obesity related fat deposits.

Patients tolerated the treatment sessions well. It is basically a painless procedure. There is no downtime, no compression garments required, and no special instructions to follow. Although the skin is heated up to 42°C and the underlying fat to 46°C, the majority of patients described the treatment as “just warm feeling, like standing in front of a radiator”. Possible side effects include mild redness and swelling for one hour or so, temporary increased skin sensitivity to heat, and occasionally, excessive sweating at the end of the treatment.

As this is a targeted spot reduction treatment, and not a weight loss system, patients should still maintain a healthy lifestyle. The fat reduction is permanent if the patient does not gain weight. Treatment does not affect patient’s ability to gain weight. Healthy nutrition and sufficient exercise are always recommended.

DISCLOSURES

Expenses of the clinical trial were covered by BTL. Kateřina Fajkošová, Alena Machovcová, Meltem Onder, and Klaus Fritz have no relevant conflicts to declare.

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