Evaluation of non-invasive body sculpting method based on novel efficient application of high-frequency energy administered to human adipose tissue

BLANKA BERANKOVA, M.D.
PETRA SIMOTOVA, M.D.

Abstract

The novel delivery of high-frequency energy represents a new approach in circumferential reduction and the elimination of unwanted fat deposits. The purpose of this study is to evaluate and verify the results and safety of a four-month trial using the BTL EXILIS Device.

A group of 60 volunteers was treated with the BTL EXILIS device. Each patient underwent 4-5 sessions over a two--month period. Differentiation of treated areas (abdomen [n=58] , flanks [n=56], thighs [n=55]) was monitored by circumferential measurements after each session and at a two-month follow-up. The control mechanism was established through computed 3D body analysis, body composition measurements and ultrasound investigation. Safety monitoring measures included temperature measurement and skin contact cooling.

The therapy was concluded in all cases without any complications or patient complaints. A single EXILIS treatment resulted in an average ircumferential reduction of – 1.2 cm on abdomen, - 1 cm on buttocks and -0.8 cm on flanks. Measurements of circumferential reduction were reevaluated in the two-month follow up due to further physiological tissue processes and in total resulted in the following: abdomen +- 7.2 cm, thighs +- 5.8 cm and flanks +-6.1 cm. For control methods, the Prevas 3D system, ultrasound investigation, weight measurement and body composition monitoring were used.

No side-effects were observed. Mild erythema occasionally appeared on the treated area and diminished within a few minutes of completing the therapy.

The EXILIS device is based on a new delivery method of high-frequency - a safe and effective technology for body sculpting therapy.

Key words
Circumferential reduction, radiofrequency, noninvasive tissue treatment, aesthetic

INTRODUCTION

Aesthetic medicine has experienced both rapid growth and development in recent decades. The most marked development can be seen in the development of different approaches to non-invasive treatment methodologies. Technological progress has resulted in sophisticated electromagnetic systems, which allow for improved utilization of treatment methods such as laser, electro-stimulation, radio frequency and ultrasound treatment.

Appropriate application of high-frequency (RF) energy has been shown effective in various medical areas, for example in RF usage in oncology and physiotherapy.

Efficient administration of RF in aesthetic therapy induces positive changes in fatty tissue structures and improvements in body shape. Fat cells are localized in compact groups known as lobules and connected by a fibrotic net. As adipocytes increase in volume, the function of local

capillary networks is adversely affected. Tissue metabolism is directly dependent upon blood exchange rates and adipose tissue is particularly sensitive to deficiencies in blood flow, resulting in higher FFA and TAG storage in fat cells and an increase in adipose tissue volume.
High frequency energy causes thermal heating and in conjunction with the new delivery system it induces tissue responses such as increased metabolism, enhanced permeability of the cell membrane, and increased blood flow. Usage of appropriate treatment parameters allows the energy to reach and be fully absorbed by concrete fat structures. The aim of this study is to evaluate the EXILIS system's use of RF energy delivered via a single hand piece and to record human body tissue changes in the form of girth reduction and skin tightening.

MATERIALS AND METHODS

TREATMENT PROCEDURE

This study was administered under the guidance of a clinical specialist. All necessary hygienic and sanitary conditions were enforced to ensure the personal safety of patients and medical staff.
Treatment was conducted according to protocols established by BTL in cooperation with the medical practitioner supervising the study. Before each treatment patients were questioned and examined to eliminate any possible contraindications. EXILIS treatment parameters were established according to patient physiological parameters (fat layer thickness, size of treated area, etc.) and pre-designated treatment protocols.
Two differently sized templates (10cm x 15cm and 20cm x 20cm) were used with standard body marker pens to define therapy range. The average treated area of each patient was 400cm2 with a maximum of 800cm2.
A thin layer of mineral oil was applied to the treatment area to ensure efficient transmission of energy from the applicator head. Each participant received an appropriate level of energy over an average time period of 20 to 30 minutes. The handheld applicator was applied directly to the skin and kept in constant motion over the treated area for the duration of the treatment. Treatment temperature was monitored by a built-in thermometer to constantly display skin surface temperature. Session length depended on the body area treated, size of the treatment area, patient tolerance and thickness of the fat layer.
No anesthesia was required before or after the treatment. Photos, measurements, weight and body composition data were taken after each therapy session. All participants were also asked to complete a subjective patient evaluation form.

PATIENTS

A total of 60 participants (52 women, 8 men), from ages 18 to 65 (average age 35.68) participated in this trial. The following areas were treated: abdomen (n=58), thighs (n=56), and flanks (n=55). All participants gave informed consent and all necessary medical information and signatures indicating informed consent were obtained before beginning the trial. Exclusion criteria were defined as:
- Pregnancy
- Cardiovascular Disease
- Kidney or Liver Failure
- Metal Implants
- Tumors

EXILIS DEVICE

Treatment with the EXILIS system is based on the principle of new controlled delivery of RF high-frequency energy. The resulting thermal interaction leads to tissue activation and the physiological degradation of fat cells. Released fat cell contents, primarily TAG and FFA, are metabolized through regular physiological pathways.

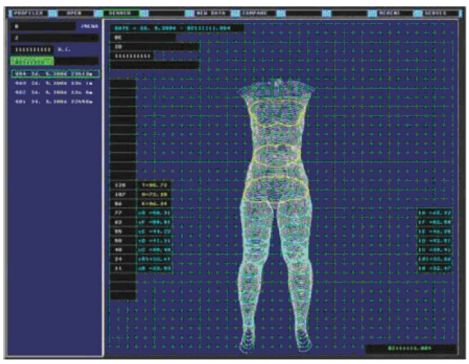
SAFETY MONITORING

The applicator tip is constantly cooled throughout the treatment process to protect superficial dermal structures and allow energy penetration into deeper, sub-dermal layers. The electrical circuit is closed via an adhesive reference electrode positioned adjacent to the treated area, with the quality of the circuit connection controlled via an acoustic alarm warning – the alarm sounds with even a minor interruption in connection quality. As mentioned above, the handheld applicator is fitted with an IR thermometer to allow highly accurate monitoring of skin surface temperature. This feature was crucial to proper therapy regulation. Patients were asked to report their perception of heat sensation throughout the treatment session. When heat sensations were reported as uncomfortable, treatment was paused and the treated area was actively or passively cooled.

MEASUREMENTS

At the beginning of the trial a patient parameter baseline was established by measuring patients' circumferential details, weight, and fat layer thickness. Additional measurements were conducted after each treatment session and during the two-month follow-up. Standardized measurement positioning criteria (navel, apex of hip bone, trochanter major, etc.) were employed to ensure consistent measuring practices. Ultrasound assessments of fat thickness were performed with a device specifically constructed to ensure correct transducer position and pressure.
Body weight was measured before and after each session using a calibrated scale which also measured body composition (i.e. body fat percentage). All values were taken into account in setting treatment protocols.

PREVAS 3000 series 5.0 a
This 3-D optoelectronic measuring diagnostic system is used to measure and compare body dimensions and volumetric changes. No special treatment preparations, such as medication or special positioning, are required. The patient stands erect in the Prevas frame (see fig. 2) and the body is scanned, resulting in circumference measurements with an accuracy of +-3mm.
The system then renders and displays a 3-D model of the patient as well as relevant body parameters.



RESULTS

Of the 60 volunteers who participated in the study, two did not finish due to reasons unrelated to the treatment. The number of sessions ranged from 4-5 (mean=4.5), average session time ranged between 20-30 minutes (mean=23.6 minutes) depending on size of treated area.

A significant decrease from baseline measurements was observed in every patient and in every treatment area.

There were no statistically significant differences in response between men and women.

Figure 2 demonstrates the progression of recorded data throughout the trial (abdominal area) and shows a significant decrease (10% circumferential decrease = approx. 10 cm decrease) between the first and last treatment sessions. A similar data curve was observed in all treated areas. The graph also demonstrates significantly less reduction during the interval between the final treatment session and the 2-month follow-up, indicating immediate efficacy of the treatment. This evidence indicates that physiological processes are induced by treatment and effects do continue even after treatment without sudden changes such as tissue destruction or dramatic weight loss.

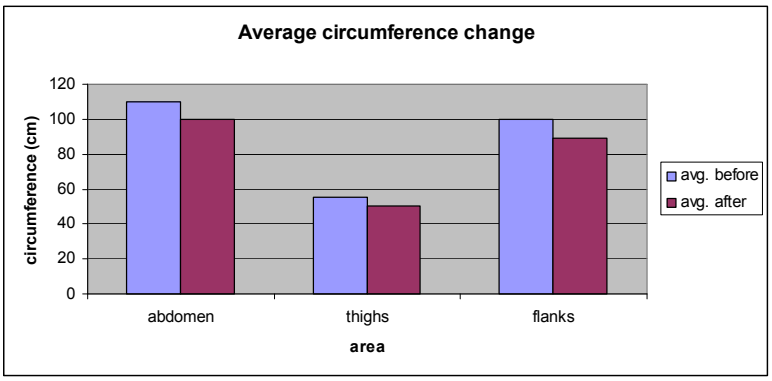


Fig 1. Comparison of average change of treated areas in group of 60 people between baseline and 2-Month follow-up. The proportion of percentage change was similar in all body areas.

Fig 2. Session monitoring. Average outcome of abdomen treatment.

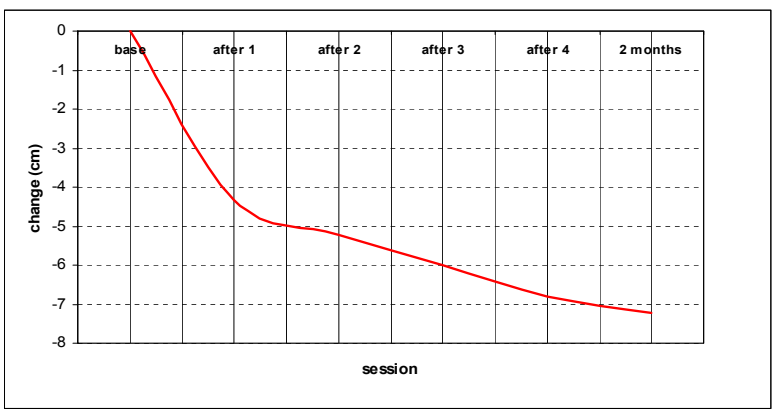


Fig 3. Average decrease of circumference by EXILIS application reduction is 7 cm +- 1 cm SD after 3-month follow-up.

ULTRASOUND INVESTIGATION

The Minderay BG 54 ultrasound diagnostic device was used to measure fat layer thickness, between the muscle fascia and stratum corneum (fig. 6). Standardized measurements were conducted on the abdomen, thighs and flanks.
These measurements were taken so as to ensure patient safety and appropriate treatment with the EXILIS device. The convex ultrasound head was used and standardized conditions ensured proper positioning and pressure.

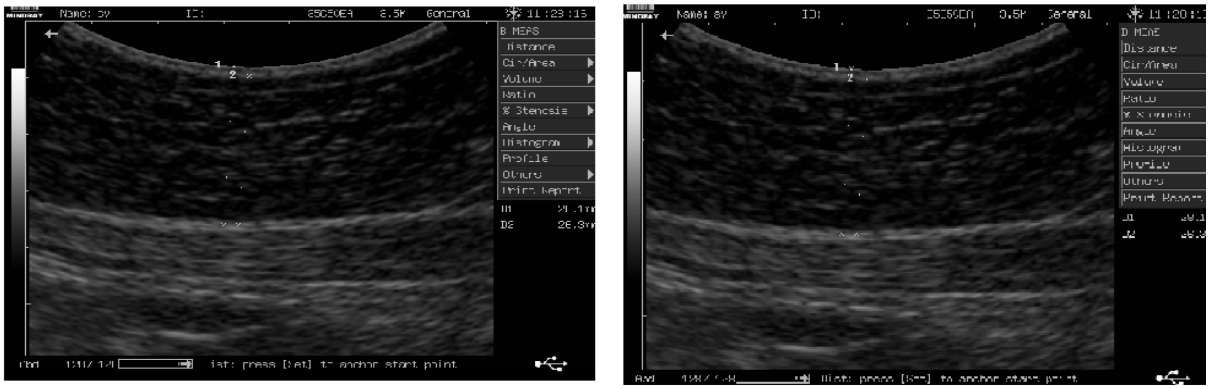


FIG. 4
Abdomen skin before treatment (left) and 2 months after treatment (right). Measurable fat layer reduction of 0.9mm.

Figure 4 and Tab.1; represent the fat tissue dimensional changes. No unwanted changes like tissue destruction, blood lesions or pathological degradation were observed. Significant blood flow increase was detected.

Average ultrasound fat thickness evaluation					
	no.	Before (mm)	After (mm)	Change (mm)	SD
abdomen	58	4,5	3,9	**- 0,6**	0,3
thighs	56	2,5	2,1	**- 0,4**	0,2
flanks	55	3,8	3,2	**- 0,6**	0,3

Tab. 1

WEIGHT

No significant changes were observed in patient body weight. The average weight of patients was 68kg (149.94lbs) with a standard deviation of +-0.2kg. In female patients average weight decreased by 0.7 Kg. In male volunteers there was a decrease of 0.2kg. This is relevant to support a claim of EXILIS treatment resulting in diminished fat volume.

DISCUSSION

There are numerous treatment options for the removal of fat tissues from problematic body areas. Non-invasive techniques such as high-frequency wave treatment are gaining popularity as effective treatment options for skin-tightening, rejuvenation and body sculpting. However, until now there has been no system which utilizes efficient method of RF energy delivery.
The dermal temperature control system and handpiece thermometer enable a more even spread of energy flow into the targeted area. This built-in thermometer also saves substantial amounts of time since the operator can monitor internal and external tissue temperature without having to remove the handpiece from tissue or use a separate instrument. RF actively acts upon deeply situated fat layers and reduces adipose tissue. Circumferential decreases were seen in the abdomen, thighs and buttocks. The only observed side effect was a mild redness of the superficial dermal tissue at the treatment site which diminished within minutes of the conclusion of treatment. Further positive effects such as smoother, thicker and more resilient skin at the treatment sites were also observed.

CONCLUSION

This study presents the EXILIS device as a safe, effective and progressive non-invasive body-sculpting treatment option. This treatment methodology is ideal for patients seeking a pain-free fat-reduction treatment alternative to surgical intervention or as a combination treatment to enhance the results of standard liposuction. Dimensional reduction in typical fat mass areas was substantial and achieved in four treatment sessions over a short, 8 week period. Treatment times were short and performed by ancillary personnel with only a short amount of training. Typical treatment time was less than 5 minutes per area allowing scheduling of patients to a 30 minute time period.

References:

1. Gautherie, Michel: Methods of external hyperthermic heating; 1990
2. Rudolph R.: Problems in Aesthetic Surgery;1986
3. Gautherie M., Hand J.W., Hynynen K., Shrivastava P.N., Saylor T.K.: Methods of External Hyperthermic Heating. Springer-Verlag Berlin 1990.
4. Juong G. Rhee. PH.D., Chung K. K. Lee, M.D., James Osborn B.S., Seymour H. Levitt, M.D. and Chang W. Song, PH.D. Precooling prevents of subcutaneous fat in the use of capacitive heating
5. Peter B. Fodor, MD; Kathryn A. Stecco, MD, MA; Jody Johnson, BSEE-The Precision of High-Intensity Focused Ultrasound (HIFU) for Non-Invasive Body Sculpting: In Situ Thermocouple Measurement of the HIFU Treatment Zone within Adipose Tissue
6. Arnoczky SP, Aksan A. Laboratory for Comparative Orthopaedic Research, Michigan State University, East Lansing, Michigan, USA.Thermal modification of connective tissues: basic science considerations and clinical implication