Reduction of Subcutaneous Adipose Tissue Using a Novel Vacuum-Cavitation Technology

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Abstract

Background and Objectives: The purpose of this study was to evaluate the efficacy and safety of a novel vacuum-cavitation device combining intermittent vacuum and cavitation induced by low-frequency ultrasound in a single applicator for reduction of unwanted local adipose tissue. The outcomes of the study were compared with the results of the previous study on cavitation treatment conducted by the same research group.

Study Design/Materials and Methods: Eight (8) female patients aged 35 to 64 years were involved in the study. Each received a single vacuum-cavitation treatment followed by lymph drainage. The measurement of abdominal circumference and weight as well as the ultrasound evaluation of the fat layer thickness were performed before and after the treatment. Safety was determined by blood analysis (cholesterol, triglycerides, liver markers) before, 2 hours after the treatment, and 20 (30) days after the treatment.

Results: All patients experienced a notable reduction in fat thickness within the treatment site. The mean reduction in circumference after a single treatment was 2,938 + 0,623 cm. The ultrasound measurement results showed the mean subcutaneous fat thickness reduction of 2,96 + 2,01 mm. Weight remained unchanged throughout the study, indicating that the reduction in circumference and fat thickness was not related to weight loss. No significant change in levels of cholesterol, triglycerides, and liver markers was observed. Side effects were limited to slight erythema that persisted up to 1 hour after the treatment.

Conclusions: The study concludes that vacuum-cavitation treatment is safe and effective for reduction of local fat tissue. The results of vacuum-cavitation treatment have been found to be superior over the results of cavitation treatment both in terms of clinical efficacy and repeatability.

Key words: cavitation; vacuum-cavitation; low-frequency ultrasound; fat reduction

Introduction

Busy lifestyles, improper diets, and inactivity have dramatically increased the number of overweight people in recent years. A strict diet, strong will, and hard work in the gym can certainly help to reduce weight, but persistent bulges on the thighs, abdomen, flanks, and buttocks usually remain. For years, the only solution has been surgical removal of fat cells by means of liposuction. But it is a surgical procedure that brings a risk of complications [1].

Low frequency ultrasound (cavitational) treatment is a relatively new procedure offering non-invasive, painless reduction of unwanted fat deposits [2-8].

Cavitation is a natural phenomenon based on low-frequency ultrasound. The ultrasound field creates bubbles that gradually grow and implode at a certain size. Energy is released in the form of heat (minor effect) and pressure waves (major effect) [10]. As membranes of fat cells do not have the structural capacity to withstand such vibrations, the effect of cavitation easily breaks them while sparing vascular, nervous and muscular tissue.

Cavitation with vacuum has been reported to improve the results and make them less dependable on the treatment technique. Vacuum creates a skin fold and presses it tightly to the applicator, thus providing highly selective and safe treatment. This combination ensures that the cavitation effect occurs only within the skin fold, targeting nothing but the subcutaneous adipose tissue. The controlled and constant pressure to the skin fold uniforms the treatments and thus improves the repeatability of treatment results.

The objective of this study was to evaluate the safety and efficacy of vacuum-cavitation treatment for reduction of local adipose tissue.

Materials and Methods

Study Design

This study evaluated the efficacy and safety of a vacuum-cavitation device for reduction of subcutaneous adipose tissue. Each patient received a course of vacuum-cavitation treatment with a standardized algorithm. The results were evaluated 2 hours and 20 (30) days after the treatment. The degree of reduction was assessed by measuring the circumference and fat layer thickness. Blood tests were performed in order to determine the levels of cholesterol, triglycerides, and liver markers before and after the treatment.

During the study, within 24 hours after the treatment and 20 (30) days after the treatment, patients were also monitored for potential adverse effects.

Study Population

Eight (8) patients aged 35 to 64 years were enrolled in the study. All of them were female patients with a Body Mass Index (BMI) of 22,12 - 33,59, abdomen circumference at umbilicus (96,00 cm - 121,50 cm) and fat thickness of at least 2 cm in the treatment area (range 26,20 mm - 59,60 mm).

Prior to the treatment, the patients received an explanation of the technology and expected effects on the tissue. They read and signed a consent form as well as filled out a health questionnaire. Major exclusion criteria included pacemakers, severe liver and kidney diseases, pregnancy, cancer, and a history of blood coagulation problems.

Treatment Procedure

Prior to the treatment, pre-treatment measurements, including height and weight, were taken. The circumference at the umbilicus level was measured with a standard measuring tape. The measurement site was marked with a waterproof marker. Fat thickness in the treated area was assessed with the ultrasound device (Toshiba, Nemio XG, Japan) by a certified doctor. The location of the measurement site was clearly marked. Blood tests were performed to determine pre-treatment levels of cholesterol, triglycerides, and liver markers (AST, ALT, GGT). No topical anesthesia was applied to the treatment site.

The patient was then put in the right flank position. A sufficient amount of ultrasound gel was applied to the area to be treated.

Table 1: *Baseline measurements*

	Mean± SD
Circumference (cm)	107,69±10,37
Fat Thickness (mm)	40,20±11,09
Cholesterol (mmol/L)	6,13±1,61
Triglycerides (mmol/L)	1,59±1,09
AST (IU/L)	24,25±5,78
ALT (IU/L)	32,00±7,96
GGT (IU/L)	25,50±5,16
Weight (kg)	78,14±7,41

Treatment time for the right side of the abdomen was 20 minutes. The patient was turned onto the left flank position, and the treatment was administered for another 20 minutes.

The treatments were performed with the new vacuum-cavitation device (Iskra Medical d.o.o., Slovenia) allowing the simultaneous application of cavitation and intermittent vacuum.

Cavitation parameters were set according to the manufacturer's instructions, and vacuum values were adjusted according to the patient's fat tissue. Vacuum value settings were high enough to suck the

skin tightly to the applicator surface, but still enabled smooth movement of the applicator over the treatment area.

The circumference was measured immediately after completion of the treatment. Post-treatment fat thickness evaluation was performed by the same equipment and ultrasonographer and at the same site as pre-treatment measurement.

All patients received lymph drainage therapy as a complementary therapy.

Two hours after the therapy, blood samples were taken again and analyzed for levels of cholesterol, triglycerides, and liver markers (AST, ALT, GGT).

	Mean ±SD
Circumference (cm)	104,75 ±10,09
Fat Thickness (mm)	34,53 ±10,81
Cholesterol (mmol/L)	6,04 ±1,51
Triglycerides (mmol/L)	1,46 ±0,84
AST (IU/L)	25,00 ±5,53
ALT (IU/L)	32,00 ±7,12
GGT (IU/L)	24,88 ±5,64
Weight (kg)	77,98 ±7,16

Table 2: *Post-treatment measurements*

Four patients underwent control blood tests 20 days and four patients 30 days after the treatment.

The patients did not receive any other fat reduction or body sculpting procedure during the study. However, they were advised to maintain a low-sugar and low-fat diet.

Statistical Analysis

Sigma Stat 3.5 (Systat Software CA, USA) software was used to perform statistical analysis of acquired data. Paired t-tests were applied to detect changes before and after a single treatment. A p-value of = 0,05 was considered to be statistically significant.

Results

Study Population

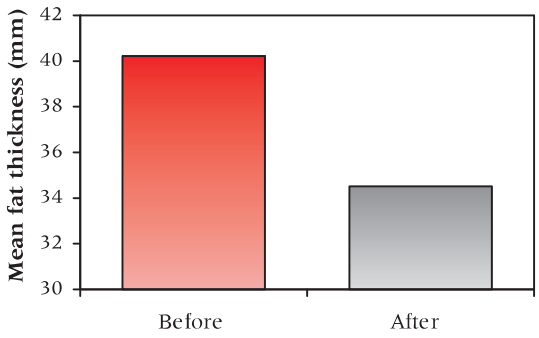
Of the 8 subjects enrolled into the study, all completed it. The study population was fairly diverse in terms of age (35 to 64 years) and Body Mass Index (22,12 to 33,59). Area treated was limited to abdominal region in all patients.

All patients were able to return to their normal daily activities immediately after the treatment.

Efficacy

Efficacy was determined by changes in fat thickness and circumference measurements.

Fig 1: *Mean fat thickness before and after a single treatment session*



The mean pre-treatment fat thickness assessed by ultrasound was 40,20 + 11,10 mm whereas the mean post-treatment fat thickness was 34,53 + 10,80 mm. Fat thickness before treatment ranged from 26,20 mm - 59,60 mm compared to 19,80 mm - 48.00 mm after the treatment.

The mean fat thickness reduction of 2,96 + 2,01 mm (p = 0,05) achieved in a single treatment session represents a significant change in post-treatment fat thickness when compared to the baseline value.

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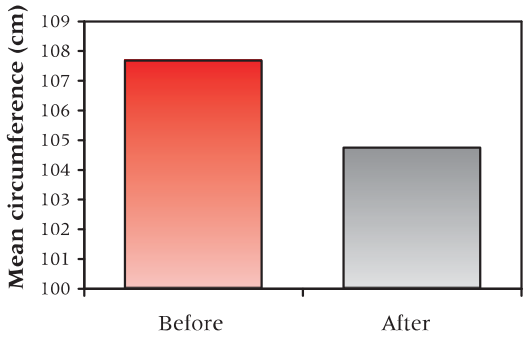
Table 3: *Fat thickness reduction after a single treatment session*

	Mean (mm)	SD (mm)	Range (mm)
Reduction	2,96	2,01	1,00-6,40

The baseline mean circumference of 107,69 + 10,37 cm (range: 96,00 - 121,50 cm) was reduced to the post-treatment value of 104,75 + 10,09 cm (range: 93, 00 - 119,00 cm).

Fig 2: *Mean circumference before and after a single treatment session*



A considerable change in the mean circumference reduction (2,94 + 0,623; p = 0,05) was also observed with the fat thickness assessments.

Table 4: *Circumference reduction after a single treatment session*

	Mean (cm)	SD (cm)	Range (cm)
Reduction	2,94	0,623	2,00-4,00

Table 5: *Values of triglycerides (TG), cholesterol (CH), and liver markers (AST, ALT, GGT) before treatment (baseline) and after treatment (2 hours, 20(30) days)*

	Baseline Mean±SD (cm)	2 h Mean±SD (cm)	20(30) days Mean±SD (cm)
CH (mmol/L)	6,13 ± 1,61	6,04 ± 1,51	6,27 ± 1,08
TG (mmol/L)	1,59 ± 1,09	1,46 ± 0,84	1,31 ± 0,43
AST (IU/L)	24,25 ± 5,78	25,00 ± 5,53	25,43 ± 4,76
ALT (IU/L)	32,00 ± 7,96	32,00 ± 7,12	28,14 ± 5,93
GGT (IU/L)	25,50 ± 5,16	24,88 ± 5,64	26,43 ± 6,08

Conclusions

All patients experienced a significant change in fat thickness and circumference. As no weight loss was observed after the treatment, the circumference and fat thickness reduction can be considered to be a result of the vacuum-cavitation treatment.
No serious adverse effects were reported during the treatment and follow-up period (up to 30 days). Mild erythema resolved within an hour. The levels of cholesterol, triglycerides, and liver markers did not change significantly and stayed within normal ranges.

All patients stated no discomfort during the treatment and follow-up period. They all returned to their daily activities immediately after treatment. This study therefore found the combined cavitation (low-frequency ultrasound) and vacuum device to be safe and effective for non-invasive local fat reduction.
The results of this study were compared with a previous study of cavitation devices [8].
The average circumference reduction achieved in cavitation treatment was 2,00 + 0,866 cm whereas combined treatment resulted in an average circumference reduction of 2,94 + 0,623 cm. A higher circumference reduction and lower standard deviation show that vacuum-cavitation treatment is superior over the cavitation-only treatment in terms of effectiveness and repeatability.

Acknowledgements: Research was part financed by the European Union, European Regional Development Fund.

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