Medical University - Sofia

Faculty of Public Health
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INFLUENCE OF SOME CONTEMPORARY PHYSICAL METHODS ON THE QUALITY OF LIFE OF OVERWEIGHT AND OBESE PEOPLE

AUTHOR'S ABSTRACT

of

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The dissertation paper is illustrated with 37 figures and 26 tables.

The bibliography includes 222 references, 34 of which in Cyrillic and the remaining 188 in Latin. Over 70% of them are from the last 5-10 years.

The public defense is scheduled for 28 March 2024 at 12:00 in the conference hall of the Faculty of Public Health "Prof. Dr. Tsekomir Vodenicharov, MD" at University Hospital "Tsaritsa Yoanna – ISUL", 8, Byalo More St., Sofia.

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The materials related to the defense are available at the Dean's secretary's office of the Faculty of Public Health "Prof. Dr. Tsekomir Vodenicharov, MD" – University Hospital "Tsaritsa Yoanna – ISUL", 8, Byalo More St., Sofia, and on the website of MU-Sofia.

Note: The numbering of the figures does not correspond to that of the dissertation paper.

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LIST OT ABBREVIATIONS USED

BMI - Body mass index

EMS - Electromuscular stimulation

EndoRadioMag - endodermal vacuum with bipolar radiofrequency and magnetotherapy

FEP – fibro-sclerotic edematous panniculopathy

HPTC - High performance contact thermography

IR – infrared

PFs- physical factors

RF – radiofrequency

TOTOX - total oxidation index

VLEP- Vibration, Laser and Electroporation

WHO- World Health Organization

WHR – waist-to-hip ratio

WHtR – waist-to-height ratio

1. INTRODUCTION

„Genes load the gun. Lifestyle pulls the trigger"
Dr.Elliot Joslin

Obesity is a socially significant problem that poses a serious threat to public health. Its incidence is constantly increasing globally. Its prevalence rate is steadily increasing in all parts of the world, making it the 'global pandemic' of the 21st century. In the recent years, it has been one of the leading problems in global healthcare. Unfortunately, few in society are aware of the seriousness of this problem, which leads to an impaired quality of life, increased risk of cardiovascular disease and mortality. The constantly rising standard of living, dynamic daily routines accompanied by chronic stress, unhealthy diets and lack of physical activity are increasing the risks to the health of the society. Statistics show that almost every second person in Western Europe is overweight, which in the long term causes many complications in the body. A study on health literacy in 8 countries of the European Union (2011) shows that Bulgarians occupy the last place. This makes it necessary to work on this problem and to focus attention on health promotion and prevention of obesity, which poses serious health risks.

Obesity leads to many complications as well as premature death. Trends in the geographical distribution of this condition show that, while until recently it was mainly found in developed countries, it is now affecting more and more people in low- and middle-income countries. This shows that the development of overweight and obesity in the population needs to be studied in depth, which continues to be a challenge for all medical professionals.

Epidemiological data on the prevalence of overweight and obesity justify the use of the term "obesity pandemic", respectively the serious medical and social importance of the condition and the need for active counteraction for its prevention and treatment.

A detailed analysis of the available literature, including electronic media, shows the importance of the problem of overweight and obesity. There are a large number of publications on the socio-medical significance of obesity, its health consequences, and recommended exercises and dietary regimens. However, there is a lack of systematic studies on the impact of modern preformed-physical factors, which is why we decided to focus our attention on their study.

2. AIM, TASKS AND METHODOLOGY

2.1. Research hypothesis

Null Hypothesis - H0 : Overweight and obesity are conditions determined by congenital and acquired risk factors that can only be acted upon by diet, exercise and behavioral therapy (which is what the literature suggests and what the accepted recommendations are); but not by reformulated physical factors.

Our opinion is in favor of the **Alternative Hypothesis - H1**, namely: preformed physical factors are able to influence effectively the prevention and therapy of overweight and obesity.

2.2. The aim of this study is to qualitatively and quantitatively assess the effect of the application of various modern preformed physical factors on the anthropometric indices of overweight and obese individuals and their quality of life.

2.3. Tasks:

2.3.1. Study of obesity as a socially significant problem and analysis of the literature;

2.3.2. Selection of the most accurate functional assessment methods;

2.4.3. Training the patient in proper eating and exercise habits;

2.3.4. Selection of topical therapeutic methods with preformed physical factors (PF);

2.3.5 Distribution of patients by groups - according to the applied preformed PF;

2.3.6. Investigation of the effectiveness of physiotherapeutic procedures on the anthropometric indices of the patient;

2.3.7. Assessment of the dynamics in the quality of life of patients;

2.3.8. Analysis the results obtained from the physiotherapeutic algorithms, formulation of conclusions from the scientific study, giving/suggesting recommendations for prevention and practice.

2.4. The object of the study is assessment of the impact of complex rehabilitation programs, with a comparative analysis of the effect of the application of different reformulated PF - on the anthropometric indicators of patients (BMI, respectively body weight; skinfold thickness; waist and hip circumferences; waist/hip and waist/height ratio; degree of fibrosclerotic-edematous panniculopathy (FEP) and on their quality of life.

2.5 The logical unit of observation of this study are 136 overweight and obese patients (women and men).

Inclusion criteria: overweight and obese individuals who have predominantly sedentary occupations, low physical activity and limited time for sports.

Exclusion criteria: pregnancy and other conditions and diseases that are contraindications to the application of the reshaped physical factors, such as: cancer; thrombophlebitis, cardiovascular insufficiency; endocrine disorders such as diabetes mellitus in the decompensation stage; presence of metal implants or electronic devices in the body; severe infections; surgical interventions performed in the last three months.

Signs of units of observation:

- Biological (age, sex, weight, BMI, waist and hip circumference, waist/hip and waist/height ratio, skinfold thickness and degree of FEP);
- Behavioral (physical activity and diet);
- Psycho-emotional (mood, calmness, self-esteem, interests)

2.6. Technical unit of observation and stages of the survey:

The study was carried out from 01.03.2021 to 30.09.2023 at the Dermatological center "DermaPro Clinic", Sofia - one of the first centers equipped with modern devices.

The study **phases** are presented in Table 1:

1. Choice of current topic of the scientific work;
2. Analysis of the literature mainly from the last 5-10 years on the relevant issues;
3. Formulation of aim and objectives;
4. Choice of the most appropriate diagnostic methods to assess results;
5. Organization and conduct of research activities;
6. Processing and analysis of the obtained results;
7. Formulation of conclusions and recommendations.

Table 1. ***Stages of the study: 2021 –2023***

Stages	Sub-goals	Time period	Activities
1.	Significance of the issues and preparation of a literature review-researched and referenced literature sources, mainly from the last 5-10 years.	1.03 - 31.12.2021	Analysis of overweight as a socially significant problem
2.	Organization and conduct of research activities. Choice of the most appropriate evaluation methods. Allocation of patients into groups. Conducting the physiotherapeutic procedures.	1.01.2022-30.04.2023	A total of 136 individuals (125 overweight and 11 obese grade I) were divided into 4 groups according to the severity of the problem (FEP grade).
3.	Final processing and analysis of the results..	01.05.-30.09.2023	Discussion of the results. Formulation of conclusions.

2.7. Material and methodology of the study

Methods and techniques of information gathering:

In order to obtain primary information about our log units of observation, a **documentary method** was used. The main document that we used to collect the necessary information and enter it into a database for subsequent processing and analysis of the results was a patient chart uniform for all groups, in which the data were entered before the start of therapy and after its completion in order to track the effect of the methods applied.

Throughout the treatment, patients had to give us constant feedback - about how they felt and any discomfort during and after the procedure.

Proper conduct of the rehabilitation program is key to the effect, and this was only possible with the active participation of the patient in the process.

As required by the Helsinki Declaration, all patients received comprehensive information about the proposed methods of testing and therapy, and signed informed consent. The patients declared that they had been examined by the specialist and that the procedure did not pose a risk to their health. They had to provide as complete and truthful information as possible about their state of health. The patients ensured that they did not suffer from any of the diseases/conditions presented by us as contraindications for the respective therapy. By doing so, the respective patients gave us permission to perform the treatments and to take photographs before and after the therapy at the discretion of the therapist. We ensured that the patient had read and understood the information presented about the procedure, the recommendations for diet and exercise, as well as the aftercare advice. The patients allowed the therapist to keep

record of their personal file with information about the procedures. The consent was valid for the duration of the course of treatments and the patients were obliged to inform us promptly in case of any change in their health condition (pregnancy, allergies, medication intake, oncological disease, etc.)!

Sociological method - we used the 5-item *World Health Organization Well-being* index *(WHO-5)* to measure and assess the **quality of life**. This index is a widely used global rating scale measuring subjective well-being. First published in 1998, the questionnaire has been translated into more than 30 languages and is used in research worldwide. The scale is most widely used in the field of endocrinology and was therefore developed in a European study in patients with diabetes. This makes it very suitable for our study and that is why we apply it exactly. The questionnaire has high clinimetric validity and is a sensitive and specific tool. WHO-5 focuses on the subjective quality of life based on assessment of positive mood (good mood, relaxation), vitality (being active and waking up fresh and rested) and general interest (being interested and eager in the things you do). The final score is calculated by summing the numbers of the five responses, which ranges from 0 to 25. To obtain a percentage score that allows us to analyze, ranging from 0 to 100, the original score is multiplied by 4 with '0' representing the worst possible quality of life while a score of '100' represents the best possible quality (Table 2).

Table 2. Well-being Index *(WHO-5 Well-being Index)*

	Please respond to each item by marking <u>one box per row,</u> regarding how you felt in the last two weeks. Please answer each item by ticking the box about how you felt in the last two weeks	***All the time*** All the time	***Most of the time*** Most of the time	***More than half of the time*** More than half of the time	***Less than half of the time*** Less than half of the time	***Some of the time*** Some of the time	***At no time*** From time to time
WHO 1	*I have felt cheerful in good spirits.*	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
WHO 2	*I have felt calm and relaxed.*	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
WHO 3	*I have felt active and vigorous.*	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
WHO 4	*I woke up feeling fresh and rested.*	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
WHO 5	*My daily life has been filled with things that interest me.*	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0

2.8. Statistical methods

2.8. 1. Descriptive statistics

- The quantitative variables are represented by the summary statistics - mean (Mean), median (Median) and standard deviation (SD);
- Categorical variables are represented by *absolute frequencies (n)* and *relative frequencies (%)*

2.8. 2. One-Sample Kolmogorov-Smirnov test to check the shape of frequency distributions for quantitative variables.

2.8.3. Chi-square test or Fisher's Exact Test - when examining relationships between descriptive (categorical) data with two or more categories.

2.8.4. Paired Samples t-test comparing two related groups (repeated measures) - with a normal distribution of the variable under study.

2.8.5. Wilcoxon Signed Ranks Test comparing two related groups (repeated measures) - when the distribution of the variable under study is different from normal.

2.8.6. Mann-Whitney Test - when comparing more than two independent groups on rank data or when the shape of the frequency distribution does not match the shape of the normal distribution.

2.8.7. Analysis of variance (ANOVA test) comparing more than two independent groups when the shape of the frequency distribution matches the shape of the normal distribution.

2.8.8. Tukey's post-hoc test (Tukey HSD) for pairwise comparisons after analysis of variance.

2.8.9. Kruskal-Wallis Test - when comparing more than two independent groups on rank data or when the shape of the frequency distribution does not match the shape of the normal distribution.

The accepted **threshold level of significance** is **α=0.05**.
Statistical significance is assumed when the p value is less than α (**p<0.05**).
For the processing of the data from the survey, specialized **statistical package SPSS** (Statistical Package for the Social Sciences) version 20.0 was used.

2.9. Characteristics of the studied patients:

The study included 136 patients divided into four groups.

All of them received instructions to follow a hygienic and dietary regime, drink more fluids, increase background physical activity and perform a daily kinesitherapeutic complex.

A different apparatus was included in each group. Each patient received 20 treatments (2 per week) along with one session per week of EMS. Those in the first group had treatments with the LPG apparatus. in the second group with Velashape, in the third with Eximia and in the fourth with D-finitive EVO as all participants had been diagnosed with FEP at different stages.

Out of 136 persons - 131 were women and 5 were men. Of these, 125 were pre-obese (overweight) and 11 were obese - grade I (included in the latter group). They were divided into 4 groups as follows.

- First group 35 women (II degree FEP)
- Second group 34 women (grade III FEP)
- Third group 32 women and 2 men (grade III FEP)
- Fourth group 30 women and 3 men (grade IV FEP)

Table 3. Distribution of patients by sex in the separate groups

Sex		LPG	Vela shape	Eximia	D-finitive EVO	Total
Men	N	0	0	2	3	5
	%	0,0%	0,0%	5,9%	9,1%	3,7%
Women	N	35	34	32	30	131
	%	100,0%	100,0%	94,1%	90,9%	96,3%
Total	N	35	34	34	33	136
	%	100,0%	100,0%	100,0%	100,0%	100,0%

Patients ranged in age from 20 years to 65 years. All were overweight or obese. The complete age characteristics in the different groups are presented in Table 4

Table 4. Age characteristics of the patients in the groups

Group	N	Age			
		Mean	SD	Min	Max
LPG	35	39,17	11,04	20,00	62,00
Vela shape	34	40,53	11,07	22,00	65,00
Eximia	34	42,44	10,51	23,00	61,00
D-finitive EVO	33	42,97	11,36	24,00	63,00
Total	136	41,25	10,98	20,00	65,00

An android (visceral) pattern of fat storage (fat distribution) was found in 97 patients, a gynoid (gluteo-femoral) pattern in 33 and a mixed pattern in 6. The detailed distribution of the contingent in the respective groups is presented in Table 5.

Table 5: Distribution of patients by body fat storage type (Fisher's Exact Test)

Model for storage of adipose tissue		LPG	Vela shape	Eximia	D-finitive EVO	Total
Android	N	23_{a}	24_{a}	27_{a}	23_{a}	97
	%	65,7%	70,6%	79,4%	69,7%	71,3%
Gynoid	N	12_{a}	$10_{a, b}$	4_{b}	$7_{a, b}$	33
	%	34,3%	29,4%	11,8%	21,2%	24,3%
Mixed	N	0_{a}	0_{a}	3_{a}	3_{a}	6
	%	0,0%	0,0%	8,8%	9,1%	4,4%
Total	N	35	34	34	33	136
	%	100,0%	100,0%	100,0%	100,0%	100,0%

2.10. The assessment methods included:

2.10.1. Somatoscopic diagnosis and manual palpation - Pressing test. During somatoscopy, a careful examination of the affected areas is performed, after which we can manually determine the presence/degree of edema, elasticity, fibrosis, macronodules (lipodystrophic nodules), pain on pressure, etc.

2.10.2. Anthropometric assessment:

- *Body mass index (BMI),* which is the ratio of body weight (kg) to height (m)2. Weight reflects the total mass of the human body, which includes bones, muscles, subcutaneous fat and internal organs. When measuring it, as well as height, the patient should be without shoes and without clothes (or wearing light clothing). It is recommended that the measurement be taken at the same time - in the morning on an empty stomach. BMI is the most commonly used uniform method of assessing obesity, correlates with the amount of fat tissue in the body and reflects changes in body fat over time. However, BMI cannot give us an estimate of adipose tissue distribution to determine the type of obesity (android or gynoid). Height determines the length of the body along its vertical axis. The patients stand against the wall facing the therapist with the heels, buttocks, and shoulder blades against the wall. The head is upright and the distance from the vertex to the floor is measured.

- *Centimetry - waist and hip circumferences*. The former is a good anthropometric predictor of visceral obesity, which has a higher cardiovascular risk. Waist circumference is measured by placing the centimeter along the horizontal plane that lies midway between the superior border of the iliac bone and the inferior border of the 10^{th} rib, after normal relaxed expiration. It is gender and ethnically standardized. The upper limit above which obesity is now accepted in the Caucasian race for females is >80cm and for males >94cm. Hip circumference is measured in the trochanteric horizontal. An increase in the waist circumference is closely associated with a decrease in the cell sensitivity to insulin. It is a serious warning sign.

- *Anthropometric indices - waist/hip ratio and waist/height ratio*. The World Health Organisation (WHO) accepts a Waist-to-hip ratio (WHR) below 0.80 for women and below 0.95 for men as normal. A ratio below 0.85 is considered gynoid obesity and a WHR greater than 0.85 is considered android obesity. A cut-off value of 0.5 is recommended for the Waist-to-Height ratio (WHtR), above which cardiovascular and metabolic risk increases.

- *Calipermetry* - measurement of the thickness of the skin fold, which is carried out with a caliper, which can be mechanical or electronic. Through controlled pressure, the skin fold is gripped and the amount of body fat is accurately read. Measurements are taken on the right half of the body at specific points. The skin fold is grasped with the thumb and index finger with a distance of about 5 cm between the fingers and two layers of subcutaneous fat between them. Pull it up carefully and measure its thickness. If the thickness of the skin fold is about 1-1.5cm, then the body fat is normal, but if it is over 2.5cm, then there is an excess amount of fat.

2.10.3. **Instrumental assessment**:

Thermodiagnostics (High performance contact thermography-HPCT) - harmless, fast and highly scientific diagnostic method for overweight analysis by contact thermography

(Contact thermography for adiposity/cellulite analysis/detection). Its history begins with the screening of breast pathologies and has evolved over time to its current use in aesthetic medicine. Contact thermography uses high-resolution thermographic plates incorporating microencapsulated liquid crystals that have the ability to change color depending on the temperature of the tissue they come into contact with. Thanks to the image obtained and the interpretation/analysis of the corresponding color images, we can identify the different stages/types, presence/absence of obesity, and track the evolution/effect of the application of the program. The test can be repeated several times and is without side effects for the patients. Contact thermography devices allow for quick and efficient analyses and easily guide us to the most appropriate individual therapy. The thermographic plates are placed on the area to be analyzed and after a few seconds it is now possible to see the condition of the underlying tissues, distinguishing edematous, fibrotic and sclerotic areas. Contact thermography is also excellent from a preventive point of view, as it makes it possible to detect the presence of FEP, even when it is not yet visible to the naked eye or not diagnosable on palpation. Its application is of great benefit as it is known that there are many situations that could lead to the onset of FEP. These can be combined into six main groups:

- Lipoedema: an increase in subcutaneous fat and free water;
- Lipo lymphedema: an increase in subcutaneous fat and the amount of lymph fluid;
- Fibrous FEP: fibrosclerosis of the connective fibers;
- Lipodystrophy: interstitial and fatty allergy;
- Localized obesity: an increase in localized adipose tissue;
- False FEP: relaxation of the skin with fibrosis.

The grades that contact thermography diagnoses are four in number, with grade one being normal and the other three being pathological images:

- ***"Normality or uniform", no F.E.P.*-thermographically** normal appearance (*absent of cellulite*). A uniform thermal image without the appearance of distinct colors indicates optimal blood flow in the capillary network of the subpapillary plexus of the skin. It is characterized by a temperature distribution. The image that appears on the thermographic plate is homogeneous. Complete absence of staining spots indicates hotter or cooler spots (absence of hyperthermal regions equals absence of cellulitic nodules). The skin surface is smooth. Palpation of the surface and in depth reveals no substance variations (fluid retention). No nodular formations are detected. There is no pain.

Pathological thermographic images:

- ***"Mottled or edema", mild F.E.P.*** - second stage of liposclerotic process-edema and changes in blood circulation, mainly at microcirculatory level. This initial stage is characterized by the formation of edema (fluid retention in cells), which thermographically appears as large patches - soft cellulite. "Mottled"-spotted (blotchy appearance on the image), i.e. hyperthermic spots of varying shape with poorly shaped (fuzzy) edges, at the time of contact (edema, venous blood stasis), surrounded by cooler areas - areas of reduced blood supply, indicating a reduction in local blood supply, which may be significant in size. The skin begins to roughen slightly. By palpation, a moderate increase in adipose tissue may be detected and sometimes the elasticity and tone of the skin may decrease to some extent.
- "***Leopard skin", moderate F.E.P.*** - third stage-stage of vascular-venous stasis with formation of micronodules **(bird eyes spots with small black holes).** The stage that follows the edematous stage is characterized by the formation of micronodules (multiple fat cells

joined together) that appear on thermographic imaging as small clear spots. The 'Leopard skin' thermographic image is characterized by numerous hyperthermic spots, which may be smaller than those mentioned above, generally with well-defined edges, scattered irregularly mainly over the cold zone - micronodules. A change in the elasticity of the skin, as it is reduced, and the tone bordering on laxity.

- ***"Black holes", severe F.E.P.*** **-** When several micronodules combine, they grow into macronodules**.** This is felt to the touch and is painful on pressure. The correspondence of micronodules and liposclerotic areas, we see thermographically as an image that is reminiscent of a black hole image, i.e. surfaces of different shapes and sizes, black or brown and sharply "hypothermal" (ischemic areas), adjacent to hyperthermal patches of different sizes. Significant changes in microcirculatory flow occur with venous stasis. On palpation, fine granules are felt in the deeper layers and/or the presence of macronodules. By grasping a fold of skin between the thumb and index finger (Pressing-Pinch test), acute pain can be induced, lasting a particularly long time even after the test has been completed.

The advantages of contact thermography are:

- It is a high-tech method of diagnosing the minor symptoms of stage 1 and 2 FEP (*minor symptoms*) associated with an initial circulatory disturbance and represents an alarming signal in the process of the slow evolution to fibro-sclerotic tissue, which may develop only after years
- allows the evaluation of temperature variations and therefore it is possible to detect changes in local blood flow (hyperthermal zones/ hypothermal zones)
- absolutely harmless and non-invasive method that can be repeated - in order to track the modifications of the "heat map" of the skin, therefore improvements in blood circulation, allowing verification after therapy. The main prerequisite in the fight against FEP is the improvement of venous circulation and the increase of arterial blood supply (in the second stage, the warmer areas-blue in color-illustrate venous stasis, while the coldest areas-violet-green-are observed less). All of this affects skin temperature, which apparently becomes more even as microcirculation improves. In the thermographic examination performed after physiotherapy, it is possible to observe an increased number and enlargement of hyperthermic areas after treatment. This relieves microcirculatory maldistribution.
- guides to the most appropriate treatment for the individual patient, further allowing to check the response after the respective therapy
- can also be diagnosed and the so-called "*cushions of fat*", which are an expression of harmless localized obesity, in which there is nothing more than an accumulation of healthy fat cells - larger than normal, but fully functional, even thermographically with the absence of microcirculatory stasis - venous and lymphatic flow is not compromised.
- this is based on advanced technology that makes it possible to modify in a specific way both the size of the microencapsulated *cholesteric liquid crystals* and the thickness of the layer in which they are arranged. In this way it is possible to create so-called panoramic plates ("screening plates") in which each different colour corresponds to a temperature difference of 6-8 different colours. These technical specifications allow the HPCT to reveal multiple aspects of the thermal state of the skin and thus to detect the different thermal aspects in a very clear way, as well as to illustrate complete thermovascular maps.

2.10.4. **Photosomatoscopy** - photographic images of patients.

It is desirable to take photographs at the first visit and after the last therapy session (after patient permission). These photos also report the therapeutic effect of the treatments we have applied. For the most objective evaluation of the results, it is advisable that the photographs are taken against the same background and that the patients are wearing the same clothing whenever possible.

We believe that the combination of all these different methods allows for a precise and rapid assessment of overweight (including FEP) and provides the option of applying a strictly individual therapeutic program (parameters) according to the condition of the subjects.

2.11. Treatment methods - rehabilitation programs

Reformulated physical factors, as an important element of the means and methods of physical and rehabilitation medicine, find application in influencing this condition and improving the quality of life of patients. There are a number of non-invasive devices with different combinations of synergistically acting reshaped physical factors. They all deliver some form of energy from the outside in, which results in changes in the underlying adipocytes. This can be just mechanical vacuum with representative Endermology (LPG System); radiofrequency + infrared light (VelaShape); ultrasound + electro(laser) poration (Eximia); radiofrequency + low-frequency lipolytic laser + cryotherapy (lipolysis) (D-finitive EVO), etc.

2.11.1. LPG Endermology

The LPG Endermology procedure is a non-invasive mechanical vacuum technique to stimulate cell metabolism, improve blood and lymph circulation and help the body release retained fluids. The LPG device has a touch screen menu of three main programs to choose from when operating, which incorporate a range of different readings (sub-menus) according to the individual patient's condition with graphical protocols: **Health** (Inflammation; Oedema; Vein Insufficiency; Pain; Tired legs; Water retention; Lymphoedema; Liposuction Pre and post-operative; **Beauty** (Android Lipomassage Treatment; Gynoid Lipomassage Treatment; Lipomassage Total care; Cellulite Smoothing Treatment; Draining ; Firming and Contouring; Endermo Draining Treatment) and **Sport** (Recovery; Lesion ;Ligament, tendon lesion).

During the procedure, a special elastic full-body leotard is put on. It protects the skin from the passage of the massage rollers, which do not allow the movement to be applied directly to the skin (unlike the Velashape apparatus). This leotard itself does not have any slimming functions (Fig. 1).

Fig.1. Procedure with the LPG apparatus

In addition to the body tips, the device also has facial tips, which we did not apply in our study. The patented Ergodrive Head (bodywork head) has two specially designed motorized rollers and a sequential suction flap that grip a large skin fold, allowing it to work in depth. This head has three varieties - KM50 , KM70 and KM80 with different application (applicator size). In the Ergodrive Head of the latest Alliance device, only one roll is metallic (Fig.2). It also features a new identification sensor with artificial intelligence, thanks to which the stimulation automatically adapts precisely to each individual feature and the intensity of the therapy is as optimal as possible. Lipomassage acts through the vacuum massage rollers on fat deposits, the impact being entirely mechanical - this significantly reduces the contraindications of the device, unlike those that involve preformed physical factors. This is one of the few devices that can be applied even during pregnancy (on the buttocks) for drainage, but our groups do not include such patients.

Using this methodology
we can have active action for:

- CONNECTIVE TISSUE
- VASCULAR SYSTEM
- METABOLIC FUNCTION
- ADIPOSE TISSUE
- STATUS OF THE SKIN
- COLLAGEN PRODUCTION
- LYMPHATIC DRAINAGE

Фиг.2. Ergodrive head

Depending on the method and speed of movement of the individual rollers relative to each other and depending on the aspiration, we distinguish several movements in the processing of the skin fold (Fig. 3) :

- **Roll`in**- the two rollers move inwards, processing the skin fold. This is for a profound effect in local fat accumulation - to stimulate the β-receptors of the adipocytes.
- **Roll`up minor** - both rollers move either up or down. This is for a more superficial impact in FEP.

- **Roll`up major** - with the same movement and action as Roll`up minor, but with a slightly greater depth of processing.
- **Roll`out** - the two rollers move outwards, the tip does not grip the skin fold - the sensation is a tapping (vibration) - complete relaxation after the application of all other movements and tightening.

Fig.3. Types of movements of the tip during the procedure

In the individual protocols, the combination of these movements is different. The direction of movement relative to the area being worked on may be parallel or perpendicular. There is the possibility for the therapist to work with ready-made programs, in which all parameters and durations are pre-set, as well as free unlocked ones, in which he can program the parameters as they can be changed at any moment of the therapy. The techniques of moving the tip during the work are different: rock; swinging; sanding; bouncing; static application; twisted application (Fig. 4A and 4B).

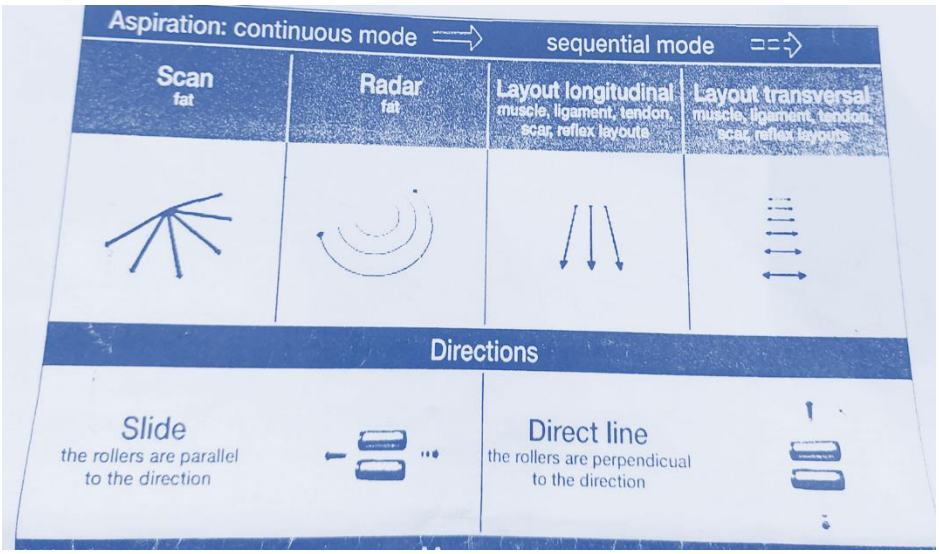

Fig.4A. Techniques of movement of the tip during operation

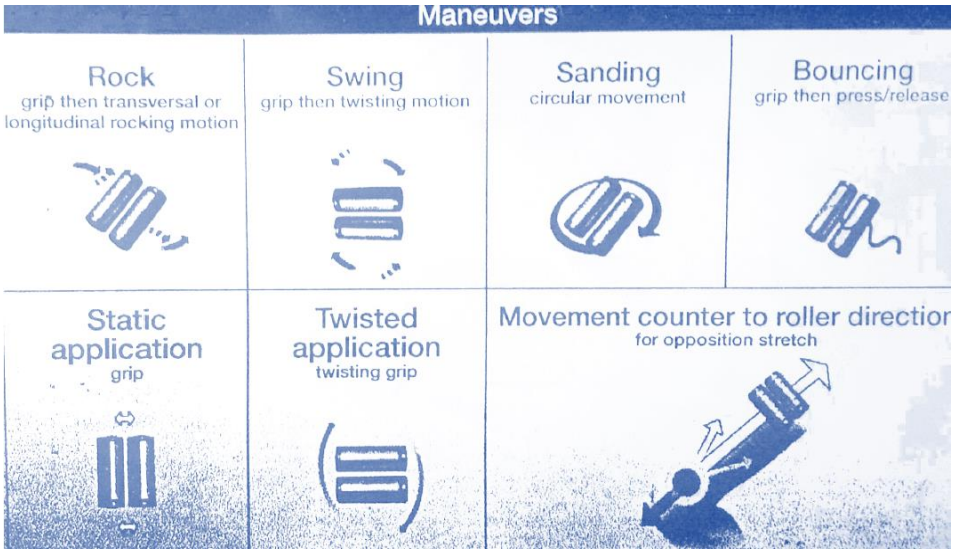

Fig.4B. Techniques of the tip during operation

These special maneuvers allow precise adjustments and perfect individual adaptability to each tissue type. The double tissue stimulation in combination with the basic torsion maneuver called "swing" ensures mobilization and drainage from the epidermis to the hypodermis.

During the treatment (from a lying position), isometric exercises with elastic bands for the arms and thighs can also be applied to increase the effect of the therapy. The method is called lipo-isolation because it allows the therapist to work in a focused manner on the fat deposits that are "isolated" during muscle contractions (Fig. 5). The treatment is done twice a week with a standard treatment time of about 35 min. More time may be spent on localized problem areas in overweight patients, but whatever the problem, the basic principle is to treat the whole body.

Fig.5. Lipoisolation

The different phases of application that are also related to the readings are:

- Vascularization phase, to reactivate microcirculation;
- Drainage phase, to drain lymphatic stasis;
- Stimulation phase, to stimulate fibroblasts;
- Invigorating phase, to stimulate psycho-emotional tone;
- A phase of exercise in which the patient actively cooperates with isometric contractions indicated by the therapist to achieve tissue and muscle toning;
- Visceral phase, to stimulate the abdominal visceral tissues;
- Lipomassage phase, to increase the metabolism of adipose tissue.

A basic rule to ensure proper treatment is the absence of pain and smoothness of the massage technique. The therapist should not provide additional force with the rollers; on the contrary, the technique should be light, gliding smoothly over the body leotard.

Indications: lymphatic and venous congestion, edematous tissue, respectively FEP, overweight, chronic fatigue, lack of tone. Absolute contraindications are: high fever, infections, after surgical intervention, oncological diseases. Relative contraindications (the area is bypassed): myoma, hernia, phlebectomy, moles, warts, lipoma.

It is not advisable to drink water for 30 minutes after the procedure, as the main purpose of the therapy is to release the retained fluids, and the above, if not observed, leads to the acquisition of such immediately after the procedure, which is not desirable.

2.11.2. VelaShape - this is a device that combines electro-optic synergy - elos technology with mechanical manipulation of the area by vacuum. The system combines the following technologies with synergical functioning:

- Infrared optical energy (IR) wavelength 700-2000 nm (VelaShape II), 850 nm (VelaShape III);
- Bipolar Radio Frequency (RF) with maximum power - 60 W for VelaShape II up to 150 W (Velashape III);
- Mechanical impact (pulsating vacuum with two massage rollers in spiral shape)-360 mbar.

The tip features two metal rollers that massage the skin inwards. The applicator must be in tight contact with the skin on all sides to obtain a pressurization that allows negative pressure suction-vacuum. This pressure causes vascular dilation and increases perfusion locally. IR emission is confined to the applicator chamber and is initiated when the therapist presses the trigger button after full contact with the treated surface. The tip should be directed only to the targeted area. Before starting the treatment it is absolutely necessary to apply "VelaSpray Ease", a product developed by the company itself and not any lotion. This is essential for the correct operation of the device (Fig. 6).

Fig.6. Procedure with the Velashape apparatus

The system has three therapy modes that can be controlled by the therapist depending on the patient's tolerance: 0 - no work reported; 1st degree (low); 2nd degree (medium); 3rd degree (high) (Fig. 7).

Fig.7. Tip of the apparatus

High IR levels are not used on very dark skin or skin with a tan. In the initial procedure, always start with a sample area by gradually increasing the grades and always monitor the patient's individual response and comfort. Once the settings are set, the applicator is placed on the area and moved with moderate pressure. If the lights on the tip are flashing - it is an indication that the therapist must adjust the position of the applicator to make good contact, which ensures the effectiveness of the treatment, or that the cap is pre-burned and needs to be replaced with a new one. In relation to the application of RF and IR, the applicator must be moved fast enough not to burn the skin, but slow enough to heat up and reach the required target temperature of 44-45°, after which it is maintained for some time. The duration of the treatment is individually according to the area being worked on until the required temperature is reached and maintained until the patient is comfortable (does not feel the burn). The area to be treated is anatomical - e.g. anterior, posterior surface of the thigh. Each area is divided into strips as wide as the applicator head. If the anatomical area is very large, it is necessary to divide it into two parts because this will make it easier to reach the warming point. The movements for treating the abdominal area are in a clockwise direction. On the thighs, they are back and forth

(from the knee to the inguinal crease and back) until the desired temperature is reached and then continue in circular or zigzag patterns to maintain the warming for several minutes, emphasizing the areas with localized fat deposits. Finally, one can finish with a few movements in the direction of the lymph for drainage (Fig. 8).

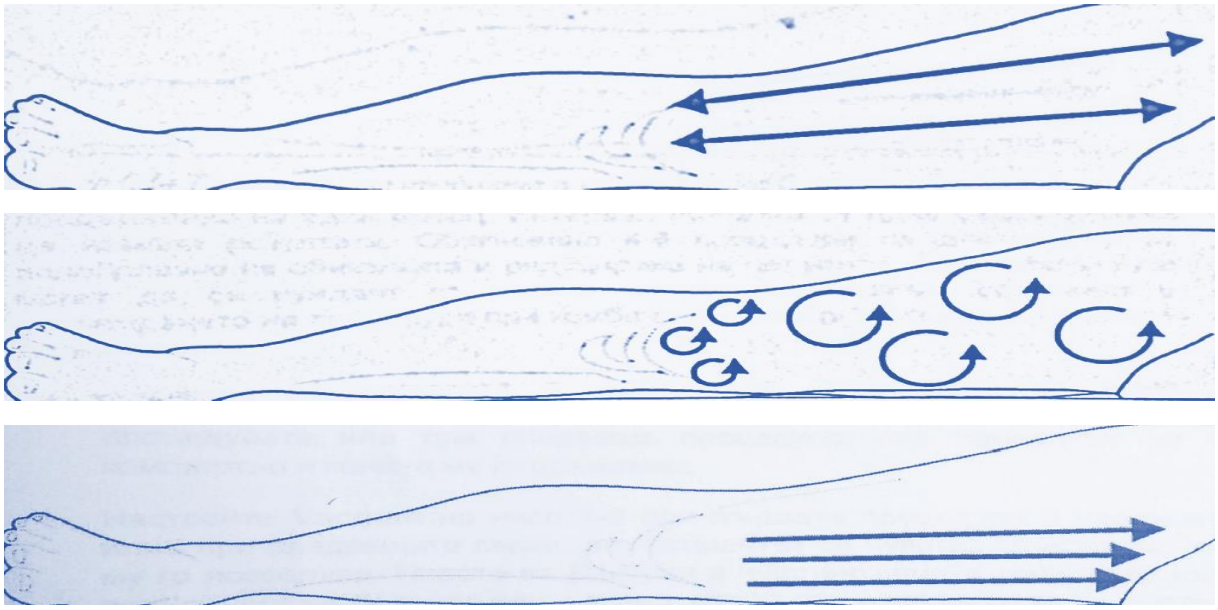

Fig.8. Directions of movement with the applicator

The treatments are held twice a week. The therapy includes 20 sessions according to the individual condition. With each successive generation of the device (VelaShape III), the number of treatments required is less. To maintain the result, it is advisable to do one maintenance treatment per month. Possible side effects that may occur during or shortly after the procedure are: pain; excessive redness of the skin; detachment of hairs from the mechanical rollers; appearance of bruising, burning. If there is a patient who bruises easily, we may recommend taking arnica. After procedures, other heat sources such as sauna, Jacuzzi, solarium, laser hair removal and similar with risk of overheating should be avoided.

Indications: FEP and overweight to reduce girth; to improve blood circulation and local blood flow; to target mild muscle cramps

The contraindications for VelaShape are much more, since besides the mechanical impact there is also a thermal component - two reshaped physical factors that impose these limitations: pacemaker or implantable defibrillator; metal implants in the area to be treated; skin cancer and all other cancers; severe comorbidities (e.g. cardiovascular); pregnancy and lactation; compromised immune system due to use of immunosuppressive medications (AIDS, HIV); diseases that can be unlocked by the light (heat) source such as Systemic Lupus Erythematosus, Herpes Simplex on the treated area; poorly controlled endocrine disorders such as diabetes; inflammation, eczema, psoriasis in the area; use of drugs, herbs, supplements known to cause photosensitivity (e.g. Isotretinoin, Tetracycline, St. John's wort, etc.); history of coagulopathies with bleeding; recent surgical procedure; tattoos on treated area; varicose veins; broken capillaries.

The degree of response is strictly individual in individual patients, as it depends directly on their clinical and physiological condition. A room temperature between 20°-25°C and humidity no higher than 80% is required for optimal functioning of the device.

2.11.3. Eximia - a non-invasive safe multi-technology platform for eliminating fat deposits in a natural way for the body, which includes several reformulated physical factors in

different versions of the Eximia Med and Eximia Platinum HR77 apparatus. The sequence and alternation of the technologies is dependent on the individual needs of the patient (Fig. 9).

Fig.9. Eximia apparatus

Eximia Med has two large tips and one small tip. Programs include:

A. VLEP- Electroporation + Laser + Vibration. The simultaneous action of the technologies is photobiostimulation of the subcutaneous adipose tissue to activate lipolysis and reduce the volume of adipocytes, entirely by physiological means. Multy Laser Poration acts selectively and does not affect the surrounding biological structures i.e. it is completely safe. The synergy between these three technologies is that electroporation has the role of transdermal "injection" of the active ingredients of the lipolytic product, which is applied through the epidermal barrier. It has ingredients such as caffeine, L-carnitine and others. The laser (635 nm) disrupts cell lipid bonds and creates the effect of transient virtual micro-channels in the cell membrane, and the vibrations offer non-invasive neurostimulation that assists for more effective and faster results. In the previous version of the applicator, laserporation was still ultraporation. Unlike the well-known 3MHz or 1MHz ultrasound, which acts at surface level, the low frequency 33 KHz ultrasound acts at greater depths between 0.5 and 2 cm.

B. MPRF- pneumatic vacuum massage + radiofrequency. This technology is a synergy of the simultaneous action of radio frequency technology and pneumatic system to stimulate connective tissue and lymphatic system.

C. RFEP- Radio Frequency and Electroporation. Natural stimulation of the fibroblasts by activating the synthesis of new collagen and elastin i.e. stimulating the skin's natural capacity to form new collagen fibers. Electroporation enhances the action of the active ingredients and radiofrequency activates cell metabolism (Fig. 10).

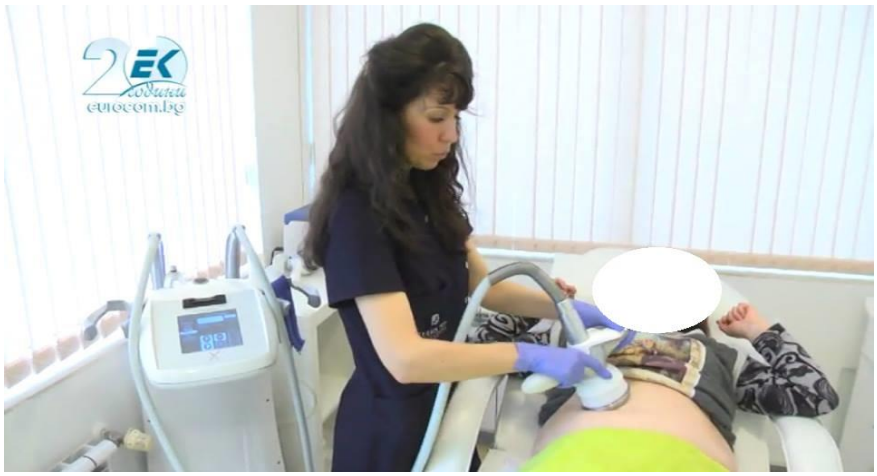

Fig.10. Procedure with the Eximia apparatus

In the case of Eximia Platinum, the technologies are similar:

First step - multipolar laserporation (dermoelectroporation) with vibration (Vibrating Multipolar Laserporation) is a contemporary patented technology, which helps to reduce the volume of adipose tissue. Vibration is innovative and integrated into the Multipolar Laserporation - LowLaserTherapy 635nm manipulation, provides non-invasive neurostimulation during treatment that leads to results that are more effective. The production of endorphins helps to reduce pain by stimulating microcirculation and toning tissue. Microvibration - pulsed rhythmic movements allow, in addition to treating the connective tissue, also the treated muscle group, developing a sedative effect on the motor and sensory nerves thus significantly reducing pain. The vibrations generated at 1000 Hz activate the skin mechanoreceptors and sensitize the lipolysis process. The result is the transformation of the intracellular fat into glycerol and 3 fatty acid molecules. As during the laser treatment, the fat cell goes through several phases until it reaches its volume reduction (Fig. 11): Phase 1 - Stimulation of the fat cell; Phase 2 - Activation of the lipolysis process; Phase 3 - Dual effect of lipolysis; Phase 4 - Reduction of the adipocyte volume

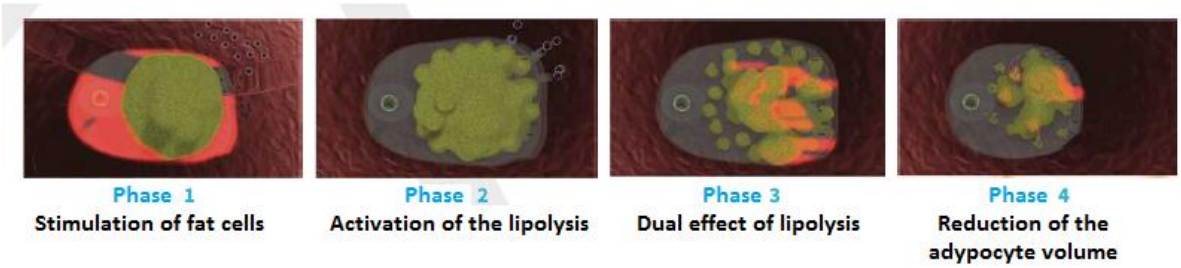

Fig.11. Result of Eximia application

Second step - EndoRadioMag - the tip combines 3 technologies in one - endodermal vacuum (massage with detoxifying and oxygenating effect at tissue level) with bipolar radiofrequency and magnetotherapy (Fig.12).

The endodermal vacuum has 4 phases (stimulation Mag 4 Motion): suction-pressure, suction-pause generating a mechanical action at the skin level that transmits signals in depth to the adipocytes and fibroblasts, generating a physiological response-stimulation of collagen, production of new elastin and reactivating lipolysis. All these processes are enhanced by the simultaneous action of radiofrequency and magnetic rollers. This tip promotes lymphatic drainage and is the second step of the procedure. It facilitates the release of fatty acids and

glycerol into the lymphatic system to prevent their reabsorption. Thanks to the 4-stage vacuum, there is no risk of capillary lesions, ecchymoses (bruising) and allows drainage even in people with any circulation problems. There are 22 different programs depending on the condition. An additional applicator is the "Skin Report". It is applied once before starting the program and guides us which is the most suitable program/step to treat on the area. This allows a personalized therapy thanks to the pre-set programs and the flexible parameters of the reshaped physical factors.

Fig.12. Before and after application of the EndoRadioMag tip

Contraindications: pregnancy and lactation; oncological diseases; thrombophlebitis; acute phase of chronic diseases; cardiovascular diseases; metal implants in the body.

2.11.4. D-Finitive EVO - This is an innovative platform for non-invasive and painless remodeling, that includes three applicators, two large - dynamic and static and two small ones:

The dynamic system, also called Digital Rotation Vacuum System (DRVS), includes (Fig.13): progressive vacuum rotation with rotation up to **90º**; multipolar radio frequency; LEDs: red (vasodilators) and blue LEDs (anti-inflammatory).

The DRVS system allows operation by gradually increasing the rotation angle from 10° to 90° and the rotation frequency from 1 to 5 Hz. It allows operation on any type of FEP. This dual system of rotational vacuum and radiofrequency reduces the resistance and resistance of the fibrous tissue in the subsequent treatment with the second tip - Endothermy. Most devices have one universal vacuum tip while this device has 3 separate applicators with different diameters adaptable to each anatomical area - small, medium and large. Moreover, since this is a robotic massage, it allows programming of different parameters according to the problem and individual adaptation to each person's tolerance. The rotation of the vacuum mimics a twisting motion, which makes a good lymphatic drainage. When the skin is lax, the vacuum force should be less (20-30Kpa), and when it is tight, the vacuum can be stronger (50-60 Kra). In case of discomfort and/or pain (e.g. fibro-sclerosis), it is advisable to reduce the angle of rotation.

Fig.13. DRVS tip

Endothermia- static vacuum system with radio frequency 0,8 and 2,6 MHz + contact applicator for cryotherapy or thermotherapy (Fig.14). Static application, high heating power and comfort for the therapist without physical strain. There are two selectable frequencies according to the required depth of effect - 0,8MHz in depth (for lipolysis) and 2,6 MHz - superficial (for FEP). Peltier cells, two metal plates, allow applicator temperature selection up to 44°, and for heat intolerance or sensitive skin- applicator contact selection down to -5°. Cryo-frequency is a non-abrasive and non-invasive treatment method targeting complaints associated with localized obesity and skin laxity. The method (patent for the Heat & Cold Thermal contrast device) consists of generating radiofrequency waves that produce heat upon contact with subcutaneous tissues. The difference to cryo-frequency is that this method uses a surface cooling system producing a thermal shock by combining deep heat and surface cold. Maximum safety without patient discomfort due to the low temperature. The two tips can be used separately or in combination one after the other, in one procedure - according to the pathology. During the procedure, a warming sensation is felt (slight hyperemia occurs) or a cooling sensation - if we apply the low temperature applicator.

Fig.14. Static Endothermia tip

Hexapolar radiofrequency combined with a lipolytic diode laser. The applicators are vacuum-free, ergonomic and lightweight with convenient application. The lipolytic diode laser acts on adipocytes by applying low-intensity laser energy with a wavelength of 650 nm. It induces an "emptying" effect on the adipocytes at the intracellular level and significantly improves drainage functions to remove excess fluids and toxins. The application is painless. For a better effect, the hexapolar radiofrequency, the laser results in an effective way to stimulate the membrane permeability of adipocytes without attacking the adjacent tissues, causing a lipolysis effect without risk to the surrounding cells. Combined, the two technologies tighten the skin very well. The effectiveness and mechanism of low-intensity laser energy (LLLT) is due to the 635-680 nm wavelength and acts as a non-invasive method of body contouring intervention. LLLT achieved safe and significant circumferential loss and improved skin condition (Fig. 15).

Fig.15. Hexapolar radiofrequency and lipolytic diod laser

High Intensity Mechanical Focused Ultrasound (HIMFU 3D Evo): this is an option for disrupting edematous areas through a mechanical but athermal effect, disrupting the cytoplasmic membrane of fat cells. HIMFU operates in a 200 kHz/pulse mode, so it does not heat tissue - this modality of pulsed HIFU (High Intensity Focused Ultrasound) is not an option for body tightening. The device allows the emission of energy in 3 modes: single, double and triple, focusing and concentrating the energy to the depth required for treatment, allowing for very high precision work.(Fig.15) It is recommended to apply a lymphatic drainage after the procedure to help lymph flow in the area.

Applications: dense areas (more than 30 mm fat); medium areas (between 20 mm to 30 mm); thin areas (between 10 mm to 20 mm) (Fig. 16).

Fig.16. 3D EVO tip

Contraindications are the same as the previous two groups (2nd and 3rd) due to the thermal effect.

2.11.5. Electro-Muscular Stimulation (EMS) -Miha BodyTec - also known as biostimulation, which induces muscle contractions through the use of concentrated electromagnetic pulses at a safe level of intensity. The electromagnetic fields penetrate the body and interact with motor neurons, which lead to intense muscle contractions. During the workout, the muscles are forced to remain contracted for several seconds, which aids in calorie burning. When muscles are repeatedly exposed to an electrical impulse, muscle tissue is forced to adapt thereby increasing its tone. In addition to its firming and strengthening effects, EMG can successfully replace sports training, but this in no way limits the recommendation to include any additional movement/sport during one's possible free time, especially and walking - strolling. EMS trains the whole body, it does not target a specific muscle group, it also stimulates agonist and antagonist at the same time. During the workout, muscle stimulation causes reconstruction and recovery of muscle tissue. Thus, it is sometimes possible the occurrence of muscle soreness afterwards, as after classical physical training. Increased physical activity should be a priority in any weight reduction program. A workout with electro-muscular stimulation with the German device Miha Bodytec is presented in Fig. 17.

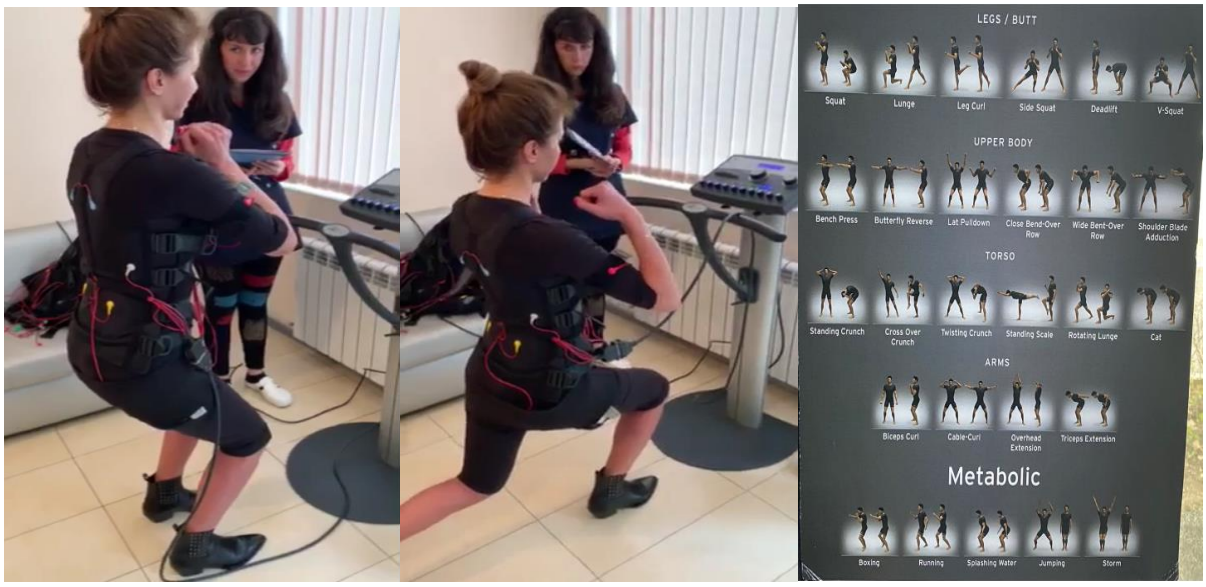

Fig.17. Procedure with Miha Bodytec

The last meal should be 2-3 hours before the procedure, and 30-40 minutes before the workout, at least 500 ml of water should be drunk, so that the body is sufficiently hydrated. In EMS, a special workout leotard (undergarments) of breathable antibacterial material is worn, consisting of a top and pants. A vest (i-body) is placed on top of it, on which there are several pairs of electrodes (red- for the right half of the body, black - for the left). Before putting it on, the places where the electrodes are (pump spray bottle) should be wet with water. On this vest there are static electrodes (for back, abdomen and chest) and there are also removable ones that are attached with cuffs (straps flex for arms and thighs) and a special belt (belt) with electrodes for buttocks. Once all have been fitted to the patient, therapy (training) can begin. The leotard, vests, cuffs and belt have different sizes for men and women (Fig. 18). Each person has a personal training card, in which the parameters of each session are saved, which are used ready for the next training session and can be gradually increased. The benefits of EMS are muscle stimulation and increasing muscle trophicity for better oxygen and nutrient uptake. EMS-Training combines passive muscle stimulation via electrical pulses with an active element of simple self-weight bearing exercises. This targeted approach can easily be tailored to meet individual goals for people who want to strengthen their bodies and stay active in everyday life as well as their priority being their health and well-being. The workout is done once a week and lasts 20 minutes. We use two programs: Basic and Advanced.

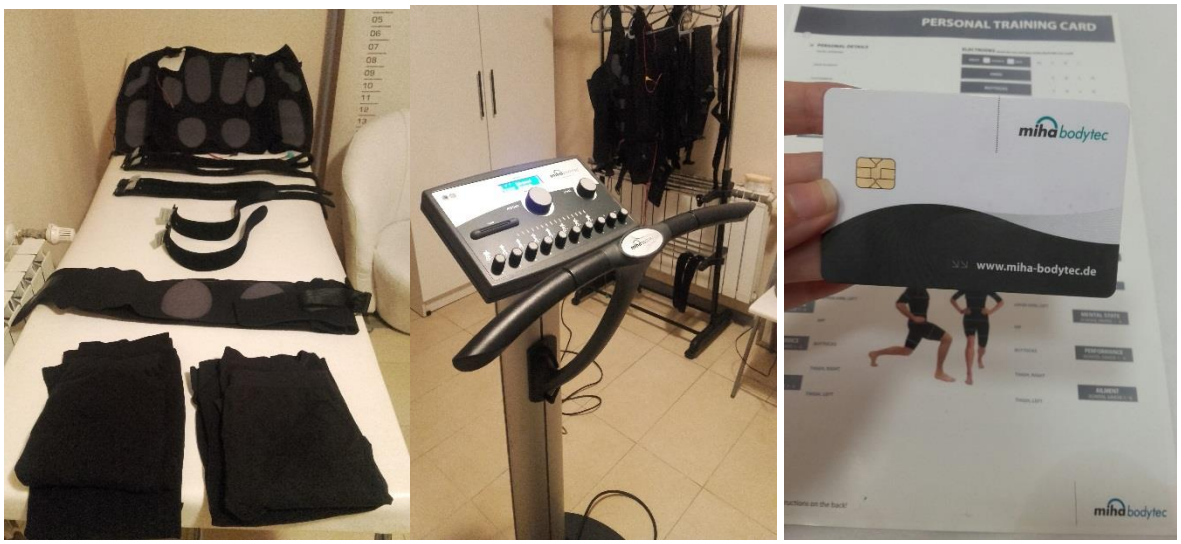

Fig.18. Special wear *i-body* for training with *Miha Bodytec и Personal Training Card*

Contraindications: metal implants in the body; pacemaker; pregnancy; oncological diseases; acute bacterial or viral infections; severe arterial hypertension, uncontrolled diabetes; neurological disorders - epilepsy, vestibular problems; discal hernia; inguinal or abdominal hernia.

2.11.6. Increase of the physical activity

"Walking is the best medicine for man"
Hippocrates

Physical activity includes all movements that increase energy expenditure. It can aid the weight reduction process and maintain it. It has a beneficial effect on circulation (similar to treatments) and reduces cardiovascular risk factors such as high lipid levels and arterial hypertension. It also helps reduce stress, especially when one is in the sun and fresh air. We advised our patients to participate in activities that make them feel good and they enjoy, even 30 minutes of walking a day to maintain at least a minimal level of physical activity (walking

to the supermarket, not using the elevator but taking the stairs, parking their car further away, walking the dog, getting off the bus 1 stop early, etc.). After the walk the body becomes more sensitive to insulin again and thus glucose can be used up more efficiently. Afterwards the liver and muscles slowly rebuild their glucose stores. Sport can therefore lower blood sugar for a few hours.

Physical activity should be tailored to everyone's lifestyle. For example, if a person finds it harder to get up in the morning, he/she may exercise/train in the afternoon or evening. Although it would be good to start the day with a series of exercises. Interest in additional physical activity plays an important role in success. For example, if swimming has bored them since childhood, we have recommended that they turn to e.g. hiking or another sport.

All of these recommendations were given and relied solely on responsible and active participation from patients outside the office. They are not reported to the results obtained (but only from the procedures we performed in the office), as we cannot guarantee their full implementation, which does not bring us credibility and statistical significance. We hope that the advice has served to build some long lasting proper eating and exercise habits to maintain a normal body weight. Exercise and a change to a healthier lifestyle have huge benefits and can reverse the trend of not getting type 2 diabetes in the pre-diabetic period, an important condition from a health perspective that should not be ignored. This condition is a signal that a lifestyle change needs to occur. It is a condition in which blood sugar levels are higher than normal, but not enough to warrant a diagnosis. It may also be found under the name NGT - impaired carbohydrate/glucose tolerance. But we can have control over this condition precisely by making exercise and healthy eating part of our daily routine to maintain a healthy weight and normal blood sugar levels.

Our recommendations for background physical activity included walking at least 30 min/day or 8000-10,000 steps/day. The benefits of physical activity, in addition to weight control, include improving coordination and muscle strength; normalizing blood pressure; reducing inflammation and stress; improving immunity; and improving psycho-emotional tone.

2.12. Patient education in proper eating habits

"Everything is moderation"
Dr. P. Beron

Our main task was to try to build a habit in the patient of mindful eating- "mindful eating", not emotionally - through the TV, at the movies, as others around you are eating, etc. So we have to distinguish between the feeling of hunger and that of craving. For example, young children eat intuitively, only eating when they feel hungry and stopping when they are full. But for the elderly, who are constantly bombarded by advertisements of various food delicacies, this influences us and we lose the connection between hunger and appetite. We have been advised to keep portions small, less frequent, and to have dinner a few hours before bedtime. Eating 5 small or medium portions (instead of 2, 3 large) during the day has been shown to improve metabolism and influence thermogenesis. The thermogenic effect of food is the nutrient-induced production of heat energy required to process it, digest it, and extract nutrients from it. It is also called "postprandial thermogenesis" The thermic effect of a food is determined by the amount and ratio of nutrients in it i.e. not all products have similar value. E.g. fats are easier to process and have little thermal effect; proteins are harder to process and have a much greater thermal effect. Raw fruit and vegetables have a particular thermogenic effect as they have a negative calorie balance i.e. they require more energy to digest than the energy we get from them. The protein that generates heat is called thermogenin (a heat-splitting protein) because it allows the energy derived from oxidation of substrates to be transformed

into heat rather than being used to produce ATP. We should stop eating before we feel full (avoid overeating) as the signaling mechanism to the brain takes longer, about 20 minutes, to signal that the stomach is full. We recommended sufficient water intake (which does not include fruit juices, energy drinks, coffee, etc.) according to body weight as 1kg=0.30ml water i.e. per 70kg, the daily requirement is at least 2.10l. Lemon, ginger or mint can be added to the water for easier intake especially in summer. So-called water calculators are available to calculate the exact amount according to individual physical activity, weight and gender. Meals should mainly include dishes prepared by baking or boiling and avoid frying or breading. Alcohol contains a lot of calories and sugars and should be reduced, as should smoking. Preferred foods are those that contain higher amounts of cellulose - fresh seasonal fruits, raw vegetables, oatmeal (bran). Reduce consumption of salt (both visible, which is cooked with, and hidden, in products) and sugar and derivatives-sweets, ice creams, etc. Sugar provides energy, but on its own contains almost no vitamins, minerals or fibers. It satiates us for a short time, but causes a rapid rise in blood sugar levels. Intake of raw nuts and seeds is recommended, moderate consumption of dairy-no further sweetening.

The Mediterranean diet includes increased intake of vegetables, legumes, fruits, grains, moderate or increased intake of fish, reduced saturated fat and increased unsaturated fat, particularly olive oil, low or moderate dairy intake, low meat intake.

Low-carb - carbohydrates that are ingested during a meal are broken down to glucose and provide energy to the body. This is why they are responsible for raising blood sugar levels. Therefore, it is important that one is careful with the amounts that he or she takes of them. They are of two main types: complex (starches)-bread, rice, potatoes, pasta, breakfast cereals and simple (sugars)-fruits and sweets. We need to choose carbohydrate sources that lead to a slow rise in blood sugar.

Foods, that do not cause a sharp rise in blood sugar, have low glycemic index. These are most vegetables and fruits, whole grain breads, hanging nuts (bran) and legumes. Fruits and vegetables supply the body with vitamins, minerals and fiber. Foods with a high glycemic index are white bread, pastas, potatoes, etc. Another similar diet is the anti-inflammatory diet. It consists of foods that reduce inflammation in the body. Anti-inflammatory principles are to avoid sugary drinks, fried foods, white bread, snacks, desserts, alcohol. More vegetables and fruits, lean meats, dairy products, antioxidants should be included in the menu.

Split feeding also gives good results. As with it, proteins and carbohydrates should be eaten separately, but both can with vegetables. Since proteins (dairy meat) require acid-digestive juices, and carbohydrates (rice, potatoes)-basic. Increased consumption of fruits, vegetables, legumes and grains. Elimination of unsaturated and trans fats. Fruits are eaten separately half an hour at least before meals or 2-3 hours after. Any carbonated and sweetened beverages are excluded from the menu. As well as alcohol. If the plate method is followed, then ½ of it should be filled with vegetables, ¼ with protein (meat or seafood) and ¼ can carbohydrates-bread, some brown rice, etc. A healthy fat such as olive oil, avocado or nuts can be included. Optimal food composition is characterized by high nutrient and low energy density.

For the convenience of the patients, a table with recommendations and ready options of different menus for overweight and obesity were offered. These menus were developed by leading specialists in the country. Easy to implement seasonal menus were presented: spring; summer and autumn-winter regimes.

Overweight people are at risk of deficiency of important micronutrients such as vitamin D, B12, iron, Mg and others. Excess fat requires large amounts of extra vitamin D, reducing the amount available for other body processes. An intake of 1000IU of vitamin D per 25kg of body weight is recommended. In turn, vitamin D acts synergistically with K2 (the so-called "Forgotten vitamin"), as it promotes the incorporation of calcium to bones rather than blood

vessels as it activates osteocalcin and matrix-GLA. Magnesium, in turn, is necessary for the functioning of insulin, which makes it possible for cells to obtain energy from glucose. Without magnesium, insulin cannot enter the cell and therefore cannot transport glucose.

Cells become resistant to insulin because they no longer respond to the hormone and do not absorb glucose. As a result, our body produces more insulin in an attempt to control glucose levels. This leads to an increase in fat tissue formation, which is directly linked to weight gain. Overweight people generally have lower serum and intracellular magnesium levels compared to those of normal weight. The better absorbed forms of Mg are citrate, chloride, lactate as opposed to carbonate, oxide and sulfate. It is the amount of elemental magnesium that is important as this is the actual amount that is absorbed in the body. Taking B vitamins, including B12, lowers levels of free circulating homocysteine (which in turn is a risk factor for the development of cardiovascular disease such as atherosclerosis and coronary artery disease especially in obese patients), levels that are elevated in patients on metformin therapy. Its prolonged intake may lead to a reduction in B vitamin levels. It is advisable to take the active forms of the vitamins e.g. B12-methylcobalamin. A scientific collective of Cardiff University developed novel drug delivery systems, for the reason that the effectiveness of conventional tablets (sublingual, buccal and transdermal) is reduced. These innovative methods apply new molecules for better absorption of these vitamins and minerals. Unexpectedly, these obese persons often fall into severe deficiencies, which we also found in some of our patients when we did blood tests. We presented our experience with some of them as clinical cases at scientific conferences.

Another recommendation for supplementation in people who are at risk of becoming overweight and developing diabetes mellitus is the intake of berberine, a potent adenosine monophosphate protein kinase activator (AMPK). It can also be found under the name "metabolic master switch". It plays an important role (scientifically proven) in regulating blood sugar levels, blood pressure, in maintaining healthy cholesterol levels and in controlling body weight. AMPK can be activated naturally by restricting caloric intake, by physical activity, and by taking berberine. The latter influences the increase in the number of insulin receptors and AMPK, increases glucagon secretion and glucose absorption, and slows the breakdown of carbohydrates to simple sugars. Our opinion is that the intake of Omega 3 must be included for dyslipidemias and for a good cardiovascular health. It is important to consider the TOTOX index (total oxidation index) , which indicates the degree of oxidation of fish oil, as well as the ratio of eicosapentanoic to docosahexaenoic acids.

Most drastic diets deprive the body of essential vitamins and minerals. An example of this is the condition orthorexia, which involves obsessive behavior (pathological obsession) towards healthy diets, restrictions and can endanger a person's health. Other eating disorders are binge eating disorder, in which people are obsessed with making muscle mass, and pregnorexia - pregnant women deprive their bodies of important nutrients, obsessed with maintaining their figure. Restrictive diets often have quick instant results, but over an extended period, a return to baseline is seen if one reverts to their old binge-eating regimen-good effect, but with short-term results. Our goal was to create proper long-term healthy eating habits in patients that would last a lifetime to maintain the results achieved.

Hypovitaminosis and overweight are seemingly incompatible things and sound paradoxical together, but in fact, it is not. A growing problem, especially in overweight people, is the body's inability to absorb nutrients from food due to the impaired functioning of the digestive system. Being overweight often indicates not only excessive caloric intake, but also possible vitamin and mineral deficiencies. It can be the result of metabolic disorders, malabsorption, gastrointestinal disorders, poor eating habits, intake of medications (proton pump inhibitors, laxatives, metformin, etc.).

3.RESULTS AND DISCUSSION

3.1.Statistical analysis of patient contingents by groups

3.1.1.Group 1 - *LPG Endermology*

The first group consisted of 35 overweight women with mild FEP who were treated with the LPG Endermology device. The program was combined with a balanced diet and intensified physical activity + exercise - electro-muscular stimulation. A total of 20 treatments were done to each patient, 2 per week LPG and 1 EMS exercise on a different day than the LPG therapy. The treatments were not done every day, but every second day - 3 times a week (Monday-Wednesday-Friday or Tuesday-Thursday and Saturday) with EMS in between two LPG treatments.

Patients' characteristics: the shortest patient in the group was 154 cm tall and the tallest was 175 cm. The average is 163.37cm. The patient with the lowest weight in the group weighed 62kg and the highest weighed 78kg. The average weight in the group was 68.36kg. Based on the weight and height data of all patients, the lowest BMI was 25 and the highest BMI was 26. The mean arithmetic value for the respective group was 25.66. The smallest waist circumference was 74cm and the largest was 101cm. The average waist circumference for the group was 85.97cm. In the patient with the narrowest hips, it was 85cm and with the widest hips, it was 115cm. The mean hip circumference was 96.79cm. The minimum T/X ratio was 0.80 and the maximum was 0.96. The minimum T/B ratio is 0.45 and the maximum is 0.62. The results of calipermetry, show the smallest skin fold to be 26.70cm and the densest 28.80. Thermography showed that there were only women with first and second degree FEP in the group with 3 having first degree and 32 having second degree. The quality of life test showed the least points scored 0 and the most scored 60. Taking the mean value as 27.09 (Table 6).

Table 6. LPG group characteristics

Parameter	Group	N	Mean	SD	Min	Max
Height-m	LPG	35	163,37	5,05	154,00	175,00
	Group	N	Mean	SD	Min	Max
Weight (kg)	LPG	35	68,36	3,85	62,00	78,00
	Група	N	Mean	SD	Min	Max
BMI	LPG	35	25,66	0,48	25,00	26,00
	Група	N	Mean	SD	Min	Max
Waist (cm)	LPG	35	85,97	7,32	74,00	101,00
	Group	N	Mean	SD	Min	Max
Hip (cm)	LPG	35	96,79	7,13	85,00	115,00
	Group	N	Mean	SD	Min	Max
Waist/hip ratio	LPG	35	0,89	0,04	0,80	0,96
	Group	N	Mean	SD	Min	Max
Waist/height ratio	LPG	35	0,53	0,04	0,45	0,62

	Group	N	Mean	SD	Min	Max
Skin-fold thickness (mm)	LPG	35	27,72	0,59	26,70	28,80
	Group	N	Mean	SD	Min	Max
Quality of life	LPG	35	27,09	15,13	0,00	60,00
	Group	N	Mean	Median	SD	Min	Max
Termography degree	LPG	35	1,91	2,00	0,28	1,00	2,00

3.1.2.Group 2 - *Velashape*

A second group included 34 overweight women with intermediate FEP who were treated with the Velashape device. The program was combined with a balanced diet and intensified physical activity + exercise - electro-muscular stimulation. We did 20 treatments per patient, 2 Velashape treatments per week and 1 EMS training session on a different day than the Velashape treatment. Treatments were not done every day, but 3 times weekly (Monday-Wednesday-Friday or Tuesday-Thursday and Saturday).

Patients' characteristics: the shortest patient in the group was 155 cm and the tallest was 170 cm. The mean is 164.41cm. The patient with the lowest weight in the group weighed 64kg and the highest weighed 80kg. The mean of the weight in the group was 72.09kg. Based on the weight and height data of the patients, the lowest BMI was 26 and the highest BMI was 28. The mean arithmetic value for the group was 26.56. The smallest waist circumference was 76cm and the largest was 107cm. In the patient with narrowest hips it was 85cm and with widest hips it was 118cm. The minimum T/X ratio was 0.79 and the maximum 1.07. The minimum T/B ratio was 0.46 and the maximum 0.64. Calipermetry results, show the smallest skin fold to be 28.90cm and the densest 31.60. The quality of life test shows the least points scored 0 and the most scored 40. Taking the average, the mean value was 21.76. The thermography shows that there are only women with second and third degree FEP in the group with 4 having second degree and 30 having third degree (Table 7)**.**

Table 7: Velashape group characteristics

Показател	**Група**	**N**	**Mean**	**SD**	**Min**	**Max**
Height-m	Velashape	34	164,41	4,32	155,00	170,00
	Group	N	Mean	SD	Min	Max
Weight (kg)	Velashape	34	72,09	4,03	64,00	80,00
	Group	N	Mean	SD	Min	Max
BMI	Velashape	34	26,56	0,66	26,00	28,00
	Group	N	Mean	SD	Min	Max
Waist (cm)	Velashape	34	87,59	7,78	76,00	107,00
	Group	N	Mean	SD	Min	Max
Hip (cm)	Velashape	34	98,91	7,92	85,00	118,00
	Group	N	Mean	SD	Min	Max

Waist-to-Hip ratio	Velashape	34	0,89	0,06	0,79	1,07
	Group	N	Mean	SD	Min	Max
Waist-to-Height ratio	Velashape	34	0,53	0,04	0,46	0,64
	Group	N	Mean	SD	Min	Max
Skin-fold thickness (mm)	Velashape	34	30,01	0,95	28,90	31,60
	Group	N	Mean	SD	Min	Max
Quality of life	Velashape	34	21,76	12,62	0,00	40,00

	Group	N	Mean	Median	SD	Min	Max
Thermography degree	Velashape	34	2,88	3,00	0,33	2,00	3,00

3.1.3. Group 3 - *Eximia*

The third group consisted of 32 women and 2 men with overweight and moderate FEP, who were treated with the Eximia Body Concept device. The program was combined with a balanced diet and intensified physical activity + exercise (electro-muscular stimulation). A total of 20 treatments were done to each patient in the group, 2 per week of Eximia and 1 EMG training on a different day than the Eximia treatment. Procedures, like in the first two groups, were not done every day but during the day (Monday-Wednesday-Friday or Tuesday-Thursday and Saturday).

Contingent characteristics:The shortest patient in the group was 150 cm and the tallest was 186 cm. The mean was 166.09cm. The patient with the lowest weight in the group weighed 63kg and the highest weighed 97kg. The mean weight in the group was 75.68kg. Based on the weight and height data of the patients, the lowest BMI was 26 and the highest BMI was 28. The mean arithmetic value for the respective group was 27.41. The smallest waist circumference was 77 cm and the largest was 112 cm. The patient with the narrowest hips had a waist circumference of 93 cm and the widest 116 cm. The minimum W/H ratio was 0.80 and the maximum 1.13. The minimum W/Ht ratio was 0.50 and the maximum 1.00. Calipermetry results, showed the smallest skin fold to be 28.90cm and the densest 31.60. The quality of life test shows the least scored 0, and the most scored 40. Taking the average, the mean value was 21.06. The thermography showed that the group of patients had second and third degree FEP with 4 patients having second degree and 30 patients having third degree (Table 8).

Table 8. Eximia group characteristics

Parameter	Group	N	Mean	SD	Min	Max
Height-m	Eximia	34	166,09	7,30	150,00	186,00
	Group	N	Mean	SD	Min	Max
Weight (kg) Before	Eximia	34	75,68	7,33	63,00	97,00
	Group	N	Mean	SD	Min	Max
BMI Before	Eximia	34	27,41	0,56	26,00	28,00

	Group	N	Mean	SD	Min	Max
Waist (cm)	Eximia	34	92,22	8,15	77,00	112,00

Before						
	Group	N	Mean	SD	Min	Max
Hip (cm) Before	Eximia	34	99,71	6,24	93,00	116,00
	Group	N	Mean	SD	Min	Max
Waist-to-Hip ratio BEFORE	Eximia	34	0,92	0,06	0,80	1,13
	Group	N	Mean	SD	Min	Max
Waist-to-Height ratio BEFORE	Eximia	34	0,57	0,09	0,50	1,00
	Group	N	Mean	SD	Min	Max
Skin-fold thickness (mm) BEFORE	Eximia	34	30,17	0,80	28,90	31,60
	Group	N	Mean	SD	Min	Max
Quality of life – Before the program	Eximia	34	21,06	11,62	0,00	40,00

	Group	N	Mean	Median	SD	Min	Max
Thermography degree	Eximia	34	2,88	3,00	0,33	2,00	3,00

3.1.4. Group 4 - *D-finitive EVO*

A fourth group included 30 women and 3 men with overweight, obesity and severe FEP who were treated with the D-finitive EVO device. We combined the program with balanced nutrition and intensified physical activity + exercise - electro-muscular stimulation. Twenty treatments were performed on each patient, 2 per week with the D-finitive EVO and 1 EMG training session on a different day than the Evo treatment. The treatments, like in the other groups, were not done every day but every other day.

Contingent characteristics: the shortest patient in the group was 153 cm and the tallest was 190 cm. As an average, it was 165.70cm. The patient with the lowest weight in the group weighed 68kg and the highest weighed 103kg. The mean weight in the group was 81.47kg. Based on the weight and height data of the patients, the lowest BMI was 28 and the highest was 33. The mean arithmetic value for the group was 29.64. The smallest waist circumference was 86.00cm and the largest was 116cm. In the patient with narrowest hips it was 84cm and with widest hips it was 131cm. The minimum W/H ratio was 0.77 and the maximum 1.10. The minimum W/Ht ratio was 0.51 and the maximum 0.74. The results of calipermetry, show the smallest skin fold to be 31.70cm and the densest 33.60. The quality of life test shows the least scored 0 and the most scored 28. Taking the average, the arithmetic mean is 13.82. The thermography shows that there are mainly patients with third and fourth degree FEP in the group with 3 having third degree and 30 having fourth degree (Table 9).

Table 9. Characteristics of the D-finitive EVO patient group

Parameter	**Group**	**N**	**Mean**	**SD**	**Min**	**Max**
Height-m	D-finitive EVO	33	165,70	9,05	153,00	190,00
	Group	N	Mean	SD	Min	Max

Weight (kg)	D-finitive EVO	33	81,47	7,91	68,00	103,00
	Group	N	Mean	SD	Min	Max
BMI	D-finitive EVO	33	29,64	1,34	28,00	33,00
	Group	N	Mean	SD	Min	Max
Waist (cm)	D-finitive EVO	33	98,06	8,24	86,00	116,00
	Group	N	Mean	SD	Min	Max
Hip (cm)	D-finitive EVO	33	104,67	10,64	84,00	131,00
	Group	N	Mean	SD	Min	Max
Waist-to-Hip ratio	D-finitive EVO	33	0,94	0,08	0,77	1,10
	Group	N	Mean	SD	Min	Max
Waist-to-Height ratio	D-finitive EVO	33	0,59	0,05	0,51	0,74
	Group	N	Mean	SD	Min	Max
Skin-fold thickness (mm)	D-finitive EVO	33	32,56	0,53	31,70	33,60
	Group	N	Mean	SD	Min	Max
Quality of life	D-finitive EVO	33	13,82	7,88	0,00	28,00

	Group	N	Mean	Median	SD	Min	Max
Thermography degree	D-finitive EVO	33	3,91	4,00	0,29	3,00	4,00

3.2. Results of the comprehensive program in Group 1 - LPG

Table 10 demonstrates the statistical significance of weight reduction, compared to the initial data before the start of the program, and it is on average - 2.68 kg for the group. The lowest weight is now 58.30kg and the highest weight for the group is 74.70kg. BMI also decreases significantly and there is a difference of - 1.07 units down on average. This reduction in BMI was a result of and correlated with the reduction in body weight during the program. The lowest BMI was 23.90 and the highest was 25.50. Waist measurement also showed statistically significant differences with an average of -2.64 cm. The smallest waist was 72cm and the largest was 96.50. Reduction in hip circumference was also recorded in the group and was statistically significant. It is by -1,90cm.

Because of the reduction in waist and hip circumferences, we report a 0.02 reduction in the waist/hip ratio, respectively. The statistically significant reduction in the waist circumferences of the patients in the group also resulted in a reduction in the waist-to-height ratio also by 0.02. The reduction in weight and waist and hip circumferences also led to a statistically significant and reliable reduction in skin-fold thickness by -0.78cm (78mm) on average.

Table 10. Results of the anthropometric indices after the LPG program

Parameter	Group	N	Mean	SD	Min	Max	p
1.Weight (kg) AFTER	LPG	35	65,67	3,73	58,30	74,70	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**2,68**	0,71	2,44	2,93	22,37	34	<0,001

	Group	N	Mean	SD	Min	Max	p
2. BMI After	LPG	35	24,59	0,43	23,90	25,50	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**1,07**	0,37	0,94	1,19	17,11	34	<0,001

	Group	N	Mean	SD	Min	Max	p
3. Waist (cm) AFTER	LPG	35	83,33	6,95	72,00	96,50	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**2,64**	0,69	2,40	2,88	22,61	34	<0,001

	Group	N	Mean	SD	Min	Max	p
4. Hip (cm) AFTER	LPG	35	94,90	6,45	84,00	113,50	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**1,90**	2,17	1,15	2,64	5,17	34	<0,001

Parameter	Group	N	Mean	SD	Min	Max	p
5. Waist-to-Hip ratio AFTER	LPG	35	0,87	0,04	0,79	0,94	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**0,02**	0,01	0,01	0,02	16,58	34	<0,001

Parameter	Group	N	Mean	SD	Min	Max	p
6. Waist-to-Height ratio AFTER	LPG	35	0,51	0,04	0,43	0,59	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**0,02**	0,00	0,02	0,02	24,39	34	<0,001

Parameter	Group	N	Mean	SD	Min	Max	p
7. Skin-fold (mm) AFTER	LPG	35	26,93	0,53	26,00	28,00	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				

BEFORE-AFTER	**0,78**	0,21	0,71	0,86	21,69	34	<0,001

Initial contact thermography data showed that there were 3 patients with grade 1 FEP in the group, and 32 with grade 2, were followed up and changed to 31 with grade 1 and only 4 with grade 2 after the end of therapy, indicating a high statistical significance (Fig. 19).

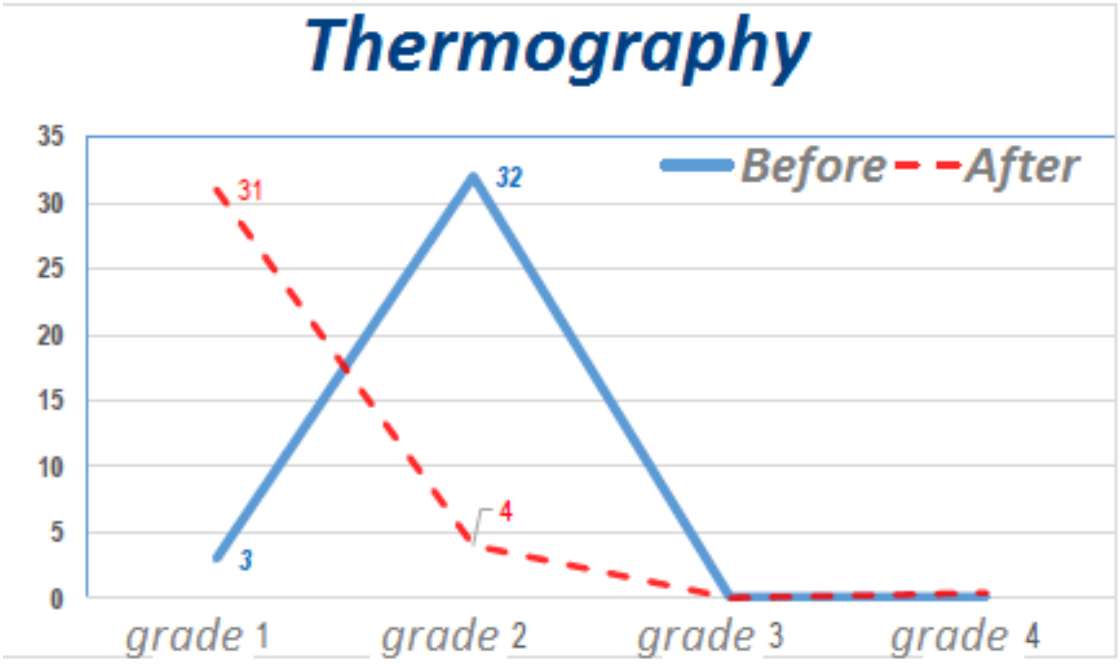

Fig.19. Results of the contact thermography in group 1

Table 11 shows that the mean decreases to 1.11 compared to the original mean of 1.91. This is a result of the fact that after the program, a larger number of patients now have first degree FEP.

Table 11. Results of the contact thermography after the program

Parameter	Group	N	Mean	Median	SD	Min	Max	p
Degree After	LPG	35	1,11	1,00	0,32	1,00	2,00	<0,001

Table 12 presents the quality of life after the program. We can see that it is much better than before the program. The minimum value is 60 i.e. there were no patients with worst quality of life = 0. In addition, the maximum 100 indicates that we already had patients who reached their best quality of life level immediately after the program.

Table 12. Results of the quality of life after the program

Parameter	Group	N	Mean	SD	Min	Max	p
Quality of life - after	LPG	35	84,00	11,60	60,00	100,00	<0,001

The mean Well-being index scores were 84 as opposed to 27.09 before the start of the program i.e. quality of life improved significantly after the program (Fig. 20) This showed the high level of patient satisfaction with the effectiveness of LPG and the results achieved.

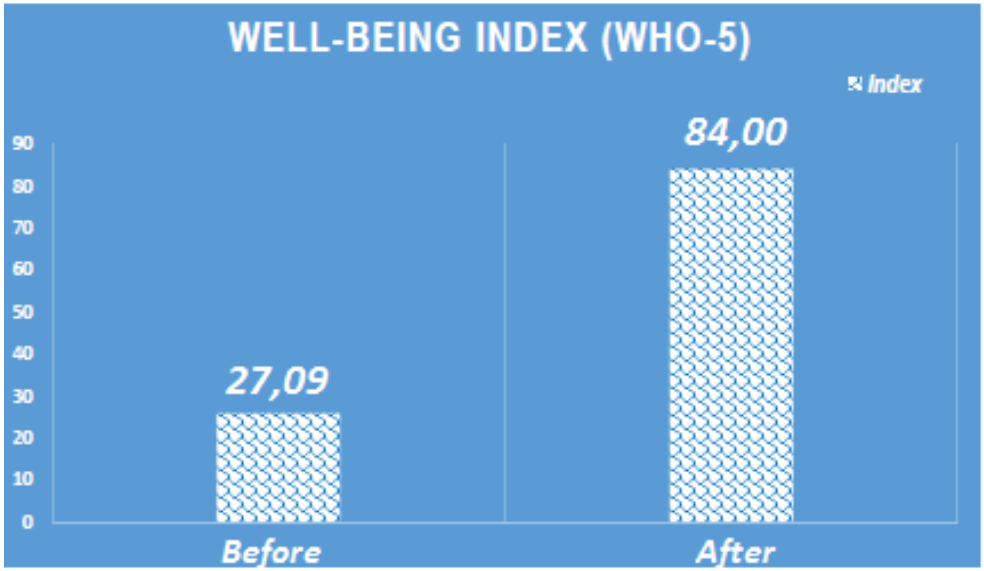

Fig.20. Results of the assessment of the quality of life before and after in group 1

The anthropometric results of the first group are depicted in Figure 21. In all the follow-up examinations performed after the program, we noticed a statistically significant significant decrease in the initial values of the indicators. This indicates that the patients were affected by the course done with the device. LPG Endermology gives good results in the 2nd stage of F.E.P. i.e. the edematous phase, also called "**Mottled or oedema", mild F.E.P.,** when the changes are still limited only to disturbance of blood and lymph circulation, mainly at the microcirculatory level. The stage is characterized by the formation of oedema, which explains the benefits of the device due to its strong draining action. Other advantages of the device are non-aggressive, painless, natural therapy that stimulates blood and lymph circulation, increases oxygenation and tissue trophicity, eliminates toxins from the body and reduces edema. There is an increased lipolytic response resulting from LPG mechanostimulation through increased activity from β-adipocyte receptors. At the same time, the absence of inflammatory factors has been demonstrated, indicating that this highly effective therapy mobilizes fat metabolism without any traumatic damage. Significant improvement in skin quality (tone, turgor, edema and fat elimination) and increased elasticity were observed. Patients were also monitored at each visit for any adverse effects of treatment, but none were reported. No patients experienced bruising, formation of new telangiectasias, or any serious side effects after treatment. In conclusion, LPG endermologie is an effective, well-tolerated, and satisfying noninvasive technique for reducing FEP and waist and hip circumferences.

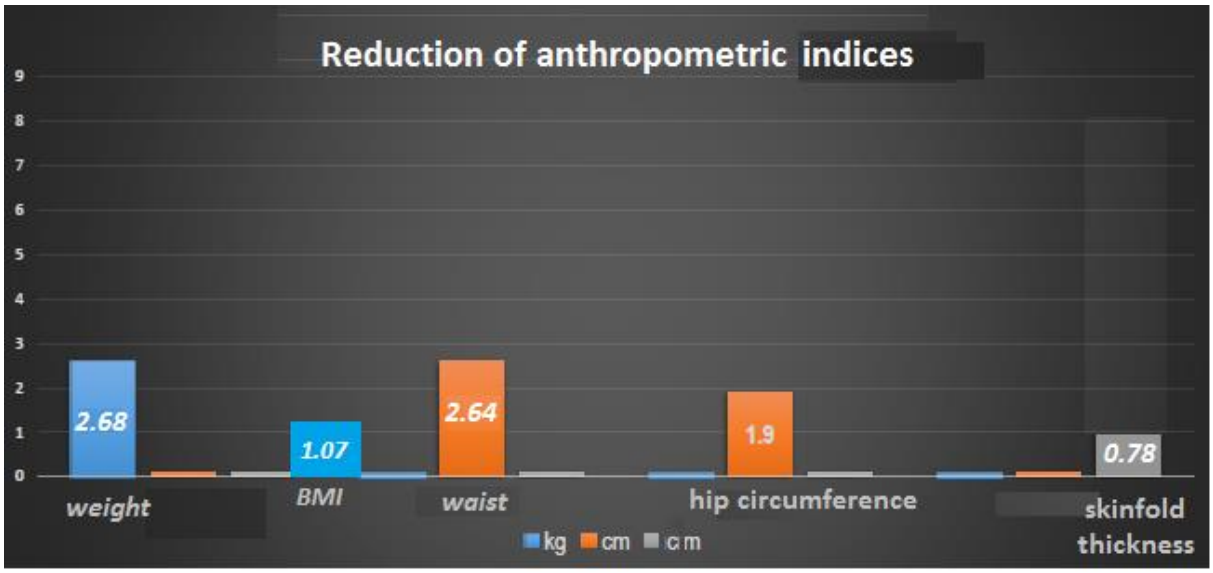

Fig.21. Results of the assessment of anthropometric indices in group 1

3.3. Results of the complex program in group 2 - Velashape

From the post-program data presented in Table 13, it can be seen that there is statistical significance of the weight reduction compared to the original data before the start of the program, with an average of -3.59kg for the group. The lowest weight is now 60.70kg and the highest weight for the group is 75.70kg. BMI also decreased significantly and a difference of -1.24 units down on average is obtained. This reduction in BMI was a result of and correlated with the reduction in body weight during the program. The lowest BMI was 24.40 and the highest 26.50. In waist measurement, we also reported statistically significant differences with an average of -3.54 cm. The smallest waist was 72.70cm and the largest 104 cm. Hip circumference reduction was also reported in the group and was statistically significant. It is by -2,49cm.

Because of the reduction in waist and hip circumferences, we report a 0.02 reduction in the waist/hip ratio, respectively. The statistically significant reduction in the waist circumferences of the patients in the group also resulted in a reduction in the waist-to-height ratio by 0.03. The reduction in weight and waist and hip circumferences also led to a statistically significant and reliable reduction in skin-fold thickness by -1.32cm on average.

Table 13. Results of the anthropometric parameters after the Velashape program

Parameter	**Group**	**N**	**Mean**	**SD**	**Min**	**Max**	**p**
1. Weight (kg) After	Velashape	34	68,49	4,01	60,70	75,70	<0,001
Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**3,59**	0,51	3,42	3,77	41,44	33	<0,001
	Group	N	Mean	SD	Min	Max	p
2. BMI After	Velashape	34	25,32	0,48	24,40	26,50	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**1,24**	0,39	1,10	1,37	18,47	33	<0,001

	Group	N	Mean	SD	Min	Max	p
3. Waist (cm) After	Velashape	34	84,05	7,80	72,70	104,00	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**3,54**	0,30	3,43	3,64	67.97	33	<0,001

	Group	N	Mean	SD	Min	Max	p
4. Hip (cm) AFTER	Velashape	34	96,43	7,89	83,00	115,00	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**2,49**	0.65	2,26	2,71	22,36	33	<0,001

Parameter	Group	N	Mean	SD	Min	Max	p
5. Waist-to-Hip ratio AFTER	Velashape	34	0,87	0,05	0,76	1,04	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**0,02**	0,01	0,02	0,02	17,45	33	<0,001

Parameter	Group	N	Mean	SD	Min	Max	p
6. Waist-to-Height ratio AFTER	Velashape	34	0,51	0,04	0,43	0,62	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**0,03**	0,01	0,02	0,03	26,18	33	<0,001

Parameter	Group	N	Mean	SD	Min	Max	p
7. Skin-fold thickness (mm) AFTER	Velashape	34	28,69	0,93	27,40	30,70	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**1,32**	0,23	1,24	1,40	33.39	33	<0,001

The contact thermography results, reported after the program, showed that 4 patients had grade 1 FEP, 25 had grade 2 and only 5 had grade 3. As in the initial data, 30 had third degree and only 4 had second degree (Fig. 22). The results after the program showed great statistical significance.

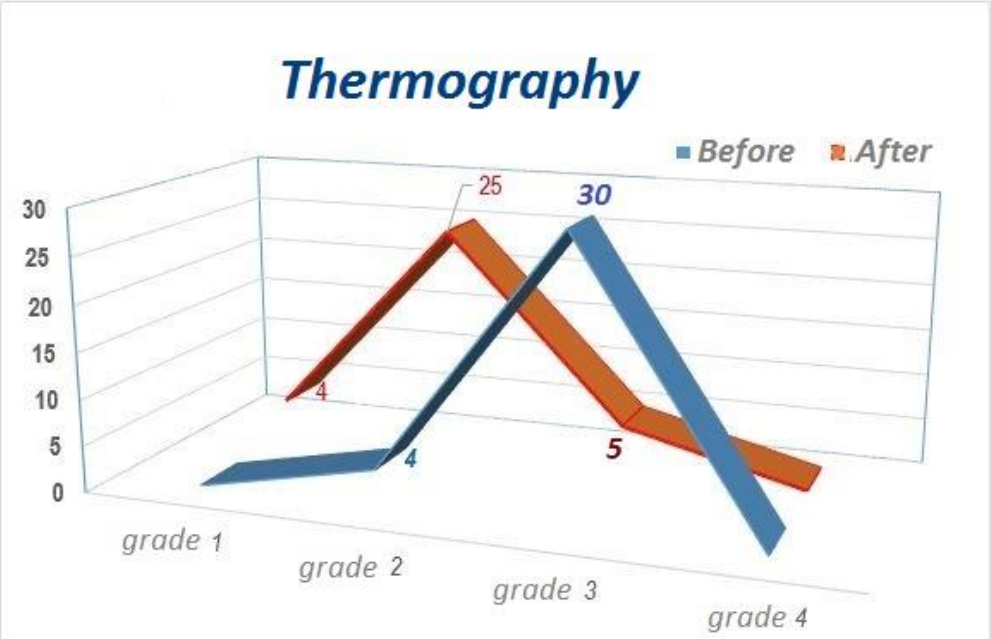

Fig.22. Contact thermography results in group 2 - before and after

Table 14 shows that the mean decreases to 2.03 compared to the original mean of 2.88. This was a result of the fact that after the program a higher number of patients now had a second degree FEP rather than a third.

Table 14. Contact thermography results after the program

Parameter	Group	N	Mean	Median	SD	Min	Max	p
Degree After	Velashape	34	2,03	2,00	0,52	1,00	3,00	<0,001

Table 15 presents the quality of life after the program. We can see that the results are much better than before the program, but overall it is lower than in the first group. The minimum value is 44 i.e. no patients with worst quality of life = 0. And the maximum value of 100 indicates that there are already patients reaching their best quality of life level immediately in the middle of the program.

Table 15. Results of the quality of life after the program

Parameter	Group	N	Mean	SD	Min	Max	p
Quality of life - After	Velashape	34	78,35	14,21	44,00	100,00	<0,001

The mean Well-being Index score for the group was 78.35 in contrast to the pre-program score of 21.76, i.e. quality of life improved significantly after the program (Fig. 23).

Fig. 23. Results of quality of life assessment before and after in group 2

The results achieved in the second group are depicted in Fig. 24. They show that non-invasive Velashape therapy resulted in reduction of waist and hip circumferences, skin-fold thickness, body weight and BMI. The three technologies - roller vacuum + RF and IR work synergistically and increase fat cell metabolism. The mechanical action of the vacuum helps drain excess fluids. Thermotherapy induces deep tissue heating of the dermis and hypodermis or fat cells, creating endogenous heat, surrounding connective tissue and dermal collagen fibers, this increases blood circulation, lymphatic drainage, cell metabolism and collagen stimulation. In addition, fibroblast and extracellular matrix activity is stimulated and remodeling is initiated to effectively reduce fat cell size and smooth the skin surface. The warming effect stimulates fat cell metabolism and the gripping of the skin fold by the vacuum, brings the skin closer to the energy source in the device and in combination with the deep tissue massage, helps to stretch the connective tissue barriers. Radiofrequency and infrared light energy cause deep heating of fat cells and lead to tightening of the treated area and reduction of fat cell volume. As a result, we observe a reduction in waist and hip circumferences, body weight and skin-fold thickness. Due to the deep tissue massage associated with VelaShape, some patients experienced localized bruising in the treated area, but this is a normal process. After the treatment, the skin had a mild erythema that disappeared after a few hours. We recommended to stop taking aspirin or other anticoagulants for a week before the treatment to avoid unnecessary bruising.

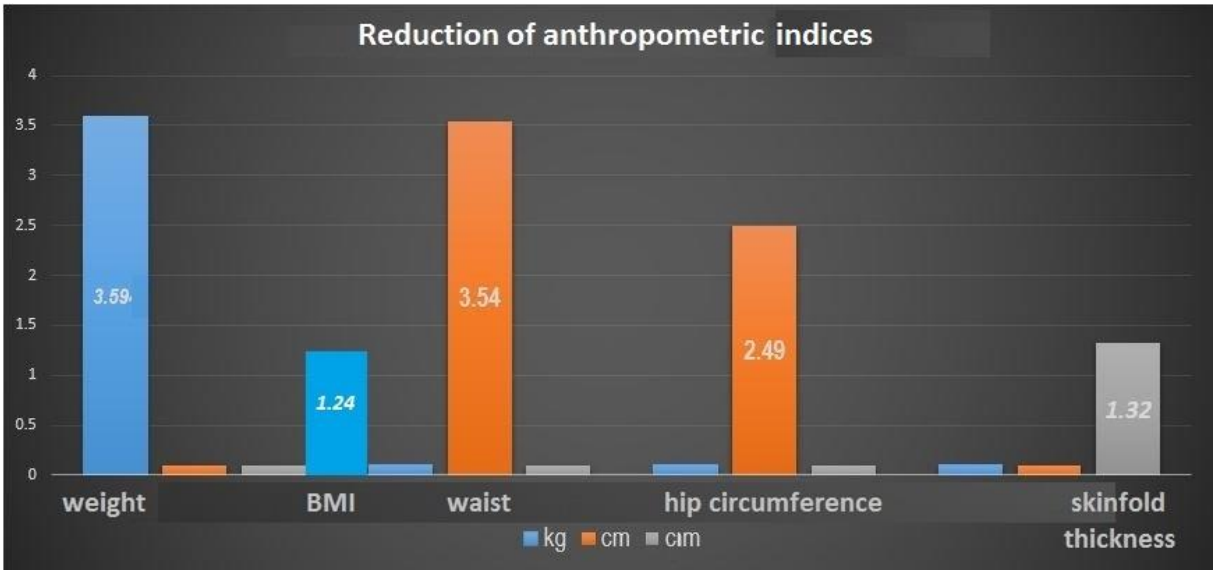

Fig.24. Results of the assessment of the anthropometric indices in group 2

3.4. Results of the complex program in group 3 - Eximia

From the detailed data of anthropometric indices recorded after the program, which are presented in Table 16, we notice that there is a statistical significance of weight reduction compared to the initial data before the start of the program, with an average of -3.62 kg for the group. The lowest weight is now 58.90 kg and the highest weight for the group is 92.80 kg. BMI also decreases significantly and there is a difference of -1.35 units down on average. This reduction in BMI was a result of the reduction in body weight during the program and correlates directly with it. The lowest BMI was 24.90 and the highest 26.90. Waist measurement also showed statistically significant differences with an average of -3.69 cm. The smallest waist was 73.60cm and the largest 105.30cm. Hip circumference reduction was also reported in the group and was statistically significant. It is by -2,45cm.

Because of the reduction in waist and hip circumferences, we report a 0.02 reduction in the waist/hip ratio, respectively. The statistically significant reduction in the waist circumferences of the patients in the group also resulted in a reduction in the waist-to-height ratio by 0.03. The reduction in weight and waist and hip circumferences also led to a statistically significant and reliable reduction in skin-fold thickness by -1.40cm on average.

Table 16. Results of the anthropometric indices after the Eximia program

Parameter	Group	N	Mean	SD	Min	Max	p
1. Weight (kg) After	Eximia	34	72,06	7,19	58,90	92,80	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**3,62**	0,52	3,44	3,80	40,64	33	<0,001

	Group	N	Mean	SD	Min	Max	p
2. BMI After	Eximia	34	26,06	0,51	24,90	26,90	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**1,35**	0,31	1,24	1,46	25,26	33	<0,001

	Group	N	Mean	SD	Min	Max	p
3. Waist (cm) After	Eximia	34	88,53	7,86	73,60	105,30	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**3,69**	0,75	3,43	3,95	28,83	33	<0,001

	Group	N	Mean	SD	Min	Max	p
4. Hip (cm) AFTER	Eximia	34	97,25	6,05	90,50	114,00	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**2,45**	0.69	2,21	2,69	20,75	33	<0,001

Parameter	Group	N	Mean	SD	Min	Max	p
5. Waist-to-Hip ratio AFTER	Eximia	34	0,91	0,06	0,79	1,09	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**0,02**	0,01	0,02	0,02	12,02	33	<0,001

Parameter	Group	N	Mean	SD	Min	Max	p
6. Waist-to-Height ratio AFTER	Eximia	34	0,54	0,09	0,47	0,98	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**0,03**	0,01	0,02	0,03	24,79	33	<0,001

Parameter	Group	N	Mean	SD	Min	Max	p
7. Skin-fold thickness (mm) AFTER	Eximia	34	28,77	0,73	27,70	30,20	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**1,40**	0,29	1,30	1,50	28,55	33	<0,001

The contact thermography results reported after the program showed that 4 patients had grade 1 FEP, 26 had grade 2, and only 4 had grade 3. As at the initial data, 30 were with third and only 4 with second degree. The results after the treatments showed great statistical significance (Fig. 25).

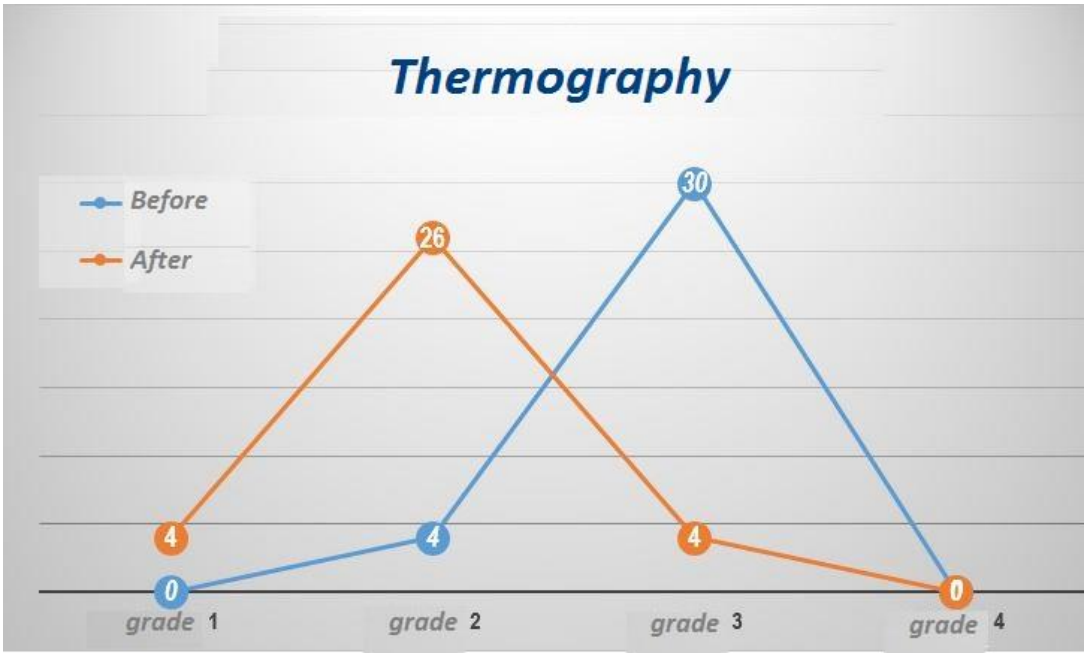

Fig.25. Results of the contact thermography in group 3 – before and after

Table 17 shows that the mean decreases to 2.00 compared to the original mean of 2.88. This is a result of the fact that after the program a larger number of patients now have a second degree FEP rather than a third.

Table 17. Contact thermography results after the program

Parameter	Group	N	Mean	Median	SD	Min	Max	p
Degree after	Eximia	34	2,00	2,00	0,49	1,00	3,00	<0,001

Table 18 presents the quality of life after the program. We can see that the results are much better than before the program, but overall it is lower than in the first group. The minimum value is 40 i.e. no patients with worst quality of life = 0. And the maximum value of 96 indicates that no patients reached their highest level of quality of life immediately among the program. This is due to the fact that even the initial quality of life values were much lower.

Table 18. Quality of life scores after the program

Parameter	Group	N	Mean	SD	Min	Max	p
Quality of life - After	Eximia	34	75,65	16,43	40,00	96,00	<0,001

The mean Well-being index score for the group was 75.65 in contrast to 21.06 before the start of the program, i.e. quality of life improved significantly after the program (Fig. 26).

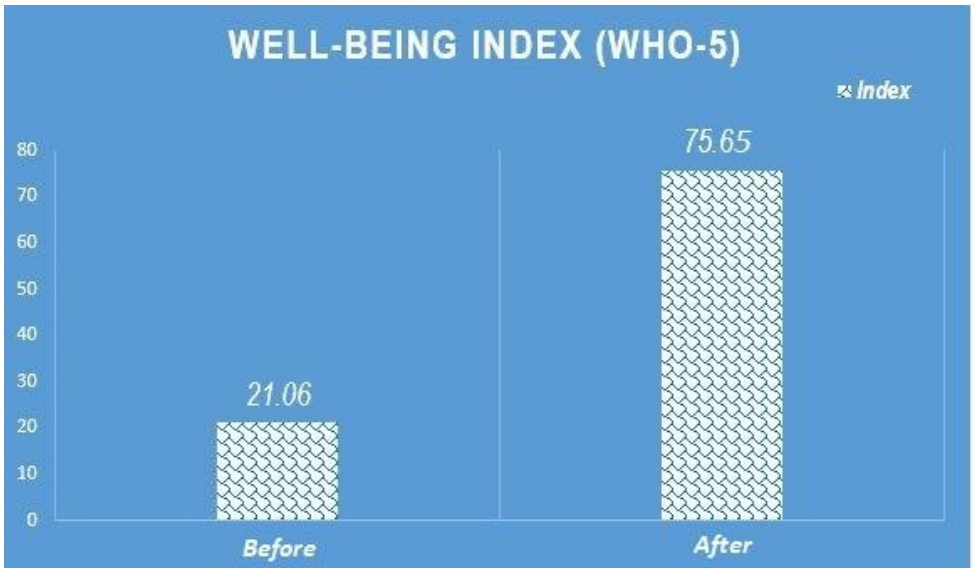

Fig.26. Results of quality of life assessment before and after in group 3

The changes achieved in anthropometric indices in the third group are presented in Fig. 27. We notice that there is a decrease in excess fat and an acceleration of adipocyte metabolism, which is accounted for by a reduction in waist and hip circumferences, skinfold thickness and body weight. The mechanical vacuum leads to neurostimulation during therapy and helps the lipolysis process to be faster and more efficient. The mechanical effect manifested in active massage affects the connective tissue at a deep level, stimulating blood and lymph circulation, helping to eliminate toxins (detoxification) and water retention. The thermal effect leads to an increase in the level of nutrients and improves oxygenation, supports the production of collagen and favours the elimination of adipose tissue.

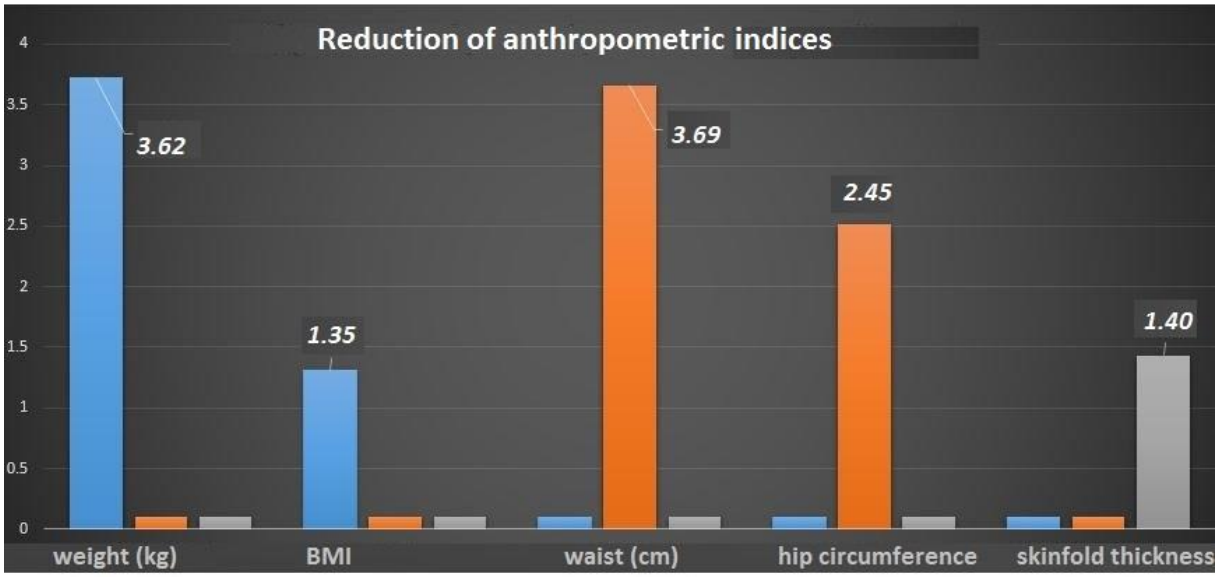

Fig.27. Results of the assessment of the anthropometric indices in group 3

3.5 Results of the complex program in group 4 - D-finitive EVO

From the results of the anthropometric indices reported after the program, which are presented in Table 19, we notice that there is a statistical significance of the weight reduction compared to the initial data before the start of the program, with an average of -5.03 kg for the group. The lowest weight is now 62.10 kg and the highest weight for the group is 97.90 kg. The BMI also decreases significantly and there is a difference of -1.86 units down on average. This reduction in BMI is a result of the reduction in body weight during the program and correlates in direct proportion to it. The lowest BMI is 25,90 and the highest is 31,10. Waist measurement also showed statistically significant differences with an average of -5.11 cm. The smallest waist was 81.20 cm and the largest was 110.50 cm. Hip circumference reduction was also reported in the group and was statistically significant. It is by -3,20cm.

Because of the reduction in waist and hip circumferences, we report a 0.02 reduction in the waist/hip ratio, respectively. The statistically significant reduction in the waist circumferences of the patients in the group also resulted in a reduction in the waist-to-height ratio by 0.04. The reduction in weight and waist and hip circumferences also led to a statistically significant and reliable reduction in skinfold thickness by -2.65cm on average.

Table 19 Results of the anthropometric indices after the EVO program

Parameter	**Group**	**N**	**Mean**	**SD**	**Min**	**Max**	**p**
1. Weight (kg) After	D-finitive EVO	33	76,44	7,77	62,10	97,90	<0,001
Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**5,03**	0,60	4,82	5,24	48,56	32	<0,001
	Group	N	Mean	SD	Min	Max	p
2. BMI After	D-finitive EVO	33	27,78	1,22	25,90	31,10	<0,001
Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**1,86**	0,41	1,71	2,00	25,78	32	<0,001
	Group	N	Mean	SD	Min	Max	p
3. Waist (cm) After	D-finitive EVO	33	92,95	7,78	81,20	110,50	<0,001
Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**5,11**	0,71	4,86	5,36	41,45	32	<0,001
	Group	N	Mean	SD	Min	Max	p
4. Hip (cm) AFTER	D-finitive EVO	33	101,47	10,36	81,00	126,30	<0,001
Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**3,20**	0.68	2,95	3,44	26,89	32	<0,001
Parameter	Group	N	Mean	SD	Min	Max	p
5. Waist-to-Hip ratio AFTER	D-finitive EVO	33	0,92	0,08	0,75	1,08	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**0,02**	0,01	0,02	0,02	11,99	32	<0,001

Parameter	Group	N	Mean	SD	Min	Max	p
6. Waist-to-Height ratio AFTER	D-finitive EVO	33	0,56	0,05	0,48	0,70	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**0,04**	0,01	0,03	0,04	40,28	32	<0,001

Parameter	Group	N	Mean	SD	Min	Max	p
7. Skin-fold thickness (mm) AFTER	D-finitive EVO	33	29,91	0,36	28,80	30,80	<0,001

Comparisons	Paired Differences				t	df	p
	Mean	SD	95% CI				
BEFORE-AFTER	**2,65**	0,52	2,46	2,83	29,35	32	<0,001

Contact thermography results reported after the program showed that 3 patients had grade 2 FEP, 24 had grade 3 and only 6 patients had grade 4. As in the initial data, 30 had grade four and only 3 had grade three (Fig. 28). The results after the program showed great statistical significance.

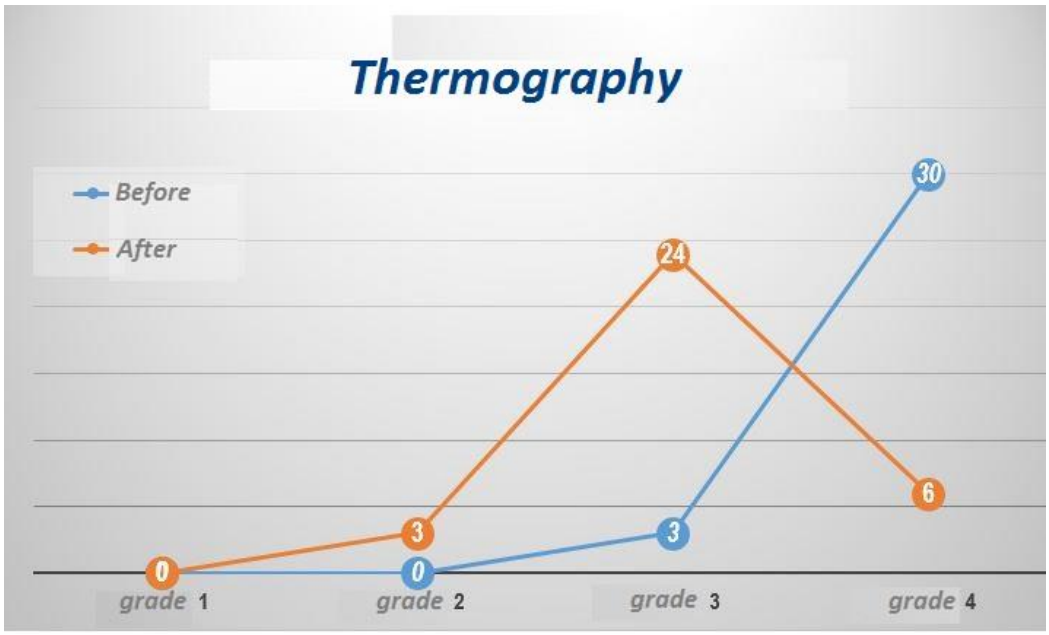

Fig.28. Results of contact thermography in group 4 – before and after

Table 20 shows that the mean decreases to 3.09 compared to the original mean of 3.91. This is a result of the fact that after the program a larger number of patients now have a second degree FEP rather than a third.

Table 20. Results of contact thermography after the program

Parameter	Group	N	Mean	Median	SD	Min	Max	p
Degree After	D-finitive EVO	33	3,09	3,00	0,52	2,00	4,00	<0,001

Table 21 presents the quality of life after the programme. We can see that the results are much better than before the programme, but overall it is lower than in the other three groups, as it is inversely correlated with high BMI and more severe FEP. The minimum value is 32 i.e. no patients with worst quality of life = 0. And the maximum is 80, indicating that there are also no patients reached their highest level of quality of life immediately among the program. This is because the initial values were much lower.

Table 21. Results of the quality of life after the program

Parameter	Group	N	Mean	SD	Min	Max	p
Quality of life - After	D-finitive EVO	33	53,70	13,57	32,00	80,00	<0,001

The mean Well-being index score for the group was 53.70 in contrast to 13.82 before the start of the program i.e. quality of life improved significantly after the program (Fig. 29).

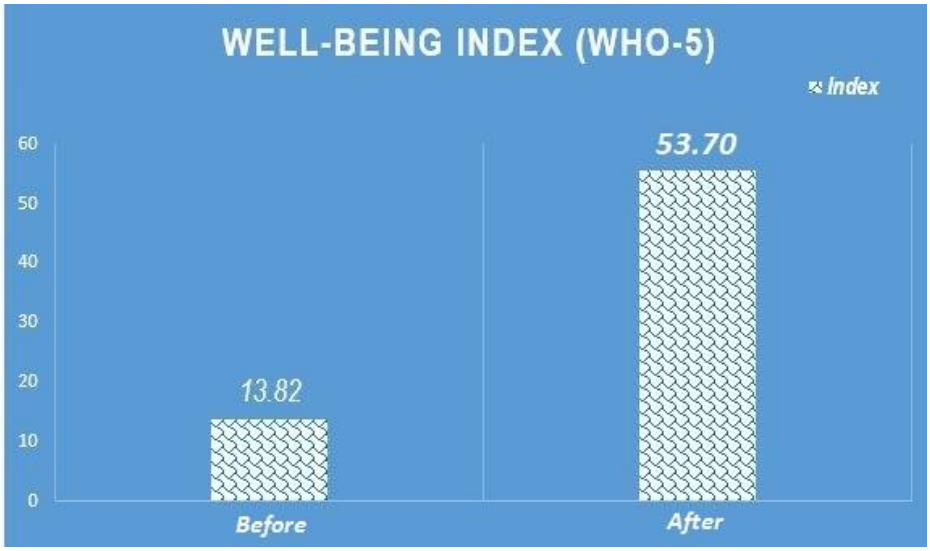

Fig.29. Results of the assessment of the quality of life before and after in group 4

The achieved changes in the anthropometric indices of the patients are presented in Fig. 30. We observe a significant reduction in waist and hip circumferences, skinfold thickness, weight and BMI, respectively. This is the result of the lipolytic action of the device - the therapy and the synergistic action of the reshaped factors accelerates the breakdown of fat in adipose tissue due to the effect of lipolytic enzymes, which reduce adipocytes and increase fat metabolism, i.e. facilitates the reactivation of natural metabolic processes. Helps to reduce the metabolic waste of cells such as glycolyzed and oxidized proteins, which are also a major cause

of aging (as they prevent collagen formation) and stimulates antioxidant enzymes. Vacuum drainage in turn stimulates microcirculation of blood and lymph, at the same time the rotating tip performs a micromassage locally on the area thus increasing the distribution of nutrients released from the bloodstream. It also reduces muscle tension by relaxing the muscle fibers. The thermal effect stimulates the burning of subcutaneous and visceral fat. Obese individuals have extremely limited oxidation capacity as through the program it is improved.

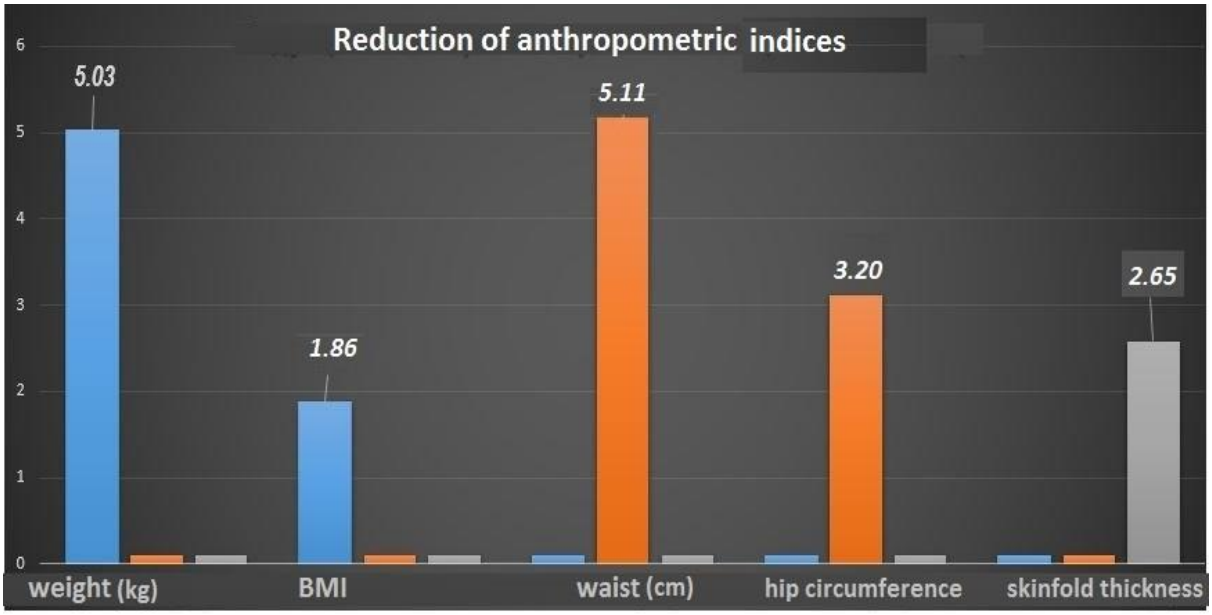

Fig.30. Results of the assessment of the anthropometric indices in group 4

3.6. Results of the complex program on the quality of life of patients

From the data presented in each group, related to the results of the quality of life assessment, we notice that in all groups there is an improvement in well-being and psycho-emotional tone (mood and self-esteem) after the program. Quality of life was inversely correlated with BMI. The higher the BMI, the worse the quality of life. The same is true for the degree of FEP - the milder it is - the better the quality of life of these people. Patients in group one have the best quality of life, while those in group four have the worst quality of life; respectively, those in group one have the highest Well-being index score, and those in group four the lowest.

In the LPG group, the mean quality of life before the program was 27.09 and after the program was 84.00. Here we observe the highest increase in scores i.e. improvement in well-being. Here the patients had the lowest BMI. In the Velashape group, the mean quality of life before was 21.76 and after the program it increased to 78.35. In the Eximia group, it was 21.06 initially and 75.65 after the program. In group four, before the program (13.82) as well as after 52.70 is the lowest quality of life. Here the patients also had the highest BMI. In this group, besides overweight, there are also obese individuals. Obesity can seriously impair the quality of life of individuals. The higher the BMI, the more often anxiety and depressive symptomatology is observed. Weight loss significantly improves patients' well-being, self-esteem, mood and activity (Table 22).

Table 22. Results of the assessment of the quality of life before and after

Parameter	Group	N	Mean	SD	Min	Max	p
Quality of life – before the program	LPG	35	27,09	15,13	0,00	60,00	<0,001
	Vela shape	34	21,76	12,62	0,00	40,00	
	Eximia	34	21,06	11,62	0,00	40,00	
	D-finitive EVO	33	13,82	7,88	0,00	28,00	
Parameter	Group	N	Mean	SD	Min	Max	p
Quality of life – after the program	LPG	35	84,00	11,60	60,00	100,00	<0,001
	Vela shape	34	78,35	14,21	44,00	100,00	
	Eximia	34	75,65	16,43	40,00	96,00	
	D-finitive EVO	33	53,70	13,57	32,00	80,00	

The anthropometric indicators, combined with the negative societal attitude towards obese people, affect the psycho-emotional tone of these individuals and seriously impair their quality of life, which prevents them from fully developing their potential in the social environment. Being overweight is often associated with negative social consequences. The program we implemented (in all four groups) showed a significant improvement in the quality of life of the patients. The reduction of anthropometric indices (physical parameters) leads to a positive impact on psychological and social well-being (Fig. 31).

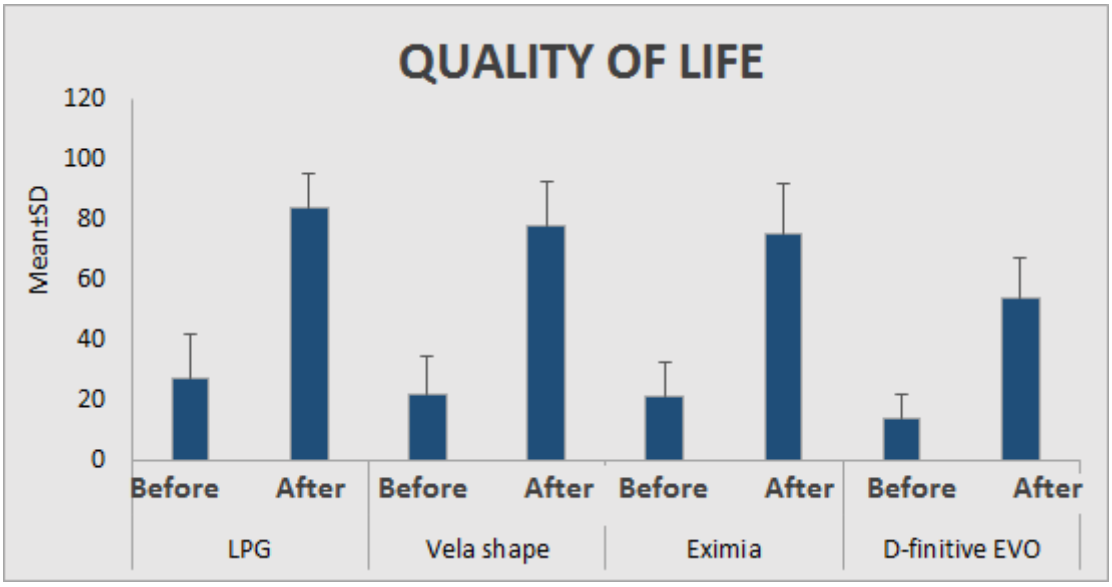

Fig.31. Assessment of the quality of life before and after the program

3.7. Intergroup comparisons of the results of the complex program:

"There`s never a better way of living than just improving our quality of life"
Adrian Grenier

From the data presented so far for each group separately, a significant reduction in anthropometric indicators (weight, girth, skinfold thickness) was observed, confirming the effectiveness of the implemented program. This reduction varies from group to group, depending on the severity of the problem and the means used, but in all cases weight is affected and a reduction is observed. The benefits of this are great, as fat cells produce pro-inflammatory substances - cytokines - which cause inflammation in the body. The more excess adipose tissue there is in the body, it becomes an endocrine organ, which produces the greater amounts of cytokines and this leads to a chronic inflammation in the body. For this reason and overweight and obese people are more susceptible to all sorts of diseases. In group 1 weight decreased -2.68kg, in group 2 by -3.59, in group 3 by -3.62 and in group 4 by -5.03 (Table 23). The constant decrease in body weight was also attributed to the decrease in BMI. We observe that the more reshaped physical factors there are in the apparatus that act synergistically, the greater the results. In edematous FEP, there is even a result of mechanical vacuum, which plays the role of lymphatic drainage. In fibrotic, in addition to vacuum, therapy with an apparatus with at least 1 reformed factor - radiofrequency, ultrasound, infrared light or electroporation - must be included. Fibrosclerotic tissue is very resistant and is the most difficult to affect, for this reason it should be treated with vacuum and at least 2 other physical factors -lipolytic diode laser, cryo- and thermotherapy. The effects achieved by these devices overlap with the benefits of physical activity: enhancing lympho- and blood circulation; enhancing metabolism and cellularity; improving oxygenation and tissue trophicity; improving the temperature of areas with low such and toning the musculature. But this in no way precluded in any spare time having extra activity, walking, sports etc. Obesity is the most common risk factor for prediabetes, but we still have control over it by changing our eating and exercise habits to maintain a normal body weight, which is helped by the program we have implemented.

Table 23. Differences in the weight (kg) after the program in different groups

Comparisons	Group	Paired Differences				t	df	p
		Mean	SD	95% CI				
Weight (kg) BEFORE-AFTER	LPG	2,68	0,71	2,44	2,93	22,37	34	<0,001
	Vela shape	3,59	0,51	3,42	3,77	41,44	33	<0,001
	Eximia	3,62	0,52	3,44	3,80	40,64	33	<0,001
	D-finitive EVO	5,03	0,60	4,82	5,24	48,56	32	<0,001

Waist circumference is an important indicator of cardiovascular risk. By reducing waist circumference, this also reduces the risk of cardiovascular disease. Visceral obesity is much more serious to a person's health than gluteo-femoral obesity. In all the four groups, we observed a decrease in waist circumference with -2.64cm for group 1, -3.54cm for group 2, 3.69cm for group 3 and 5.11cm for the last group (Table 24). The reduction in waist circumference also gives an impact on WHR and WHtR ratio.

Table 24. Differences in the waist circumference (cm) after the program in the groups

Comparisons	Group	Paired Differences				t	df	p
		Mean	SD	95% CI				
Waist (cm) - BEFORE-AFTER	LPG	2,64	0,69	2,40	2,88	22,61	34	<0,001
	Velashape	3,54	0,30	3,43	3,64	67,97	33	<0,001
	Eximia	3,69	0,75	3,43	3,95	28,83	33	<0,001
	D-finitive EVO	5,11	0,71	4,86	5,36	41,45	32	<0,001

When measuring hip circumference, we also report statistically significant differences before and after the program. In the first group, there was a decrease in girth of 1.90 cm, in the second -2.49 cm, in the third 2.45 cm and in the last -3.20 cm (Table 25). The decrease in the hip circumference further decreases the WHR ratio.

Table 25. Differences in the hip circumference (cm) after the program in the groups

Comparisons	Group	Paired Differences				t	df	p
		Mean	SD	95% CI				
Hip (cm) – BEFORE-hip – AFTER	LPG	1,90	2,17	1,15	2,64	5,17	34	<0,001
	Vela shape	2,49	0,65	2,26	2,71	22,36	33	<0,001
	Eximia	2,45	0,69	2,21	2,69	20,75	33	<0,001
	D-finitive EVO	3,20	0,68	2,95	3,44	26,89	32	<0,001

The significant reduction in waist and hip circumferences respectively also resulted in a reduction in skin-fold thickness of -0.78cm in group one, -1.32cm for group two, -1.40cm for group three and -2.65cm in the latter group (Table 26).

Table 26. Differences in skin-fold thickness(cm) after the program in the groups

Comparisons	Group	Paired Differences				t	df	p
		Mean	SD	95% CI				
Skin-fold thickness (mm) BEFORE-Skin-fold thickness (mm) AFTER	LPG	0,78	0,21	0,71	0,86	21,69	34	<0,001
	Vela shape	1,32	0,23	1,24	1,40	33,39	33	<0,001
	Eximia	1,40	0,29	1,30	1,50	28,55	33	<0,001
	D-finitive EVO	2,65	0,52	2,46	2,83	29,35	32	<0,001

3.8. Discussion

3.8.1. Comparative assessment between our results and similar results available in the literature

Our results showed a significant reduction in the anthropometric indices of overweight and obese patients, as well as a significant improvement in their quality of life.

The results of the analysis of anthropometric indices in the LPG group were consistent with the results of a 2013 study by Zekayi Kutlubay et al. published in the Journal of Cosmetics and Laser Therapy involving 118 patients. Our study outperformed it as it included a larger contingent (n=136) and analyzed a greater number of anthropometric indices (Kutlubay, 2013).

The benefits of the LPG procedure that we presented are in principle consistent with those of Viktoria Mezencevová and co-authors, published in Technological Engineering, on the topic "Endermologie new approach in the medicine treatment" (Mezencevová, 2017).

The results we obtained in a second group with the Velashape device, by the simultaneous application of radiofrequency, infrared light and mechanical vacuum, are consistent with those made by Maurice Adatto et al., from a publication in the journal "Lasers in Medical Science" (Adatto, 2014).

These results are also consistent with the conclusion made in a study by Carmen Romero et al. in the Journal "Cosmetics and Laser Therapy". However, our work outperforms both, as only 12 patients were included in the first study and 10 in the second (Romero, 2008).

The conclusions we draw for the third group are consistent with those in a publication of Pier Antonio Bacci, discussing the role of Dermoelectroporation (Bacci, 2014).

The results achieved by physical modalities in a fourth group for significant circumference reduction are consistent with those of a publication by Mary K Caruso-Davis et al in "Obesity Surgery". The study included 40 men and women (Caruso-Davis, 2011).

The results of our study corroborate those of the authors cited above. However, we have analyzed a much larger number of individuals and objective indicators, using not only standard anthropometric indices (weight, BMI, waist circumference), but also calipermetry, hip circumference, waist-hip ratio and waist-height ratio; and we have also applied an innovative method of assessment – the contact thermography, and the WHO-5 Well-Being index.

In the available literature, we found no publications on the effect of our procedures on patients' quality of life.

3.8.2. Analysis of the mechanisms of action of the reformulated PFs

A. LPG

The mechanism of action of the LPG Endermologie procedure possesses several main actions (Bacci, 2006; Gulec, 2009; Rostom, 2022):

- Tissue mobilization with subsequent activation of microcirculation;
- Traction of connective tissue;
- Activation and stimulation of adipocytes;
- Rhythmic tissue compression with lymphatic drainage.

The benefits of this innovative patented technology are that it is non-invasive, non-aggressive, painless, completely natural and proven safe by stimulating vascular and lymphatic flow, which increases oxygenation and ameliorates the trophy of the tissue; eliminates toxins and lactic acid; removes pain, edema, muscle spasm, etc.

The apparatus has a pronounced draining effect. Edema is the result of an imbalance between the delivery of fluids and their removal, and we observe a fluid accumulation in the interstitial spaces of the body. Increasing volume of interstitial fluids leads to stagnation. The stagnation of toxic substances in the tissues over time changes the state of the interstitial matrix (a structure of great importance that ensures the maintenance of the basic balance of our body),

causing intoxication of the tissues and their subsequent modification, with evolution towards fibrosis. LPG Endermology is able to affect edematous panniculopathy by enhancing the activity of the lymphatic system, producing a pumping action with progressive fluid displacement, thus restoring the "Starling Equilibrium" - responsible for maintaining homeostasis inside the vessels and the extracellular matrix. This provides deep lymphatic drainage that eliminates the excessive fluids and the accumulated toxins in the body. The application of compressive microvibration reduces edema.

Other benefits of LPG Endermology are:

-Activates lymphatic and blood circulation (stimulates vascular and lymphatic flow);

-Reduces fatigue, eliminates lactic acid by over 30% - relaxes musculature;

-Increases fat burning;

-Improves recovery;

-Increases tissue oxygenation and trophicity;

-Non-invasive, painless and completely natural therapy;

-Improves concentration and increases energy;

-Reduces stress and improves overall health;

-Advanced operating system based on modern methods, which actually replaces the traditional "suction-traction massage" - phase of tissue compression and vibration.

B. VelaShape

The three technologies in the Velashape device lead to heating of the dermal and subdermal layers, which improves blood circulation and increases metabolic processes in the adipose tissues. Vacuum helps to enhance the effects of Elos technology and facilitates deeper heat penetration, delivering energy to the hypodermis, resulting in hyperemia of the area and higher oxygen diffusion. The mechanical action also helps drain excess intracellular fluids. These effects, in turn, increase the metabolic breakdown of accumulated adipose tissue by lipolysis of fat cells, reducing the size of fat cells and shrinking the connective tissue barriers between them. Thus, the circumference of the treated area is reduced. The principle of action is depicted in Figure 32 (source-Vela shape clinical training book, 2021).

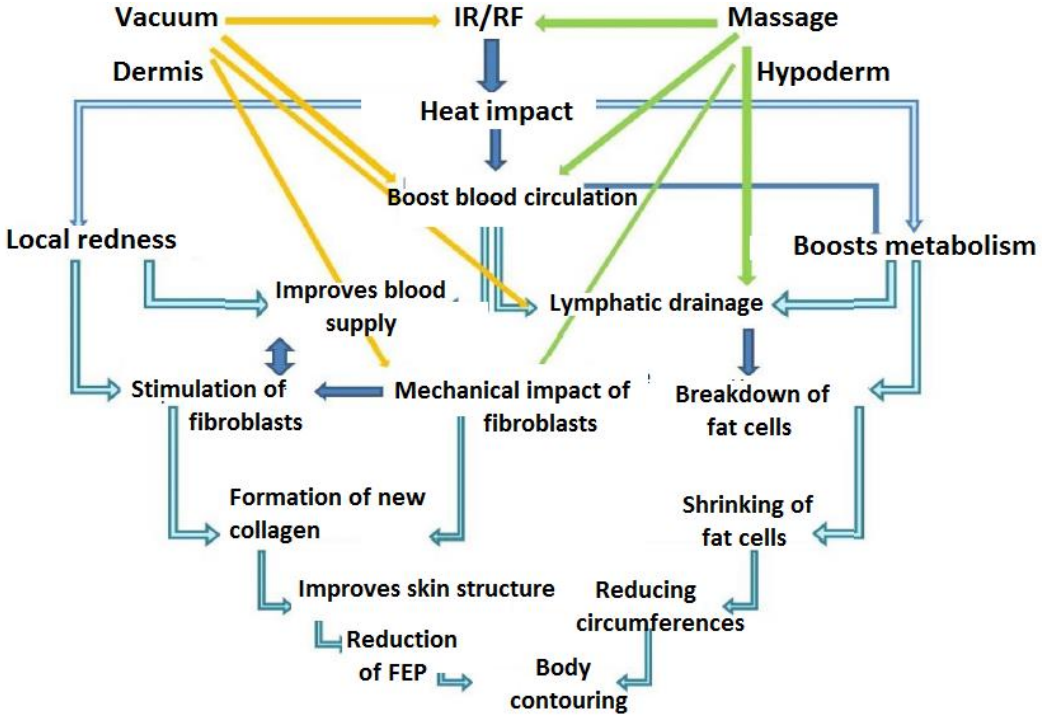

Fig.32. Principle of action of Velashape device
(Velashape Clinical Training book, 2021)

Improving the degree of FEP and reducing girth requires heating the connective tissue to activate new and stronger collagen and elastin. Thermal damage to connective tissue is based on reaching a "thermal threshold"- a "thermal dose" threshold. This is a combination of increased temperature and exposure time. Reaching a temperature endpoint and maintaining it over time is a key element in achieving clinical outcomes. There is a wide variation in tissue impedance between patients. The thermal effect on metabolism results in:

- Production of deep endogenous heat produced by IR/RF;
- Oxygen dissociation from Oxi-Hb ;
- Extraction of nutrients and oxygen ;
- Fat metabolism reactions in adipocytes ;
- Prolonged use of stored energy in adipocytes leads to shrinkage of the cells themselves;
- The fat chambers shrink and there is less stress on the fibrous septae;
- The metabolism of fibroblasts leads to collagen synthesis and to an overall improvement of the skin surface.

Benefits of Velashape (Sadick, 2005; Nootheti, 2006; Alster, 2005):

- Selective heating of fat cells by radiofrequency and infrared light accelerates lipolysis by leading to the breakdown of the contained triglycerides to free fatty acids and glycerol. Thus reducing the volume of the fat cell and hence the girth ;
- The vacuum in turn drains and plays the role of lymphatic drainage, together with RF and IR improves lymphatic and blood circulation;
- Metabolic processes in resistant fat cells are increased;
- The connective-tissue barriers between them are softened, leading to a reduction in fibrosis and a return to their original shape;
- Focused action that activates the production of elastin and collagen.

C. Eximia

The low-frequency lipolytic laser in the Eximia device produces effects outside the cell by increasing ATP, reactive oxygen species and nitric oxide. Triglyceride lipase is activated by cyclic adenosine monophosphate (cAMP). The latter is synthesized from ATP. By stimulating the activity of adenylyl cyclase, the amount of cAMP synthesized and therefore the amount of triglyceride lipase responsible for the cleavage of triglycerides to fatty acids and glycerol is increased. Improving cell communication helps to increase lipolysis. Nerve cells from the hypodermis stimulate the lipolytic activity of adipocytes. These play a key role in cell communication. In the hypodermis, they promote the lipolytic activity of adipocytes (Fig. 33).

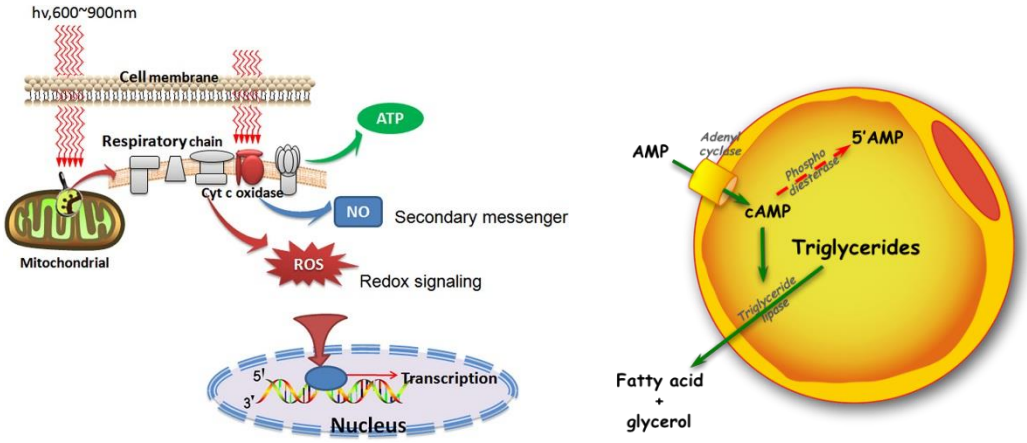

Fig.33. Mechanism of action of Eximia device
(Eximia Manual, 2023)

Benefits of Eximia (Juhász, 2018; Sabbour , 2009):

- Vacuum improves microcirculation and facilitates drainage to the lymphatic channels by activating the flow of lymphatic fluids;
- Improves oxygenation and detoxification ;
- Optimizes muscle tone and eliminates muscle tension;
- Stimulates lipolysis by causing adipocytes to naturally break down their components, resulting in a reduction of excess fat;
- Reactivates the functionality of fibroblasts ;
- Stimulates metabolism.

D. D-finitive Evo

The benefits of D-finitive EVO procedures are (Costa, 2020; Wanner, 2008)

- Anti-fibrotic action and lymphatic drainage
- Increases vascularization
- Impact on persistent fat deposits by thermocontrast Heat-Cold-vasodilation (thermotherapy) - vasocontraction (cryotherapy). This makes them more sensitive to these external influences and are effectively affected by the procedure by reducing resistance from the tissues.
- The rotating vacuum acts as a "pump", lowers capillary stasis and reduces the risk of hematoma formation after treating the area with this complex platform
- Stimulates cellular oxygen saturation and increases cellular ATP
- Different anatomical applicators according to the size of the area to be treated

E. EMS

The strong muscle contractions in EMS increase the level of energy consumed, which is produced by fat cells, and epinephrine transmit signals to initiate lipolysis. Intense supramaximal contractions, in turn, enhance epinephrine release, causing the cascade effect that leads to supramaximal fat cell lipolysis. These intense muscle contractions stimulate a muscle response that leads to remodeling of the internal structure, resulting in an increase in muscle fiber density and volume. Prior to therapy, the muscles are thinner and their circumference is narrow. Myofibrils are weak and of low density. After therapy, the muscles are stronger (more durable), their girth is greater, and the myofibrils are stiffer and have a higher density. Muscle exposure to this type of contraction leads to a strengthening of the musculature and stimulates the release of free fatty acids, which break down accumulated fat, tone and strengthen the

muscles and the effect is similar to that of physical exercise. The treatments in combination with the electro-muscular training have very good results and benefits for people where physical activity is very low, it is also joint-friendly training i.e. it does not stress the joints. Through EMS, muscle strength increase, tightening and fat burning is achieved due to muscle contractions (Choi, 2018; Kim, 2015; Cox, 2017; Rostrup, 2014).

F. Summary of the effects of application of preformed physical modalities

The observed benefits of our PF programs are manifested in a range of effects: draining; analgesic; vascularising; transformative; metabolic and tonic:

- *Drainage effect* - before the program, we observed a reduction of the lympho-venous microcirculation of the affected areas, and after it - a decrease of fluid stagnation and elimination of toxic substances;
- *Analgesic effect* in inflammation and fibrosis of tissues. Therapy improves tissue sensitivity and reduces inflammation;
- *Vascularizing effect* - before the program we noted a decrease in microcirculation (reduced dermal-epidermal temperature), and after the procedures - improved microcirculation and temperature increase;
- *Transformative effect* - the physiology of FEP leads to changes affecting the local microcirculation of the panniculus adiposus, causing an inflammatory-degenerative process with stagnation of toxic substances and formation of edema, as well as metabolic-structural changes of connective tissue and subsequent organization of the tissue into painful micronodules. The remodeling of fat cells occurs due to the synergy between remodeled physical factors that cause compression on adipocytes and their fibrous septa, which in turn degrade and become less sclerotic. The underlying muscle layers, which offer active resistance, enhance the defibrotic action of the procedures. In this way, it is possible to influence even the most stubborn fat deposits. These effects lead to localised remodelling, favoured by the physiological restructuring of tissues obtained thanks to vascular, metabolic and purifying activities, as well as the remodelling of the connective system;
- *Metabolic effect* - improvement of metabolic-structural problems in fat cells with acceleration of lipolysis (resulting in girth and weight reduction) occurring due to excessive fat accumulation ;
- *Toning effect* (incl. on muscles), increase of psycho-emotional tone,
- *Improving quality of life.*

G. Summary of the advantages of the application of preformed PFs

The advantages of the devices with the reshaped physical factors are:

-non-invasive administration (no need for anesthesia) and no recovery time

-painless, safe, comfortable, effective

-user-friendly and for the therapist himself saving effort and time on his part, with minimal risk of chronic trauma or fatigue resulting from repetitive movements by the therapist

-convenient to use through an easy and intuitive touch interface with ergonomically designed applicators adaptable to different anatomical areas (focus on problem areas)

-Ability to program different modulation/application protocols with flexible application of a wide range of parameters according to the individual needs of each patient

-combining different technologies with synergistic action for visible and long-lasting results

- treatments using these devices are a more effective therapy with audio-visual real control that eliminates the possibility of human error

-innovative technologies with clinical evidence

4. INFERENCES:

4.1. The fat reduction program, applied in all four groups, showed a statistically significant reduction of anthropometric indices. This was observed in all results of comparison of anthropometric indices - BMI (weight), waist and hip circumferences, skin-fold thickness. Analysis of the grades reported by contact thermography after therapy also showed improvement in the status of problem areas with fibrosclerotic-edematous panniculopathy.

4.2 The results of the Well-being index showed that the implemented programs had a positive impact on the psycho-emotional tone of the patients, significantly improving their quality of life.

4.3. The preformed physical factors have shown high effectiveness and can be part of an overall comprehensive overweight and obesity prevention program. The procedures accelerate the reduction of accumulated excessive body fat in order to reduce the impact of negative health effects more rapidly. The comprehensive rehabilitation program has an overall beneficial effect on the health of patients.

4.4. The comprehensive programs we presented, with physical treatments, increased background physical activity and patient education in a proper hygiene and dietary regimen, showed important practical relevance in the management of overweight and obesity.

4.5. Our practice shows that patient-therapist communication should be stimulated in order to provide timely information about the risks of the patient's condition, self-assessment of the seriousness of the problem with the aim of active participation in the prevention process.

5. RECOMMENDATIONS

"Take care of your body - it's the only place you'll live in"
Jim Rohn

5.1. RECOMMENDATIONS TO PATIENTS

5.1.1. Take their own health seriously and have regular check-ups, especially when abdominally obese. Visceral fat deposits significantly increase the risk of developing arterial hypertension, type 2 diabetes mellitus and disorders of fat metabolism.

5.1.2. To observe a hygienic and dietary regime. Increase background physical activity and strive for a healthy diet. Regular exercise helps to maintain low blood glucose levels; reduce insulin resistance, which facilitates the entry of glucose from the blood into the cells. Reduce downtime in front of digital devices (tablet, phone, TV, laptop). Physical activity is an integral part of the whole program in overweight.

5.1.3. Patients who are already overweight or obese should aim for a hypocaloric reduction diet, increased fluid intake /water/, daily background physical activity, 2-3 times a week active exercise. The complex rehabilitation program with reformulated physical factors should be carried out 3-4 times a year, and in the breaks between the courses - a maintenance procedure should be done at least once a month.

5.1.4. Before visiting a centre, it is important to find out whether the professionals working there are medically trained and have the necessary additional qualifications to work with the relevant devices. This will ensure that the procedures are carried out correctly and that they are safe during the program.

5.2. RECOMMENDATIONS TO THE FAMILY DOCTORS

5.2.1. Insist on regular preventive check-ups for all persons over 50 years of age, especially those who are overweight and obese.

5.2.2 Stimulate at-risk patients' motivation for increased personal responsibility and active participation in the weight management process.

5.2.3. Refer all obese patients to Endocrinology and Physical and Rehabilitation Medicine clinics/departments/offices for diagnostic clarification and inclusion in weight reduction programs.

5.3. RECOMMENDATIONS TO SPECIALIST DOCTORS

5.3.1. Refer overweight and obese patients for inclusion in therapeutic weight management groups.

5.3.2. Insist on a periodic comprehensive physical treatment program for obesity, including diet, exercise regimen and reformulated physical factors.

5.4. RECOMMENDATIONS TO THE MINISTRY OF HEALTH

5.4.1. Introduce screening programs for the early diagnosis of overweight and obesity - among the adult population as well as among children and adolescents.

5.4.2 Require the Ministry of Education and Science to include in the curricula the training of children and adolescents in proper diet, exercise, work and rest. Physical prevention and systematic physioprophylaxis can prevent the development of the health consequences of obesity and improve the health status of the Bulgarian population.

5.4.3. To insist to the NHIF on the inclusion of our applied modern physiotherapy procedures with reformulated factors in the list of paid procedures for obese persons, with a view to their implementation in the overall process of overweight prevention, which will accelerate weight reduction in a shorter period of time and improve the quality of life of overweight and obese persons.

5.5. RECOMMENDATIONS TO THE NATIONAL HEALTH INSURANCE FUND

5.5.1. To include our applied advanced physiotherapy treatments with reformulated factors in the list of paid treatments for people with a disability.

6. CONCLUSIONS:

"If you don`t take time for your wellness,
you will be forced to take time for your illness"
Joyce Sunada

Chronic non-infectious diseases, which include obesity (Homo obesus), have a severe impact not only on people's health and quality of life, but also on their finances and economy. The prevention of this condition, which is part of social medicine, and the development of any practically useful programs (such as ours with FF) to prevent this worrying global phenomenon - globesity, can contribute to improving public health and save the economy millions of leva.

The health of a person is related to the state of physiological, metabolic and circulatory equilibrium of the different layers of the skin (dermis and epidermis, the subcutaneous adipose panniculus and deep musculature). With the accumulation of subcutaneous fat and excess weight, an imbalance between these layers occurs, and our program allows the balance to be restored. The treatments effectively oxygenate the tissues, stimulate microcirculation of blood and lymph, activate lipolysis and fibroblasts, reduce muscle tension and eliminate accumulated toxins in the body.

Successful weight loss requires long-term changes in lifestyle, eating habits and physical activity. It takes serious motivation and a long-term struggle against old patterns of behavior.

All industrial societies with an elevated standard of living face the complexity of the problem of "metabolic syndrome" leading to the development of CVD, stroke and serious circulatory disorders. Lifestyle change (prevention) aimed at weight reduction is therefore key.

CONTRIBUTIONS:

Theoretical contributions:

1. A comprehensive literature review on overweight and obesity with the most up-to-date literature is conducted.
2. For the first time in Bulgaria, complex algorithms for physical prevention, physio-prophylaxis and physiotherapy have been structured with modern devices including preformed physical factors - to improve the quality of life of overweight and obese people.

Scientific and applied contributions:

1. For the first time in our country, the possibilities of modern reformulated physical factors for the prevention and treatment of overweight and obesity, respectively - for the reduction of the associated health consequences, have been proven.
2. The presented algorithms and recommendations can be implemented in practice with the aim of comprehensive overweight management, self-control and prevention of complications associated with this condition.
3. The need for an interdisciplinary approach to the problem, increasing health awareness and the important role of prevention in reducing risk factors and the prevalence of obesity has been demonstrated.

FULL-TEXT PUBLICATIONS ON THE TOPIC:

1. Koleva. I, **Eneva V**, Kaminska.I, et al. (2021) Physical prevention and rehabilitation algorithms in overweight, obesity and cellulitis. - The 63-th International Scientific Conference of Daugavpils University, Latvia; 76-87
2. **Eneva V**.,Koleva. I. (2022) Effectiveness of LPG-Endermology in panniculopathia fibro-sclerotica. CONTACT 2022; 36-41 (**Results from 1st group**)
3. **Eneva V.,** I. Koleva (2023) Effect of D-finitive EVO technology on improving the quality of life of overweight patients. CONTACT 2023; 26-32 **(Results from 4-та group)**
4. **Eneva V**., Koleva I. (2023) Possibilities of Velashape technology for influencing some health consequences of overweight and obesity. Health and Science; XII, 1-2; 210-214 **(Results from 2nd group)**

PUBLISHED ABSTRACTS:

5. Koleva I., **Eneva V**. (2023) An algorithm for physical prevention of the overweight and obesity pandemic. Physical Medicine, Rehabilitation and Health.3; Year XXII; 13-14
6. **Eneva V.,** Koleva I. (2023) The potential of the technology Eximia for the improvement of the quality of life in patients with overweight and obesity. Journal of Biomedical and Clinical Research. Vol 16,No 1,Suppl.1;55 **(Results from 3rd group)**

Remark:
The originality and credibility of the publications on the topic I have mentioned are declared in Appendix 17 in the dissertation.

Participation as a lecturer in 14 scientific events on the topic of the dissertation for the period 02.12.2020-02.12.2023, certified by certificates of participation in the annual reports.

NOTICED CITATION

Citation of publication №2 ***(Eneva V.**, Koleva. I. (2022) Effectiveness of LPG-Endermology in panniculopathia fibro-sclerotica. CONTACT 2022; 36-41)* in monograph:

Gerenova J. (2023) Health and psychosocial problems in patients with lymphedema after cancer surgery. Sofia.