

*Evaluation Study***Ultrasonographic picture of the skin and subcutaneous tissue
in the treatment of cellulite using the Compressive Microvibration®**

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ABSTRACT

In recent years, the demand for non-invasive methodologies in aesthetic medicine for treating localized adiposity, cellulite, and sagging skin has increased significantly, particularly the demand for massage techniques with mechanical vibrations. The aim of the present study is to evaluate the effectiveness of Compressive Microvibration® in reducing the expression of cellulite and improving skin conditions in women of different ages under ultrasound control during 60 days of observation. A prospective, single-center, nonrandomized study enrolled 27 women with mild to moderate gynoid lipodystrophy, aged 40 to 69 years, who have been subject to twelve sessions of Compressive Microvibration® (Endospheres®). A specialized high-resolution digital ultrasound system, the DUB SkinScanner (tpm GmbH, Germany), has been used to visualize the skin. Also, the sample anthropometric parameters have been measured, the body mass index has been calculated, and photographs have been taken. In the patients included in the study, in all age groups, after complete treatment of Endospheres®, a decrease in BM has been noted, with a reduction of the bitrochanteric and hip circumference. An improvement in the morphological topography of the skin in terms of regularization of skin irregularities, leveling of reliefs, reduction of depressions, and increase in skin elasticity and density has also been recorded. After a cycle of therapy on the anterior surface of the abdomen and the thigh anterior and posterior surfaces, the scannograms revealed a decrease in the thickness of the epidermis at various levels, the resolution of the phenomenon of hyperkeratosis, a compaction of the dermis, and an increase in its homogeneity and echogenicity. The effect obtained was still present during a control examination two months after the conclusion of the treatment. The analysis of the dynamics of ultrasound criteria demonstrated the effectiveness of the Compressive Microvibration® in women with mild to moderate gynoid lipodystrophy to improve their skin conditions and maintain the obtained effect for 2 months of observation without unwanted side complications.

INTRODUCTION

Cellulite (or gynoid lipodystrophy) is a morphological and aesthetic alteration of the skin and the subcutaneous adipose tissue, which occurs in almost 90% of post-pubertal women, mainly in the abdomen, thighs, and buttocks, characterized by weakening of skin tone, venolymphatic stasis and changes in skin topography of different severity, associated with the appearance of dimpling or waving of the skin (1-3).

The development of cellulite can be influenced by several reasons, especially by anatomical characteristics, gender differences, metabolic disorders, reduced muscle activity, sedentary lifestyle, veins and lymphatic vessels diseases, and environmental hormonal and genetic factors (4, 5).

It has been ascertained that the pathophysiology of cellulite occurs through a complex of interconnected processes, and many of its aspects have not yet been fully clarified. The development and severity of cellulite are directly related to increased subcutaneous adipose tissue due to adipocyte hypertrophy. The dysfunction of the local microcirculation leads to a chronic reduction in their metabolism and an imbalance between lipolysis and lipogenesis in favor of the latter (6, 7).

Collagen fibers in adipose tissue are weakened due to the increased activity of matrix metalloproteinases (MMPs), responsible for collagen degradation, and are unable to withstand the pressure of fat trabeculae (8). The progression of septa fibrosis, which provides structural support to the skin, increases its tension and forms compartmental structures typical of cellulite (9).

Interestingly, the "two hits" hypothesis, according to which the "first hit" is associated with an alteration of the microcirculation in the gluteal-femoral tissue. In contrast, the "second hit" is mediated by tissue hypoxia, which causes fibrosis of the subcutaneous connective tissue (10).

Understanding the pathophysiology of cellulite contributes to the best diagnosis with the use of the most suitable dermo-aesthetic procedures aimed at improving the appearance of the skin, such as "cellulite camouflage," and influencing the structures of the deeper tissues (11, 12).

Mesotherapy or topical use of various drugs and invasive (liposuction) and non-invasive aesthetic technologies (therapeutic massage, cryolipolysis, laser therapy, ultracavitation, carboxytherapy, ultrasound, etc.) are in demand today (13-15).

At the same time, it is worth recognizing that, despite the undeniable successes in the treatment of cellulite, there remain some unresolved problems related to the definition of a method that allows an objective evaluation of the results obtained, the use of criteria for evaluating effectiveness and safety of the cosmetic and therapeutic measures applied, or the definition of timing for maintaining the positive results obtained.

In this regard, high-frequency ultrasound diagnostics seems very promising since it provides a direct visualization of the skin surface and a quantitative assessment of the echogenicity of the dermis and hypodermis (16, 17).

The aim of this study is to evaluate the effectiveness of Compressive Microvibration® in reducing the appearance of cellulite and improving skin conditions in women of different ages under ultrasound control for an observation period of 60 days.

MATERIALS AND METHODS

Study participants

The prospective single-center study has included 27 women of perimenopausal and postmenopausal age (40-69 years) with mild or moderate gynoid lipodystrophy, who have been grouped in 3 comparison groups of 9 subjects each based on age criteria: group 1 before menopause (age 40-49 years); group 2 in menopausal period (50-59 years) and group 3 in postmenopause (60-69 years).

The inclusion criteria in the study were: female sex, age between 40 and 69 years, informed voluntary consent to participate in the research and processing of personal data; the patient has mild or moderate edematous fibrosclerosis in the form of fat deposits, cellulite, and edema;

Non-inclusion criteria: male gender, age under 40 and over 69 years, pregnancy or breastfeeding; skin diseases, cancer, diabetes mellitus 3-4 degrees, varicose veins of the lower extremities, phlebitis, thrombophlebitis and presence of acute diseases or exacerbation of chronic diseases.

Exclusion criteria included withdrawal of informed consent, refusal to participate in the study process, and the occurrence of any acute illness or exacerbation of a chronic disease during the study period.

Description of the procedure

The Compressive Microvibration® method has been used through an original cylinder containing 50 hypoallergenic silicone spheres arranged in the shape of a honeycomb, whose rotation generates low-frequency mechanical vibrations capable of qualitatively modifying the state of the dermis and the hypodermis with cellulite, activating the microcirculation processes, stimulating lymphatic drainage, increasing muscle tone, improving skin trophism, and reducing fibrous alterations, maintaining the effect for a relatively long period.

The Endospheres® technique is based on the impact of a special handpiece with rotating spheres which, by transmitting low-frequency vibrations in a range from 29 to 355 Hz, generate rhythmic impulses that act on the tissues.

All participants completed the program Endospheres® according to a standard protocol, consisting of 12 sessions of 60 minutes by Compressive Microvibration®, twice a week, using Endospheres® Body device (produced by Fenix Group S.R.L., Italy, Registration certificate RZN 2016/3863 of December 29th, 2017).

The sessions have been performed by qualified employees of ItalConsult LLC (Moscow, Russia) in compliance with the Endospheres® Therapy Guide.

The study was carried out from April to September 2022, evaluating the ultrasound picture before the cycle Endospheres®, immediately after the end of the sessions and two months after the treatment, to have data on the effectiveness and duration over time of the Compressive Microvibration® treatment.

All patients maintained their daily diet and usual physical activity throughout the study.

Research methods

The leading indicators of the effectiveness of Compressive Microvibration® in women with mild or moderate gynoid lipodystrophy are ultrasound criteria, i.e., thickness of the dermis, acoustic density of the dermis, and hypodermis.

The skin areas for ultrasound examination in the anterior thigh, posterior thigh, and anterior abdomen were marked by manual pigmentation with a special pen equipped with disposable sterile microneedles.

The black pigment was injected into the upper layers of the skin at a depth of 1mm and with a marked size of 1x1 mm.

The ultrasound (US) examination of the skin has been performed using a specialized high-resolution digital ultrasound system, the DUB SkinScanner (tpm GmbH, Germany), equipped with a 75 MHz sensor with a resolution of 21 µm and a scanning depth of 4 to 6 mm.

As further criteria for evaluating the effectiveness of Endospheres®, photographic recording and anthropometric parameters (linear and weight body dimensions) have been used, measured according to standard methods with an anthropometer, floor scales, and a tape measure. Finally, the body mass index was calculated, and the circumferences of the hips and waist were measured.

A statistical analysis of the data has been performed using the SPSS Statistics 21.0 application package. Standard sample processing included the calculation of arithmetic averages, errors of averages, dispersion, and standard deviation values.

The comparison of indicators for quantitative characteristics was carried out through a non-parametric method using the Wilcoxon matched pairs test or the Mann-Whitney U test. When comparing two groups with a normal distribution of data, an independent group t-test has been used. The differences were considered statistically significant for all types of analyses at $p < 0.05$.

Ethics of the study

Each study participant provided written informed consent to undergo the Endospheres® procedures.

The study was conducted according to the Declaration of Helsinki of the World Medical Association. The research program was approved in a meeting of the Independent Ethics Committee at the State Healthcare Budget Institute named after MONIKI - MF Vladimirovsky (protocol no. 7 of 28 October 2021) at GBUZ MO "Moscow Regional Research Clinical Institute (MONIKI), named after M. F. Vladimirovsky" Moscow, Russian Federation.

The study was conducted in the Federal State Budgetary Educational Institution of Higher Education, "Russian State University named after A.N. Kosygina," Moscow, Russian Federation, by Kardashova Ziver Zaidin Kyzy, Ph. D., with financial support of ItalConsult LLC (Moscow, Russia).

All authors have contributed substantially to the realization of this work by sharing all aspects. All authors confirm that there are no conflicts of interest.

RESULTS

The criteria for evaluating the effectiveness of Endospheres® treatments before and after the entire therapy cycle were the dynamics of the weight-height ratio (BMI), the hip and waist circumference, and the nature of the cellulite depressions recorded in the photographs.

In the patients included in the study, in all age groups (40-49, 50-59, and 60-69 years), the average BMI value at zero point (before the start of the cycle) was between 26.9 and 28.9, corresponding to their excess of body weight. However, each group had participants of different weight categories (Fig.1).

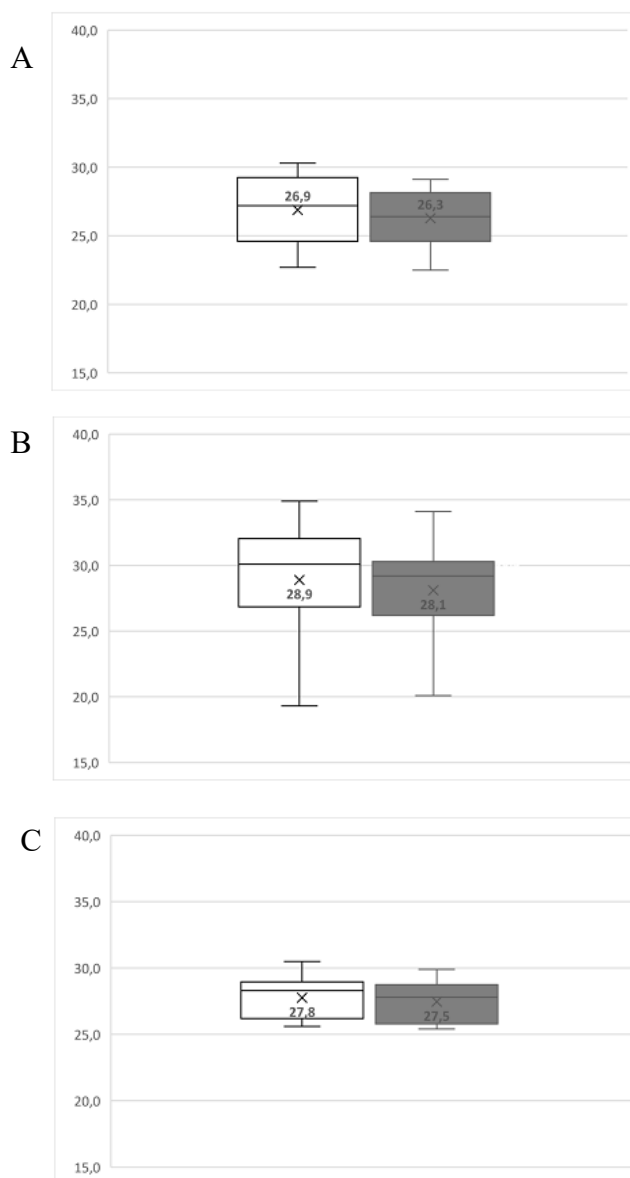


Fig. 1. Dynamics of BMI before (white boxplot) and after (gray boxplot) 12 Endospheres® procedures in study participants of different age groups: 40-49 years (A), 50-59 years (B), 60-69 years (WITH).

Therefore, in the group of premenopausal women (40-49 years), only a third (33.3%) of the participants had an average initial weight, while 66.7% were obese. At age 50-59 years, overweight was recorded in 33.3% of the participants, and obesity was recorded in 55.6% of the participants. Furthermore, 11.1% of women in this group were underweight. In the postmenopausal age group (60-69 years), 22.2% of the participants had an average weight, and the rest (77.8%) were overweight.

After the Endospheres® cycle, the average BMI decrease was only 3-4%. At the same time, an improvement in infra-group indicators has been noted. Among women aged 40 to 49, only 44.4% remained overweight, i.e., 22.3%, while hip and waist circumference decreased respectively by 3.0 ± 1.1 and 5.3 ± 1.1 cm.

Among participants aged 50 to 59, only 22.2% remained in the “obesity” category (a 2.5-fold decrease from initial indicators). 66.7% of women moved into the “overweight” category. At the same time, the hip and waist circumferences of the participants in this group decreased by 2.2 ± 0.9 and 4.1 ± 1.3 cm, respectively.

In women aged 60 to 69, a minimal decrease in BMI was recorded (by 1%) with a good body correction effect: a reduction in hip and waist circumference was respectively 2, 5 ± 0.9 , and 6.3 ± 1.5 cm.

Fig. 2 displays the characteristics of cellulite skin.

A



B



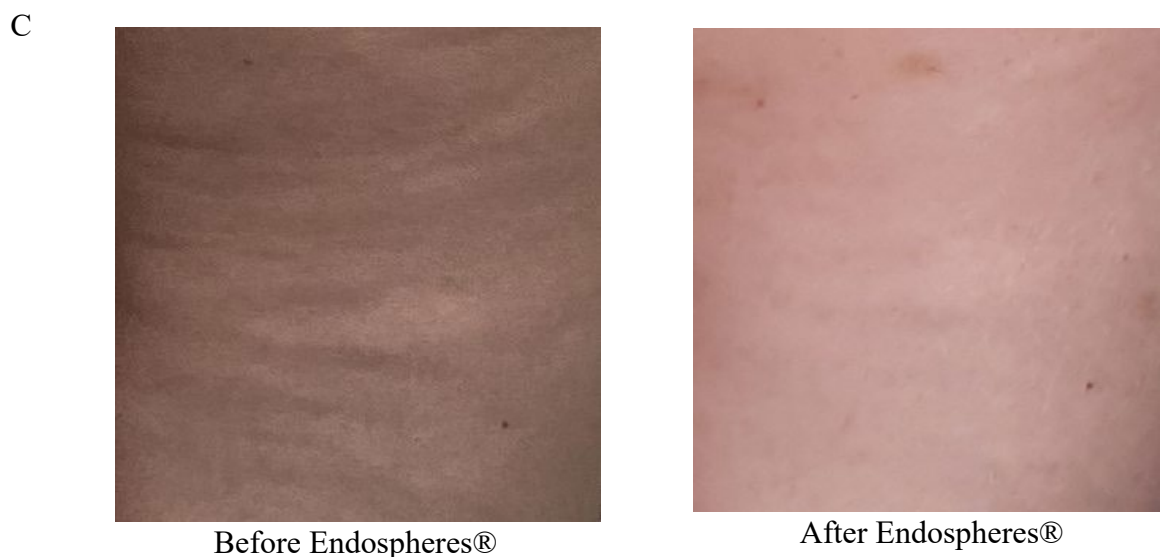


Fig. 2. Examples of photographs of the anterior thigh area before and after 12 Endospheres® sessions in study participants of different age groups: 40-49 years (A), 50-59 years (B), 60-69 years (C).

At the beginning of the treatment, all patients presented superficial irregularities, depression, and mild or moderate skin sagging, more pronounced in patients aged between 60 and 69 years. After 12 Endospheres® sessions, participants in all groups noticed a significant improvement in their skin topography regarding bump-smoothing, reduction of depressions, and increased skin elasticity and density.

The characteristics of the dynamic ultrasound picture of the dermis-hypodermis (before the Endospheres® cycle, after 12 procedures, and 2 months after treatment) are illustrated in Fig. 3.

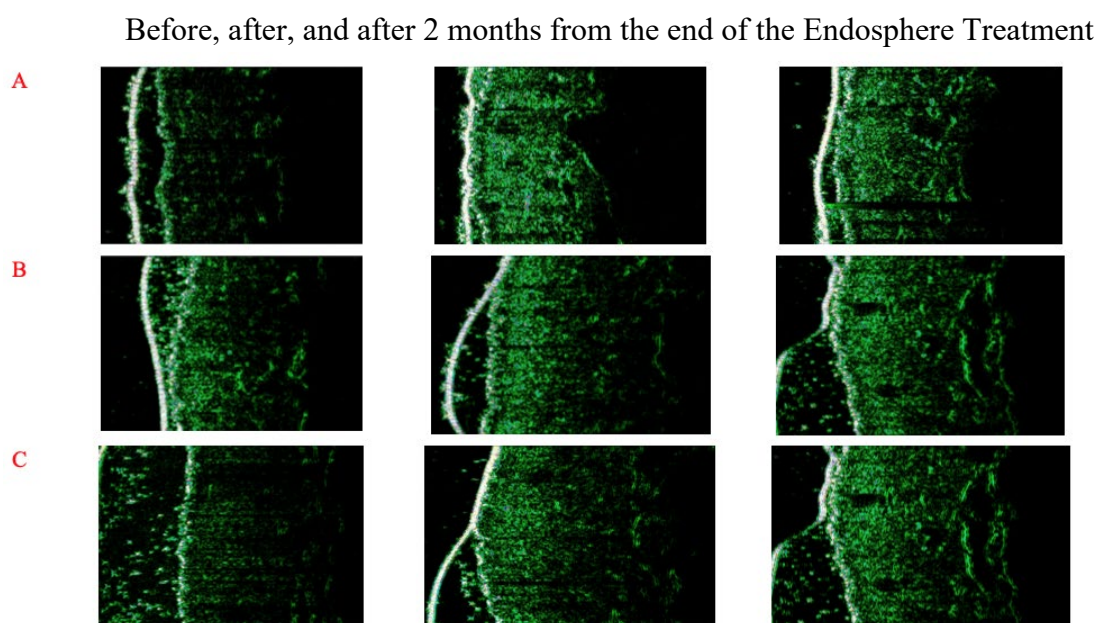


Fig. 3. Examples of scanograms of the skin of the anterior thigh area before treatment, after 12 Endospheres® procedures, and 2 months after the course of therapy in study participants of different age groups: 40 – 49 years (A), 50-59 years (B), 60 – 69 years old (C).

In these images, the epidermis increases its hyperechogenicity, showing a stratified structure with or without signs of exfoliation in the form of a white stripe with blue and green shades.

The dermis is visualized as a heterogeneous structure with green lines intersecting with white inclusions, an image of collagen and elastin fiber bundles. The hypoechogenic area corresponds to the subcutaneous adipose tissue, whose structure echoreflex signals from fibrous structures and vessels are recorded.

The intensity of fibrosis and the presence of fibrillar structures or septa, responsible for the degree of lobulation of adipose tissue and the appearance of the skin, are indirectly assessed through changes in the echogenicity of the hypodermis, based on the technical capabilities of the ultrasound scanner used.

The scans demonstrate, in the initial ultrasound picture in women of premenopausal and menopausal age, an irregular thickening of the epidermis, which reflects an increase in the skin model, an increase in the thickness of the dermis, and a decrease in its echogenicity. In postmenopausal patients, the thickening of the epidermis is uniform along its entire length, accompanied by mild hyperkeratosis and reduced echogenicity of the dermis over its entire thickness.

After a cycle of Endospheres®, all participants showed different degrees of reduction in the thickness of the epidermis, resolution of the hyperkeratosis phenomenon, compaction of the dermis, and increase in its homogeneity and echogenicity. The effect obtained persists 2 months after the therapy.

The nature of the dynamics of the thickness of the dermis, the echogenicity of the dermis, and the hypodermis in the areas of the anterior surface of the thigh, the posterior surface of the thigh, and the anterior surface of the abdomen are shown in Fig. 4.

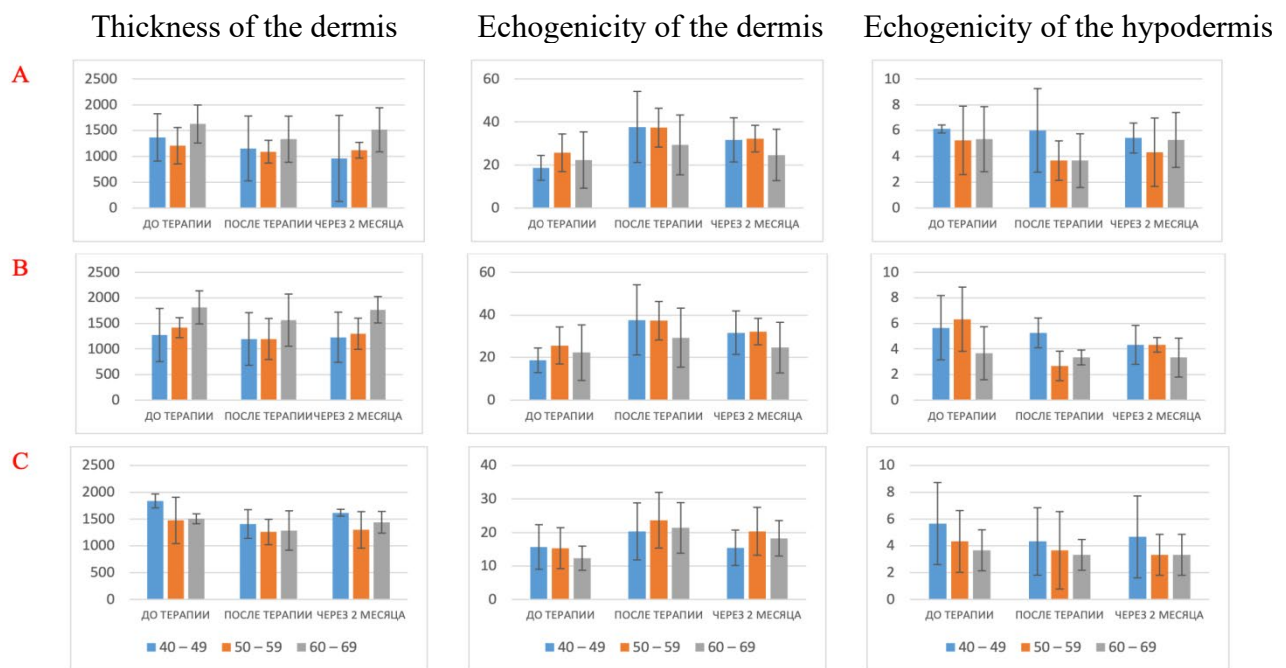


Fig. 4. Dynamics of ultrasonographic parameters (dermal thickness (μm), echogenicity of the dermis and hypodermis) before therapy, after 12 sessions, and 2 months after the course of Endospheres® in study participants of different age groups (40-49, 50-59, 60-69 years) in the area of the anterior thigh (A), posterior thigh (B) and anterior abdomen (C).

After the cycle with Endospheres®, premenopausal patients showed a statistically significant decrease in the average dermis thickness in the anterior thigh and anterior abdominal surface area of 15.6 and 23.4% ($p < 0.05$) compared to the baseline. In women aged 50 to 59, the dermis's thickness in the anterior, posterior thigh, and anterior abdominal surface area decreased by 9.5, 15.7, and 14.7% compared to the initial data ($p < 0.05$).

In the age group 60-69 years, the thickness of the dermis in the areas of the anterior surface, posterior surface of the thigh, and anterior surface of the abdomen, compared to the initial data, decreased by 18.1, 13.8, and 14.5% ($p < 0.05$).

The average echogenicity of the dermis in the age group 40 to 49 years on the anterior and posterior surface of the thigh and the anterior surface of the abdomen increased by 2, 1.4, and 1.3 times, respectively.

In the group aged 50 to 59 years, the scanned areas of the bitrochanteric region exceeded the initial values by 1.4 times and the area of the anterior abdominal surface by 1.5 times. In the age group between 60 and 69 years, similar results were obtained: the echogenicity of the dermis increased by 1.3, 1.5, and 1.7 times, and its structure became more homogeneous.

Regarding the initial results in the age group of 40-49 years, the quantitative indicator of echogenicity of the hypodermis in the anatomical areas studied after the cycle with Endospheres® decreased by 30.8, 43.2 and 23.6% ($p < 0.05$), in the 50-59 years group it decreased by 27.6, 57.8 ($p < 0.05$) and 15.2% ($p < 0.05$), in the 60-69 years group decreased by 31.2 ($p < 0.05$), 05), 9.3 and 9.3% ($p < 0.05$).

In the measurements carried out two months after the cycle of therapy, all participants confirmed the maintenance of the positive corrective effect associated with an increase in tone, density, and improvement in skin elasticity, which demonstrates not only the good aesthetic impact of the Endospheres® treatments but also its preservation in the following months, in the form of lasting improvement in the topography and structure of the skin.

At the same time, we have not recorded any complaints or dissatisfaction from patients. Immediately after the Compressive Microvibration® procedure, some reported a slight tingling with redness of the treated area, with slight muscle soreness, typical of the vascularising and fasciomuscular effect of the treatment, with spontaneous resolution in a few minutes.

DISCUSSION

Overweight, cellulite, and accumulated localized adipose tissue are widespread aesthetic problems that are common and complex to correct, especially with age. For these reasons, there is no end to interest in treating cellulite and developing new methods of fixing the body silhouette and reshaping the skin, both among specialists and consumers. The high demand for such procedures is confirmed by data from the American Society of Plastic Surgeons, which recorded 86,350 different cellulite treatments in 2020, exceeding the number of procedures performed by 261% in the study carried out in 2000 by ASPS (18).

Various types of non-invasive methods are currently used for the treatment of cellulite, for the correction of body contours, and for the reduction of the volume of subcutaneous adipose tissue, including cryolipolysis, radiofrequency therapy, low-intensity laser therapy or high-intensity focused ultrasounds (19, 20).

A high percentage of satisfaction is demonstrated by massage techniques with mechanical vibration therapies that allow modeling shapes and volumes, modifying the aesthetic topography of the skin and significantly reducing the visible signs of cellulite (21, 22).

Of great diffusion and scientific interest is the Compressive Microvibration® method (Endospheres®), which improves microcirculation, provides deep lymphatic drainage, activates metabolic processes and the transport of metabolites, increases the skin tone and elasticity, and shapes the silhouette (23, 24).

The satisfaction reported above all by women of mature age (perimenopause and postmenopause) who suffer from cellulite caused by vegetative-vascular and metabolic-endocrine alterations is constant.

Ultrasound examination is widely used to evaluate the effectiveness of aesthetic and physiotherapeutic procedures objectively.

The capabilities of high-frequency ultrasound in monitoring skin conditions during anti-cellulite treatments make it possible to visualize the characteristics of changes in the thickness and structure of the epidermis, dermis, and hypodermis to control the thickness of the adipose tissue, the qualitative composition of collagen fibers in adipose tissue and the presence of fibrous alterations that lead to an increase in the acoustic density of the tissue (25).

The results obtained based on the analysis of ultrasound criteria objectively confirm the effectiveness of the Compressive Microvibration® in achieving a positive anti-cellulite effect in women of different ages, with results lasting more than two months.

The limitations of the study are the lack of a comparison group and the impossibility of obtaining a statistically significant difference when comparing the data obtained with individual variability of the values. It is necessary to conduct further studies on patients with more severe forms of cellulite to obtain additional evidence of the effectiveness of the Compressive Microvibration®, as well as to increase the duration of observation of maintenance of the achieved anti-cellulite effect.

CONCLUSION

Endospheres® is a pathogenetic anti-cellulite therapy method where, thanks to mechanical vibrations transmitted to the tissues by low-frequency impulses (Compressive Microvibration®), morphofunctional changes are obtained in the various layers of the skin and the subcutaneous tissue, with effects on local microcirculation, muscle tone, lymphatic drainage, and tissue trophism, with a reduction of cellulite.

The results obtained based on ultrasound criteria have demonstrated the effectiveness of the Compressive Microvibration® in women with mild and moderate gynoid lipodystrophy, improving their skin conditions, with a reduction of the so-called "mattress" compartments, evident even two months after the end of the treatment, without side effects or complications.

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