

Thermographic and clinical data (TCD Code) in the evaluation of cellulite treatment by Endosphères Therapy

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Abstract

Cellulite represents an annoying and multifactorial female aesthetic pathology that requires a complete diagnosis and a precise clinical classification, which is ultimately essential to set up the best treatment protocol, that always requires a physical therapy associated with medical or surgical therapies aimed at the different alterations of adipose, microcirculatory, endocrine or connective tissue. The attempt to classify cellulite is as old as its first description,

around 1920. However, the difficulty of clearly defining and framing its clinical aspects and pathophysiological evolution has produced various and different classifications, all interesting and validated, but all with some limits. In 2001, an important controlled and randomized scientific study on the diagnosis and treatment of cellulite was organized, but precise identification of cellulite and the results was necessary to give greater validity to that international study.

For this reason, a new clinical classification was devised, with a repeatable test and a final number that could be used both statistically and for interpretation of results. The TCD Code is the numerical sum of several numbers that express various thermographic, clinical and symptomatic parameters. In the present study, twenty female patients with cellulite were treated by a non-invasive method called "Endosphères Therapy", which uses mechanical micro-vibrations and

Introduction

Cellulite is a complex aesthetic pathology classifiable in several stages and different forms. Therefore, doctors have difficulty in his classification and the propose of the therapeutic protocols. For this reason, in 2003, at the Congress of the Italian College of Phlebology in Udine, a new classification was presented, named "TCD Code", as a practical test that offers a final

Cellulite

The term "Cellulite" was born in France in 1920, Drs. Alquin and Pavot thus defined that skin imperfection of the female lower limbs, characterized by irregularities of the skin, like "orange peel" or "dimpling skin", with other alterations such as localized adiposity, oedema or skin trophism (7-9).

Cellulite is not only an alteration of the skin at "orange peel", but the result of a series of biochemical and biophysical alterations that begin at the level of the interstitial matrix, with microvascular alterations, and then evolve in various and different stages with an evolutive fibroedema, sometimes disabling as in lipoedema

micro-compressions to obtain vascularizing, analgesic, draining and restructuring effects. Twelve therapy sessions were carried out in five weeks, the results before and after were evaluated using the TCD Code, which highlighted the reduction of the initial value of 40.14% significant of the clinical and aesthetic improvement of cellulite. The study has finally proved the validity and the practical utility of the TCD Code.

number, valid for the clinic repetition of the test and statistical or therapeutic control of the results of the treatments carried out (1-6).

The present work presents the results of an observational study on twenty patients suffering from cellulite and treated by Endosphères Therapy, the evaluation of the results was made using the TCD Code.

(10). There are three different trains of thought:

-Curri School, linked to the excellent research work in molecular biology done in Milan by the prestigious school of Prof. Sergio Curri in the last century, defines cellulite as the consequence of functional microvascular alterations venulolymphatic stasis that evolves into fibrosis and connective sclerosis (11-18).

- American train of thought, linked above all to plastic surgery, considers cellulite an imperfection caused by hypertrophy or hyperplasia of fat cells, with consequent hormonal and endocrine alterations. At the same time, other authors point to cellulite as a non-existent disease (19-21).

-Italian train of thought considers cellulite as a skin imperfection caused by a mesenchymal or endocrinopathy linked to microvascular dysfunction or tissue pollution by hormones, lifestyle, and overeating phlebolympathic damage secondary to functional dysfunctions of the interstitial matrix and adipose tissue (22-25). Beyond the different opinions about the physiopathological evolution of cellulite, now

Cellulite therapies

Cellulite is a multifaceted pathology that expresses itself in different stages and forms. The various stages start from tissue oedema and end in fibrosis and connective alterations. At the same time, the different forms may show the prevalence of oedema or the alterations of the adipose tissue, the fibrosis of the connective tissue or the transformation of the subcutaneous panniculus into lipoedema, the skin irregularities or the tissue laxity, but after the initial juvenile phase all forms always present tissue pain. Since there are different forms and stages, there are consequently different therapies:

- 1) Mesotherapy for edematous forms (26, 27)
- 2) Carboxytherapy for hypovascularized forms and fibrosis (28, 29)
- 3) Oxygen-Ozone therapy for painful and lipodystrophic forms (30, 31)

Compressive microvibration

Endosphères Therapy is a non-invasive methodology born in Italy in 2008 to treat muscle pain and lipodystrophy. In those years, the new methodology of "Compressive Microvibration"

everyone agrees on a concatenation of hormonal, microcirculatory and inflammatory causes that lead to the complex evolution of the skin imperfection, that always ends up becoming an aesthetic pathology that requires, above all, a precise "diagnosis as early as possible", with the treatment in its initial stages, always remembering that cellulite treatment involves the lifestyle too.

- 4) The Liposculture for adipose cellulite (32, 33)
- 5) The Subincision for skin irregularities (34)
- 6) Cryotherapy for small, localized fat deposits (35-36)
- 7) Endolaser therapy for skin laxity and varicosity (37-38)

Each therapy has its best indication, and aesthetic doctors know all the methodologies, using them in the right indications. However, one single therapy is rarely used, preferring the integration of various methods, perhaps at different times for a better result (39-41).

At the base of each protocol is the lifestyle, with the importance of walking and sleeping, the suitable nutrition that is always personalized, and finally the physical therapy, such as the Endosphères Therapy by Compressive Microvibrations.

was revolutionary because it used special "micro-vibrations and micro-compressions" produced by 55 soft silicone spheres with a diameter of 19.5 mm, which rotate inside a cylinder at

different speeds. This rotation transmits different mechanical vibratory frequencies into the tissues, producing different results, with vascularizing, draining, toning or analgesic action.

Classification of cellulite

Cellulite is a multifaceted disease that occurs in different evolutionary phases, requiring a precise diagnosis and a correct classification for a better therapeutic protocol. There are many attempts at classification in the literature, even scientifically valid, but all containing some limits of use (43). The first attempt of cellulite classification dates back to 1974 by Prof. Binazzi (XLIII), a vascular physician at the Bologna University, dividing cellulite into three clinical classes: "Hard, Mixed, Soft", then analyzing the morphological aspects of cellulite, but the traditional classification is the one described by Nurmberg-Muller, in 1978, which proposes four clinical evolutionary stages and is based on the pinch test (a skin pinch between index and thumb) to evaluate tissue characteristics (44).

The CSS (Cellulite Severity Scale) scale is also used, which uses a photonic scale with various scores to evaluate cellulite's clinical and morphological aspects concerning gravity; therefore, it is only useful for localized cellulite on the buttocks and thighs (45). Very similar to CSS is Di Bernardo measurement of dimples, which is

This study was based on the treatment of cellulite by the non-invasive methodology called *Endosphères Therapy with a Compressive Microvibration* (42).

based on a photonic scale that measures the number and shape of dermal dimples caused by gravity (46, 47).

In 1988, Prof. Sergio Curri, holder of the chair of Molecular Biology at the University of Milan (48-50), studied a classification based on clinical data and thermographic pictures to have reproducible images that could be computerized and studied, both statistically and clinically. In the beginning, prof. Curri described five classes of cellulite characterized by different types of tissue temperature, which revealed the state of microcirculation and oxygenation of tissues, then we have the "Curri Scale", which divides cellulite into four evolutionary stages characterized by the reduction of vascularization and the increase in hypoxic-fibrous areas (51-53).

To classify cellulite, we have many proposals. However, the international aesthetic medicine mainly uses the four stages proposed by the Italian molecular biologist Sergio Curri in 1993, which report the evolution of tissue alterations: from initial oedema with arteriolar spasm to the evolutionary fibrosclerotic alterations (Table I).

Table I. The classification of cellulite in the 4 stages of Curri (from Terranova) (54).

Stage	Clinical classification	Pathogenesis	Histology and Histochemistry
Stage I°	Pale, Pasty skin	Microcirculatory maldistribution, defective vasomotion	Anisopoichilocytosis, localised lipoedema
Stage II°	Cutaneous iperelastivity and hyperthermia, paresthesia	Stasis sludge, microvessel ectasia, zonal hypoxia	Regressive adipocyte manifestations, massive microvessels dilatation
Stage III°	Orange peel skin, palpable small lumps	Reduction in capillary flow, increase in the areas of relative hypoxia	Neofibrillogenesis, degenerative adipocytes encapsulated in micronodules
Stage IV°	Painful nodules	Stasis, Hypovolemia, teleangectasia	Scleroting macronodules. Local dystrophic phenomena of the skin

In this classification, cellulite is identified as a chronic microcirculatory poor distribution, in turn, due to a primary defect of the arterial device that modulates blood flow or to the inadequacy of vasomotion. The consequences are a reduction in microcirculation with erythrocyte mud phenomena and alteration of the hydrostatic capillary, up to alterations of the adipose and connective tissue with skin irregularities

(dimpling skin). The classification of prof. Curri is therefore based on histopathological aspects, but it has limitations like other classifications in practice. This classification can be useful in a clinic to identify the patient, but it does not allow a quantification of the pathology and the results; for this reason, the TCD Code was created to have a numeric identification of the pathology the possibility of standardization of the results.

TCD Code

There are works with interesting observations about the pathophysiology and classification of cellulite in the scientific literature, where it is possible to perceive the difficulty in clearly identifying the various evolutive stages from a clinical point of view (55-57).

In 2001, an important controlled and randomized study on the diagnosis and treatment of cellulite was organized; however, to give greater validity to that international study, precise identification of cellulite and the results was necessary, so a new idea was used, with a repeatable test which gave

a final number useful for the management of the results and the statistical analysis. The TCD Code is the sum of several numbers, the expression of various thermographic, clinical or symptomatic parameters (58-59).

To improve the classification of cellulite in a clinical sense, it was necessary to find a test with a final number that would allow us to better identify the global state of cellulite in its major characteristics, both of vascular alteration, both in clinical and aesthetic aspects and in tissue pain. The VAS scale is useful for the clinical and

aesthetic aspects, but also for the pain symptom because used with the collaboration of the patient, while for vascular alterations, we prefer to use the answers given by the thermographic plates, which have been used for a long time for this purpose (60-61).

In 2003, a new schema was presented at the "Congress of the Italian College of Phlebology" in Udine, to improve the classification of cellulite. Named "TCD Code", the new proposal was a practical test that allowed a final number useful both for clinical and research purposes, particularly for statistical control of the results (62-64).

In the present study, the "TCD Code" was used, consisting of three sections: T Factor, C Factor and D Factor, whose letters mean "Temperature – Clinic – Distress of tissues". This test completes the clinical diagnosis by investigating the vascularization of the thigh tissues, the visibility of cellulite and the painful symptoms reported

T Factor

The "T Factor" investigates the variation in skin vascularity, detecting the temperature variation of the tissue employing a system of liquid crystal thermographic plates which, while producing data of complex interpretation that require an evaluation relative to the general clinic, the "T Factor" remains one of the most used diagnostic methods for the classification of cellulite and for checking the effectiveness of treatments.

Thermographic examinations were conducted by an 8-color Thermo-Cell-Test-Mac® High-Resolution

by the patients, with a final number whose variation indicates the response obtained with the treatment performed.

The data we obtain is the numerical sum of the three TCD factors is a numerical judgment relating to the TCD detected evaluations integrated with a subjective evaluation of the patient. At the same time, the final value (TCD-CF) represents the result of the numerical sum of the TCD factors integrated by a Correction Factor, in practice a final number between 5 and 51 which indicates the state of cellulite. The study evaluations were carried out with a VAS scale from 1 to 10. In contrast, for the medical-clinical evaluation, the TCD Code was used, investigating the vascularization of the tissues, the status and visibility of the orange peel, the tenderness of the tissues, with a final number whose variation indicates the response obtained with the treatment carried out.

system from IPS, using microencapsulated liquid crystal (ELC) plates from the RW-S Professional Kit (65-66).

All patients were examined before and after treatment in an environment with a temperature not lower than 18° and not higher than 25° in supine position, to detect data on the anterior part of the thigh on the vertical line and 15 cm from the saphenofemoral junction of the right lower limb (Fig. 1).

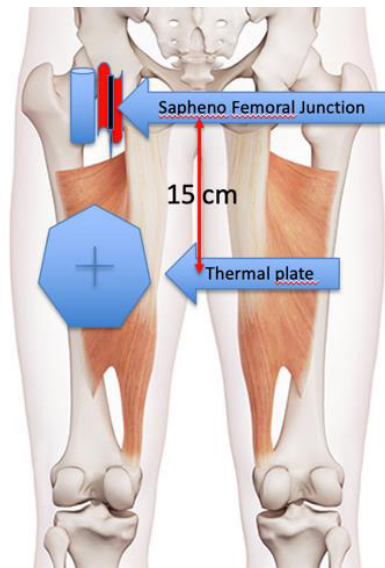


Fig. 1. Schema for detecting data.

Different thermographic pictures are identified for different vascular situations, data have been collected and interpreted according to Sergio Curri scheme, with small modifications that allowed a graduated scale from 0 to 25, referring to the thermographic reference frames.

In Fig. 2, the T0 area is characterized by the uniformity of the blue color, which denotes a harmonious vascularization; in the T1 area, different colors are observed, which indicate areas with arteriolar spasm alternating with well-

vascularized and “thermally hot” areas, while from T2 to T4 there is a progression of increasingly dark, poorly vascularized and “thermally cold” areas, characterized by evolutionary fibroedema and tissue fibrosis. In Fig. 2, we can see the thermographic schema, where at the left we have “T0 area”, with thermographic images of “Normal zones”, in T1-T4 we have images of “pathological zones” with ipovascularisation and “cold areas” (Fig. 2).

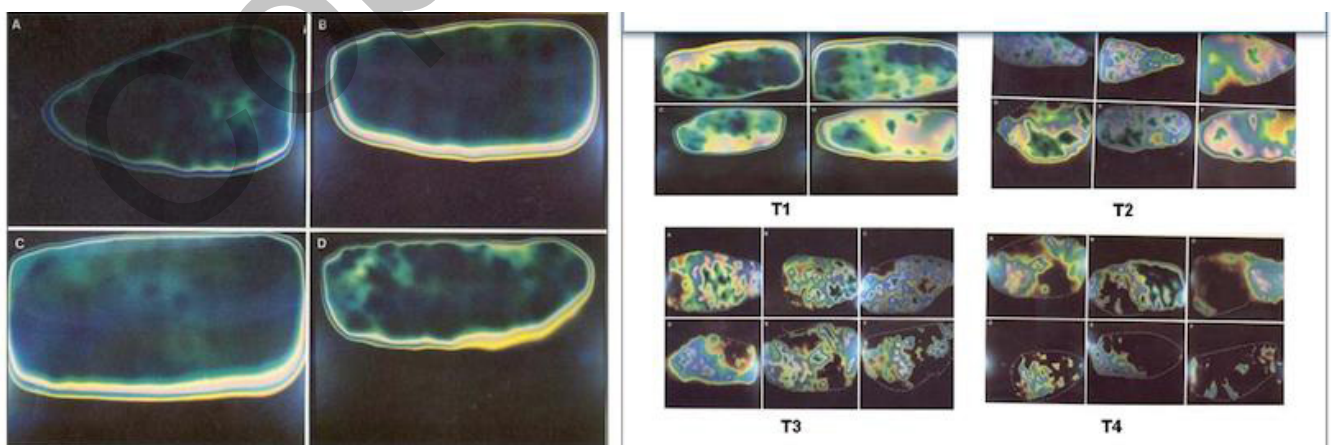


Fig. 2. T Factor: Schema for detecting value of thermographic areas with scale 0-25.

In young, healthy subjects, in standard conditions and an environment devoid of humidity, the vascularization of the skin is regular and uniform, the gradients reflect the distribution of the microvascular supply and, above all, the absence of cold areas, i.e., areas where microcirculation is reduced.

In these different thermographic pictures, the values from 0 to 3 indicate the vascular normality (T0). In contrast, from 4 to 7 indicates

the initial microcirculatory alteration (T1), the values from 8 to 13 indicate the aggravation of the microcirculatory situation with the venolymphatic stasis (T2) while the values from 14 to 19 indicate areas decidedly colder from the vascular point of view, with hypothermic areas and images of "black holes" (T3), finally the values from 20 to 25 indicate clear tissue connectivization and liposclerosis (T4).

C Factor

The "C Factor" investigates the type of orange peel and cellulite by identifying nine different states attributable to skin imperfections objectively detectable by the doctor, with the collaboration of the patient, through a dedicated VAS scale, with a progressively increasing number concerning the greater visibility of the detected cellulite at the level of the right thigh, finally offering a final data useful for the diagnosis.

C1 – Orange peel not visible to the naked eye

C2 – Orange peel visible only on palpation (Pinch

test)

C3 – Orange peel visible only to a seated patient

C4 – Orange peel barely visible to the naked eye

C5 – Orange peel visible to the naked eye

C6 – Orange peel very visible to the naked eye

C7 – Orange peel very visible to the eye and compact

C8 – Orange peel very visible to the eye and fibrous

C9 – Orange peel very visible to the eye with tissue laxity

D Factor

The "D Factor" (Tissue Distress) investigates the "pain" symptom by identifying seven different states characterizing the pain of the dermohypodermic panniculus of the right thigh (skin and subcutis up to the fascia), noting both the pain reported by the patient and pain caused by palpation, pressure, or pinch test. Classification is then made between "painful cellulite" and "painless cellulite" using a progressively

increasing number with greater suffering of the tissues of the right thigh.

D0 – Painless cellulite (not even at the pinch test)

D1 – Slightly painful cellulite (which does not aggravate with pinch test)

D2 – Painful cellulite in the thigh (but without heavy legs)

D3 – Slightly painful cellulite in compression

D4 – Painful cellulite with heavy legs

D5 – Painful cellulite that increases with compression or pinch test

D6 – Painful cellulite with adipose thigh and swollen feet

D7 – Painful cellulite with fibrous nodules

Correction Factor (CF)

The Correction Factor (CF) is a number that represents the sum of two evaluations of the patient, whose judgment is of enormous importance as it reflects the psychosomatic damage of cellulite, the pathophysiological state of the tissues and the presence of pain, which is the expression of the toxic lymphatic stasis

in the tissues and the microarteriolar spasm; these factors strongly interfere in the quality of life of the patient, that considers cellulite a pathology, and is poorly tolerated. Therefore, a visual analogue scale (VAS) from 1 to 10 is used for evaluation.

Vas A scale

Before starting the treatment, the patient receives a questionnaire (VAS A) on which, after a thoughtful and careful reflection, she must put a sign in the number she deems most appropriate for the subjective evaluation of her cellulite, with a progressively increasing number in a negative way, that is from the best to the worst state of cellulite, concerning the pain symptom and the acceptance of its cellulite.

Four cut-off values are identified: from 1 to 3 means “initial cellulite”, from 4 to 5 means “medium cellulite”, from 7 to 9 means “advanced cellulite”, while the number 10 identifies cellulite that is dramatic for the patient, in the symptoms or the aesthetic aspects. In the “VAS A” questionnaire, the patient can give a value from 1 to 10, where 1 is the minimum score (therefore practically

without cellulite), and 10 is the maximum score, therefore with unwatchable, fibrous, and painful cellulite.

VAS Questionnaire A

VA10 – Advanced cellulite with tissue laxity

VA 9 – Advanced, fibrous, and painful cellulite

VA 8 – Painful cellulite with edema and heaviness

VA 7 – Adipose and painful cellulite

VA 6 – Inesthetic and adipose cellulite, but not painful

VA 5 – Non-adipose but painful unsightly cellulite

VA 4 – Medium non-adipose and painless cellulite

VA 3 – Light and painless orange peel

VA 2 – Small areas of cellulite

VA 1 – Very slight cellulite

Vas B scale

At the end of all treatments, the patient receives

a different questionnaire (VAS B) on which, after

a thoughtful and careful reflection, she must put a sign in the number she deems most appropriate for the subjective evaluation of treatments, both of the improvement of his cellulite, and the eventual worsening. The patient positively uses a progressively increasing numbering, from the possible worsening up to the greater improvement or disappearance of her cellulite, therefore also improving her quality of life.

The patient can give a value from 1 to 10, where 1 is the minimum score (therefore no improvement but worsening of her initial state), and 10 is the maximum score, therefore with the disappearance of cellulite and the perception of well-being of the legs. For this, four cut-off values are identified: 1 to 2 means no improvement, 3 to 5 means a small improvement, 6 to 8 means a significant improvement, 9 to 10 means a great improvement.

Vas Questionnaire B

VB10 – Cellulite disappeared – light legs

VB 9 – Cellulite almost disappeared – light legs

VB 8 – Much improved cellulite – light legs

VB 7 – Improvement of cellulite and light legs

VB 6 – Improved cellulite but heavy legs

VB 5 – Little improved cellulite and heavy legs

VB 4 – Improvement of cellulite but with irregular areas

VB 3 – Improved cellulite but more relaxing tissues

VB 2 – Cellulite not improved

VB 1 – Cellulite worsened

The TCD code expresses a number between 1 and 51 which indicates the state of cellulite, integrating various parameters so that a high

number of TCD corresponds to worse cellulite, a low number corresponds to initial cellulite. So, we should always have a high number before the treatments and a lower number at the end of the treatments: the greater the difference, the greater the treatment effect; a correction factor was inserted to improve the quality of the test, which is a number resulting from the difference (positive or negative) of the two questionnaires, with the formula “VA minus VB”.

The VA questionnaire indicates the state of cellulite before the treatments, while the VB questionnaire indicates the result after the treatments. Therefore, in the case of cellulite improvement, the number obtained in VB should be greater than that obtained in VA, and therefore the equation “VA minus VB” should give a negative number to be subtracted from the number of the final TCD. On the other hand, in the case of worsening caused by the treatments or even improvement, the equation “VA minus VB” shows a positive number to be added to the final TCD, therefore with a residual cellulite that has not been improved.

For example, in the first case, if we have “VA 7 minus VB 5”, the difference will be +2, a positive that is added to the final TCD value, indicating a worse state of cellulite and reducing the overall judgment on the treatments. In the second case, for example, if we have “VA 5 minus VB 7” a difference will be -2, a negative which is subtracted from the final TCD number, therefore an improvement of the initial cellulite and good results of the treatments.

This result increases the final evaluation of the treatments, lowering the final value of the TCD Code.

TCD/CF code

The “TCD Code” is a numerical data representative of the sum of the various numerical factors “T-C-D”, to which a number given by a correction factor is added or subtracted, as an expression of patient satisfaction.

The “T” factor goes from 1 to 25; “C” factor goes from 1 to 9; “D” factor goes from 1 to 7, therefore with a subtotal that can vary from 3 to 41. To this number, the “CF” is added or subtracted (Correction factor); this final number is the numerical sum of the three TCD factors, integrated with a subjective evaluation of the patient. In practice, we have a final TCD-CF Code with a final number between 5 and 51, indicating cellulite’s global, clinical, and aesthetic status.

If we refer to the four stages of Curri, we can identify a TCD code between 5 and 13 as the first stage, a TCD code between 14 and 22 as the second stage, a TCD code between 23 and 31 as the third stage, a TCD code over 32 as the fourth stage.

Materials and Methods

For the treatment of cellulite in twenty female patients, Endosphères Therapy by Compressive Microvibration was used in this study. The TCD

Endosphères therapy

Endosphères Therapy is a non-invasive methodology born in 2008 to treat muscle pain and lipodystrophy. It uses special “micro-vibrations and micro-compressions” produced by 55 soft silicone spheres with a diameter of 19.5 mm

The TCD Code evaluates the vascularization of the tissues, the state and visibility of the orange peel and the pain of the tissues, with a final number whose variation also indicates the response obtained after the treatments performed. The TCD code also allows the physician to evaluate actions of treatment in different areas, for example, the effect in vascularity of tissues, the effect in the reduction of pain or the adipose tissue, the toning effect or any complications.

A recurring problem in executing anti-cellulite treatments is the classification and standardization of the results, as the subjective and objective indicators are above all “indicative” or “photographic”. The TCD-CF Code has overcome this problem by allowing a final number to evaluate the values obtained in a repeatable and statistically classifiable scale, with a “before” and an “after”, which is extremely useful in the relationship between doctor and patient.

Code was used for the classification of cellulite and the evaluation of the results.

that rotate inside a cylinder at different speeds. This rotation transmits different mechanical vibratory frequencies into the tissues, producing different results.

The integration of three different mechanisms

of action, such as the type of frequency used, the direction of rotation of the spheres and the compression exerted on the handpiece containing the operating cylinder, produce elastic responses in the tissues and particular stimuli on the various mechanoreceptors or energy points that they can activate various actions, vascularizing, draining, toning and analgesic (67).

The objectives of the treatment of cellulite, always requested by patients, are the reduction of pain, the improvement of vascularity, the reduction of "orange peel skin", and oedema and fibrosis.

Patients

Between February and May 2019, in the Center of Phlebology and Aesthetic Pathologies of Arezzo, were followed twenty female patients between 18 and 50 years (average age 34) who had spontaneously presented themselves to undergo treatment for painful cellulite e dimpling skin. All patients referred heaviness of the lower limbs with soft oedema in the evening or after prolonged standing, and they showed cellulite in different stages, according to the classification of Curri:

1° stage: Interstitial oedema with adipocyte hypertrophy

Treatment

Treatment was performed by official equipment for Endosphères Therapy named "AKN Body Med", made in Italy by FenixGroup of Montesilvano (Pescara). This instrument used the methodology of Compressive Microvibration with an operating frequency between 30 and 384Hz (Ts), where TsT

However, in the clinical evaluation of the results, we can use only a few indicators, such as patient satisfaction, ultrasound data, photography and circumference detection (68).

Endosphères Therapy allows a significant vascularization with a thermal increase that activates the metabolic functions of the tissues, with a reduction of pain and inflammatory or degenerative processes, to slow down the evolution of unsightly and symptomatic alterations cellulite or oedema of lymphoedema or lipolymphedema.

2° stage: Adipose Hypertrophy and connective Hyperplasia.

3° stage: Micronodules in the tissues as an expression of encapsulated adipocytes by connective fibers.

4° stage: Fibrose tissue with macronodules and evidence of orange skin appearance.

No patient had any ongoing disease or primary lymphedema they did not use cortisone, estrogen or thyroid hormones, or other metabolic or vascular drugs. All patients signed informed consent for the non-invasive treatment requested and agreed upon.

is the estimated time of treatment that changes depending on the movement of advancement of the handpiece in the different indications.

The standard protocol of treatment was used in the front and back of the thigh for a total of twelve sessions, of which three per week for the

first two weeks and two per week for the other three weeks, making checks every six sessions to evaluate the effect of the treatments and possibly adapt the protocol to new situations.

Each session lasted 40 m according to protocol which indicated in the anterior region of the thigh the treatment of the adductive zone, the

lateral band, the quadriceps and the anterior tibial zone, as well as in the posterior region of the buttock, the lateral band, the gastrocnemius and plantar fascia. All treatments were carried out in a caudocranial direction; the recommended frequencies were 80, 110 and 130Hz, repeated in the same area three to five times (69, 70).

Evaluation of results

To evaluate the results, the TCD Code with the final correction factor was used. The values of the different TCD codes were recorded before, after six sessions and at the end of the treatments,

adding the final correction factor and evaluating the percentages of improvement or a possible worsening of cellulite.

Results

The results highlighted a significant clinical and aesthetic improvement, confirming the scientific value of the methodology used and the

practical utility, even statistical, of the TCD Code assessment test.

TCD Code

Before the treatments, TCD Code of twenty patients was evaluated, with a variance of a minimum of 19 and maximum of 34, from second to fourth Curri Scale, with an average of 27.55 (i.e. in blue in Fig. 3).

The intermediate TCD code was evaluated after six sessions, which showed a minimum of 18 and a maximum of 32, then from a second to the third stage of Curri, with an average of 23.55 (p.ex. in orange in Fig. 3), while at the end of the treatments the TCD code showed a minimum of 11 and a maximum of 29, then from a first to the third stage of Curri, with an average of 17.65 (p.ex. in green in Fig. 3).

We can observe the interesting decrease in the baseline TCD code number, which demonstrates an objective global improvement of the patients' cellulite, where it went from an initial average value of 27.55 (third stage of Curri) to a final TCD value of 17.65. (second stage of Curri), with an average improvement of the TCD code of 37.04% (Fig.3). On the right in Fig. 3, we can see the average reduction line of the TCD code; this is the expression of the average improvement of cellulite in the twenty patients.

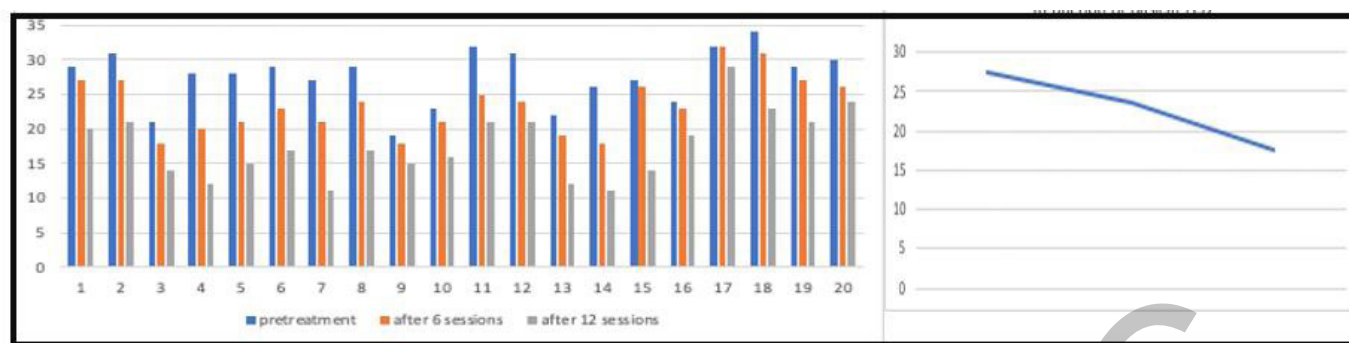


Fig. 3. Clinical and aesthetic improvement of cellulite evaluated with TCD Code.

The Correction Factor (CF)

The Correction Factor “CF” is the expression of the patient’s judgment and is added or subtracted from the baseline of the TCD code. The Correction Factor is based on two questionnaires: the VAS-A, which reports the assessment of each patient about her cellulite before the treatments, the VAS-B, which reports the patient’s assessment at the end of the treatments; in both questionnaires, the VAS scale is used from 1 to 10.

In the present study, the VAS-A questionnaire shows an average value of 6.35, revealing “annoying and unsightly cellulite”. In contrast, the VAS-B questionnaire reports the patient satisfaction by the performed treatments, with an average value of 7.45, which can identify a definable improvement with “much-improved cellulite and light legs”. (Table II).

Table II. Clinical and aesthetic improvement evaluated with TCD Code and FC correction factor.

TCD1	TCD2	TCD3	VAS A	VAS B
1	29	27	20	6
2	31	27	21	7
3	21	18	14	5
4	28	20	12	8
5	28	21	15	6
6	29	23	17	5
7	27	21	11	8
8	29	24	17	7
9	19	18	15	4
10	23	21	16	4
11	32	25	21	7
12	31	24	21	9
13	22	19	12	5
14	26	18	11	4
15	27	26	14	7
16	24	23	19	5
17	32	32	29	9
18	34	31	23	8
19	29	27	21	6
20	30	26	24	7
	27,55	23,55	17,65	6,35
				7,45

$$\bullet 6,35 - 7,45 = -1,1$$

-> Correction factor

$$\bullet 17,65 - 1,1 = 16,55$$

-> Final TCD

In Table II, on the left, we can see the evolution of the treatments, with the column of TCD1 that reports the TCD Codes detected before the treatments, TCD2 that reports the TCD codes detected after six sessions, TCD3 that reports the TCD codes detected at the end of the treatments. At the base of the columns, we can see the

The TCD-CF Code

Using the formula of the Correction Factor "VAS-A minus VAS-B", we obtain " $6.35 - 7.45 = -1.1$ ", a negative number we must subtract from baseline TCD; So, by removing the CF number " -1.1 " from the TCD number " 17.65 ", we obtain

numerical average of the different TCD codes in the various phases of treatment, indicating the average value of the state of cellulite in the 20 patients. The columns of the VAS-A and VAS-B indicate the values of the questionnaires in detail and the final global average.

a final TCD-CF with a result of " 16.55 ", which demonstrates a further objective and subjective improvement of cellulite after the Endosphères Therapy, with an average reduction of TCD-CF Code of 40.145% ($p < 0.05$) (Fig. 4).

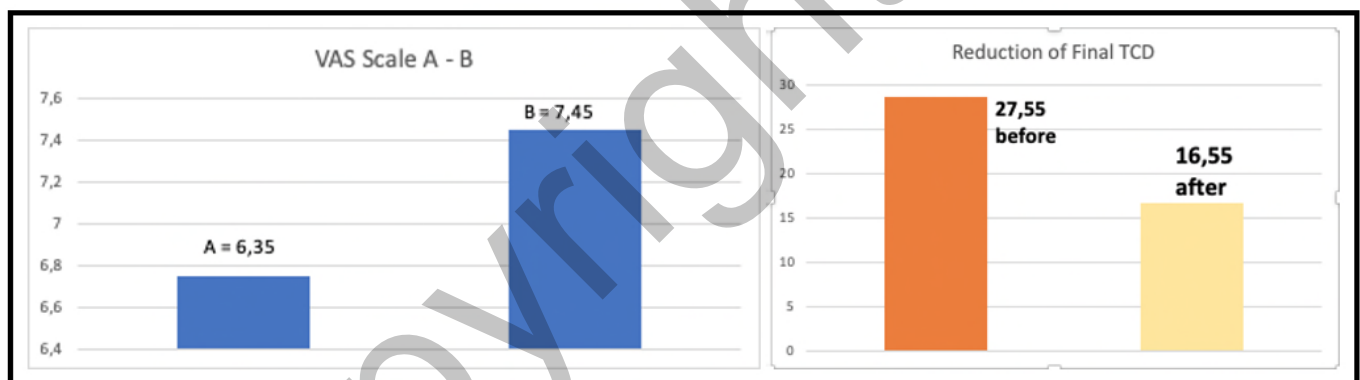


Fig. 4. At the left the patient's questionnaires VasA-VasB, at the right the final TCD/CF Code.

Discussion

In the discussion of the present study, we have to consider three key points: cellulite, the therapy

used and the evaluation test.

Cellulite

Cellulite is a female aesthetic pathology characterized by an evolutionary fibroedema caused by a reduction in mitochondrial activities

and microvascular oxygenation, venous lymphatic stasis, and degenerative processes that alter the quality of the adipose and lead to fibrosis in the

connective tissue. The causes of cellulite are to be found in hormonal alterations, in the pollution of the interstitial matrix due to food excesses, heavy metals, sedentary lifestyle, overweight, intestinal dysbiosis and endocrine-adipose alterations, finally in the altered physiological purification of the extracellular matrix.

The so-called “ECM – ExtraCellular Matrix” is the largest organ in the human body and the site where the most important physiological reactions useful

for life take place, its most important feature is “plasticity”, that is the ability to adapt to various situations by modifying the functional actions of cells. When this characteristic is altered, since its organoleptic structure tends to stiffen, passing from a “sol” form to a more “gel” one, the ageing processes of the tissues are activated, including the formation of lipodystrophy, the evolutionary female fibroedema of the so-called cellulite.

Therapy

Endosphères Therapy has shown that it can promote the slowdown of degenerative processes thanks to greater vascularization and an increase in the temperature of the tissues, with better oxygenation and adipose regularization, with better metabolic activity. Furthermore, the mechanism of action used by the rotating spheres of the “Compressive Microvibration” facilitates the remodeling of the skin and connective tissue, thanks to the physiological restructuring of the tissues that brings lightness to the legs, reduces pain and also improves the aesthetic appearance (71-72).

Among the most interesting effects of the “Endospheres Therapy” there is an important lymphatic drainage action, a significant vascularization of the tissues with an increase in skin temperature, a reduction of the superficial adipose tissue with a restructuring of the tissue trophism of the thigh and lower limbs, a constant reduction of pain with reduction of inflammatory processes, finally the improvement of cellulite blemishes.

The action mechanism is based on the rotation

speed variation of the rotating spheres of soft silicone, which are contained in the operator's cylinder and which, in rotation on their axis, produce micro-vibrations that are transmitted to the tissues. The rotation speed variation creates different frequencies that can vary from 30 to 450 Hz (TsT), where TsT is the estimated treatment time on each point, which changes according to the advancement movement of the handpiece in the different indications.

In addition to the “rotation speed” that creates the typical microvibrations, the “direction of rotation” of the spheres and the “direction of movement” of the operating cylinder are also associated, these actions facilitate the lymphatic drainage. At the same time, the vibratory frequency transmitted to the tissues, together with the pressure exerted by the handpiece, transmits to the tissues a “compressive microvibration” that carries out a complex pulsed and rhythmic action, with a “positive/negative pump” effect which is the basis of the main vascularization and stimulation effect obtained thanks to the stimulation of the mechanoreceptors. This methodology is

used for the non-invasive therapy of painful neuromuscular pathologies, but above all for the clinical and aesthetic treatment of cellulite,

lipodystrophy, lipoedema and lipolymphedema; the present study has confirmed the main effects of Endosphères Therapy.

Evaluation test

The documentation of the classification of cellulite and the stage of aesthetic pathology treated, together with the documentation of the therapies carried out, is important, both in the control of the results of the treatments and in the doctor-patient relationship or any disputes, the TCD code allows to keep this documentation with significant validity. It is very useful in daily practice to control the treatments carried out.

The main advantage of this code is the possibility of obtaining a number that can be recorded, standardized, compared, and statistically studied. The relative ease of testing is another added value, together with simple and inexpensive equipment. The limits can be found above all in thermography, which requires precautions

to be well performed, or in the patient's responses that can sometimes be affected by the psychoemotional state in the acceptance of cellulite. In any case, if the doctor compares well the patient's answers and the clinical expression of the pathology in question, the numbers will certainly have greater validity. Although the test is useful and has a clinical validity, the limitations lie in the different interpretations of the concept of "cellulite", which too often is seen only as a "skin pathology", instead of a complex and evolutionary aesthetic pathology that requires a precise and meticulous clinical diagnosis. In these terms, the TCD code can have great clinical and statistical validity.

Conclusion

One of the greatest difficulties in diagnosing and treating the aesthetic pathologies of cellulite, in its various forms and stages, is the classification of different forms and the evaluation of the results, which are almost always left to photography and thermography on a plate with liquid crystals. The proposal presented by Bacci in 2003 on the TCD Code proved to be interesting and was also used by other authors, even with improvements and adaptations that do not change the baseline principles of the TCD Code.

The TCD Code primarily investigates the vascularization of tissues by seeking thermal

variations with the reduction of cold hypoxic areas to improve microcirculatory harmonization; in this sector, the TCD Code has high reliability, especially if linked to the semeiological clinical diagnosis.

The second datum is the evaluation of pain, and the changes that occur with the treatments, the VAS scale used is now considered valid and is of daily use in painful syndromes, but also for the evaluation of the heaviness of the more or less edematous lower limbs. Finally, the classification with the Vas Scale for the visibility of cellulite carried out by the doctor proved to be useful

and, above all, significant in its symptomatic and pathophysiological connections. Finally, the numerical value of the TCD is the sum of these three factors, each of which has a precise value and expresses a precise alteration, for which the final evaluation has both an indicative value and a diagnostic content.

The possibility of adding a "Correction Factor" based on the "improvement/worsening" of the subjective symptoms and perception of cellulite that the patient herself reports offers an additional numerical value which, added or subtracted from the numerical value of the TCD Code, allows to have a subjective and objective

picture of the state of cellulite and the effects of the treatments carried out. Therefore, these final data are very useful in the management of the treatments carried out and in the "doctor / patient" relationship of trust, as well as in the management of documentation and statistical data. The relative ease and repetitiveness are finally an added value of the TCD-CF Code.

There are various proposals for the classification of cellulite; each one has its usefulness according to the purposes the doctor wishes to obtain; the TCD-CF code is especially useful in the daily management of therapies and statistical studies; thanks to an easily obtainable final number.

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