Doctor Marisa Mosca
Specialist in allergology
Specialist in dermatology

Doctor Claudia Rona
Specialist in pharmacology

EFFECTIVENESS EVALUATION OF A SLIMMING AND ANTI-CELLULITE GARMENT

Aim of the study

The study was carried out in order to verify the effectiveness of a transpiring and hypoallergenic garment, made in Texenergy fabric, in having slimming and anti-cellulite effects.

Reasons for the study

Edematous-fibrosclerotic panniculopathy, which is generally called cellulite, is a very common ailment that shows itself through the appearance of "orange peel" or "mattress-like" skin on the affected areas and that is caused by a change in microcirculatory and lymphatic systems. These systems become less effective and this results in edema formation and subsequent damage of the dermis fibrous component because of the sclerotic degeneration of fibres and of their impaired metabolism. There is also an altered trophic reaction of fat cells to neuroendocrine stimuli together with edema and to vascular and connective tissue damage. The situation may be made worse by the accumulation of toxins and compounds that have not been metabolized, such as sugar, lipids and proteins that get stored in fat cells as triglycerides. The ailment entails a related damage of the lipolytic system as well.

The reason for the use of a garment exploiting the benefits of metallotherapy for the treatment of cellulite lies in the properties of the fabric it is made of. To be more precise, the fabric has been patented and it exploits minerals' therapeutic potentialities through the copper, zinc and silicon yarns that are interwoven in it.

Copper and zinc together create an infinitesimal current that provokes a kind of biostimulation aimed at restoring microcirculation and at removing accumulated liquids and fat, while silicon acts as a conductor and, at the same time, it protects the skin by keeping it naturally healthy.

Features of the study

The study, the duration of which was fixed to be 8 weeks, was carried out on 21 people of female sex, aged between 21 and 65, on whose thighs cellulite had developed from stage 1 to 4. The volunteers were selected according to precise criteria:

Inclusion criteria

- Women aged between 18 and 65, in a general state of good health
- Women that had not shown any hypersensitivity to any component of the above-mentioned garment and any hypersensitivity in general.
- Women that had stopped any other topical treatment on the examined parts for at least a week, and that did not change their eating or physical activity habits.
- Women that agreed not to use/wear any other product claiming to have anti-cellulite properties for the whole duration of the study.
- Women that did not have any lesion on the examined parts, lesions that could interfere with the evaluations to be carried out.
- Women that accepted to sign a consent to undergo the test.

Exclusion criteria
- Pregnant women
- Women that did not comply completely with inclusion criteria.

Every volunteer was given 3 garments.

The volunteers were instructed to wear the above-mentioned garment for at least 8 hours on end every day, for a period of 8 weeks.
The plan of the study involved the execution of three checks: before the beginning of the treatment, four weeks after the beginning of the treatment and at the end of the treatment.
Clinical and instrumental evaluations were carried out as described below.

Clinical evaluation
Carried out on the basis of a scale assigning the following points:

0 = no cellulite
1 = slight dimpling of the skin
2 = slight dimpling combined with hollow areas
3 = pronounced dimpling of the skin combined with an alternation of hollow bands
4 = hollow bands and nodules

The clinical evaluation was supported by measurements of the thigh circumference.

Instrumental evaluation
During the study non-invasive methodologies of skin bioengineering were used to check some of the skin biophysical features on which the garment should have had an effect in order to fulfil its function.

Echography – to evaluate the reduction of the hypodermis thickness. This technique
permits to assess the thickness of the different components of the skin and, as a consequence, to monitor over the time possible local situations of thickening and/or atrophy. This instrument works on the basis of the following physical principle: when an ultrasound beam passes through structurally different parts of tissue, echoes are produced that differ according to the acoustic features of the examined areas; the echoes produced are recorded by the instrument and represented as bands. The distance between the bands stands for the thickness of the different components that have generated them.

Elastometry – in order to evaluate the skin biomechanical features, the instrument (cutometer) performs a series of suctions/relaxations on the area to be measured. A software processes and represents these data as curves from which the parameters to be examined are extrapolated. They are:

r_0 – skin stretchability, a parameter that is inversely proportional to the skin tone and, as a consequence, to the quantity and quality of the dermis collagen fibres. It represents the maximum height the skin gets to at the end of a suction.

r_2 – skin elasticity, a parameter that is related to the quantity and quality of the dermis elastic fibres, and that represents the skin capability and rapidity to recover its original position after a stretching.

r_6 – viscoelasticity, a parameter that is related to the quantity and quality of the dermis fundamental substance and that represents the skin capability to adapt itself to articular movements.

Laser Doppler flowmetry – in order to measure the skin microcirculation. The instrument is based on the Doppler effect: when a laser light hits a still object, it is reflected at the same frequency as the one it was emitted at, while, if the object is moving, the laser light frequency changes if compared to the frequency it was emitted at, and the change is proportional to the speed the object is moving at. In particular, the speed at which red blood cells move is directly proportional to their number and, as a consequence, to the size of the flow.

Thermography – in order to evaluate the local skin temperature. In fact, anti-cellulite products should improve superficial microcirculation and, as a consequence, local temperature. Thermography is an electro-optical method to represent temperature: it is a technique that, by means of a probe equipped with thermal contact sensors, makes possible the detection of the heat produced by the body as infra-red radiations and the registration of the skin temperature by the real time creation of the relevant colour thermogram, where black-blue indicate the lowest temperatures and red-white the highest ones.

The instrumental evaluation was carried out in standard temperature and humidity conditions, and after an acclimatisation time of about 20 minutes.
The evaluations were always carried out on the same points for each person that had been selected, that is to say on the reference points calculated on the basis of the distance between the antero-superior iliac spine and the point of the thigh where cellulite was the most evident. The distance in cm was recorded in the file of every person, so that the researcher could take the measurements on the same points during the following checks.

Statistical analysis and results

The study aimed at verifying the following primary *end point*:

► *slimming action*, evaluated on the basis of the improvement of the echographic data. The choice of the primary end point depends on the measurement reliability and on the parameter pertinency. The measurement is accurate on the basis of:
- Literature evidence
- The fact that the evaluation is always carried out by the same researcher
- The fact that the evaluation is always carried out on the same points (reference points).

Then, the following secondary end points were verified:

► *action of stimulation of the skin microcirculation*
► *action of increase of local temperature*
► *action of stimulation of biomechanical features*

The statistical analysis of the data was carried out with the Student test for non coupled data.

Results

The results are explained below together with the statistical significativity level that, for most of them, was satisfying even after 4 weeks of treatment, thus showing a quick slimming effect.
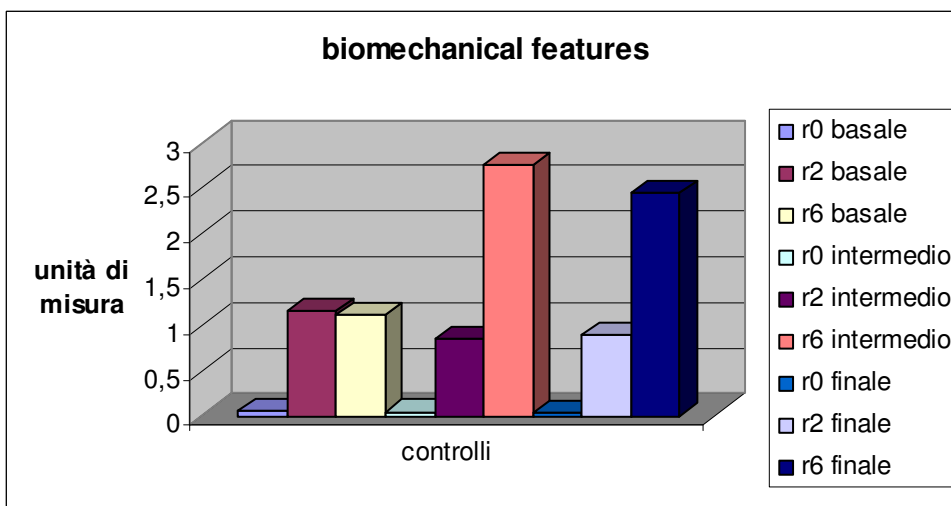In particular:

thigh circumference
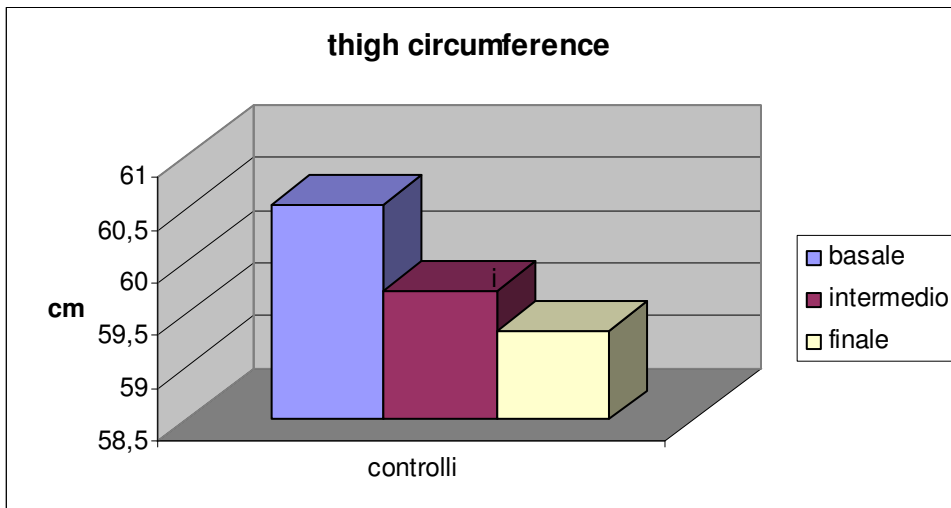
Captions:
CONTROLLI = CHECKS
BASALE = INITIAL
INTERMEDIO = INTERMEDIATE
FINALE = FINAL

THE PARAMETER DECREASED SIGNIFICANTLY EVEN AFTER 4 WEEKS OF TREATMENT.

4 WEEKS: $p = 0.00000249269$
8 WEEKS: $p = 0.00000143194$

biomechanical features

Captions:
CONTROLLI = CHECKS
BASALE = INITIAL
INTERMEDIO = INTERMEDIATE
FINALE = FINAL
UNITA' DI MISURA = MEASUREMENT UNIT

*The stretchability value (r0) is expected to decrease since it is inversely proportional to the skin tone.*
The elasticity value (r2) is expected to increase since it is a direct measure of biological elasticity.
The viscoelasticity value (r6) is expected to increase since it is a measure of the skin overall quality.

In particular:
STRETCHABILITY AND ELASTICITY PARAMETERS REVEAL A POSITIVE IMPROVEMENT TREND, ALTHOUGH NOT STATISTICALLY SIGNIFICANT; VISCOELASTICITY PARAMETER REVEALS A STATISTICALLY SIGNIFICANT INCREASE EVEN AFTER 4 WEEKS.

4 WEEKS: $p = 0.000136$
8 WEEKS: $p = 0.0000297$

thickness of the subcutaneous layer
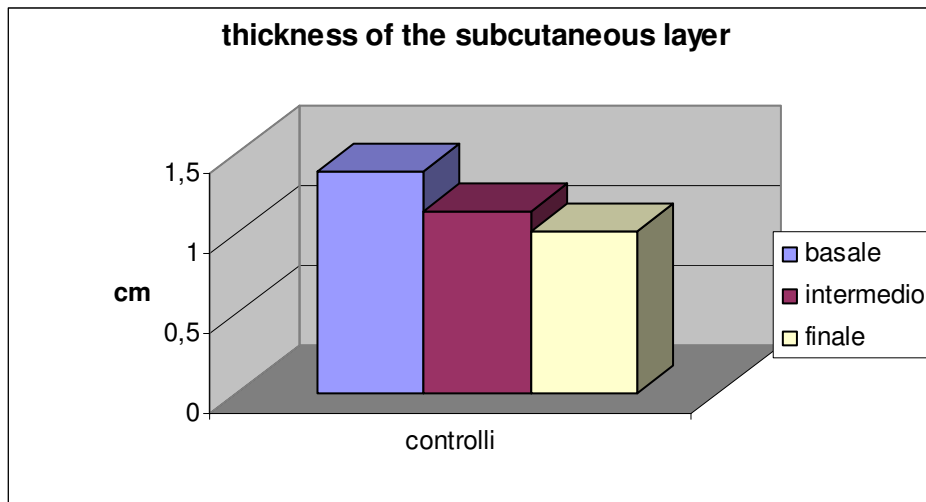
Captions:
CONTROLLI = CHECKS
BASALE = INITIAL
INTERMEDIO = INTERMEDIATE
FINALE = FINAL

ECHOGRAPHIC DATA DECREASED SIGNIFICANTLY EVEN AFTER 4 WEEKS OF TREATMENT.

4 WEEKS: $p = 0.00046336$
8 WEEKS: $p = 0.000513848$
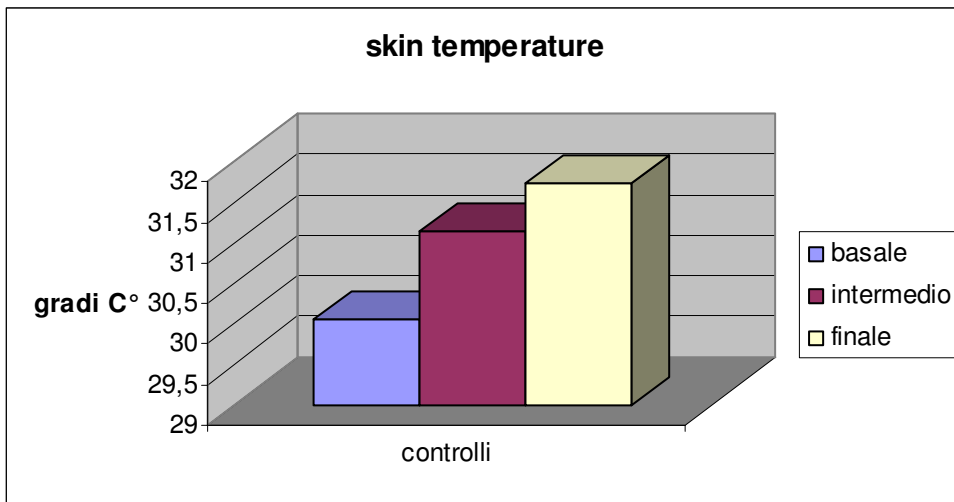
skin microcirculation
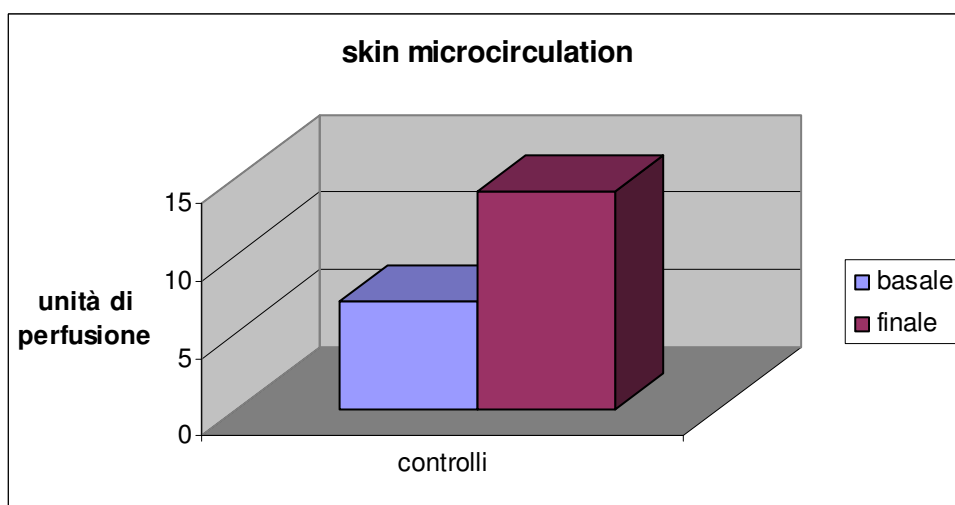
Captions:
CONTROLLI = CHECKS
BASALE = INITIAL
FINALE = FINAL
UNITA' DI PERFUSIONE = PERFUSION UNIT

THE PARAMETER INCREASED SIGNIFICANTLY AFTER 8 WEEKS OF TREATMENT.
8 WEEKS: p = 0.00000062121

skin temperature

Captions:
GRADI C° = C° DEGREES
CONTROLLI = CHECKS
BASALE = INITIAL
INTERMEDIO = INTERMEDIATE
FINALE = FINAL

IN ACCORDANCE WITH LASER DOPPLER FLOWMETRY, THERMOGRAPHY REVEALED A SIGNIFICANT INCREASE IN LOCAL TEMPERATURE EVEN AFTER 4 WEEKS.
4 WEEKS: p = 0.000306
8 WEEKS: p = 0.000906901

The ___clinical evaluation___ revealed a statistically significant reduction of cellulite appearance even after 4 weeks.
4 WEEKS: p = 0.000000300656
8 WEEKS: p = 0.0000000386611

clinical evaluation
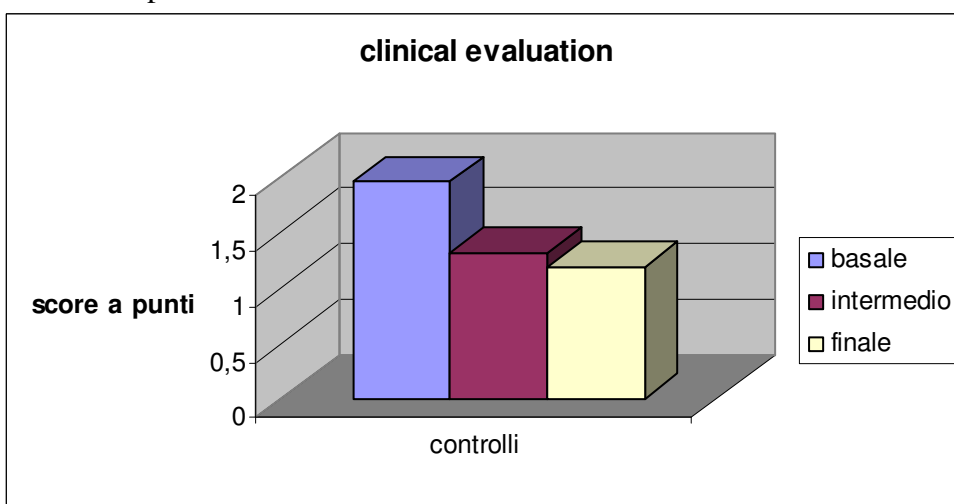
Captions:
SCORE A PUNTI = SCORE
CONTROLLI = CHECKS
BASALE = INITIAL
INTERMEDIO = INTERMEDIATE
FINALE = FINAL

**Autoevaluation**, carried out through a questionnaire that the volunteers had to fill in, showed that the subjects had noted a slimming and anti-cellulite action and that they had not complained about any nuisance. On the contrary, they had stressed the lack of excessive perspiration on the affected parts and the comfort in wearing the garment, under close-fitting clothes as well.

As to tolerability, the product did not cause any adverse reaction.

Conclusions

The study carried out made possible the collection of both subjective clinical and objective instrumental data about the capability of the examined product to have a slimming and anti-cellulite effect. None of the people under examination complained of itches, burning sensations or other symptoms that could be related to the use of the examined garment.

The subjects' compliance to the treatment was completely satisfactory even in very hot days.

From an instrumental point of view, a significant improvement of all the parameters under examination was noted: the thickness of the subcutaneous layer decreased; among the biomechanical features, i.e. those linked to the quality of dermis, which is the skin support tissue, viscoelasticity, in particular, increased very significantly; moreover, the garment helped to improve microcirculation, in accordance with thermographic data, which revealed an improvement as well.

Most of the subjects examined at the beginning of the treatment, after 4 and 8 weeks showed a firmer skin, with a reduction of the so-called "orange peel" skin.

As a consequence, we think it fair to conclude that the garment we examined can be a valid support in the treatment of cellulite affecting lower limbs.

Pavia, June 3rd 2003

People in charge of the study

Doctor Marisa Mosca   Doctor Claudia Rona

[signature]   [signature]

Bibliography

1) C. Rona, E. Berardesca (1999)
    Anticellulite – In: Cosmetics, controlled efficacy studies and regulation
    Cap. 13 – Springer Verlag ed. – Germany
2) Lucassen GW, van der Sluys WLN, et al (1997)
    The effectiveness of the massage treatment on cellulite as monitored by ultrasound imaging.
    Skin Res technol 3: 154-160
3) Serup J (1995)
    Skin imaging techniques in bioengineering and the skin: methods and instrumentation. CRC
    Press, Boca Raton pp. 65-79
4) Bernardi L, Berardesca E (1995)
    Measurements of skin blood flow by laser doppler flowmetry in bioengineering and the skin:
    methods and instrumentations. CRC Press, Boca Raton, pp 13-28
5) Sherman RA et al (1996)
    Comparative effectiveness of videothermography and infrared beam thermography for scanning
    relative skin temperature.
    J Rehabil Res Dev 33 377-386
6) Elsner P (1995)
    Skin elasticity in bioengineering and the skin: methods and instrumentations. CRC Press, Boca
    Raton, pp 53-64
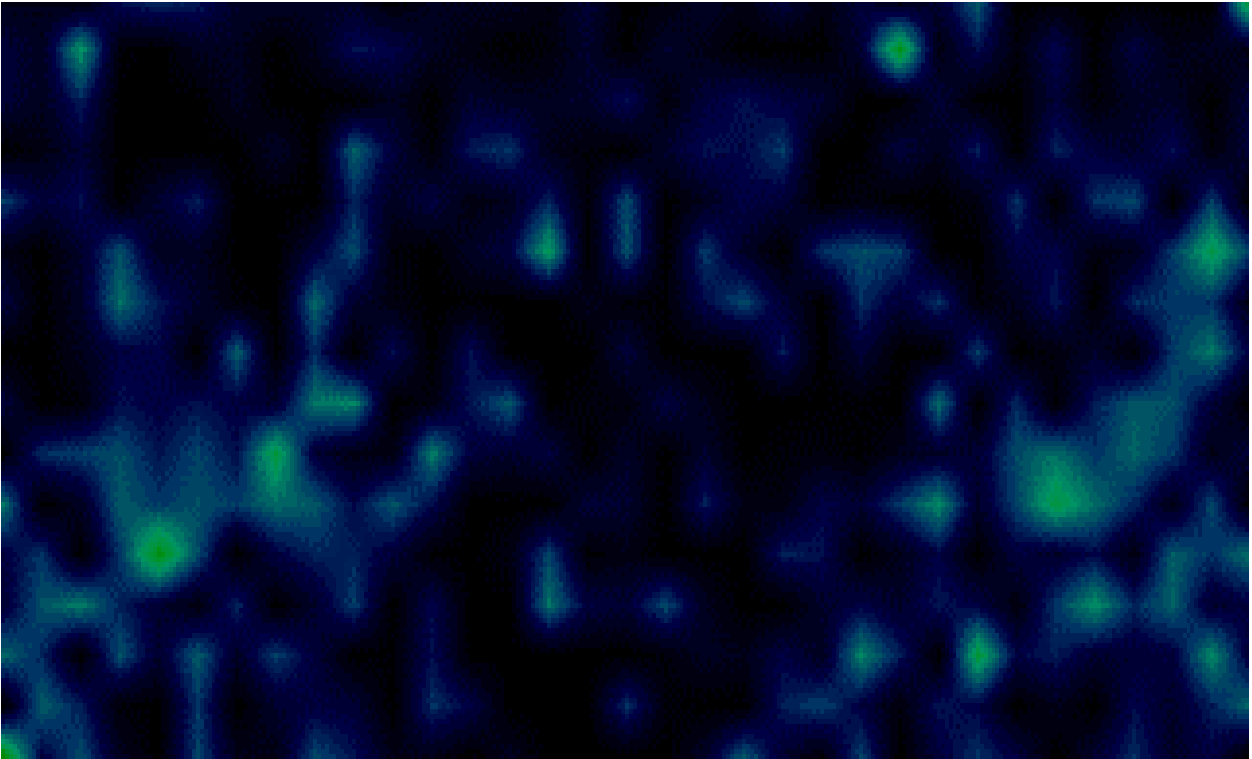
Authentication of the study

The undersigned, Dr. Marisa Mosca and Dr. Claudia Rona, in charge of the evaluation, declare on their own responsibility that the test was carried out according to the principles of good clinical practice and of the Helsinki Declaration (1989).
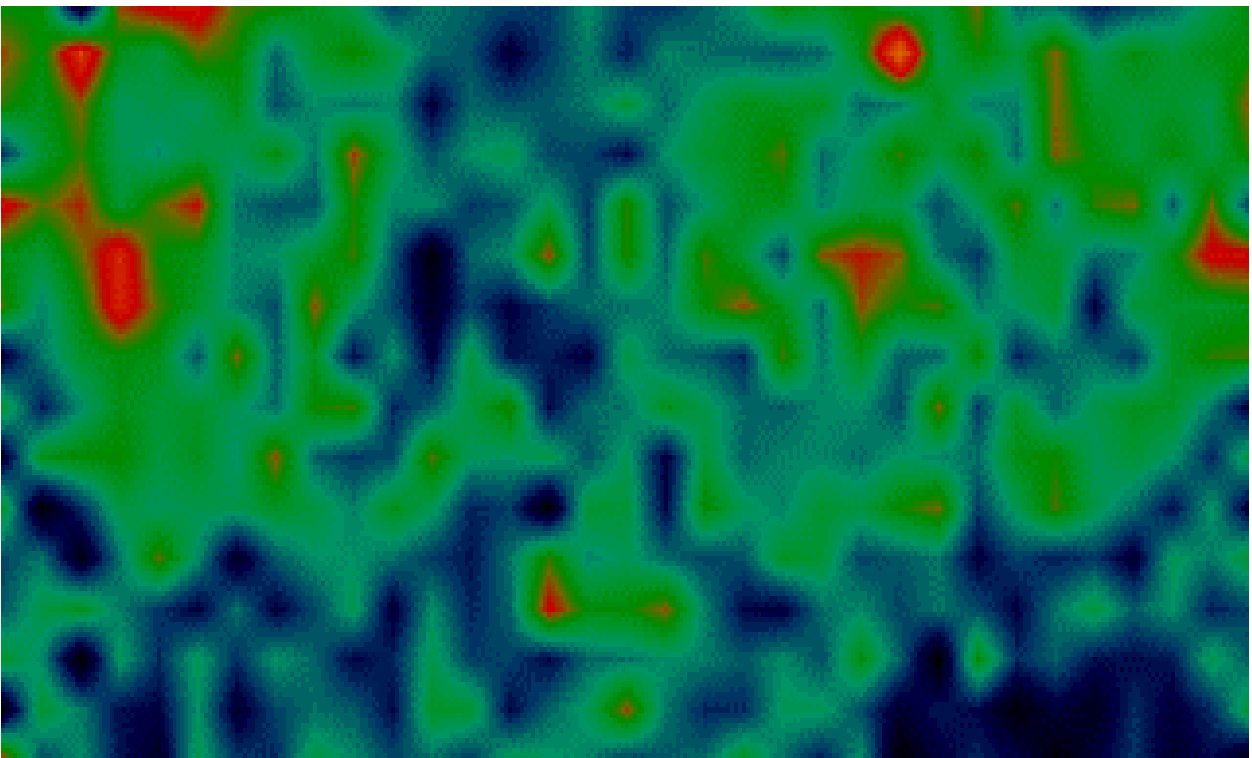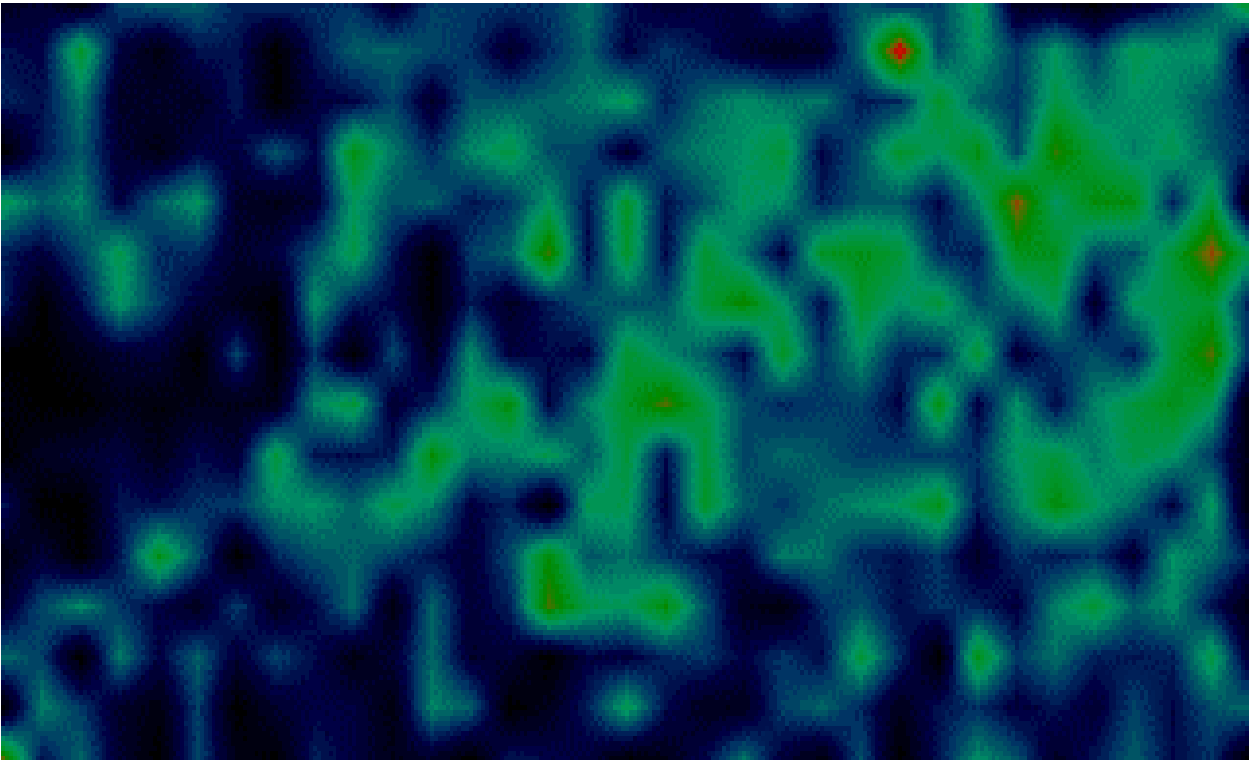
Pavia, 3rd June 2003

THERMOGRAMS

FIRST CHECK

SECOND CHECK

FIRST CHECK

SECOND CHECK