

**Clinical study for the effectiveness of the FORMOSTAR[®] in depth thermal treatment for weight
(and size) loss and degenerative joint and spinal column illnesses
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Introduction and literature-practices review

Heat irradiation, in its most diverse form, has been used in internal medicine, Gynecology and Orthopaedic Medicine. In addition, heat has long been used as a therapeutic measure (2, 6, 12).

Thus it has been used for example in the treatment of partially and chronically degenerative inflammatory since the beginning of the 20th century under more or less clinical conditions (11, 17). And for some years heat has been used even in tumor therapy (10, 13, 20).

The thought to use local heat treatment, in whatever form, for weight reduction is not new. On examination of the metabolic functions of over-weight persons, it was found that the heat effect increased basic conversion and thus higher energy consumption occurs, with a consequent decrease in weight (24).

In more recent times it has been found that local heat therapy finds an even broader application with the treatment of Cellulitis.

The objective of this study was to determine the effectiveness of infrared heat treatment, with the help of a commercial deep heat system named FORMOSTAR. At the same time, it is to be examined as to what extent the equipment can be used for other medical purposes. For this, patients with inflammatory joint conditions took part.

First however we would like to review current literature on the subject of heat therapy:

Generally, heat therapy is harmless, as long as it is used in the context of subjective well-being, and no secondary side effects are to be expected (1, 7, 9)

The opinion today, for the effectiveness of heat therapy, is that is the result of a disturbed energy balance (3, 14, 21, 22, 24).

One study proved that the mechanism for weight reduction, by the use of heat treatment, is the conversion of the energy from food intake into heat which is then radiated from the body. This appears to be as a result of the fact that the enzyme activity of the fat cells is lowered (4)

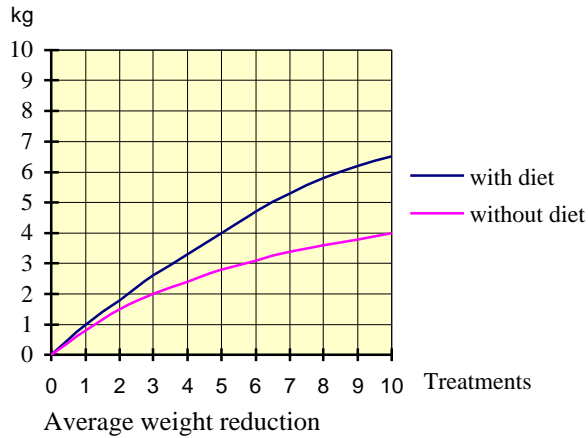
Also, the heat treatment results in increased blood circulation and a rise in the body's metabolism leading to a change in cellulose (3, 10, 14, 19, 21, 22, 24).

1. By local heating, the internal thermal receptors lead to increased heat emission steered by the hypothalamus, i.e. more energy consumption (9, 19).
2. By the heating up of the skin and the fatty tissue under the skin, the blood circulation is increased up to 3.5 times. (19, 20).
3. Both experimentally with animals and with humans it was shown that there was increased elimination of fats due to local heat therapy (5, 12, 20).

Heat therapy has been used effectively on acute and chronic inflammatory illnesses.

1. Degenerative diseases react well to heat because of the relaxation of the muscles and the analgesic effect of the heat.
2. The therapy was used to a large extent with older and more difficult to move patients (2, 6, 8, 11, 15, 16, 17, 18, 23).

Graph of average weight reduction - with diet (mit diat) and without diet (ohne diat). In Kg's of weight loss on the Y axis and number of treatments on the X axis.



Material and method

In the weight study project we used 12 subjects that submitted to the treatment cycle at 10 meetings. Of these 12, six were also subjected to a calorie reduced diet.

In the degenerative joint study, 6 groups submitted to a treatment cycle at 5 meetings. Additionally, two groups were also studied with acute inflammatory illnesses and two groups with no degenerative or inflammatory diseases but with a desire to try the heat treatment.

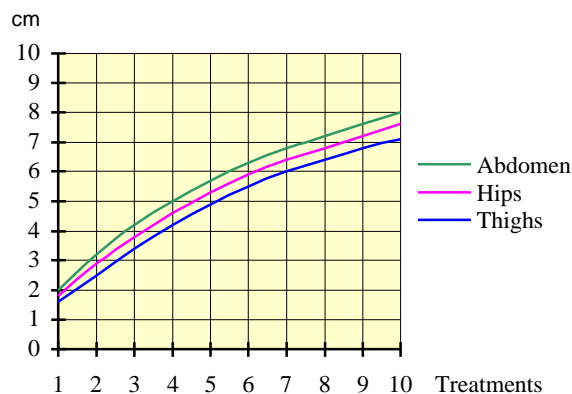


Graph of average cm's lost without diet for the abdomen, hips and thighs shows cm s lost on the Y axis and number of treatments on the X axis.

The disease picture covered 5 degenerative spinal column illnesses and 3 knee joint illnesses, of which 2 was inflammatory. As treatment equipment a FORMOSTAR served as deep heat equipment (manufacturer: electro medical tool-making GmbH Hamburg) with body wraps, with which the groups were wound. A humidity gel was used to avoid skin irritations.

For the weight program, the heat treatment was for 50 minutes at each meeting. The session length for the other group was 30 minutes.

Before and after each treatment, for both groups their pulse rate and blood pressure was recorded. For the weight study, height and weight were recorded and for the degenerative diseases study, joint mobility was also recorded.



Average loss with diet

Graph of average cm's lost with diet for abdomen, hips and thighs shows cm s lost on the Y axis and number of treatments on the X axis.

Moreover, in order to detect any possible effect of the treatment, the following laboratory parameters were checked:

Weight Study:

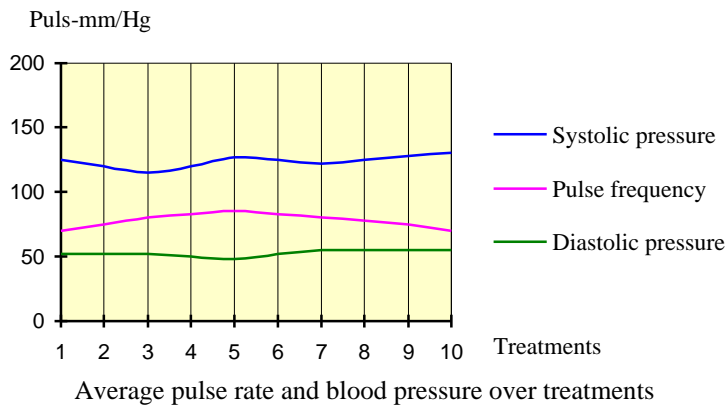
- Blood picture
- Blood sedimentation

Joint illnesses:

- Blood picture
- Blood sedimentation

Transaminasen
Cholesterol
Triglycerides

The age of both groups ranged between 25 and 73 years, with mostly males in 5 of the groups and mostly females in 7. The average elapsed time for the weight group was 21 days and 12 days for the other study.



Results

Group 1 Weight Study:

Clinical laboratory parameters:

Laboratory controls of blood - picture and blood sedimentation, trans fatty acids, cholesterol and triglycerides showed that these values were all in the standard range.

Group 2 Degenerative illnesses Study:

Blood sedimentation at the beginning of the study was 15/28 mm water guage and at the end it was almost unchanged at 12/28 mm.

The blood picture remained almost unchanged during the treatment.

Also no rising of the body core temperature was recorded.

Refer results graphs above.

Discussion

In this study of deep thermal treatment, weight loss conditions were examined under clinical conditions for the first time.

With a control group, the results present themselves as follows:

1. With the application of local heat treatment of the subcutaneous fatty tissue, even in a relatively short period of 20 days, a significant weight reduction is reached.
2. If the patient also engages in a reduced calorie diet during the heat therapy, the weight loss is accentuated.
3. Under the treatment, female patients found most decreases in the thigh area, while male patients decreased evenly in all treated zones.
4. Degenerative changes of the holding and movement capabilities are improved by this therapy form.
5. The quantity of the supplied heat energy is large enough to cause the therapeutic effect, without any thermal damage to the organs or the metabolic process.
6. The treatment is subjectively problem-free. It should be recommended however that the patients are cardiovascular healthy and strong, since with 2 of our patients, both with a history of health problems, it was necessary to stop the process. It should be noted that no problems persisted after the heat treatment was stopped.

In summary it can be stated that heat treatment for the reduction of weight is effective and problem free. Also, for the treatment of orthopedic conditions, and particularly for athletes, heat treatment provides a meaningful measure of relief.

This deep heat therapy should not be used if the patient has any of the following conditions:

Thyroid hyperactivity, narrowing of the arteries, heart disease, pronounced high or low blood pressure, insulin requiring diabetes, abnormal body function disturbances, heavy general infections, skin diseases, fresh wounds or during pregnancy.

5. Summary

12 persons with weight problems and 8 persons with degenerative joint conditions that restricted movement, were submitted to a course of treatment with the Formostar™ infrared, deep heat apparatus.

Under clinical conditions pulse, blood pressure, blood picture, blood sedimentation and body temperature were measured; additionally in the group with weight problems, weight and the extent of the reduction was measured, as well as liver functions and cholesterol measurements. Joint mobility improvements were measured in the second group.

It was proven that the treatment resulted in significant weight reduction and substantial improvements in joint mobility.

For persons with none of the conditions listed above, the treatment caused no measurable side effects.

For the most effective treatment, it is recommended that the weight loss patients submit to a course of 10 sessions of approximately 50 minutes per session, with an interval of 2 to 4 days between treatments.

For mobility and joint problems, 5 sessions are recommended, each of approximately 50 minutes, with an interval of two to three days between sessions.

Thank you

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