

PRESOR-03

**STUDY ON THE EFFECTIVENESS OF USING
THE SORISA PRESSURE THERAPY**

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1.0. PRESSURE THERAPY

Pressure therapy is a method of treatment based on intermittent compression with air (pneumatic massage) to promote drainage.

Pressure therapy treatment is applied by means of boots/trousers, sleeves or a girdle worn by the patient, which are double-walled and compartmented into several pneumatic chambers. With the aid of a compressor, air is blown into these chambers at the correct pressure, such that they compress that particular part of the body, this pressure having a therapeutic effect. The compression promotes reabsorption of retained fluids and normalises or potentiates their drainage towards the body's organic filter mechanisms.

1.1. The physiological effects of pressure therapy

Pressure therapy performs a circulatory massage of the zones to be treated (usually the limbs) by activating the venous return and thereby

- promoting the reabsorption of interstitial fluid
- stimulating venous/lymphatic drainage

1.2. When pressure therapy is indicated

Because of its characteristics, pressure therapy is indicated especially for:

- Stimulating venous return.
- Lymphoedema and venous oedema.
- Post-operative oedema.
- Oedema due to trauma.
- Prevention of thrombosis in the bedridden.
- After cosmetic surgery, particularly liposuction, body contouring and hydrolipoclasia, to restore the area to normal.
- During surgery, to prevent thromboembolism.
- Poor peripheral circulation.
- Preventing varicose veins.
- Maintaining normal venous return.
- Relaxation.

2.0. OEDEMA

Of the situations mentioned above, the one that holds most interest from this study's viewpoint is the treatment of oedema, whether this be with regard to shortening its course of evolution or attenuating its effects.

Oedema is the excessive accumulation of seroalbuminous fluid in the cell tissues, which may be due to several reasons: too low an osmotic pressure due to insufficient plasma protein, too high a hydrostatic pressure in the capillaries as a result of heart failure, greater permeability of the capillary walls or blockage of the lymphatic vessels.

2.1. Origin of the oedema

The oedema may be of lymphatic or venous origin:

Lymphatic: known as lymphoedema, this commences proximally and uniformly, cannot be pinched between the fingers, affects the back of the foot, involves large volumes before pigmentary alterations occur, and shows pitting; there is no venous dilatation, the swelling does not go down after a night's rest, there is no ulceration, and it can easily turn malignant (skin cancer due to hyperacanthosis), occurring in elephantiasis or due to surgery, radiotherapy or family history. In the initial stages it is very soft, traumatic oedema which lends itself to surgical correction more readily than other types, and is normally unilateral (except when congenital). Interstitial plasma proteins are found (there is more induration than with venous oedema).

Venous: this commences distally and irregularly (hardened areas), does not affect the back of the foot, and at the moderate stage it already leads to changes in the pigmentation of the distal area of the limb; there is venous dilatation, swelling reduces a great deal or completely with rest, there may be ulceration or ulcer scarring, it is not prone to malignancy, is nonpitting, does not give rise to elephantiasis, is venous in origin (varicose veins, thrombosis) and is usually bilateral.

2.2. Treatment of oedema:

It is important to treat oedema, and particularly lymphoedema, not just because of its aetiology (original cause) but because of the protein stasis involved.

Treatment basically targets the cause and is supplemented with physiotherapy measures such as exercise, circulatory diversion massage, graduated support stockings or compression bandages and pressure therapy.

3.0. STUDY ON THE EFFECTIVENESS OF USING THE PRESSURE THERAPY UNIT IN THE TREATMENT OF OEDEMA

This study was conducted by the physiotherapy team of the Red Cross in L'Hospitalet, under the supervision of Mr. Isidro Redondo.

It is a phase IV explanatory study, that is, it is not aimed at proving the efficacy of pressure therapy itself but rather at objectifying the degree of efficacy obtained by using the SORISA pressure therapy unit in the treatment of oedema (of whatever aetiology), compared with traditional rehabilitation techniques and, at the same time, its effectiveness after prolonged treatment.

The variable studied was the reduction in centimetres of the perimeter of the limb treated, compared with a control group, and its evolution following several treatment sessions, both with regard to the commencement of the treatment and in comparison with the control group.

The secondary variables considered were treatment tolerability and any adverse events that occurred, as well as any possible cause of withdrawal from the treatment.

3.1. Evaluation of the response

This was done by comparing the mean reduction in centimetres of the perimeter of the limb treated in the study group, with that of the control group, in all the treatment sessions. The reduction per session and the reduction over time (by the end of the treatment) were looked at, the measurements taken at the first session being compared with those taken at the last session (in both cases the measurements were taken before the treatment was applied).

3.2. Sample size

This study was conducted over a period of 22 months in the physiotherapy department of the Red Cross in L'Hospitalet, so the sample size was conditioned to a great extent by the type of illnesses treated there. All cases, involving either the upper or lower limbs, that complied with the selection criteria and presented no exclusion criteria, were treated.

3.3. Selection criteria

Because so few cases are treated annually in the physiotherapy department of the Red Cross in L'Hospitalet, it was decided to treat both upper-limb and lower-limb oedemas in order to increase the number of subjects taking part in the study, so that the results could be extrapolated more easily to the general population.

3.4. Exclusion criteria

Any of the following conditions invalidated subjects taking part in the study:

- Recent thrombophlebitis or phlebothrombosis
- Skin infections
- Lymphangitis
- Inflammatory arthritis
- Gross external varices
- Cardiocirculatory decompensation
- Serious disorders in blood pressure, such as arterial hypertension
- Myocardial infarction
- Cellulitis (as such)
- Neoplasias (recurring and/or active)
- Heart failure
- Respiratory failure
- Kidney failure

Although pressure therapy is not contra-indicated in the following, they were nevertheless excluded from the study on ethical grounds:

- Children
- Pregnant women
- The elderly

3.5. Treatment applied

Thirty pressure therapy sessions were applied as an adjunct to the specific treatment of the cause of the oedema (aetiological treatment). The relevant measurements of the limb to be treated were taken both before and after each session.

All patients with oedema of the lower or upper limb, whether of lymphatic or venous origin, were treated, without changing the rest of the treatment prescribed by the physician.

The patients were advised to carry out, at home, the same supplementary measures as those recommended for the control group: bandaging, contrast baths and exercise.

3.6. Methodology

The pressure therapy unit provides four different treatment programmes, although only two were used for the trial in question.

Double treatment sessions were given, and in each one two different treatment programmes were applied consecutively: in stage A1 programme 2 was applied for 20 minutes, followed by stage A2 during which programme 3 was used for a further 20 minutes. Three sessions a week were carried out until a total of 30 sessions had been completed, except in those cases in which the oedema had disappeared before the end of the 30 sessions.

STAG E	PRG.	min.	secs. comp.	secs. disinf.	1	2	3	4	5	6	7
A1	2	20	15	15	90	85	80	75	70	65	70
A2	3	20	10	05	100	93	87	80	73	65	70

STAGE	PRG.	min.	secs. comp.	secs. disinf.	1	2	3	4	5
B1	1	20	15	15	55	52	48	45	44
B2	3	20	10	05	60	57	54	50	47

This table shows the gradient of baseline pressures used for each compartment. Compartment 1 corresponds to the sole of the foot and 6 and 7 correspond to the abdomen, these latter two being applied with an inverse gradient in order to drain the lower part of the abdomen at the level of the groin. In each case, depending on progress, the pressures were gradually increased.

3.7. Control group

In any scientific study the control group is of the utmost importance. It is not subjected to the technique under study but serves as a reference for the trial group, in order to ascertain which of the two groups offers better results. This shows whether the technique studied gives better, identical or worse results than the usual treatment technique.

The following usual techniques were used with the control group:

- Contrast baths
- Leduc drainage
- Circulatory diversion massage
- Leo Burger exercises (with elevation of the limb to different levels and mobilisation of wrist or ankle).
- Bandaging

They were also given a number of measures to follow at home, such as: bandages, contrast baths and exercises (these were the same as for the patients who underwent the pressure therapy).

As the population to be studied was not very large, it was decided to use a smaller control group than the study group, chosen at random.

4.0. RESULTS OF THE STUDY

The results obtained after working for over 2 months with 25 patients divided into two groups – the trial group and the control group - are set out below. The mean loss in cm per session after over 500 sessions is as follows:

LOSS PER SESSION	PRESSURE THERAPY (all*)	PRESSURE THERAPY (cases completed correctly)
Measurements taken	4114	3756
Reduction in cm	758.5	675
Mean loss per session	0.3687	0.359

	CONTROL CASES (all*)	CONTROL (cases completed correctly)
Measurements taken	522	492
Reduction in cm	121.5	120
Mean loss per session	0.465	0.487

These figures show that the loss per session, that is, between before and after the treatment, is slightly better in the control cases. However, this changes when the loss maintained at the end of the treatment is compared with the beginning of the treatment, that is, the perimeter at the first session before application of the treatment, minus the perimeter at the last session before application of the treatment.

FINAL LOSS	PRESSURE THERAPY (all*)	PRESSURE THERAPY (cases completed correctly)
Sum of total mean losses	21.441 cm	21.551
Mean loss	1.07	1.347

	CONTROL (all*)	CONTROL (cases completed correctly)
Sum of total mean losses	2.278	1.112
Mean loss	0.569	0.370

As can be seen, the long-term results are much better in the subjects that underwent pressure therapy than in the control subjects. The loss maintained between the beginning and the end of the treatment (measurements taken at the first and last session, in both cases before application of the relevant therapy) is 1.88 times greater for pressure therapy than for the control cases when all cases are taken into account (including withdrawals), and this ratio increases to 3.6 times when one considers only those cases which have completed the treatment according to the protocol.

(*) "All cases": all the measurements taken were included, since whether or not the thirty sessions were completed makes no difference to the acute effect (loss per session) noted. It was considered pertinent to take these results into account.

The loss maintained at the end of the treatment with PRESSURE THERAPY is 3.6 times greater than that shown in the control group.

It is well known that lymphoedema secondary to lymph node removal is difficult to cure owing to the anatomical defect. In comparing oedemas resulting from trauma, the total loss in cm is much greater in the subjects treated with pressure therapy than in the control subjects: the mean loss in trauma oedema treated with pressure therapy is 1.575 cm, whereas in the control subjects it is 0.370, the ratio being 4.26 times greater in favour of the pressure therapy group.

The loss maintained at the end of the treatment with PRESSURE THERAPY in trauma oedema is 4.26 times greater than in the control group.

4.1. Withdrawals

Of the five withdrawals from the study (four patients under pressure therapy treatment and one control subject), 2 were due to a worsening of their basic illness and 3 withdrew voluntarily for different reasons (family problems, incompatibility of timetables, etc). However, in none of the four pressure therapy patients was that treatment the direct or indirect cause of their withdrawal.

Further considerations regarding Pressure Therapy

Aside from the measurable effects of pressure therapy on the progress of the oedema, patients and therapists also have their own subjective view of the treatment.

The patients:

They report a pleasant sensation following treatment with pressure therapy, the limb treated feeling light and relaxed. This pleasant sensation is particularly noticeable in venous oedemas and those of traumatic origin. In lymphoedema secondary to lymph node removal, the patients are more sensitive, although they too report a pleasant sensation with pressure therapy.

The therapists:

Those using the pressure therapy have found, at the practical level, that venous and traumatic oedemas respond more favourably than lymphoedema secondary to lymph node removal.

In neoplasias with removal of the lymph nodes, the therapists suggest pressure therapy as a good complement to all other drainage techniques.

PRESSURE THERAPY

The pressure therapy unit suffered no mishap during the 22 months of the study.

4.3. Adverse effects

There was only one case. During one session, the patient reported increased pain on the dorsolateral side of the foot following the scheduled increases in pressure applied. In the next session the initial pressure was used, although later, after a couple more sessions, when the pressure was once again increased, it was well tolerated and there was no further problem.

4.4. Some interesting facts

In all, 122080 cm were measured

The loss per session was 29079 cm

4636 measurements were taken

There was a total reduction of 880 cm (almost 9 metres)

The maximum loss in one session with pressure therapy was 3.5cm, and 2cm in the control case.

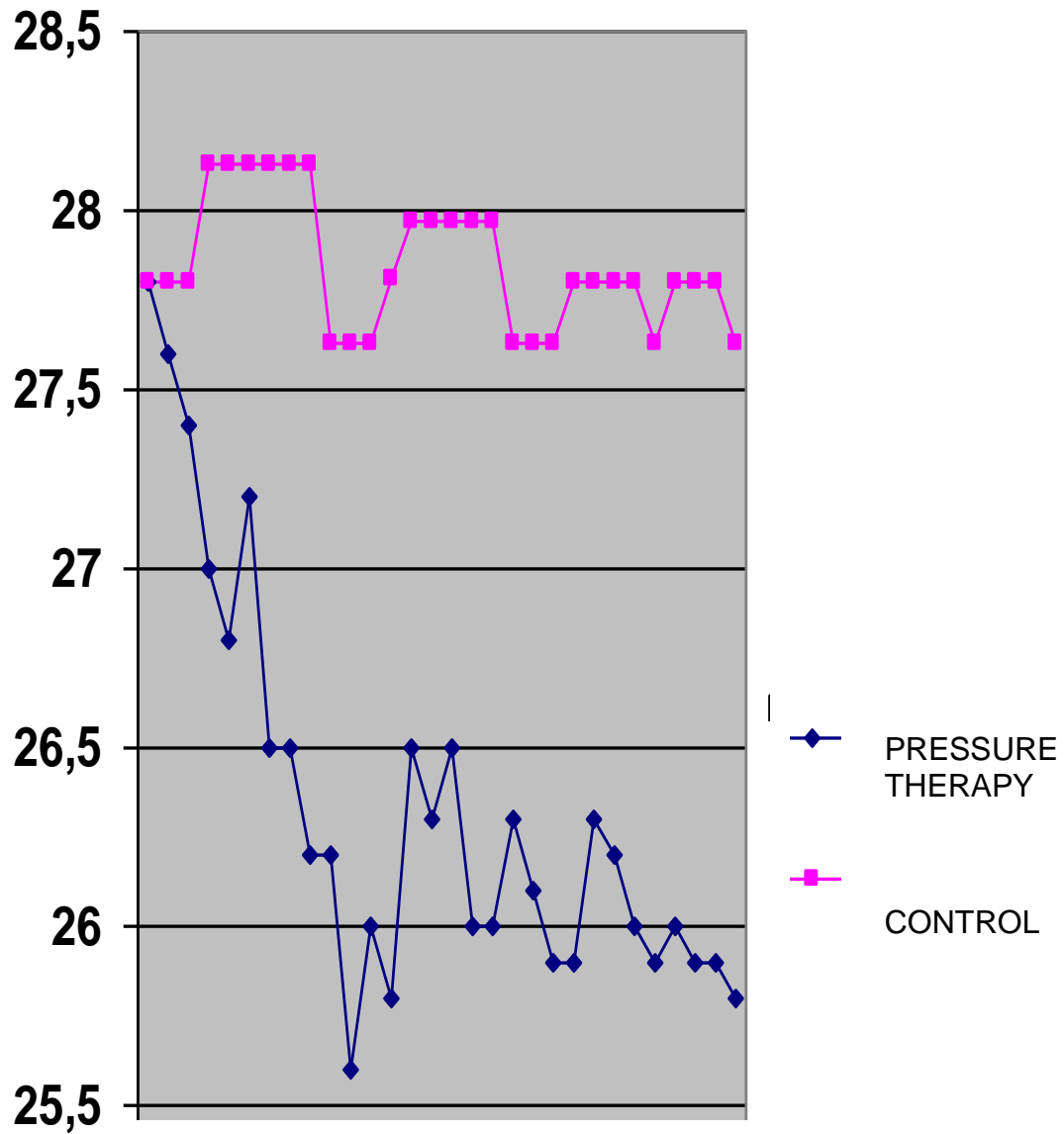
4.5. CONCLUSIONS

This study shows that the use of the SORISA pressure therapy unit is a beneficial adjunct to traditional techniques when it comes to treating oedema (whether lymphatic or venous) of the limbs.

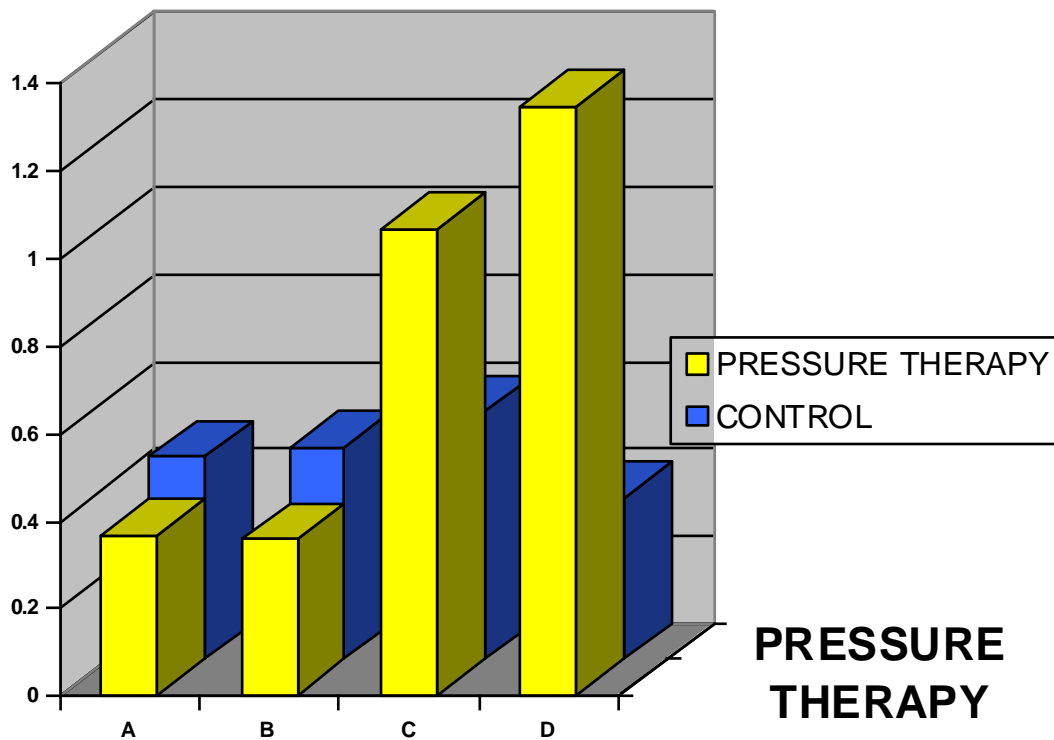
With pressure therapy, the loss in centimetres of perimeter lasts 4 times longer than that obtained with the traditional recuperation techniques.

5.0 GRAPHS

Comparison of the cm lost during the treatment period, between a case treated with pressure therapy and a control case.



Comparison of the loss in cm per session and between the beginning and end of all the sessions scheduled.



- A:** Mean loss, in cm, per session in all cases.
- B:** Mean loss, in cm, only in the cases completed according to the protocol.
- C: Total mean loss**, in cm, between the first and last treatment sessions in all cases, including withdrawals.
- D: Total mean loss**, in cm, between the first and last treatment sessions, only in the cases completed according to the protocol.