

COMPARISON BETWEEN MULTILAYER BANDAGES WITH MOBIDERM AND NON-ELASTIC MULTILAYER BANDAGES IN THE TREATMENT OF LYMPHATIC OEDEMA.

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Introduction:

In the context of phlebological diseases, lymphatic oedema is considered to be a nosological entity for which elastic compression is the most appropriate and widely recognised treatment, right from the early stages of the disease. It has now been universally demonstrated that therapy using elastic bandages accelerates microcirculatory blood flow and promotes detachment of leukocytes from the endothelium, preventing further adhesion. Furthermore, it reduces capillary filtration and encourages venular reabsorption. .

As far as the effect of elastic compression on lymphatic oedema is concerned, its efficacy can be explained by fragmentation of protein accumulations in the subcutaneous layers or by a reduction in local tissue pressure rather than by a direct activity on lymphatic transport. In both cases, the objective of elastic compression is to restore the micro and macrocirculatory pressure gradients, which are abnormally raised in a clinical condition with oedema of any type, given that the involvement of one system (venous or lymphatic) does not preclude the involvement of the other. Indeed, the term venolymphatic oedema is commonly used. This is an important concept, in that irrespective of the causes of the oedema, the pathophysiological damage is the same. The therapeutic approach therefore needs to be harmonised and should simply aim to eliminate – or at least reduce – fluid in the interstitial space.

In healthy subjects, the increase in venous pressure due to orthostatism produces a sympathetic axonic-type vasoconstrictive reflex, called the veno-arteriolar reflex (VAR), which triggers an increase in pre-capillary resistance. The cutaneous microcirculation and the VAR can be studied by Laser Doppler flowmetry. In the course of microangiopathy due to venous hypertension, the development of dynamic and anatomopathological changes induces an increase in cutaneous flow at rest in the perimalleolar region and a marked reduction in VAR.

The use of Laser Doppler technology in the treatment of lymphoedema has demonstrated that the abnormal increase in onco-osmotic pressure characteristic of this condition makes normal arteriolar contraction difficult – especially in the active fibrotic phases –, with precapillary sphincter opening and closing irregularities. The resulting volume malfunction is revealed on Laser Doppler examination by a slowing down and reduction of flow, paradoxically suggestive of an ischaemic disease. Thanks to the possibility of evaluating the real arteriolar contractile reserve by Laser Doppler in all ischaemic conditions, the post-ischaemic hyperaemia test can be correctly applied, even in lymphoedema.

The application of multilayer bandages in the treatment of lymphoedema is widely approved by health professionals due to their efficacy in comparison with the other elastic compression methods used in this disease, although it is a therapy that is sometimes difficult to manage, particularly in terms of its use by patients at home.

Recently introduced on the market, Mobiderm is an innovative product designed for the treatment of venolymphatic oedema.

Its structure, made up of lots of little capsules of compressible material, makes it possible to create compression gradients between adjoining areas with an alternating compression/decompression effect on application, in a similar way to other multilayer bandages. Due to the law of fluid

dynamics, this induces displacement of the oedema from a higher pressure zone to a lower pressure zone, with an action on venular reabsorption. This phenomenon is beneficial even in the case of lymphoedema since the bandage with Mobiderm, combined with a programme of exercises and vascular rehabilitation “making it move”, can promote the macrophagic proteolysis mechanism, with fragmentation of the protein accumulation and, consequently, its reabsorption.

Study aim:

To verify the efficacy of Mobiderm in the treatment of venous and lymphatic oedema in comparison with a fixed low working-pressure bandage, with the aim of obtaining:

- 1° on a circulatory level: a reduction in interstitial pressure by restoring normal pressure gradients
- 2) on a tissue level: a reduction in subcutaneous thickness (fibrosis index) and hence in local tissue pressure (particularly in lymphoedema)
- 3) on a clinical level: a reduction in limb volume and an improvement in quality of life.

Materials and methods:

40 patients were selected, homogeneous in terms of clinical conditions. Of these, 20 had CEAP stage III venous oedema and 20 had secondary lymphoedema (10 with primary lymphoedema of the lower limbs, 10 with lymphoedema of the upper limbs). This group was divided into 2 subgroups: 20 patients (10 with phleboedema of the lower limbs, 5 with lymphoedema of the lower limbs, 5 with lymphoedema of the upper limbs) were treated by application of a multilayer bandage with Mobiderm and a non-elastic bandage, 20 (11 with phleboedema of the lower limbs, 5 with lymphoedema of the lower limbs, 4 with lymphoedema of the upper limbs) were treated by application of a fixed bandage with a low working pressure.

The selection criteria were as follows:

- a) Age: 40 to 65 years
- b) Venous insufficiency diagnosed by Doppler ultrasound for at least 2 years
- c) Secondary lymphoedema for at least 6 months
- d) No physical treatment for at least 3 months
- e) No pharmacological treatment for at least 3 months

Methodology:

At the start of the study, the patients with venous insufficiency underwent the following assessments:

- a) a complete medical history
- b) volumetric assessment of the affected limb (measurement of ankle diameter in cm, 2 fingers above the malleolus)
- c) venous Doppler ultrasound
- d) measurement of venous pressure in the orthostatic position
- e) Laser Doppler with assessment of VAR using a probe placed 5 cm above the internal malleolus
- f) symptom questionnaire.

The patients with lymphoedema underwent the following assessments:

- a) a complete medical history
- b) volumetric assessment
- c) surface ultrasound to assess subcutaneous thickness
- d) venous Doppler ultrasound
- e) Laser Doppler using a probe placed 5 cm above the medial malleolus (in the case of a lower limb) or 5 cm above the risk (in the case of a forearm) or 5 cm above the elbow crease (in the case of an upper arm).

The patients in the first group were treated by application of a multilayer bandage with Mobiderm and short-stretch bandages. At the same time, they performed a series of isometric physical exercises for a period of 30 minutes in accordance with the phlebolympology vascular rehabilitation programme, coded with our COU (Complex Operational unit), under the supervision of our personnel. Physical exercises suitable for venous and vascular rehabilitation schedule activity

of the anterior and posterior thigh and calf muscles, with the aim of activating a sort of pump effect in the lower limbs, with separate functions depending on the muscle group concerned by the exercise. This is designed to ensure continuous flow from the superficial venous network towards the deep network and a centripetal progression of venous flow.

These exercises will work:

the anterior muscles of the thigh (vastus medialis, vastus lateralis, rectus femoris and sartorius) with:

- a) the patient lying on his/her back: 20 isometric contractions lasting 2 seconds each, repeated 5 times, with a 5-second pause between each contraction (of the whole quadriceps)
- b) the patient lying on his/her back, legs bent at an angle of 45°: 20 leg extensions with the foot in the flexed position, repeated 5 times, with a 5-second pause between each extension (contraction of the vastus medialis)
- c) the patient standing up: 10 elevations with the leg straight, repeated 5 times, with a 10-second pause between each elevation (contraction of the rectus femoris)

the posterior muscles of the thigh: semimembranosus (adduction), semitendinosus (abduction), gluteal with

- a) the patient lying down on his/her front: 20 slow calf-to-thigh flexions, repeated 5 times with a 3-second pause between each flexion (contraction of the entire biceps femoris)
- b) the patient lying down on his/her front or standing up: 20 thigh-to-pelvis extensions, repeated 5 times with a 3-second pause between each extension (contraction of the biceps femoris and the gluteus maximus)

the anterior muscles: tibial, short and long peroneal, posterior (soleus and gastrocnemius) with:

- a) the patient lying on his/her back: 20 foot extensions, repeated 5 times with a 5-second pause between each extension (contraction of all the anterior compartment muscles)
- b) the patient lying on his/her back: 20 foot flexions, repeated 5 times with a 5-second pause between each flexion (contraction of all the anterior compartment muscles)
- c) the patient lying on his/her back: 20 foot rotations to the right then 20 to the left, repeated 5 times with a 5-second pause between each rotation (contraction of the muscles of the anterior and posterior compartment of the lower leg)
- d) the patient standing up: 20 toe flexion-extension movements, repeated 5 times with a 5-second pause between each flexion-extension (contraction of the soleus, gastrocnemius, quadriceps and gluteal muscles).

At the end of the exercises, we recommend a treadmill session with an inclination of 10% and a speed of 5 Km/h for 20 minutes (contraction of the anterior tibial and gastrocnemius muscles) and/or a bicycle session for 20 minutes (contraction of the gastrocnemius and rectus femoris muscles). This part of the exercise session is performed in a gym, under the supervision of specialised physiotherapists.

The protocol schedules application of the bandage every two days, for 5 hours, and for a total duration of 5 weeks, accompanied by the home exercise programme recommended.

The patients in the 2nd group were treated by dry fixed bandaging using an adhesive non-elastic bandage (after having applied a protective cotton tubular bandage next to the skin), to be repeated every 5 days, 7 times (treatment duration: 35 days). This group also followed the home isometric exercise programme.

After 40 days, the patients again underwent the following assessments:

- a) volumetric assessment
- b) measurement of venous pressure (phleboedema)
- c) surface ultrasound (lymphoedema)
- d) laser Doppler with corresponding tests (all)

e) symptom and clinical questionnaire (assessment of clinical efficacy and impact of the method used on the patient's quality of life).

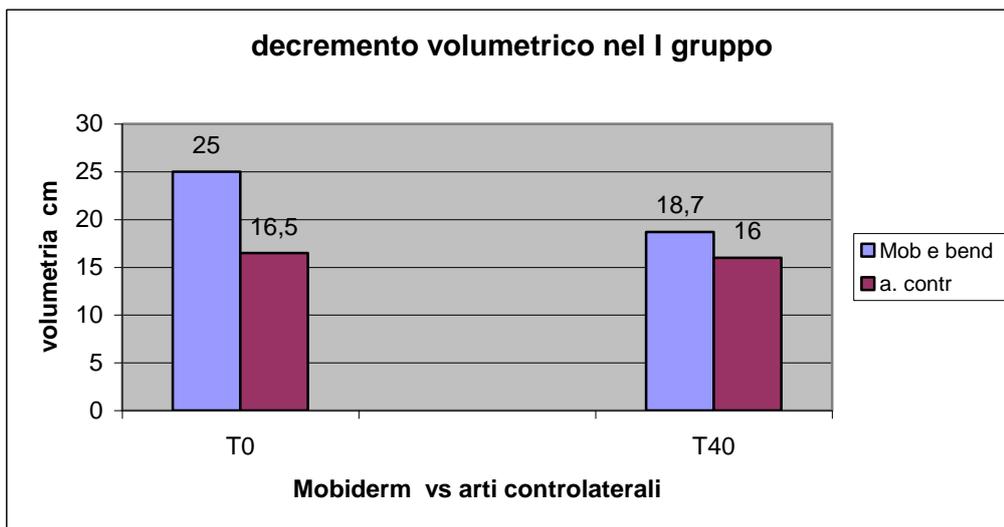
Results

On the basis of the parameters indicated as references throughout this study (measurement of affected limb volume in comparison with the healthy opposite limb, measurement of venous pressures in the orthostatic position, measurement of subcutaneous thickness using an ultrasound method, study of degree of microcirculatory compromise during oedema using a laser Doppler flowmeter, assessment of the impact of the disease on quality of life using the symptom questionnaire), we report the following observations:

1) from a clinical point of view, it was noted that all the patients undergoing the treatments had a reduction in oedematous limb volume, particularly in the groups treated with Mobiderm. The symptoms questionnaire completed before and after treatment demonstrated a subjective reduction in heaviness and swelling of the limbs in all patients, accompanied not only by better function of the oedematous limb (easier to move about, restoration of more efficient joint function) but by the acquisition of a "self-treatment" method, with a resumption of social life in all patients.

The results are indicated in tables 1, 2, 3, 4, 5, 6, 7, 8, and 9.

Tab 1.



reduction in volume in the 1st group

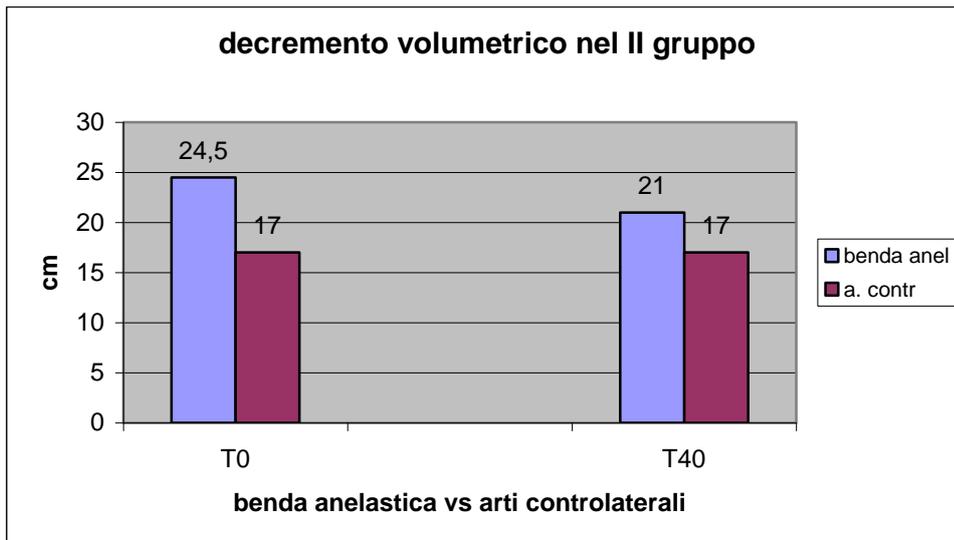
volumetric assessment

Mobiderm versus opposite limbs

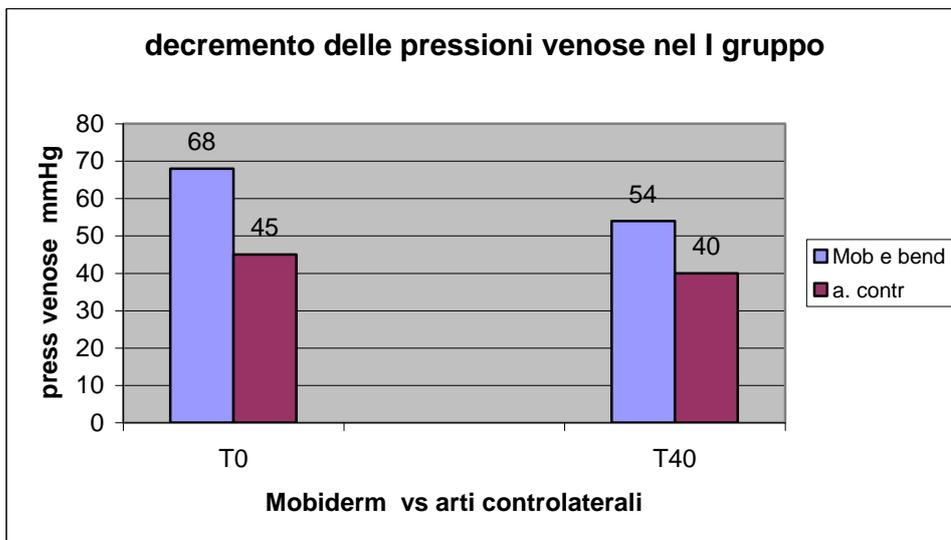
Mob and bandage

opposite limb

Tab. 2



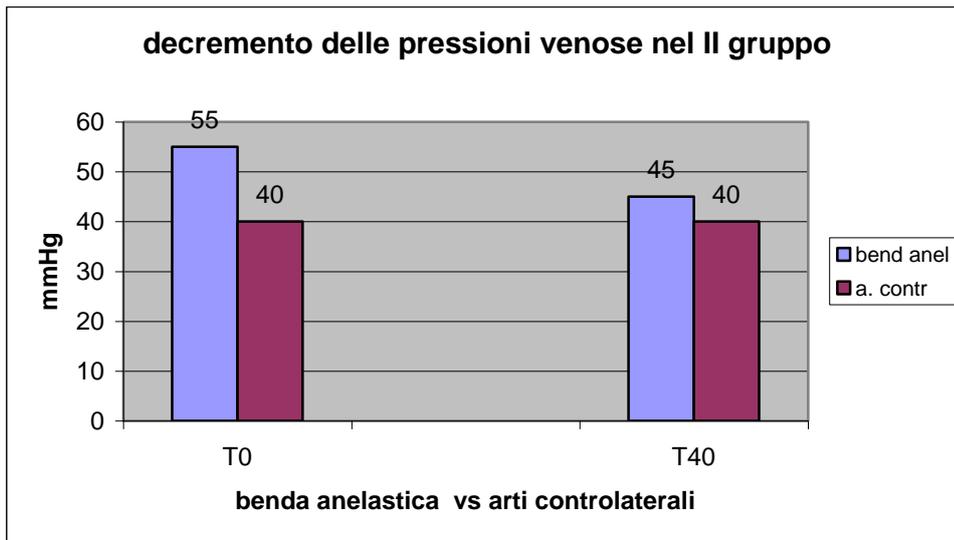
reduction in volume in the 2nd group
 cm
 non-elastic bandage versus opposite limbs
 non-elastic bandage
 opposite limb



Tab.3

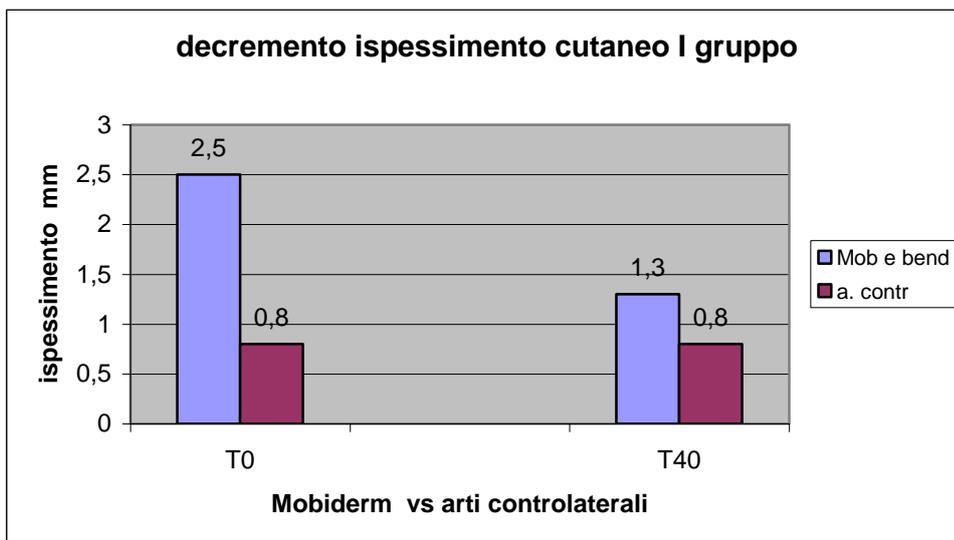
reduction in venous pressures in the 1st group
 venous pressure mmHg
 Mobiderm versus opposite limbs
 Mob and bandage
 opposite limb

Tab. 4



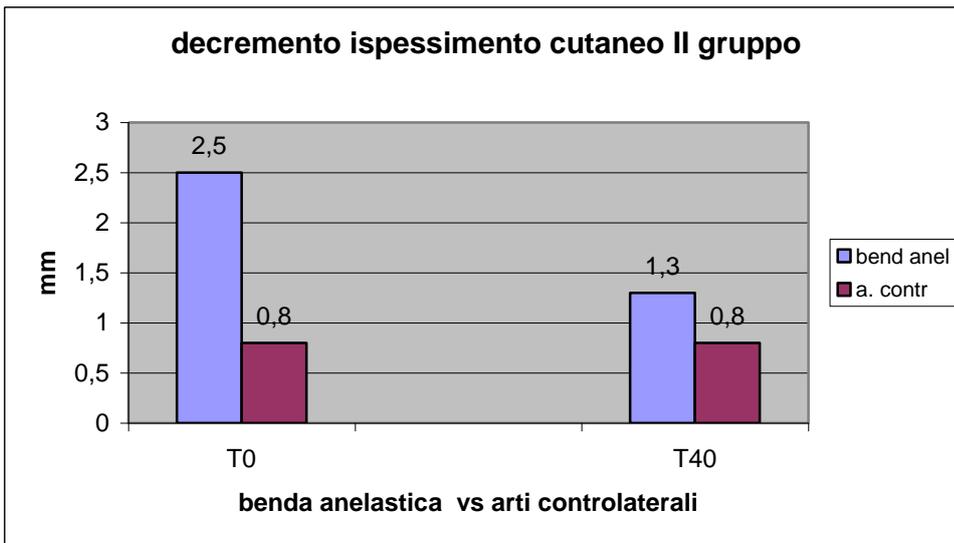
reduction in venous pressures in the 2nd group
 mmHg
 non-elastic bandage versus opposite limbs
 non-elastic bandage
 opposite limb

Tab. 5



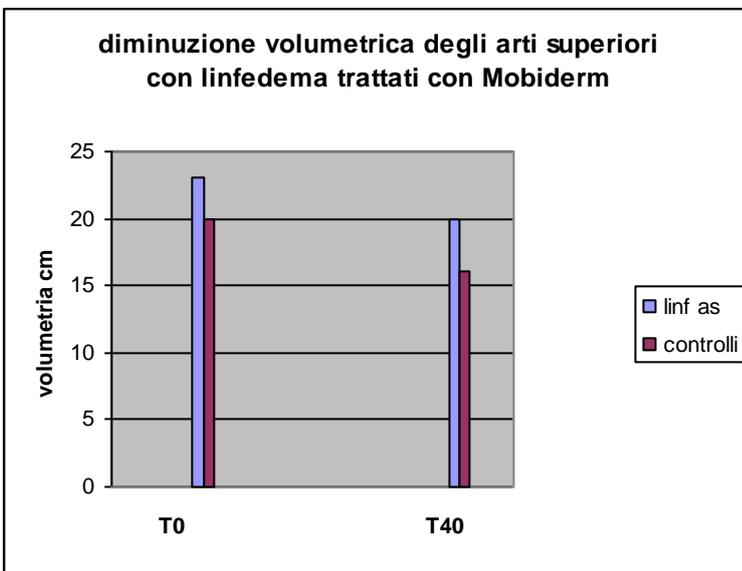
reduction in skin thickness in the 1st group
 Mobiderm versus opposite limbs
 Mob and bandage
 opposite limb

Tab. 6



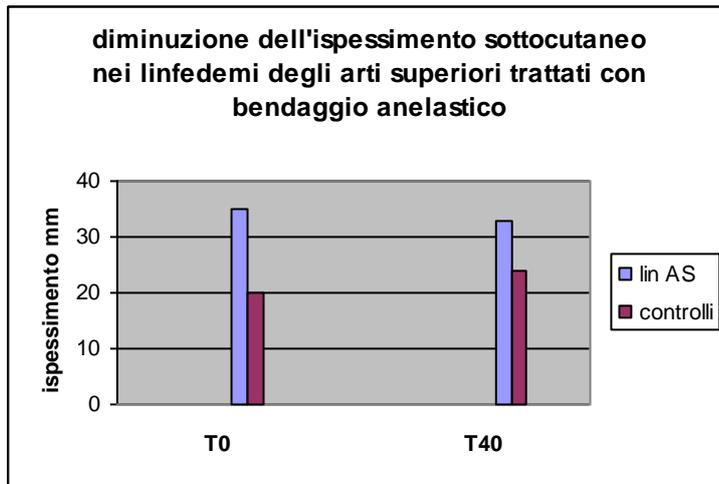
reduction in skin thickness in the 2nd group
mm
non-elastic bandage versus opposite limbs
non-elastic bandage
opposite limb

Tab.7



reduction in volume of upper limbs
with lymphoedema treated with Mobiderm
volume cm
upper limb with lymphoedema
controls

Tab. 8



reduction in subcutaneous thickness in lymphoedema of the upper limbs treated with a non-elastic bandage
 thickness in mm
 upper limb with lymphoedema
 controls

Table 9

VARIATIONS IN VENO-ARTERIOULAR REFLEX (VAR)

LD parameters in %	T0		T40	
	normal	phlebopathic lower limb	normal	phlebopathic lower limb
Baseline (RF)	25.66	34.91	30.45	37.02
Standing	6.69	25.64	21.65	27.12
VAR	75.84	41.34	34.27	31.21

Comments and conclusions

From a clinical point of view, our results are consistent with the observations made by Merlen (2) in his studies on the pathophysiological mechanisms of stasis oedema. It has been demonstrated that an increase in interstitial pressure of greater than or equal to the endocapillary pressure leads to collapse of the capillary wall, with impermeability to flow.

This phenomenon is followed by a series of haemodynamic events, at both venular and arteriolar level, with the fall in intracapillary pressure inducing a steady reduction in flow in the post-capillary and collector venules due to local engorgement and a consequent slowing down of the flow rate. This triggers a reflex dilation of the venules leading to a further increase in capillary permeability, promoting further plasma discharge and exacerbating the interstitial flooding. In addition, an increase in pressure occurs at arteriolar level, leading to increased contractile activity of the myocytes of the medium due to local compensation. This situation is temporary, however, given that the greater number of contractions in the unit of time tends to gradually decrease and ultimately stabilise at lower values as a result of probably vasoplegic phenomena. It is therefore essential that correction of these pathological events be based on a type of therapeutic measure capable of having a positive influence on each phase, particularly physical measures such as active and passive exercises or elastic compression. These measures act on the oedema and therefore lead to a reduction in oncotic pressure, with a partial restoration of flow velocity and volume in the unit of time via decollapse and reperfusion of the parts of the capillary network that were previously impermeable to the flow.

All these considerations demonstrate that, while lymphoedema is not generated by a disease directly concerning the arteriolar-venular system, it can nonetheless cause changes in tissue microcirculation due to extrinsically “compressive” phenomena since this type of oedema has a particularly high protein and macromolecule content.

A constant increase in oncotic pressure due to depletion of the compensation mechanisms indicated above, also leads to a depletion of macrophagic drainage capacity, with the macrophages undergoing hypertrophy, immobilising them at an interstitial level. This enables them to become organised with stagnating proteins to form fibroses.

Elastic compression therapy is an essential component in the conservative treatment of stasis oedema of the limbs.

This treatment requires the close cooperation of specialists and patients, both in terms of compliance with the lifestyle measures necessary to prevent infectious complications of the oedema and to contain any increase in volume of the oedematous limb.

From a practical point of view, elastic compression has two objectives:

- 1) Reduction in oedema volume
- 2) Maintenance of the maximum reduction obtained.

From a therapeutic point of view, the aim is to promote and maintain disinfiltration of the oedema by correcting abnormally raised micro/macrocirculatory pressure gradients. Due to the specific structure of the Mobiderm bandage, its use in our study enabled us to effectively obtain a pressure gradient between adjoining cutaneous zones, helping to encourage mobilisation of the oedema. This is due to the following phenomena:

- 1) venular reabsorption, demonstrated primarily by the reduction in venous pressures and variation in Laser Doppler parameters in comparison with normal subjects: increase in basic flow, reduction in the decrease percentage in VAR induction in the first group of patients. These factors are consistent with the pathophysiological data, indicating an increase in microcirculatory repletion, i.e. a condition of stasis and, consequently, weaker induction of VAR. This local reflex

is gradually and irreversibly damaged during chronic stasis. Whereas in normal subjects there is an orthostatic vasoconstrictive activity exerting a defensive action on the cutaneous microcirculation, in chronic oedema, it undergoes damage reflected by the inability to oppose the orthostatic hyper-afflux. Indeed, in patients with oedema, even higher values have been recorded in the standing position and lower decrease percentages.

- 2) displacement of lymph and fragmentation of the corpuscular component, revealed by a reduction in volume of the oedematous limb and by subcutaneous thickening in both groups, but particularly in the subgroup of patients having used the multi-layer bandage with Mobiderm.
- 3) improvement in quality of life, according to the results of the symptom questionnaire.

Within the limits of the manageability of the measures used, no side effects were observed that could be ascribed to cutaneous intolerance to the product's materials or lesions due to incorrect application of the two types of bandage. The patients' compliance was deemed to be total in all patients having used Mobiderm, despite the fact that the bandage was deemed to be "bulky".

Mobiderm stayed in place better than the non-elastic bandage alone and/or the other mobile bandages generally used and the results obtained were achieved more quickly.

Our data confirm the efficacy of the Mobiderm bandage and enable its validation and inclusion as a therapy for oedema of the limbs, particularly for the complex physical treatment of lymphoedema.

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