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COMPRESSION

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What are the differences between different compression materials?

Abstract

Lower limb compression can be provided through the use of hosiery, bandages and intermittent pneumatic compression, with all appearing to offer clinical benefits over the use of no compression in the management of a range of lower leg circulatory problems. Differences between the various forms of compression therapy have been reported and these are probably due to the details of the physical interaction between device and the lower limb, primarily the effect of the pressure applied to the leg. Three key parameters are the resting pressure (pressure sustained upon application of the compression material), the working pressure (the peak pressure achieved during activity such as walking) and the static stiffness index (the difference between the pressure applied while lying supine and upon standing up). Based upon the amount of pressure applied to the ankle various classification systems have been proposed to discriminate between the wide range of compression hosiery and bandages available to clinicians. However different classification systems use different pressure thresholds to separate the classes of compression materials and this may give rise to confusion for clinicians. While access to new imaging techniques (such as Magnetic Resonance Imaging) may open the potential for direct visualisation of the effects of compression materials this is unlikely to replace simple clinically accessible indices such as the static stiffness index due to cost prohibitions and the challenges of obtaining reliable MRI images from clinically relevant populations due to movement artefacts.

Keywords: lower leg, compression, bandages

Introduction

The use of various forms of leg compression (including hosiery, bandages and intermittent pneumatic compression (IPC)) has been widely reported to confer benefits in the management of lower limb circulatory disorders. Compared with no compression, wearing compression may grant increased healing rates of venous leg ulcers,[1,2] reduce symptomless DVT and leg oedema in airline passengers[3] while leg ulcer recurrence appears to be more prevalent where no compression is worn.[4] However different forms of compression appear to give different clinical benefits – multi-component compression bandage use results in greater leg ulcer healing compared with single component bandage systems[1] while multi-component systems that contain an elastic component also appear to give rise to greater venous leg ulcer healing compared with inelastic bandage systems.[1] Intermittent pneumatic compression may assist in the management of post-thrombotic syndrome while elastic compression hosiery does not appear to provide this benefit.[5] Where IPC is used, limited evidence suggests that rapid cycling (19 sec inflation and deflation) is more effective that slower cycles (210 sec inflation – deflation) when considering venous leg ulcer healing.[2] Given that different forms of lower limb compression appear to offer differential clinical benefits this observation may most probably be related to both the physical construction of the compression material and its physical interaction with the lower limb. Discussion of the material construction of compression materials has been reported[6,7,8] while detailed discussion of compression materials lies outside this article, it is helpful to note that compression bandages have been classified as having either single or multiple components (where the multiple components may have different functions such as retention, padding and protection).[8]

Physical interaction with the lower limb

The main purpose of compression materials is, rather obviously, to apply a known level of pressure to the lower limb. Leaving aside the consideration of IPC devices which seek to inflate, sustain and deflate the pressure within a number of inflatable cuffs that surround the leg, compression hosiery and bandage systems will provide a level of pressure when applied (the resting pressure) with changes in this level of compression observed during activity such as walking with the peak pressure applied during action described as the working pressure.[9] Depending upon the compression material (and its ability to reduce limb oedema) the resting pressure may decline over the period of time the compression hosiery or bandages are worn, and sustainability of the resting pressure is another factor that will influence the effect of the compression material.

The nature of the compression material will influence both the resting and working pressures. For example a bandage that contains elastic components may apply higher resting pressures but lower working pressures than might an inelastic bandage.[8] However there has been recent discussion over the value of the use of the terms 'elastic' and 'inelastic' (which themselves replaced 'long-stretch' and 'short-stretch').[8] While it can be feasible to define rigid, short and long- stretch bandages on the basis of *in vitro* parameters such as their maximal stretch when subjected to a 10N force per cm of bandage width these maximum stretches are unlikely to be applied during bandaging.[8] Such *in vitro* challenges to the appropriate description of bandage components can be compounded given that bandage systems that may contain 'elastic' components may behave more as 'inelastic' bandage systems when assembled[8] probably due to friction between the separate component layers. In light of these issues it has been recommended that several terms including 'elastic' and 'inelastic' are only used to refer to single component bandage systems.[8]

In vivo the measurement of the pressures applied by compression bandages can be used to discriminate between different bandage types.[8,10] Primarily bandage systems that act as 'inelastic' are likely to have much higher changes in applied pressure during exercise and more marked increases in pressure when rising from seated to standing postures.[8] The difference in the pressure applied when changing from a lying to a standing position has been proposed as a simple method to classify the effects of compression bandages. The change in the pressure measured at the gaiter area when a person stands has been termed the static stiffness index (SSI),[8] with a single threshold proposed where a 10 mmHg or greater rise in pressure from lying down to standing marking high stiffness (or inelastic where single bandage components are considered) and an under 10 mmHg rise on standing denoting elastic (single component bandage) or low stiffness bandages.

The elevation in pressure upon standing has also been seen as a surrogate for the changes in working pressure that may be observed during walking and as such provides a simple assessment of the likely effect of the bandage upon the lower limb. While a static stiffness index may be a relatively new concept it has precedents within the UK standard for compression bandages.[11] This standard included reference to three terms related to the bandage when applied to the lower limb – the working tension provided the force required to produce the desired sub-bandage pressure, the working length reported the length of the bandage at the working tension and finally the tension ratio described the impact on tension if the working length changed by 3% as was taken to occur during walking – a high tension ratio would suggest locomotion would produce minor changes in sub-bandage pressure (low stiffness) whereas a low tension ratio may mark large changes in sub-bandage pressure on walking (high stiffness).

While the focus of attention has been upon the characterisation of the amount of pressure exerted by compression materials, recent advances also allow direct visualisation and quantification of the effect of compression upon deep and superficial veins (for example 12). Using Magnetic Resonance Imaging, the effects of compression can be observed – with changes in the cross-sectional area of the superficial veins of 39% and 64% in the deeper veins upon wearing light support compression hosiery while in the prone position. While this approach has merits in terms of the direct visualisation of the gross effects of compression, it is expensive and the early work with volunteer subjects may be challenging to conduct with patients wearing compression hosiery and bandages given the need for positioning of the limb and the time required to scan the leg may induce movement artefacts among a patient population.

Classifying the different effects of compression materials

Given that different compression materials may exert different pressures to the lower limb it is unsurprising that over the years there have evolved several classification systems that attempt to relate the extent of compression with the proposed clinical indication for each compression stocking or bandage. To enable such classifications to be developed, a range of *in vitro* measurement procedures have been developed that allow quantification of the pressure applied by a compression bandage or stocking to a known surface. For example the HATRA and HOSY stocking testers used to quantify the pressures applied by compression hosiery.[13,14] Using such devices the pressures applied by different compression stockings have been classified *(Table 1)*. However the range of pressures applied by the different classes of compression stocking differ with higher ranges offered in the German standard. This could lead to clinicians applying higher or lower than expected pressures if selecting prod- →

TABLE 1 COMPARISON OF COMPRESSION STOCKING CLASSIFICATION IN THE UNITED KINGDOM, FRANCE AND IN GERMANY

CLASS	CLASSIFICATION		
	UK (13)	France (16)	Germany (15)
I	14-17 mmHg	10-15 mmHg	18-21 mmHg
II	18-24 mmHg	15-20 mmHg	23-32 mmHg
III	25-35 mmHg	20-36 mmHg	34-46 mmHg
IV	Not reported	>36 mmHg	>49 mmHg

→ ucts simply on their class without knowledge of which test method had been used to develop the classification. The indications for compression stockings under the French and UK and the German standards also differ[15] with for example a Class III stocking (UK classification) indicated for the management of severe varicose veins and moderate oedema while a German classified Class III stocking could be seen as appropriate for the management of severe chronic oedema and the prevention of recurrence of healed venous leg ulcers.

The classification of compression bandages has also been subject to question.[8] Within the UK standard for compression bandages[11] the strength of compression is described as being light (<20 mmHg), medium (21-30 mmHg), high (31-40 mmHg) and extra high (41-60 mmHg). These figures are based upon the application of pressure by the bandage to a 23cm circumference ankle when the bandage is applied with a 50% overlap between the layers. A recent consensus document[8] compared these pressure thresholds with published *in vivo* pressure measurements and recommended that the pressure ranges that mark the different strengths of compression in the UK standard are too low. New recommendations were offered that proposed that 'mild' compression was under 20 mmHg, with medium compression being 20 to under 40 mmHg, strong compression was from 40 to under 60 mmHg and finally very strong compression was provided by compression bandages that applied over 60 mmHg. The potential for confusion between different classification systems remains a challenge for clinicians who may have little time, or interest in the details of compression materials but instead rely upon the strengths of compression indicated on product packaging. One potential avenue that may prevent such confusion could be to adopt a broader description of compression bandages[8] called PLACE – containing Pressure (measured at the medial gaiter area and with strong compression marked by a sub-bandage pressure of over 40 mmHg but under 60 mmHg), Layers where a 50% overlap between layers is a double-layer bandage additional layers of additional overlap makes the system a multi-layer bandage, Components (the different layers that make up the bandage system) and Elastic (where stiffness should be considered for multi-component systems and elastic and inelastic for single component bandages). The PLACE acronym may help clinicians and manufacturers keep the key parameters of compression bandages in mind?

Conclusions

Compression materials, be they hosiery, bandages or intermittent pneumatic compression provide a raft of clinical benefits for those with lower limb circulatory problems in comparison with applying no compression. While the focus to date has largely been upon understanding the forces applied to the lower limb and to identify simple, clinically relevant indices such as the static stiffness index there remains confusion regarding the classification of compression hosiery and bandages, with no apparent systematic effort made to produce classifications of intermittent compression devices. While the potential exists to extend beyond pressure measurement as a surrogate for the performance of compression materials, for example direct imaging using MRI, this is unlikely to become commonplace and used among clinically relevant populations. If the main *in vitro* and *in vivo* comparisons of compression materials are to remain pressure and force measurement bound, then there is a need for consistent classification based upon the pressure measurements to mirror the agreed consensus upon how sub-bandage pressures are to be measured.[10] ■

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Why should wounds on the lower extremities be treated by compression?

Abstract

The majority of open wounds are situated on the lower extremity. This can mainly be explained by the fact that upright living humans are victims of gravity. The blood return in the veins towards the heart depends on several very complex mechanisms to overcome gravity which are quite susceptible to faults causing peripheral venous hypertension and damage in the dermal microcirculation. Legs are also exposed to repeated trauma leading to skin defects which may not heal in areas with compromised microcirculation. These factors are not only relevant for venous ulcers which are the majority of wounds on the leg, but also for all other leg wounds which are not caused by venous reflux and/or obstruction. Compression is the essential measure to counteract gravity in all these cases. This is the main reason why compression plays such an essential role in treating leg ulcers, even if they are not caused by venous pathology.

Keywords: leg ulcers, compression therapy, venous hypertension, gravity

Broad spectrum of wounds on the legs

The diagnosis of a venous leg ulcer is still often based on the exclusion of other, less frequent pathologies, like arterial occlusive disease, small-vessel disease ("vasculitis"), pyoderma, haematological disorders, trauma, infection, or tumour.

This attitude to call a leg ulcer "venous" because it looks like a "venous" ulcer is no longer acceptable, since the detection of an underlying venous pathology may have considerable therapeutic consequences.

How to define a venous ulcer?

Following the CEAP classification of chronic venous disorders the clinical (C) condition of an open leg ulcer (C6) is associated with a pathophysiology (P) characterized by reflux, obstruction or both ($P_{r,o}$).[1] Duplex examinations in leg ulcer patients have demonstrated reflux due to valvular incompetence in approximately 80 % of the patients, half of them in the superficial venous system, half with additional deep reflux. Additional incompetent perforators are frequent, isolated perforator incompetence, but also an isolated deep venous insufficiency is relatively rare. Following the CEAP classification this corresponds to the anatomical localisation $A_{s,d,p}$ (s= superficial. d= deep, p= perforators). The etiology (E) may be congenital (E_c), primary (E_p) or secondary, mainly post-thrombotic in most cases (E_s).

Valvular incompetence causing long refluxes down into the ulcer region is obviously the dominant hemodynamic trigger for the local tissue damage. Proximal venous obstruction causing oedema and venous claudication may play an additional role.

The resulting failure of the venous pump leads to an overloading with blood in the peripheral veins and dermal venules triggering oedema and skin changes which may exulcerate. The pathophysiological key-factor is "ambulatory venous hypertension", which is a lack of pressure fall during walking.

Under normal conditions the pressure measured at any point in the venous circulation corresponds to the weight of the blood column between the measuring point and the right heart which very much depends on the body position. The pressure in a dorsal foot vein of a human subject in the standing position is around 80-90 mmHg and depends only on the body height. In supine this pressure will fall to 10-15 mmHg. During walking blood is pumped up towards the heart against gravity and intact venous valves will prevent it from refluxing back again into the distal parts of the lower extremity. In patients with damaged vein valves the blood column will oscillate up and down in incompetent vein segments causing no or only a reduced drop of intravenous pressure during walking. This ambulatory venous hypertension leads to venular and capillary hypertension which will cause changes in the microcirculation with increased filtration of fluid, proteins and blood cells into the tissue triggering a chronic inflammatory process. Up and down movement of blood in incompetent vein segments can easily be detected by Doppler or preferably by Duplex giving exact information about the anatomic localisation of reflux.

"Hydrostatic ulcers"

Sometimes even thoroughly performed Duplex investigations are unable to detect venous pathology in "venous like" leg ulcer patients. This may for instance be the case for patients with morbid obesity, vasculitis or haematological disorders. Trauma may play an initiating role. Bjellerup has termed such ulcers which he found in about 20% of his patients "hydrostatic ulcers".[2] The pathogenesis is not yet completely clear; a constantly increased intravenous pressure seems to play a crucial role. Table I shows a schematic summary of the two principle forms of "venous ulceration".

Arterial and mixed ulcers

Reflux ulcers and hydrostatic ulcers may be associated with additional pathologies resulting in complex clinical features. Combinations with arterial disturbances are frequent.

In principle two forms of arterial or "mixed" ulcers may be differentiated:

- The more frequent form in which a patient with a venous ulcer has arterial occlusive disease as a concomitant disorder.
- Arterial occlusive disease with additional arteriolar obstructions in the skin without major venous reflux.

In both situations the compromised venous outflow due to gravity may be a reason to consider compression. However, many caveats need to be underlined which will be discussed below.

Therapeutic consequences

Compression reduces ambulatory venous hypertension

The main aim of treatment should be directed towards a reduction of the increased venous pressure.

This can be achieved by leg elevation, abolishment of venous reflux by surgery, endovenous procedures as for instance foam-sclerotherapy but also by compression treatment. Abolishing superficial venous reflux has become a routine tool in the management of "reflux ulcers". even in the presence of concomitant deep venous pathology. Sometimes this will clearly improve ulcer healing. Although some studies could not demonstrate faster ulcer healing after superficial vein abolishment, it has been proven that the ulcer recurrence rate after epithelialisation can be significantly reduced.[3]

It could be shown that inelastic bandages applied with a pressure over 50 mmHg are able to reduce ambulatory venous hypertension significantly in patients with severe chronic venous disease.[4] This effect can be explained by an increase of the ejection fraction of the venous calf pump achieved by inelastic bandages[5] and additionally by a reduction of venous reflux which could be demonstrated even in young leg ulcer patients with a congenital absence of venous valves.[6] To compress a leg vein in the standing position we need an external pressure between 60-90 mmHg.[7] During walking pressure peaks of this magnitude can intermittently be produced by using inelastic bandages but not with elastic material *(Figure 1).* With every muscle systole under an inelastic bandage intermittent pressure peaks will squeeze out the lower leg veins and will prevent them from retrograde filling.

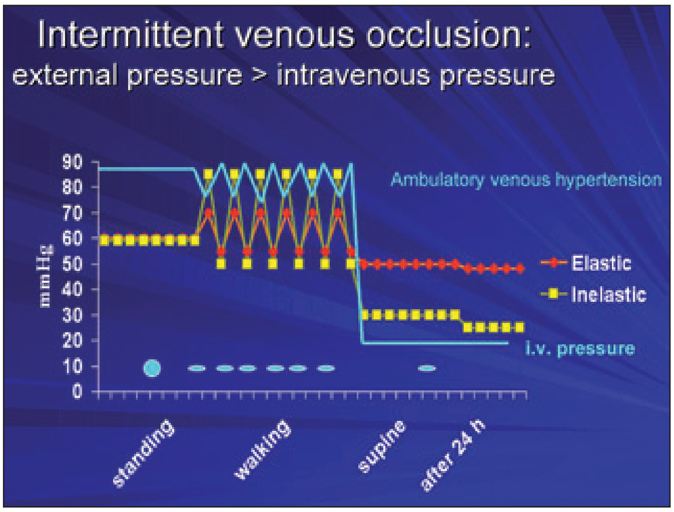

Figure 1: Schematic presentation of the intravenous pressure measured on the distal leg in a patient with severe venous reflux disease (green line) and the sub-bandage pressure exerted by strongly applied elastic (red) and an inelastic bandages (yellow). During walking the pressure peaks under the inelastic bandage will intermittently exceed the intra-venous pressure fluctuations (ambulatory venous hypertension) leading to short phases of venous occlusion (symbolized by the ovals above the x-axis). Elastic material applied with a pressure of 60 mmHg does not occlude the leg veins during walking and is poorly tolerated.

The mechanism of action of external compression in the group of "hydrostatic ulcers" is less clear. However, it has been shown that patients presenting with long standing ulceration due to sickle cell anaemia or other haematological blood disorders resistant to any kind of haematological therapy, could be healed by appropriate compression bandaging.[8] This model is very relevant for the subject under discussion, given the →

TABLE 1 PRINCIPLE CATEGORIES OF "VENOUS" LEG ULCERS

VENOUS PATHOLOGY PROVEN (REFLUX, OBSTRUCTION) "REFLUX ULCER" 80%	NO VENOUS PATHOLOGY PROVEN (NO VENOUS REFLUX, OBSTRUCTION) "HYDROSTATIC ULCER" 20%
CEAP: C6 $E_{p,s}$ $A_{s,d,p}$ $P_{r,o}$	C6 E_S A_n P ?
"Ambulatory venous hypertension"	"Integrated venous hypertension"
Examples: Long superficial axial reflux (great and/or small saphenous vein) Postthrombotic syndrome, Incompetent perforators	Examples: Morbid obesity, Immobility, Vasculitis, Hematological disorders

observation that all sorts of wounds on the lower extremity may benefit from compression therapy, even in the absence of venous reflux.

How does compression work in non-venous pathology?

Several physiological effects of compression have been shown[9]:

- Decrease of capillary filtration, but also of the extravasation of large molecules and of corpuscular elements of the blood.
- Increase of local lymph-drainage.
- Reduction of inflammation.
- Increase of arterial inflow ("pressure induced vasodilatation").

Figure 2 is a clinical example showing the efficacy of counter-pressure on the leg in a case with a knee hematoma which would certainly have progressed to the lower leg without distal compression.

The listed mechanisms depend very much on the exposed area of the body and on the kind of compression used.

The physiological effects of compression listed above may explain beneficial effects e.g. in burns or scars also in skin regions outside the legs. However, in the upright living human subject the lower leg being subjected to a steadily increased venous and venular pressure will need a higher pressure from outside in order to compensate venous hypertension. Experimental work in this area[9] has revealed some important results with considerable practical consequences also for subjects without venous pathology:

- Compression stockings with a pressure between 10 and 20 mmHg are able to prevent occupational oedema due to long standing or sitting.
- Low external pressure, in the sitting position up to 40 mmHg is able to increase skin blood flow.
- Intermittent pneumatic compression releases anti-inflammatory and vasodilating mediators from the endothelial cells in the capillaries.
- Calf compression mainly exerted by inelastic material increases the venous pumping function of the calf, even in patients without venous pathology.

Examples for practical implications of these points are e.g. the better healing of surgical incisions on the leg, faster reduction of pain and hematoma after trauma, or better performance during sport with faster regeneration.

Compression effects on the arterial inflow

In principle sustained external pressure should never exceed the pressure in the arteries and arterioles. This intra-arterial pressure can be assessed by measuring the ankle pressure using a Doppler probe. It is evident that in a patient with an ankle pressure of 50 mmHg a sustained pressure of the same magnitude that is exerted by a compression bandage may cause skin damage and is clearly contraindicated.

An intact arterial flow was shown to increase under moderate sustained external pressure.[9] In patients with severe arterial disease several studies performed with intermittent pneumatic compression (IPC) demonstrated an increase of the arterial flow when short pressure peaks of up to 120 mmHg are applied, followed by long phases without compression.

From these examples it can be followed that especially in the situation of the arterial patient two principle forms of com-

Figure 2: Posttraumatic hematoma of the knee in a patient with varicose veins. A compression stocking worn on the lower leg prevented the distribution of the hematoma into the compressed parts of the leg that would have occurred due to gravity.

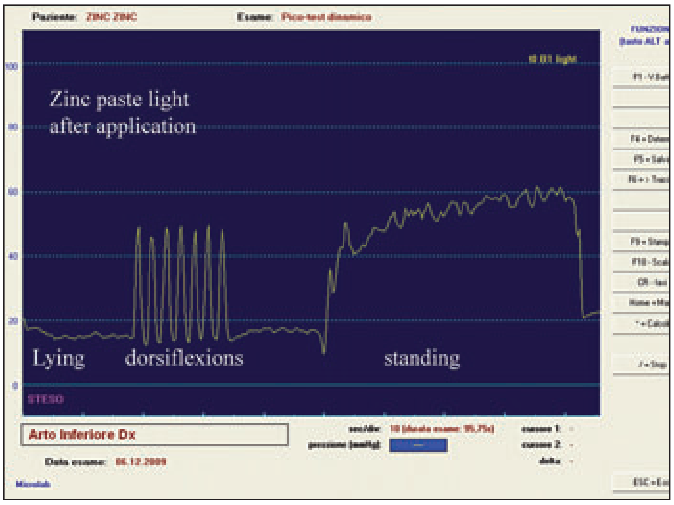

Figure 3: Sub-bandage pressure exerted by a completely inelastic bandage (zinc-paste) applied with a very low resting pressure (< 20 mmHg) in a patient with a mixed arterial-venous ulcer. The bandage shows a high massaging effect (pressure waves during ankle dorsiflexions up to 50 mmHg) and rises its pressure up to 60 mmHg just by standing up. This is an example for an "intelligent bandage" adjusting immediately to the need for compensating the increased intravenous hydrostatic pressure in the upright position.

pression need to be differentiated: sustained and intermittent compression. Elastic material exerts sustained compression and is therefore contraindicated in patients with arterial disease.

Inelastic bandages applied with low resting pressure in the supine position lead to an immediate pressure increase by standing up and to pressure peaks during walking which may simulate the rhythmic massaging of IPC *(Figure 3)*.

The amount of pressure during application of the inelastic compression bandage needs to be adjusted to the severity of the arterial occlusive disease as assessed by peripheral measurement of ankle or toe pressure.

Practical consequences

Compression therapy is the most important basic treatment modality in all cases of leg ulcers in order to compensate for the increased venous and venular pressure in the lower extremities. The dosage of this treatment is given by the compression pressure and the material used and should be adjusted to the underlying pathology:

In patients with venous reflux ulcers inelastic bandages exerting an initial resting pressure of around 50 mmHg are able to reduce ambulatory venous hypertension. Less severe ambulatory venous hypertension may also obtain a hemodynamic benefit from lower external pressure.

Ulcers without detectable venous pathology (e.g. obesity, vasculitis, haematological disorders) are a clear indication for compression which is able to counteract gravity.

Patients with arterial occlusive disease may benefit from intermittent pneumatic compression pumps in addition to inelastic compression devices applied with low pressure, especially in combination with walking exercises. ■

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Short stretch bandages for leg ulcers

Abstract

Leg ulcers are frequently due to venous disease resulting in ambulatory venous hypertension (AVH) that, through different and not yet well understood mechanisms, lead to skin damage and ulcers. Treating venous ulcers our major concern should be the reduction of the AVH trying to eliminate the main cause of the skin damage. Compression is one of the methods that can be used to reduce AVH. It has been proven to be effective in promoting ulcer healing by randomized control studies when applied with high pressure by means of multicomponent bandage. The aim of this paper is to show that the elastic properties of the materials are very important to achieve better outcomes. A significant narrowing or occlusion of the veins are necessary to prevent venous reflux and increase the venous ejection fraction so reducing the AVH. The pressure able to narrow or occlude the veins at the calf level must be higher than 60 mmHg in the standing position. Due to the fabric properties this pressure can be achieved by inelastic material starting from a lower supine pressure (usually in the range from 20 and 40 mmHg) while elastic material must be applied with a pressure higher than 50-55 mmHg to produce the same pressure. This can cause significant discomfort and even pain to the patient and can be not tolerable in the clinical setting. Data are reported on the better efficacy of inelastic compression on reduction and even abolition of oedema and on ejection fraction improvement. In conclusion: inelastic is more effective than elastic material in reducing venous reflux and in improving the venous pumping function and is better tolerated. This is the reason why inelastic bandages should be used for ulcer treatment when a venous pathophysiology is involved, that causes venous reflux and a reduced venous pumping function.

Keywords: inelastic compression, elastic compression, venous leg ulcer, venous reflux, venous ejection fraction

Introduction

Leg ulcers are frequently due to venous disease (superficial or deep venous insufficiency, deep vein obstruction) resulting in venous reflux and reduced venous pumping function. The venous hemodynamic impairment finally produces venous stasis in the lower leg and ambulatory venous hypertension (AVH).

The hydrostatic venous pressure in the lower leg in the standing position is about 70-80 mmHg both in normal individuals and in patients with venous disease; it depends on the pressure exerted by the column of blood from the right heart to the ankle.

In the normal subject this pressure decreases significantly during active movements (e.g. walking) due to venous pumping function and valvular function that fragment the blood column and reduce the hydrostatic venous pressure.[1] In patients with venous insufficiency or obstruction, pressure decreases much less or may even increase due to reduced pumping function and valvular incompetence. This is called AVH.

Venous hypertension leads to changes in the microcirculation causing leg ulcers due to different mechanisms; the most common hypothesis is based on the formation of fibrin cuffs around the capillaries preventing the capillary-tissue oxygen exchange[2] or the white cell entrapment in the peripheral capillaries with their disruption and release of proteolytic mediators that produce tissue necrosis.[3]

The main aim of treatment is to counteract ambulatory venous hypertension by applying an external pressure of the same magnitude in order to narrow or occlude the leg veins, producing a valvular mechanism that reduces venous reflux and increases the calf pumping function.[5]

Basically this is the reason why compression therapy is a milestone in ulcer treatment and is able to promote ulcer healing.[6,7]

Dealing with compression, we already know that compression is better than no compression and that compression exerting high pressure is better than compression exerting low pressure in order to speed up ulcer healing.[7] Less clear is the question whether there is any difference between different compression materials, elastic or inelastic, in producing the best results.

The aim of this paper is to summarize experimental findings showing superior hemodynamic effects of inelastic material compared with elastic material that should produce better outcomes in promoting venous ulcer healing.

Which external pressure do we need to narrow or occlude the veins?

This basically depends on the body position because venous pressure varies in different body positions. It has been shown by Duplex scanner that it is possible to narrow or occlude the veins with an external pressure of 20 mmHg in the supine position, 50 mmHg in the sitting position, 70 mmHg in the standing position.[8] In the same paper it was documented that in the sitting position a pressure of 40 mmHg is enough to narrow (but not occlude) the calf veins but when the patient is asked to do foot dorsiflexions the pressure under an inelastic cuff increased to 60 mmHg and the veins were occluded. These data were confirmed by studies with

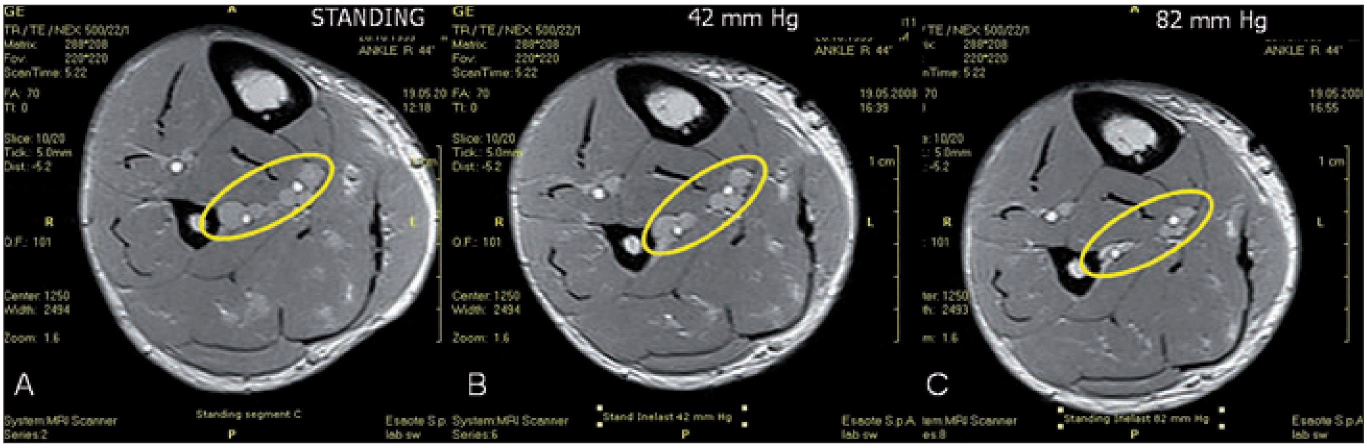

Figure 1: Calf MRI in standing position (A); elastic kits exerting a standing pressure of 42 mmHg are not able to narrow the calf veins in an healthy volunteer (B); an inelastic bandage exerting a standing pressure of 82 mmHg nearly occludes the calf veins (C).

magnetic resonance imaging (MRI) (G-Scan® Esaote, Genoa, Italy) showing that in the standing position a pressure of 40 mmHg is not able to occlude the veins that are completely occluded with a pressure of 80 mmHg *(Figure 1)*.[4]

From these studies it can be concluded that we are able to overcome the standing venous pressure by applying a strong to very strong external pressure with compression devices.[9] Using inelastic material the compression pressure will rise during walking with each step and will intermittently narrow or occlude the veins thereby restoring a valvular mechanism.[5]

Which compression material to choose?

The exerted pressure of a compression devices depends on the stretch we apply to the bandage, the number of turns applied and the radius of the leg-segment (Laplace law).[10]

An ideal bandage should exert a very strong pressure in the standing position starting with a low and comfortable resting pressure. Is it the case for all the bandages? To answer this question we have to take into consideration the main characteristics of elastic and inelastic materials.

An elastic material exerts its pressure when stretched. On one hand it tends to return to its original length when extended (squeezing effect) on the other the bandage gives way to the muscle expansion. This results in a very low difference between resting and standing pressure, typically lower than 10. This difference is termed Static Stiffness Index (SSI)[11,12] and is one of the most important indicators of the stiffness of the bandage. The same happens when walking: the difference between systolic and diastolic pressure during muscular activity, termed Walking Pressure Amplitudes (WPA) (another indicator of the stiffness of the bandage), is very low. In conclusion an elastic bandage exerts a sustained pressure. This means that we can produce a very strong pressure in the standing position with this elastic bandage provided it is applied at full stretch. However, such a bandage will also exert a very strong pressure in the supine position which will make the bandage intolerable and which should be avoided in the clinical setting.

An inelastic bandage comprising short stretch or inextensible material, exerts its effect by resisting the increase of muscle volume during standing and walking: the leg will give way.

This produces a significant increase in the standing and working pressure and the SSI is always higher than 10. During muscular exercise inelastic bandages exert an intermittently strong or very strong pressure, which is relatively low at rest and therefore well tolerated.

In conclusion it is advisable to apply an elastic bandage with a supine pressure not higher than 40-45 mmHg. This bandage will produce a standing pressure no higher than 50-55 mmHg which is not enough to occlude the veins intermittently during walking.

Inelastic bandages must be applied at full stretch and may exert a standing pressure higher than 70 mmHg that is high enough to occlude the veins and restore of valvular mechanism starting with a lower and tolerable resting pressure. For these reasons the inelastic bandage system comes close to the ideal bandage *(Figures 2 and 3)*.

Elastic or inelastic bandages in immobile patients?

Some old textbooks claim that inelastic material would only work during exercise and would therefore be ineffective in patients with restricted or absent mobility of the ankle joint. As demonstrated in *Figures 4 and 5* passive movement of the ankle by a physiotherapist, and also only very small toe movements will produce intermittent peaks (massaging effect) which are much higher under an inelastic than under an elastic bandage. Daily experience shows that especially wheel-chair bound patients presenting with swelling and leg ulceration may benefit dramatically from inelastic

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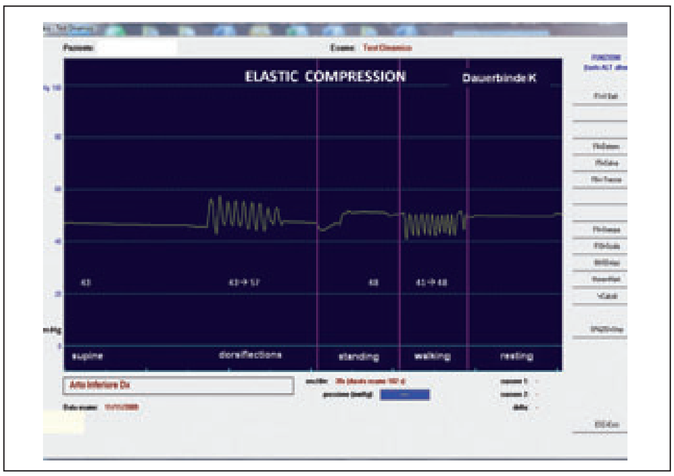


Figure 2: Sub-bandage pressure of an elastic bandage; the supine pressure is 43 mmHg; the difference of maximal and minimal pressure during dorsiflections as well as the difference between standing and supine position (SSI) and systolic and diastolic pressure during walking (WPA) are minimal.

→ bandages which may stay on the leg for several days and nights needing to be changed only when they become very loose.[13,14]

Are these different characteristics reflected in different effects on venous reflux and impaired venous pumping function?

1. EFFECT ON VENOUS REFLUX

In a previous study[15] it had been shown that inelastic is more effective than elastic material in reducing venous reflux in deep venous insufficiency. In this study the air plethysmographic parameters venous volume (VV) and venous filling index (VFI) "were significantly reduced by increasing external pressure, more strongly with inelastic than with elastic material" and the authors conclude: "Using the same bandage pressure, inelastic material is more effective at reducing deep venous refluxes than elastic bandages in patients with venous ulcers". In recent work we came to the same conclusion in patients affected by superficial venous insufficiency.

We studied the reflux volume automatically calculated by Duplex scanner.[16]

12 patients were examined in the standing position by means of the Duplex scanner Esaote Mylab 60® with a specially designed probe (Esaote IOE323® intraoperative, Linear Array 4 - 13 MHz) (Esaote, Florence; Italy) without any compression and following the application of different compression devices from the base of the toes to the knee. The finger-like 12 MHz probe was fixed with tapes at the mid-thigh over the incompetent GSV along the longitudinal axis and its position was never changed during the experiments. The reflux was elicited by tip-toe maneuvers and measured when the patient returned into the upright relaxed position after tip-toeing. After the baseline measurements without any compression we applied elastic and inelastic devices at the same supine pressure of 20, 40 and 60 mmHg. The resulting standing pressures were significantly higher with inelastic material compared to elastic and this resulted in a reduction of venous reflux significantly higher with inelastic material compared to elastic. Only when we applied elastic bandages with 60 mmHg was the reflux reduced to a similar extent, but this high pressure is intolerable and cannot be used in daily practice.

2. EFFECT ON VENOUS PUMPING FUNCTION

In different experiments comprising 68 patients affected by major reflux in the great saphenous vein (CEAP C3-C5), we measured the ejection fraction (EF) of the venous calf pump by means of strain gauge plethysmography[17] and the resting and working interface pressure of different compression devices. Strain Gauge Plethysmography was used according to a previously described protocol (Poelkens et al).[18] The investigation starts with leg elevation in order to empty the veins. The minimal volume of the leg segment proximal to the bandage is registered by the strain gauge. Then the patient stands up and the volume increase of the calf segment, which reflects venous filling, is measured continuously. "Venous volume (VV)" is defined as the difference between empty and filled veins. During a standardized exercise (20 steps on a 20 cm high stair in 20 seconds) the amount of blood that is expelled towards the heart (EV = expelled volume) reflects the quality of the venous pump. The proportion of EV in relation to VV expressed as a percentage is called ejection fraction (EF).

Figure 3: Sub-bandage pressure of an inelastic bandage; the supine pressure is 62 mmHg; the difference of maximal and minimal pressure during dorsiflections as well as the difference between standing and supine position (SSI) and systolic and diastolic pressure during walking (WPA) are very high and significantly higher than with elastic bandage.

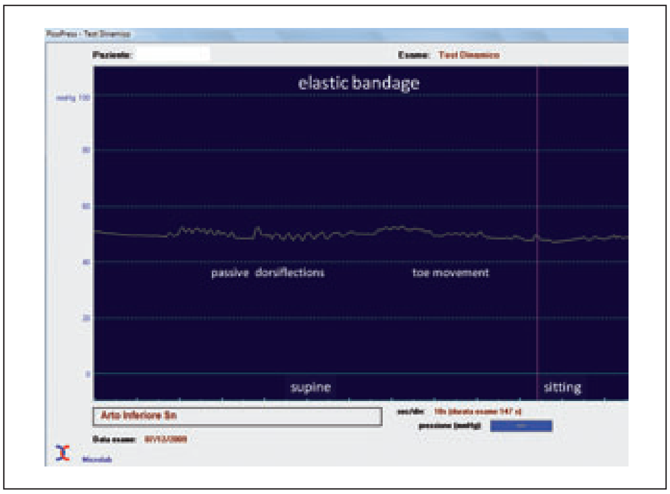


Figure 4: Sub-bandage pressure of an elastic bandage in a patient with restricted mobility. The pressure differences produced by passive dorsiflections carried out by a physiotherapist or a simple toe movements are very low even not clearly visible (toe movement); even the sitting position produces a very small pressure difference.

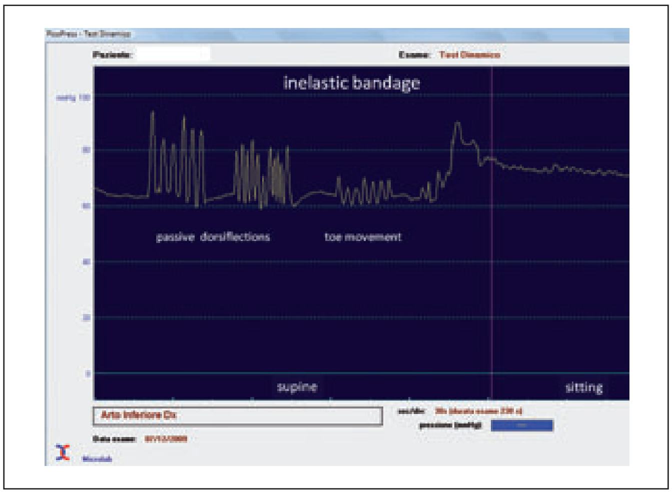


Figure 5: Sub-bandage pressure of an inelastic bandage in a patient with restricted mobility. The pressure differences produced by passive dorsiflections carried out by a physiotherapist or a simple toe movements are much higher than that produced by an elastic device. The same happens with the sitting position.

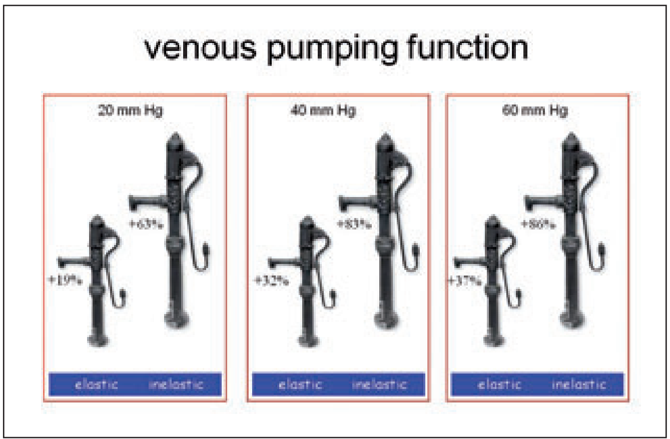


Figure 6: The Ejection Fraction improvement is significantly higher with inelastic compared to elastic bandages at every pressure range (20, 40 and 60 mmHg).

After the baseline measurements without any compression we applied elastic and inelastic materials at the same pressure of 20,40, and 60 mmHg. After standing up, the pressure increased significantly more with inelastic compared to elastic material and the EF was slightly but significantly increased with elastic material but restored in the normal range only by inelastic material[19] *(Figure 6).*

In these series of experiments three findings are worth nothing:

1. In order to prove if this difference is due to the different standing pressure (resulting from the same supine pressure) we repeated the experiments applying elastic and inelastic bandages with the same standing pressure of 60 mmHg. In order to achieve this standing pressure we had to apply the elastic bandage at higher stretch resulting in a high supine pressure of 59 mmHg (tolerable only for the short duration of the test). Despite this high pressure, the increase of EF was always modest and significantly lower compared to the improvement achieved by inelastic material. The EF improvement showed significant correlations with the standing pressure , the pressure differences during movement (massaging effect) and especially with the pressure peaks (working pressure).[17]
2. This significant superiority of inelastic material can also be seen a with a very low pressure of 20 mmHg. While at this pressure range the elastic material is practically ineffective, elastic material produces a significantly higher effect, increasing the EF values almost into the normal range. This has an important implication when we want to use inelastic compression with reduced pressure in mixed arterio-venous ulcers.[19]
3. In a recent experiment (not yet published)[20] we measured the EF not only immediately after elastic and inelastic bandage application but also after 7 days of wearing time. The reason for this experiment is that inelastic material is mistakenly thought to lose its haemodynamic effectiveness very quickly owing to the immediate pressure loss after application. Our results show that, despite a significant pressure loss, the stiffness and the efficacy of the inelastic bandage is maintained over time; this is reflected by high SSI and walking pressure amplitudes that are maintained after one week as well as EF that is still in the normal range. The effect of elastic material that is poor at the application continues to be poor after 7 days *(Figures 7 and 8).*

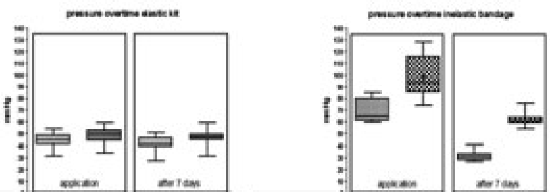
Is this difference in haemodynamic efficacy reflected by a difference in ulcer healing?

Looking at the literature many authors claim the superiority of elastic material (both elastic stockings and elastic bandages) compared to inelastic. This would contradict all the findings demonstrating more favourable hemodynamic effects of inelastic material reported above.

Unfortunately all these clinical studies have major flaws:

A) Comparison of elastic and inelastic bandages

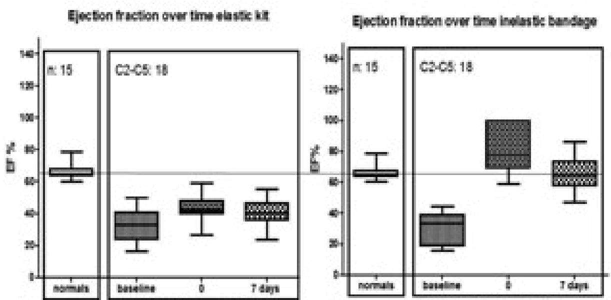
1. The bandage considered the prototype of elastic material (Profore®) is actually rather a stiff bandage. Profore is made up of 4 different mainly elastic components but overlapping of different textiles changes the elastic properties of the final bandage especially because of friction between the layers. This may explain why Profore® has a SSI similar to Rosidal sys® that is mainly composed of inelastic textile.[21] In conclusion all these studies report a comparison between two different inelastic bandages and not between an elastic and inelastic bandage.
2. The sub-bandage pressure was never measured in these studies making it difficult to understand if the bandages were correctly applied and if the exerted pressure →



	supine	standing	supine	standing
Minimum	31.00	34.00	27.00	31.00
25% Percentile	41.00	44.00	39.00	44.75
Median	45.00	49.00	42.00	47.00
75% Percentile	48.50	53.00	46.25	49.25
Maximum	54.00	59.00	51.00	59.00

	supine	standing	supine	standing
Minimum	60.00	74.00	27.00	54.00
25% Percentile	61.00	85.00	28.00	58.75
Median	64.50	93.50	30.50	61.00
75% Percentile	80.00	115.8	33.25	63.75
Maximum	85.00	128.0	41.00	76.00

Figure 7: The sub-bandage pressure of an elastic and inelastic device at application and after 7 days. The pressure exerted by an elastic bandages is slightly reduced. Inelastic devices show a remarkable and significant pressure drop over time.



	normals	baseline	0	7 days
Minimum	60.50	16.40	26.60	23.70
25% Percentile	63.70	23.55	39.73	35.68
Median	65.00	32.90	42.05	40.15
75% Percentile	67.80	40.80	48.28	46.75
Maximum	78.60	50.10	59.50	55.50

	normals	baseline	0	7 days
Minimum	60.50	15.80	59.10	47.30
25% Percentile	63.70	18.80	69.45	57.93
Median	65.00	33.40	77.90	64.55
75% Percentile	67.80	39.10	100.0	73.80
Maximum	78.60	44.80	100.0	86.50

Figure 8: The Ejection Fraction improvement produced by elastic and inelastic devices at application and after 7 days. The improvement produced by elastic devices is small and not enough to restore the EF into a normal range both at application and after 7 days. The improvement produced by inelastic devices is enough to restore the EF into a normal range; despite of a significant pressure drop this the EF, although reduced, remain in the normal range after 7 days.

is consistent in different centres or in different bandages applied by the same bandager. The lack of sub-bandage pressure measurements can be admitted in these "old" studies due to the lack of effective, simple, not expensive and reproducible devices. This can no longer be justified because these devices are now available and inexpensive[22,23] and were used in all our experiments.

B) Comparison between elastic stockings and inelastic bandages.

First of all it has to be noted that the elastic stockings taken into consideration for comparison are actually elastic kits or tubular devices exerting a high supine pressure of 40 mmHg or more and higher stiffness (although always in the range of elastic material) due to the friction between the 2 components. Secondly, once again neither sub-bandage pressure measurements nor bandagers' skills in applying the inelastic bandage have been reported. In one study the patients were even allowed to remove the bandage in the evening and re-apply it the following morning.[24]

So in most of these studies a good elastic ulcer kit was compared with a poorly applied inelastic bandage.

All these elements make it difficult to understand if the bandages were correctly applied because certainly a good elastic kit could work better than a poorly applied bandage (both elastic and inelastic).

Conclusions

Inelastic is more effective than elastic material in reducing venous reflux and in improving the venous pumping function without any doubt. This is the reason why inelastic bandages should be used for ulcer treatment when a venous pathophysiology is involved, that causes venous reflux and a reduced venous pumping function.

Nevertheless, clear clinical evidence concerning the superiority of inelastic bandages in promoting ulcer healing is lacking due to the reported major flaws in the clinical studies. A multicentre, randomized study with experienced bandagers and sub-bandage pressure measurements is highly recommended in order to dissipate any doubt. ■

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Compression stockings for treating venous leg ulcers

Abstract

Background. In order to treat venous leg ulcers, it is recommended to use high pressure compression (30-40 mmHg at the ankle), in particular multilayer bandage. Its use is operator-dependant and the pressure level cannot be guaranteed. Compression stockings which are not operator-dependant could be the best option because of their pressure control. However 30-40 mmHg compression stockings are often hard to put on, especially for the elderly. Putting two lower pressure compression stockings over each other could be a good therapeutic alternative. In Europe, anti-ulcer kits are available in order to solve that issue. Their *in vivo* properties must be specified: interface pressure and a stiffness index. A better understanding of friction coefficient could allow for better kits. **Objectives.** To compare the *in vitro* pressures given by the manufacturers of 3 anti-ulcer kits with the *in vivo* interface pressures measured in healthy subjects. To evaluate the stiffness and friction indices from those kits based on the interface pressure in order to assess their clinical properties. **Material and methods.** Using a Kikuhime pressure device, interface pressure was measured in 18 healthy subjects at the reference point B1. Two stiffness indices (Static Stiffness Index [SSI] and the Dorsi Flexion Stiffness Index [DFSI]) and a friction index have been calculated. **Results.** Both Hartmann's Saphenamed UCV® and Medi's Mediven Ulcer kit® kits get the recommended pressures whereas Jobst's Ulcer Care kit does not. The 3 kits are rigid only when a strong muscular contraction occurs (DFSI). Jobst's Ulcer Care transmits entirely the pressure in relation with a friction index close to 1. **Conclusion.** This trial confirms that it is feasible to get the recommended stiffness index above 10 mmHg using two-layer compression stockings. It provides a reference for an "ideal" anti-ulcer kit by compression stockings.

Keywords: compression ulcer kit, superposition, interface pressure, stiffness index, friction index

Disclosure agreement: The concerned laboratories provided the necessary stockings for measurement purposes.

Background

Compression increases ulcer healing rates compared with no compression.[1,2]

Thus to improve the healing process (recommandation grade 1B) it is recommended to treat venous or mixed venous (0.6> ABI < 0.9) with high pressure. A pressure between 30 and 40 mmHg should be obtained at the ankle (professional agreement).

Multi-component systems are more effective than single-component systems. Multi-component systems containing an elastic bandage appear more effective than those composed mainly of inelastic constituents. Two-layer stockings appear more effective than the short-stretch bandage.[3]

Putting on the bandages requires a great experience and the respect of the bandage strechting rules. A pressure level from 30 to 40 mmHg may not be easy to achieve.

The use of compression stockings seems to be the best option because of the pressure control it allows for and it is not operator-dependant. However 30-40 mmHg compression stockings are often hard to put on, especially for the elderly.

According to F. Amsler[4] putting two lower pressure compression stockings on top of each other is the best option to get the desired pressure level. In terms of healing process, pain level and nursing cares, compression stockings are better than bandages.

Concerning the pressure under 2 stockings on top of each other, A. Cornu-Thenard et al.[5] showed that the *in vitro* pressure, in such conditions, is equal to the sum of the pressures that each stocking induces separately.

The pressure is different *in vivo*.

For H. Partsch et al.[6], the pressure under 2 stockings on top of each other is slightly inferior to the sum of the pressures that each stocking induces separately.

JP. Benigni, A. Cornu-Thenard et JF. Uhl[7] came to the same conclusions in regards to the *in vivo* pressures and the stiffness indices.

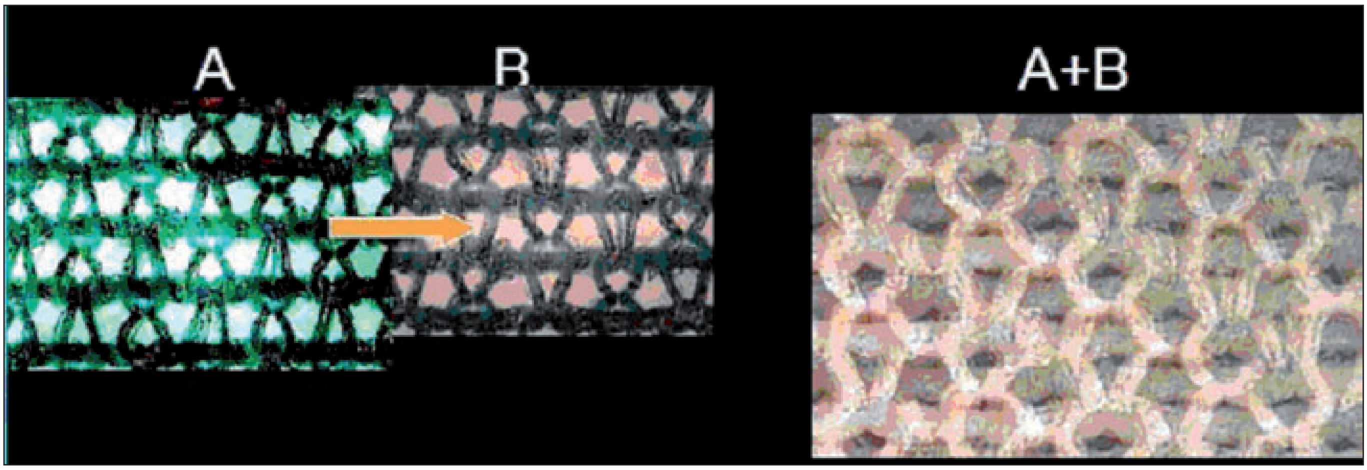
Rastel D, et Lun B[8] agree that the loss of pressure can be explained by the added pressure resulting from two elastic yarns on top of each other. Concerning compression stockings, the yarns go on top of each other in the remaining free areas *(Picture 1)*. Yarns do not rub uniformly on top of each other. Friction forces need to be taken into account in order to understand the loss of pressure transmitted.

Objectives

The aim of this report is:

1. to compare *in vivo* interface pressures at B1 measured in healthy subjects with *in vitro* pressures of 3 different superimposed anti-ulcer 40 mmHg kits.

2. to calculate their stiffness and friction indices based on the *in vivo* interface pressures, in order to appreciate the outcome.



Picture 1: Compression stockings superimposition (yarn of woof and stitch, picture obtained by 2 stockings numeric superimposition)
The *in vitro* pressure kits do not reach the "dose effect" expected. The interface pressures and the *in vivo* kits stiffness must be known. By analogy with bandages they could allow to anticipate the expected clinical effects. Moreover pressure loss happening by superimposing needs to be linked with friction consequences. A better understanding of this process should result in improved kits.

Material and methods

Eighteen healthy subjects participated in the study (6 men and 12 women), aged between 53.1 +/- 12.9 years, with an average height of 168 +/-8 cm, an average weight of 69.8+/- 10 kg with ankles of 22+/-22.9 cm at point B and of 29+/- 3 cm at point B1. Healthy patients were randomized in 3 groups of 6.

The interface pressures were measured at point B1 *(Picture 2)*. This point is described in the CEN document.[9] Measurements have been done both at rest and at work[11] in a lying position and then in a standing position.[10]

Picture 2: Point B1 (Virtual dissection of the leg with a CT scan and a 3D reconstruction without contrast medium.
G: medial gastrocnemius muscle
S: soleus muscle).

COMPRESSION ULCER KITS

Mediven Ulcer Kit® (Medi Bayreuth) compression stockings

- A Mediven® ulcer understocking with an ankle pressure of 20 mmHg (point B). this stocking is to be worn day and night. It is made of 71% polyamide, 28% elastan and 1 % silver (antimicrobial texture).
- A Mediven ulcer plus overstocking also with an ankle pressure of 20 mmHg (point B) only to be worn during the day. It is made of 75% polyamide and 25% elastan.
- *In vitro* pressure Mediven Ulcer kit® (manufacturer) 40 mmHg at point B.

Saphenamed UCV® (Hartmann) compression stockings

- A microfiber understocking to facilitate the application made of 3% Lyocell® and SeaCell® (seaweed et cellulose), 9% cotton, 18% elastan and 70% polyamide also generating a optimum pressure on the ulcer area and keeping a low graduated pressure from the ankle to the calf. It is made of smooth yarns and do not put pressure on the feet.
- An overstocking, open foot. It is made of 61% polyamide, 28% elastane, 8% coton and 3 % Lyocell®
- *In vitro* pressure Saphenamed UCV® (manufacturer): 40 mmHg at point B.

Jobst UlcerCare® (Jobst) compression stockings

- An understoking for protection, made of 78% nylon/polyamide and 22 % Spandex/elastane
- An overstocking with a zipper. It is made of 85% Nylon/polyamide and 15% dSpandex/elasthane.
- *In vitro* Jobst UlcerCare® pressure (manufacturer): 40 mmHg at point B.

The sizes of stockings were selected accordingly to the manufacturer's recommendations, depending on the circumferences measured at ankle level (point B).

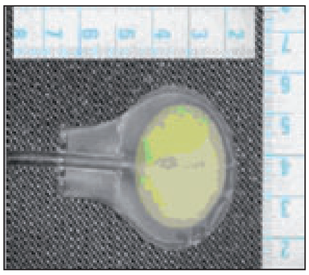
IN VIVO INTERFACE PRESSURE MEASUREMENTS

The interface pressures were measured using the Kikuhime system (TT Medi Trade, Soleddet 15, DK 4180 Soro), which is composed by:

- A Kikuhime device *(Picture 3)*
- This system uses two identical, oval-shaped measuring sensors, 30 x 38 mm, 3 mm thick when calibrated to 0 mmHg.

Picture 3: Kikuhime device.

At point B1, the interface pressures were measured on the 18 healthy subjects' right leg in 3 positions (at rest and at work in a lying position, then standing up). Each measurement was repeated 3 times as follows: with the understocking, then the overstocking alone and finally the two on top of each other. 486 measurements were completed.



Picture 4: pressure sensor.

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STIFFNESS INDEX CALCULATION

Static stiffness index (SSI) reflects the difference in interface pressures between the lying and standing positions.

In France, another stiffness index is used: the DFSI (Dorsi Flexion Static Index). It reflects the difference in interface pressures between the lying positions at rest and after a complete foot dorsiflexion.[11] We consider a compression is stiff when the SSI is higher than 10 mmHg.[10]

FRICTION INDEX CALCULATION

When on top of each other and moving, the knitting yarns rub each other. When stretching the two knitted pieces, the threads are not superimposed anymore and the transmitted pressures become smaller.

A friction index low underlines a stiffness loss when superimposing two stockings.[13]

This index equals to:

2 Superimposed stockings stiffness index (SIsup) divided by the sum of the stiffness indices of the 2 stockings used separately (SI alone).

$$IF = \frac{SI^{superimposed}}{SI^{alone} + SI^{alone}}$$

Statistical analysis

Measurement of the coefficient of variation, comparison of means for the interface pressure and the stiffness index were performed using the Student t test.

Statview version 5 statistics software was used to perform the calculations.

Results

IN VIVO PRESSURE MEASUREMENTS IN mmHg AND STIFFNESS INDICES CALCULATION

The 3 groups were comparable for sex, age, BMI, leg circumferences. For the Saphenamed UCV® (Hartmann) *(Table 1)* and Mediven Ulcer kit® (Medi) *(Table 2)* kits, the *in vivo* interface pressures at B1, in the three situations, are within the limits of pressures recommended to treat a venous ulcer. On the other hand the pressures of the Jobst's superimposed stocking kit, stay under 30 mmHg at rest. They only exceed 30 mmHg when there is a muscular activity. *(Table 3)*

For the Saphenamed UCV® (Hartmann) and the Mediven Ulcer Kit® (Medi) kits the pressures measured *in vivo*, when superimposing, are smaller than the sum of the two stockings used separately. As for Ulcer Care® (Jobst), there is no difference.

All the pressures measured under the three understockings are low hence the understockings can be kept on the leg during night, even in patients with peripheral arterial occlusive disease (with an ABI> 0,6) without ischemic risks.

The bigger the pressures get, the more the stiffness indices (SSI and DFSI) increase. Our analysis goes along previous publications.[6,7]

For the three tested kits the comparison between the *in vivo* average pressure at rest and at work (DFSI) shows a noticeable difference superior to 10 mmHg ($p<0.05$) associated with an automassage effect necessary to reduce an edema when walking. Under these conditions, the Mediven Ulcer kit® is significantly stiffer than the Jobst's Ulcer Care® kit.

None of the three kits are stiff between the resting and standing positions (SSI).

Concerning the Saphenamed UCV® of Hartmann and Mediven Ulcer kit® kits, the stiffness indices are lower than the sum when the two stockings are superimposed, whereas for the third Jobst's Ulcer care® kit, there is no difference between the results of the sum of the two pressures and the superimposition.

The calculation of a friction index is necessary to explain these differences.

FRICTION INDEX

Jobst's Ulcer Care® friction indices are 0.99 (DFSI) and 1 (SSI). In other words, the kit transmits all of the two stockings pressure.

In vivo	Overstocking	Understocking	Theoritical sum	Superimposition Measured
At rest	19,2 (1,5)	17,2 (1,3)	36,4	34,8 (5,4)* **
Dorsiflexions	26,1 (2,4)	25,1 (3,9)	51,2	47,3 (8,8)*
Standing up	24,4 (2,1)	23,1 (3,9)	47,5	43,6 (9,2)**
SSI	**5,2**	**5,8**	**11**	**8,7**
DFSI	**6,8**	**7,9**	**14,7**	**12,4**

* **p < 0.05

Table 1: Average and standard deviation of the Saphenamed UCV® kit of *in vivo* pressures at point B1 and stiffness indices.

In vivo	Overstocking	Understocking	Theoritical sum	Superimposition Measured
At rest	19,0 (3,9)	16,8 (3,3)	35,8	33,0 (4,7)* **
Dorsiflexions	28,9 (5,0)	26,8 (4,8)	55,7	48,2 (5,4)*
Standing up	25,1 (3,4)	22, 2 (3,2)	47,3	41,9(5,5)**
SSI	**6,1**	**5,4**	**11,5**	**8,9**
DFSI	**9,9**	**10,1**	**20**	**15,2**

* **p < 0.05

Table 2: Average and standard deviation of the Mediven Ulcer Kit® of *in vivo* pressures at point B1 and stiffness indices

In vivo	Overstocking	Understocking	Theoritical sum	Superimposition Measured
At rest	15,7 (3,4)	8,3 (0,8)	24	24,2 (4,5)* **
Dorsiflexions	22,4 (6,3)	12,8 (3,0)	35,2	35,3 (6,5)*
Standing up	19,8 (4,5)	12,2 (2,3)	32	32,2 (5,3)**
SSI	**4,2**	**3,9**	**8,1**	**8,1**
DFSI	**6,7**	**4,6**	**11,2**	**11,3**

* **p < 0.05
Table 3: Average and standard deviation of the Jobst Ulcer Care® kit of *in vivo* pressures at point B1 and stiffness indices

	Saphenamed	Mediven	Jobst	Saphena Vs Mediven	Saphena Vs Jobst	Mediven Vs Jobst
SSI 2 CS superimposed	**8,7 (4)**	**8,9 (4,1)**	**8,1 (3,9)**	**NS**	**NS**	**NS**
SSI sum	11 (4,6)	11,5 (4,7)	8,1 (3,9)	NS	p<0,05	p<0,05
DFSI 2 CS superimposed	**12,4 (4,9)**	**15,2 (5,5)**	**11,2 (4,6)**	**NS**	**NS**	**p<0,05**
DFSI sum	14,7 (5,4)	20 (6,7)	11,3 (4,6)	p<0 ,05	p<0,05	p<0,05

Table 4: Comparison of the stiffness indices measured with 3 kits and the stiffness indices calculated based on the sum of pressures, with α=5 % one-sided p<0,05.

However the other two kits, whose friction indices were 0.84 and 0.79 for Saphenamed UCV® and 0.76 and 0.77 for Mediven Ulcer kit®, underline that they only transmit the pressure partially. The pressure loss is about 20% for these two kits.

In these two kits, the two superimposed stockings fibers do not come on top of each other when stretched, in contrast to Jobst's Ulcer Care® kit.

Discussion

Therefore when superimposing stockings, using either the Saphenamed UCV® (Hartmann) or the Mediven Ulcer Kit® (Medi) kits, the real *(in vivo)* pressures obtained at rest, at work and standing up are similar to the ones given by the manufacturers *(in vitro)*.

However the Ulcer Care® (Jobst) shows differences when tested at rest.

Medi's Mediven Ulcer Kit® has the hightest DFSI. Hence this kit is stiffer than the other two and should theoretically have a better massaging effect.

But one should not get confused between the stiffness and the friction indices. Even if the kit is stiff the pressure loss, when superimposing stockings, can be important. The Mediven Ulcer Kit® (Medi) kit is the stiffest out of the three studied but there still is a 20% pressure loss when superimpoed. The Ulcer Care® (Jobst) kit, even though less stiff, transmits all the pressure.

This underlines the importance of the friction index. In order to understand it better, one should go back to the laws of friction for materials. Pierre-Gilles de Gennes summarizes them as follow[13]:

« Leonard da Vinci's work imposed itself as a cornerstone in this field. He observes that if an object - a piece of wood – is on a surface that is then raised up, it will slide along it up from a certain angle. This is a feature of static friction. In 1699, Guillaume Amontons repeats the experience and comes to the same conclusion. It is only in 1950 that the British school (T. P. Bowden and David Tabor) explained why a small surface has the same properties as a big one: the tight contact results from asperities and bumps. When using a small surface the pressure applied increases, hence the decrease in surface is compensated by a higher density on the contact zone. The same result is obtained than on a bigger surface».

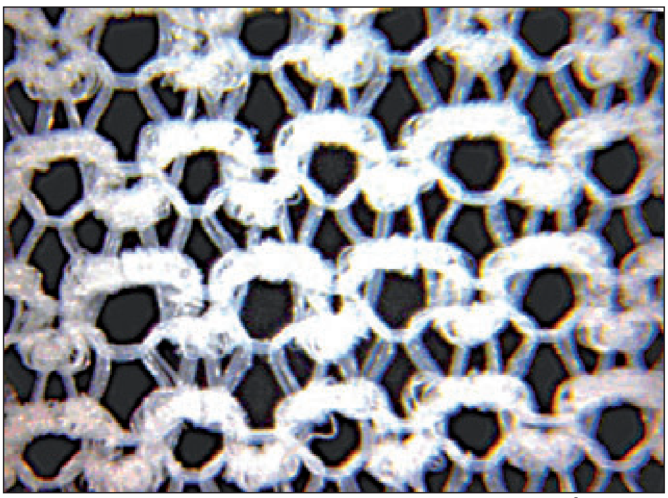
Friction Index	Saphenamed UCV® (Hartmann)	Mediven Ulcer kit® (Medi)	Ulcer care® (Jobst)
SSI	0.79	0.77	1
DFSI	0.84	0.76	0.99

Tableau 5 : Friction indices.

Jobst's Ulcer Care® kit has the biggest friction pressure possible: 1 for the SSI and 0.99 for the DFSI. There is no loss of pressure, during a muscle contraction when superimposing, in relation with the number of asperities between the two stockings although the pressures applied are smaller.

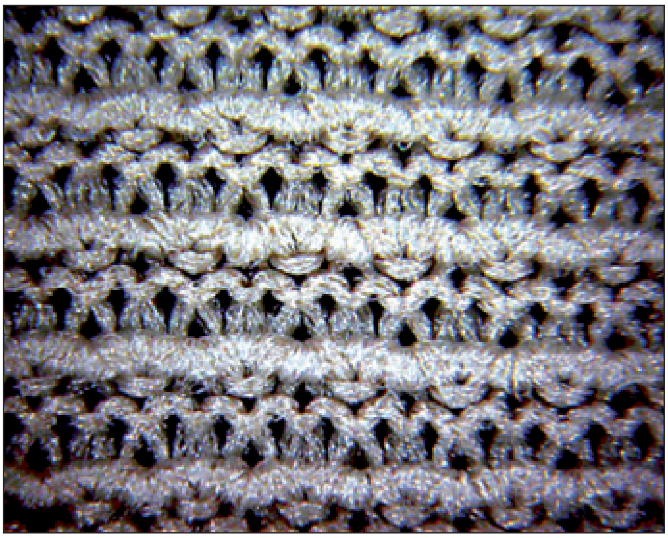
In this kit, the stitch of the overstocking is very dense. Because there are a lot of asperities, the friction of the understocking on the overstocking is high. There is no free space between the yarns of woof, hence a friction index equals to 1 *(pictures 5 and 6 numeric microscope)*.

→



Picture 5 : Stitch of the understocking from Jobst's Ulcer Care®.

→ The knitting of the other two kits is completely different. There are fewer asperities; hence the friction indexes are smaller by approximately 20% *(Pictures 7 and 8)*. In the stitch, the yarns of woof are superimposing because of the remaining free space between them.



Picture 6: Stitch of the overstocking from Jobst's Ulcer care®.

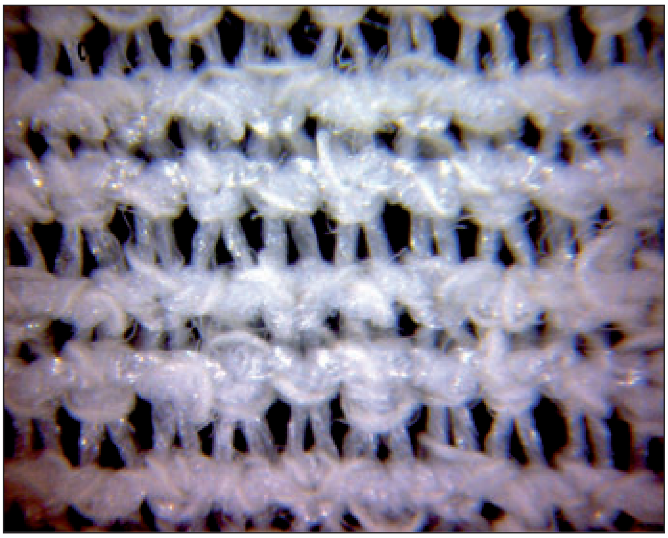


Photo 7: Stitch of the understocking from Saphenamed UCV® (Hartmann)

Photo 8 : Stitch of the overstocking from Saphenamed UCV® (Hartmann)

PUTTING THE STOCKINGS ON

Our last, but nevertheless, important issue to tackle is the putting-on phase for those three kits.

Jobst's Ulcer care® understocking is easy to put on. However the overstocking is not, it is hard to zip it up.

The lack of heel on the understocking makes the other kits easier to put on.

Hartmann's Saphenamed UCV® kit probably is the best to use when putting an ulcer bandage on. Indeed both the understocking, with its low graduated pressure, and the overstocking, with its open foot, are easy to put on. Overall this kit was the easiest to use.

Conclusions

This anti-ulcer compression stocking study underlines that *in vivo* and *in vitro* pressures can be different (Jobst's Ulcer care® kit).

The three kits stiffness is superior to 10 mmHg during a muscle contraction (DFSI) close to walking.

In order not to lose pressure, it is important to take into account the friction index when superimposing two stockings. To that end it is more important to increase the number of asperities between the two anti-ulcer stockings, through their knitting, rather than considering the actual pressure applied.

The ideal anti-ulcer compression stocking kit should have the following features:

- Low pressure understocking, between 10 à 15 mmHg at point B,
- Easy to put on the foot (bump on the back of the foot or lack of pressure on the foot),
- An open foot overstocking with a pressure of about 25 mmHg at point B,
- When superimposed and at rest, a pressure between 30 à 40 mmHg at point B1,
- An upper stiffness superior to 10 mmHg for both the le Static stiffness Index and the Dorsiflexion Stiffness Index,
- A friction index close to 1 thanks to an increased number of asperities on both of the stockings in relation with an efficient knitting.

In the future, bandages will only be used during the initial oedematous phase of venous leg ulcer treatment. The kits with the two superimposed stockings will be used during the secondary phase.

The low pressure understocking will safely treat the patients with peripheral arterial disease (with an ABI> 0,6), especially in the elderly. The care will then be provided by the patient's family. Hence significant savings for the community can be expected. ■

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Choice of different compression devices for ulcerated legs

Abstract

Compression devices vary in their technical characteristics and for that reason they have different effects on the treated limb. Factors relating to the materials used can generally be summarized as the type of pressure exerted on the limb in varying positions, the pressure gradient, and the stiffness of the end-product under static and dynamic circumstances. In patients with a venous leg ulcer the choice of compression should be based on the patient's general condition, the actual needs of the wound, size and components of the bandage or stocking and the frequency of its replacement. Evidence from trials support the choice of several materials and techniques for healing the ulcer, according to the clinical situations. Care givers should stay alert for complications and side-effects when applying compression therapy.

Keywords: medical compression treatment, wound healing, treatment management, compression bandaging, compression stockings

The effect of a medical compression "device" depends for a major part on factors relating to the materials used: the pressure exerted on the limb, the pressure gradient, and the stiffness of the end-product.[1]

The choice of compression should be based on the patient's condition (mobility, ability to care for him/herself), or the need for assistance in putting them on), the state of the wound (exudative, infected or clean granulating), size of the bandage and the frequency of its replacement.[2] Several well-conducted randomized studies comparing different types of bandages have been published, with contradictory results regarding effectiveness for healing a venous leg ulcer. Also, results of studies cannot always be transferred to the clinical setting of everyday practice. The reason for this is probably that the baseline characteristics of the real-life population with an open leg may seem to be more complex than the included study population.

Facing a compression treatment decision for a particular patient, steps in reasoning will probably be:

- What is this patient's actual clinical situation?
- What is our goal / desired outcome?
- What materials / techniques are available to reach this goal?
- Is there some evidence from literature to support this choice?
- Are there any contra-indications or complications to fear or to anticipate?
- Can we treat the whole limb with one single technique?

The patient's actual clinical situation

This title refers to the local (ulcer itself), regional (the limb) and systemic (general health) conditions.

The etiology (or combined etiologies) of the ulcer: deep and /or superficial venous insufficiency, venous obstruction, mixed underlying etiology, type of wound, healing phase and degree of exudate. The leg ulcer may need different wound management according to wound characteristics; the frequency of dressing changes will influence the choice of compression materials. When frequent dressing changes are required for an exuding ulcer, the wound needs to be readily accessible. Bandages or stockings are more appropriate than any type of sustained compression left in place for a longer period of time. Healing, granulating ulcers can be treated with a dressing left in place for several days. In this situation, any type of compression may theoretically be chosen: Unna-boot, 4-layer or analogue systems, stockings. 'Freshly' grafted leg ulcers need gentle care, dressings left in place for some days. In bedridden individuals a lighter compression will do, while for mobile persons the compression treatment needs to be more accurate and sustained.

Local wound management should not be underestimated, nevertheless it has been shown that compression treatment is more important than topical wound management for venous ulcer healing.[3]

In case of edema or lipodermatosclerosis many authors will prefer treatment with a reasonable degree of stiffness. This will apply to the clinical stages C3 to C6 of the CEAP scoring and classification system.[4] Irritant or allergic dermatitis, and the fragile skin especially due to high age or prolonged usage of corticosteroids may not tolerate high pressure values or may be traumatized by the application of rough materials onto the non-protected skin at bony prominences or overlying the tendons and joints. The shape and consistency of the limb may cause problems just like the ankle circumference. The normal range of ankle diameter for compression devices is between 18 and 25 cm. The pressure applied by a bandage or stocking is inversely proportional to the radius and may rise to high values on thin legs. Compression will be different for active mobile people compared to wheelchair-dependent patients or those with limited joint mobility of ankle, knee, hip and hands. In the latter, ankylosis impairs venous pump function, and in association with reduced muscle strength often makes it impossible to put on or to take off the compression device without help / assistance. Joint symptoms are frequent. Superposition of low pressure stockings or sustained short stretch compression may be a good choice. Thus the patient's lifestyle and concordance will direct the choice of compression device.

Patients suffering from a healed or active leg ulcer are usually elderly and sometimes in poor general health. Comorbidities like congestive heart failure, neuropathy and peripheral arterial disease present challenging situations. Reduction of oedema must occur gradually to prevent cardio-pulmonary distress. Peripheral arteriopathy is not an absolute contraindication for elastic compression therapy: short stretch bandages or any other compression system applying a low resting pressure may be tolerated when peripheral systolic pressure is superior to 80 mmHg. Assessment of the arterial status must precede any decision to apply compression treatment.

The experience and competency of the bandager / care giver, and country- specific factors like availability of materials, reimbursement and national (para-)medical resources will influence cost of treatment and choice of materials.

Treatment goal / desired outcome

In venous disease, compression therapy will aim at optimizing venous ambulatory functioning, edema reduction, normalization of secondary skin changes (C4-C6), and relieve subjective symptoms / quality of life.

Many investigators have studied the effect of compression treatment on venous flow in the deep as well as in the superficial venous system of the lower limb, using several validated measuring devices. Results demonstrate a reduced incidence of deep venous thrombosis by temporarily increasing the velocity of blood flow within veins.[5] Venous pressures in the intravascular compartment and the extent and severity of ambulatory venous hypertension correlate well with the severity of the pathophysiology in chronic venous insufficiency.

Pressures needed to narrow or to occlude varicose veins have been described in varying clinical situations. Compression treatment either by the use of bandages or elastic stockings, does not always significantly influence the ambulatory venous pressure in patients with venous disease except in varicose veins (C2).[6-8] Measuring and management of interface pressure between leg and compression device will be discussed further in this issue. Compression treatment has a strong influence on transmural pressure by increasing the interstitial pressure, thereby reducing the capillary filtration rate and thus the formation of edema. It was reported by Bell *et al* that the rise in tissue pressure induced by foot movements was always greater under non-elastic than under elastic bandages, explaining why short stretch materials (stiffness) is superior in the removal of edema.[9] Horner reported that graduation of compression by 20-30% from ankle to knee influences the ambulatory venous pressure in patients with deep venous insufficiency.[10]

Not only the mechanical effects but also metabolic and behavioral changes on the cellular level (endothelial cells, circulating leukocytes, fibroblasts) have been described on the level of the microcirculation. Alterations of the skin and other tissues may be explained by these physiological processes.[11-13] More recent publications and trials include aspects of quality of life and symptoms like pain or itch in the reported outcomes of compression studies.

Pressure values around 40 mmHg or more at the ankle are recommended to heal a venous leg ulcer. For reduction of edema, much less is needed since pressures as low as 6-20 mmHg may be effective. We do not know what mechanical forces are needed or how much is beneficial to impact on the indurated inflamed peri-ulcer skin.

Which materials and techniques are available to reach the desired outcomes

Often there is a choice between several types of compression devices which are all in principle appropriate for a patient in a given situation. Selection will be based upon the assessment of several parameters as mentioned above, in order to offer a safe, clinically effective and cost-effective care, well acceptable and to which the patient will be compliant. Aspects to consider are: frequency of application, graduation of the compression forces from ankle to knee, constant elastic pressure or varying resting and working pressures, and additional therapeutic measures including elevation of the legs, mobilization exercises, assistance devices to don the stockings, protective padding, and foot ware.

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Figure 1. Example of a cohesive bandage consisting of two superposed cohesive components: one padded cohesive layer with a foam backing and a second layer of plain cohesive bandage. The material is a laminate of nonwoven material and elastic fibers placed lengthwise to provide elasticity. The elastic wrap contains a cohesive material that makes it stick to itself but not to other materials or skin. Although the material used is 'elastic', the end-result is a multi-component multilayer cohesive and stiff bandage that will exert a sustained short stretch compression left in place for several days.

Bandages and bandaging techniques can be classified according to the way they are applied, and /or the composition of the fabric and resulting characteristics. Some bandages are medicated or coated with a zinc paste, some are adhesive or cohesive, most are plain textile with or without elastomeric fibers. Definitions and terms must be carefully used; standardized reporting avoids confusion when comparing results. Recent publications have tried to properly set the correct definitions for describing compression devices.[14-16] When bandages contain elastomeric fibers, they are called elastic. These materials are capable of stretching and then return to their original size or exert a force in the intention to do so: they can sustain a certain pressure for several days due to their ability to accommodate changes in limb shape / volume and movement. Inelastic bandages exert a low resting pressure which decreases over the first 24 hours as edema decreases or with movements, but the working pressure tends to stay high enough to be effective. As expected, pressures on the limb will be influenced by the way the bandaging is applied: the extension of the bandage and the spires: e.g. in spirals or figure-of-eight. Stiffness will also be influenced by the number of layers and the composition of the superposed materials as in multi-component and/or multilayer bandaging *(Figure 5)*. The more stiffness we build into a bandage, the more risk for 'iatrogenic' limitation of joint mobility at the ankle. For skin protection over tendons and bony prominences, a careful bandager will use a protective padding, while the pressure may need to be transferred to hollow sites with padding materials ('pelottes').

Similar to bandages, medical elastic compression stockings have varying degrees of compression, elasticity, stiffness, etcetera according to the fibers they contain and the way they are knitted and assembled. Graduation of the applied pressure is designed in the manufacturing of the stocking. They come in standard sizes or are made to measure, and they may be as effective as bandages for healing venous ulcers. Specifically for treating active leg ulcers, superposition of two low pressure stockings marketed as an 'ulcer kit' (Mediven ulcer kit®, Venotrain UlcerTek®, Tubulcus®, SaphenaMed®, *et al*) have been shown in randomized trials to offer a practical and effective solution.[17]

Assistance devices facilitate the donning of these stockings, especially when these are prescribed in superposition, and these should be prescribed and their usage explained to the patients, for this may substantially enhance compliance and self-care. The same goes for the 'Velcro-fixed' inelastic, adjustable, graduated compression devices which may be worn directly onto the skin (legging orthotics: Circaid® *(Figure 2)*) or over a padded cotton boot (Graduate™ system). Their effectiveness in healing venous leg ulcers have been demonstrated in a randomized comparative trial.[18]

In situations where compression bandaging or stockings are difficult to apply, when venous pump function is deficient due to several causes, or else in order to reinforce the effectiveness of compression treatment, pneumatic devices may be used to apply intermittent pressure. Especially used when there is associated lymphangiopathy, these intermittent pneumatic devices may eventually be used in combination with manual lymphatic drainage. Clinical trials have proven its effectiveness in patients with delayed ulcer healing.[19] They are discussed further in this issue.

Evidence for the effectiveness of the different compression treatment options

In a recent publication reviewing a comprehensive amount of the relevant literature, evidence for effectiveness of compression therapy methods was critically evaluated and scored according to the recommendations of the GRADE group to categorize their scientific reliability. The review included papers on compression stockings, bandages and intermittent pneumatic compression devices *(Figure 3)*.[20]

Figure 2. Circaid® is a 'velcro-fixed' inelastic, adjustable, graduated compression device which may be worn over a protective tubular stockinette or directly onto the skin (legging orthotics)

Contra-indications and complications of compression therapy

Local skin conditions may form a temporary or relative contra-indication for some types of compression treatment. Oozing dermatitis and diffuse maceration of the skin ask for frequent dressing changes or other management decisions which may interfere with stockings or sustained bandaging. Acute infection of the limb must be cared for before focusing on compression devices: the pain, fragility of the inflamed and swollen or blistering skin in patients with erysipelas, and the need to closely monitor the progression of the clinical signs force us to postpone compression for some time, and to choose for leg elevation instead. Intolerance or hypersensitivity / allergy to one of the components of the bandages or stockings is another reason to interrupt compression until skin tests confirm and document the responsible allergen. Most often, contact allergy

Figure 3. Evidence for effectiveness of compression therapy methods has been critically evaluated and scored according to the recommendations of the GRADE group to categorize their scientific reliability. The review included papers on compression stockings, bandages and intermittent pneumatic compression devices.

to compression devices is due to latex, adhesives, coloring agents or fabric finishing chemicals. Recent development of 'medicated stockings' and the manufacturing of 'smart or antiseptic fabrics' include a certain risk for developing contact allergy to the added ingredients. Neuropathy and micro-angiopathy due to diabetes and to hypertension are loco-regional medical conditions to be considered when prescribing compression treatment.

Systemic contra-indications concern hemodynamic parameters of tissue perfusion: obliterating arteriopathy in the stages Fontaine III of IV are considered not to be treated with high pressure elastic compression. A general rule states that if distal systolic arterial pressure measured by Doppler is less than 80 mmHg, then compression must be adapted in order to not exceed 20% of this value. In the case of congestive heart failure with cardiogenic oedema, forceful bandaging favors rapid shift of the interstitial fluid into the lymphatic / venous compartment bearing the risk of heart decompensation due to sudden fluid overload.

Compression therapy should be selected on an individual basis for each patient and each temporary situation.

Compression for prevention of leg ulcer recurrence (C5)

A Cochrane review and several studies conclude that venous leg ulcer recurrence can be prevented by the long term use of compression "of the highest class that is tolerated by the patient", or which is reasonably practicable. The level of effectiveness must of course be reached for that individual patient in order to expect any benefit, but the consensus is that there is probably a therapeutic window. Superposition of stockings or bandages makes it easier to reach the desired compression class, and since it is more comfortable for the patient who will therefore be more compliant, this is effective in many instances. Extra padding around the malleolar region may be required.

For prevention of recurrence in people suffering from superficial venous insufficiency, the combination of surgery and compression is more effective than compression alone. There was no difference between these two approaches in the presence of extensive deep reflux.[21] No studies could be found comparing compression versus no compression for the prevention of venous ulcer recurrence. The rate of recurrence is lower when stockings are worn of a high compression class as opposed to lower pressures.[22-24] For the interpretation of literature results the reader should keep in mind that compression class definitions vary widely between countries or manufacturers and that pressure values to be compared should therefore be expressed in millimeter mercury (mmHg).

Uniformity of compression device versus compartmentalization on the limb

The most frequently encountered challenges in daily practice are extreme obesity, disproportionate anatomical contours or disfigured limbs, and skin problems or wound complications on the limb to be treated. Obese limbs may need to be divided into manageable parts which can be compressed by several different materials and methods, not necessarily the same for the whole limb. Some patients present with limbs that have a hard indurated or sclerotic ankle and gaiter area, with or without ulceration, and a swollen soft obese upper part. The "champagne bottle" leg is a challenge for effective compression treatment especially in cases presenting with heavily obese thighs or arthrosis in the knee. Due to limited mobility the skin from the calf upwards may be oedematous, with papillomatous lesions due to lymph stasis, or presenting myxoedematous changes like is seen in diabetes and thyroid disease. The need for mobilisation and compression of tissues is not equal in the two different compartments of the leg, and many times compression treatment will have to be adapted towards a combination of different materials and techniques.

In grossly deformed limbs with globular overgrowth as seen in lipoedema or lymphoedema, often the skin is soft and folded (rippled) at the base of the saccular mass, suggesting that movement and compression of the tissue are able to achieve softening and drainage of tissues. Creative separate bandaging of each leg 'compartment' will eventually result in an acceptable correction of the anatomical contours, rendering maintenance treatment technically feasible.[25]

Future developments, research needed

More research is needed on the impact of compression treatment on a cellular level: on function and behavior of endothelial cells, interstitial tissue cells like fibroblasts, adipocytes and inflammatory cells, and keratinocytes. These cells react to mechanical forces in the tissues in which they reside and communicate with each other or interact with the matrix they rest on. This research could shed light on aspects of wound healing and of tissue inflammation due to venous insufficiency.

Well conducted clinical trials are still needed to document evidence of efficacy and cost-effectiveness in specific indications.[20,26]

Textile research and developments is an interesting field to follow-up concerning future evolutions in compression bandages and stockings. Smart textiles that would monitor pressures or other biological parameters, new fibers, fabric enhancement regarding durability or antiseptic properties are examples of future interests.

→

Figure 4. The most frequently encountered challenges in daily practice are extreme obesity, disproportionate anatomical contours or disfigured limbs, and skin problems or wound complications on the limb to be treated.

→ And as it is done for pharmacological substances, some authors underline the need for post-marketing medical device monitoring: reporting of side-effects and adverse events.[27]

Conclusion

In order to be effective and to stimulate compliance, it is interesting to choose the optimal treatment best adapted to the actual needs of the individual patient.

Some rules of the game must be followed to reach our purpose to heal a venous ulcer, normalize the skin changes, and prevent recurrence.

When surgery is not an option or has only partial results, compression treatment is a valuable and effective choice. High compression levels and higher stiffness are more effective than low pressure very elastic materials or bandaging systems. Protective padding is best used on sites of high pressure like prominent bone or tendon, and 'fillers' will be added in places where compression is inadequate due to anatomical configuration: in the retro and sub-malleolar region, where skin alterations and venous ulcers tend to occur.

Short stretch compression is preferred by many in the case of deep venous reflux, phleboedema, lipodermatosclerosis, or for starting up a therapy phase, all in mobile patients. The technique is not always easy to learn, and these short stretch bandages slip off more easily especially when effective in removing edema. Even when they do stay on, the pressure drops within a few hours, but the pressure wave 'amplitude' remains in the effective range. This is sometimes cumbersome, requiring more frequent re-application of the bandage. Their advantage lies in the well tolerated low resting pressure and the high pressure peaks during activity.

Long stretch bandages and elastic stockings are more easy to apply and to learn for self-care. Sustained higher pressure values may reach a level of risk in case of excessive force on top of bony prominences or tendons, and the stockings or elastic bandages must be removed at night. Special attention is needed in case of arteriopathy, microangiopathy, diabetes, or hypertension.

Another advantage of bandages in general is the fact that they will always fit the leg whatever happens to volume or configuration. Superposition of elastic materials can reach the same degree of stiffness and effectiveness since the successive spires or superposed layers of fabric limit each others' expansion (higher pressure values and friction factor). This effect is amplified when using cohesive or adhesive bandages, which can be left in place for several days, and are good choice for ambulatory patients who are unable to care for compression themselves. The option is then to leave the ulcerated area reachable for daily care or to enclose it in the sustained bandage. ■

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Why patients do not adhere to compression and how to enhance compliance with leg ulcer treatments

Abstract

70% of leg ulcers are caused by venous insufficiency. Compression treatment is mandatory to heal these venous leg ulcers. The numerous patients who do not adhere to the treatment increase the rate of non healing wounds in this population. Based on literature and personal experience, we may list some explanations for this poor compliance to compression: difficulties of bandage application especially when the legs present some degree of arthritis, psychological and aesthetic resistance, refusal to wash the legs, heat and discomfort, loss of muscular strength and associated pathologies. These patients said they would prefer to take pills or to be operated on... rather than wear compression. The need to wear compressive bandages for life, the recurrence rate, the need for someone else to help, the exclusion from normal social life and the cost of the treatments are the most common reasons to interrupt the treatment. Analysis of the effectiveness of interventions concerning enhancing compliance should be done: patients should be also encouraged to enhance physical activity (walking and practicing leg exercises) shoes should be adapted, pain must be controlled, education and training improved. The selection of adapted compression devices (2 layers rather than 4 layers, hosiery rather than bandages) is crucial, as well as the control of oedema and pain. The associated arterial insufficiency has to be checked regularly and the compression techniques adapted accordingly.

Keywords: venous leg ulcer, compression, compliance

Introduction

As 70% of leg ulcers are caused by venous insufficiency, compression treatment is mandatory to the healing process. Compression increases ulcer healing rates compared with no compression. Multi-component systems are more effective than single component systems.[6] Multi-component elastic are superior to inelastic.[5] However the numerous patients who do not adhere to the treatment and the poor quality of compression application increases the rate of non healing wounds in this population. Nevertheless, the adherence to treatment was not analysed in the Cochrane Review,[5] and healing is directly related to adherence.[2] Unfortunately, few studies on issues concerning adherence are reported in the literature. Some focus group unstructured conversation was reported by Mudge, but observational studies and Randomised Controlled Trials (RCT) are lacking.[4]

Classically admitted explanations for poor compliance

REASONS ARE MULTIPLE AND COMPLEX

Psychological resistance to compression is often cited by practitioners, as is the frustration with the absence of rapid and unique solutions: patients would prefer pills or an operation instead of having the choice between a chronic disease or a chronic constraint! The need to wear compression for life is an important source of frustration for the patient.

The high rate of recurrence, regardless of the observance of the treatment, and the negative aesthetic impact may form a second group of explanation for poor compliance.

Some technical points such as the difficulties of bandage application may also explain why the patients are not compliant.

Patient outcomes, when hosiery or self applied bandage is the the treatment choice, will be strongly related to the physiological age, the degree of adherence to the treatment, the relationships with practitioners and nurses, the associated pathologies (hemiplegia...), the degree of arthritis of the hand, the hip or the knee and the loss of muscular strength.

Difficulties with daily hygiene are increased when functional limitations are present. It becomes extremely difficult to take a bath or a shower when you wear multi-layer bandages for example. Discomfort may be present while sleeping with cohesive bandage as moving in bed becomes uncomfortable. Heat is increased in summer or in mediterranean countries. Emotional limitations, a decrease in well-being, exclusion from normal social life (odours, leakage...) will affect the body image (old, dirty and sick!) and the perception of others. Transport becomes a problem, as does shoping or going on holidays.

Practical training in the use of bandages is not sufficiently available to nurses, physicians or care givers in nursing schools. Wound healing is insufficiently taught in most medical schools, all over the world. The need for a care assistant to apply the bandage is a turning point in the observance.

What can be drawn from the literature ?

Moffatt *et al.*[3] were the first to describe and evaluate the implementation of a leg ulcer strategy, in a pre and post-implementation evaluation within population-based services after 12 weeks. In this study, a total of 955 patients were evaluated (518 pre- implementation, 437 post-implementation. 94% have measurement of the ankle brachial pressure index (ABPI). 11% to 85% are receiving compression. Healing rates is 71 of 518 (14%) to 160 of 437 (37%), OR =3.53, P < 0.001. Frequency of treatment visits were reduced from a mean (SD) of 24.0 (16.1) over 12 weeks to 13.5 (8.6), P < 0.001. Intervention led to major improvements in health-related quality of life (measured using the Nottingham Health Profile), with significant improvements for energy, pain, sleep and mobility (P < 0.01). In conclusion, this study highlights the importance of a multi-faceted approach to improve practice.

Van Hecke *et al.*[7] analysed the interventions to enhance patient compliance with leg ulcer treatment, exploring MEDLINE, Cochrane, Embase and CINAHL up to April 2005. Reference lists, wound care journals and conference proceedings were searched. Experts and manufacturers of compression systems were contacted. Studies were eligible if they included patients with venous or mixed leg ulcers and reported patient compliance outcome. Twenty studies were finally included. Most studies describe patient compliance as the extent to which the compression system was worn and/or the extent to which treatment regime was followed. Self-reporting was the most commonly used method of compliance assessment. There are indications that Class III stockings for patients with venous ulcers enhance compliance compared with short stretch compression bandages. No real evidence is found that intermittent pneumatic compression systems improved compliance. In conclusion the included studies have a lack of consistency in defining the standard and operationalization of compliance. Patient compliance plays an ancillary role in research. No study has been able to offer an acceptable and well-documented solution to the non-compliance problem.

Figure 1. Pierre Bonnard, *Femme enfilant ses bas* (1893)

In a further paper, Van Hecke *et al.*[8] looked for guidelines for the management of venous leg ulcers exploring the Cochrane Library and websites from 1998 up to June 2006. Guidelines were eligible if they were written in English, Dutch, French or German, if the scope was the treatment of venous leg ulcers, if the guideline was systematically developed and if the steps in guideline development were reported clearly. Seven guidelines were finally critically appraised. Most of these guide- →

TABLE 1 OBSTACLES TO ADHERENCE TO TREATMENT

LINKED TO THE WOUND	LINKED TO THE PATIENT	LINKED TO THE TREATMENT	LINKED TO THE MANAGEMENT
Arterial participation	Age	Permanent compression	Nurse's level of practical training
Size of the ulcer	Mode of life	Elastic bandage	Physician's knowledge (nutrition, physical activity, etc.)
Pain	Dynamism	Inelastic bandage	Therapeutic education
Leakage	Social activities	Pumps	

→ lines failed to consider the issues of dissemination and implementation. Revisions of the guidelines for leg ulcer treatment were often not available. In conclusion, it is recommended that leg ulcer guidelines should incorporate a multidisciplinary approach and patient involvement is necessary. Extensive background information and the formulation of the rationale are needed. The development of an implementation guide that addresses the barriers particular to the adoption of guidelines for leg ulcer treatment could support the process of implementation. Recommendations on pain, lifestyle advice, compliance and other quality-of-life issues should be incorporated in guidelines for leg ulcer treatment.

Recently, the same authors[9] made a systematic review of why patients with leg ulcers do not adhere to treatment to provide an overview of what is known thus far about reasons for and determinants of non-adherent behaviour. MEDLINE, CINAHL and the Cochrane database were explored from 1995 - 2007. Reference lists of retrieved articles were searched. Studies were eligible if they included patients with venous or mixed leg ulcers, reported reasons or determinants of non-adherence and were published in English, Dutch, French or German. Thirty-one studies were included. Non-adherence is a multidimensional problem. Pain, discomfort and lack of valid lifestyle advice by healthcare professionals were primary reasons for non-adherence from patient's perspective. In conclusion, healthcare professionals mainly focus on patient-related factors such as poor motivation, lack of knowledge and understanding and unwillingness.

Annels *et al.* in 2008[1] tried to describe and explore reasons for use or non-use by district nurses of compression bandaging in venous leg ulcer management. They used a qualitative descriptive/exploratory study; they collected interview data with constant comparative data analysis applied until data saturation was obtained. As could be anticipated, several basic elements needed to be present for a district nurse to use compression bandaging, like knowing that compression bandaging is best practice, knowing how to use compression bandaging and being able to determine that the ulcer is venous in nature. However, the major finding is the necessity of having a patient willing for compression bandaging to be applied and sustained; the study explored what determines willingness or non-willingness and strategies that can be used to encourage willingness. In conclusion a prime enabler of the use of compression bandaging is having a patient willing to agree to the commencement of this treatment and for this to be sustained. Consequential recommendations are offered. Evidence-based nursing requires not only knowledge of cause and effect evidence but also evidence that provides understanding about human responses and choices when there is a health challenge.

How to enhance wound healing and compliance in venous leg ulcer management ?

Most of the interventions designed to increase the compliance should be analysed The effectiveness of these interventions is a determining factor.

The patient with a venous leg ulcer should be also encouraged to enhance physical activities, such as walking and practicing leg exercises. Efforts to increase therapeutic education could be limited by comprehension autonomy in some elderly patients. The pain control should be a progressive issue, encouraging the patient to develop his own training program to progressively increase the level of compression. The situation must be checked every week, and the program repeated if not successful. Medical doctors, nurses and patients should work together.

The selection of the mode of compression is also a key factor in the observance. An adapted compression will encourage the prescription of a 2 layered bandage better than a 4 layered bandage. Hosiery is usually better accepted than bandages in most cases, even if specific adverse events linked to hosiery were listed (contact dermatitis, allergy, skin irritation, dryness, pruritus, skin trauma, pain and difficulties to apply and remove).

Suggestions to increase the compliance to compression

Each patient will have to prove to himself and his surrounding care givers and family that he/she is capable of changing his/her mind and develop a novel attitude in response to the chronicicty of the ulcer. Positive attitude is the aim of therapeutic education, a new era in taking care of chronic wounds, especaily when dealing with aged patients.

Observance has been analysed in different pathologies like

TABLE 2 INTERVENTIONS TO INCREASE ADHERENCE TO TREATMENT

TRAIN PROFESSIONALS	CHANGE THE PATIENT MENTALITY	ADAPT TO THE LIFE EVENTS	TECHNICAL SUPPORTS
Therapeutic education	Increase self-esteem	Multipathologies and prioritisation	Shoes and compression bandages
Bandaging techniques	Willingness to heal	Adapt the treatment to the social position and cost	Permanent wearing versus day/night rhythms
Limit constraints and encourage reflection on lifestyle	Capacity of changing objectives in life	Personal sensitivity to aesthetism when wearing bandages	Climate limitations to wearing bandages (temperature)

HIV or chronic renal failure. Availability of a nursing team specialized in therapeutic education is needed, to understand the different key factors which prevent a patient from taking pills, to change the rhythm of taking them, the quantity of drugs or the abandon of them. Constraint is not effective, suggestion is less effective. The best result is obtained when the patient adheres to the treatment, finds it useful for his life projects, his lifestyle and discovers by himself an interest in healing.

To build a score with major relevant risk factors of poor compliance is an important step forward. If the score is low the team would be encouraged to select the appropriate bandage for the patient. If the score is high the patient would be offered a more efficient compression device.

Nurses should be ideally trained to the choice of compression, and would put the bandage following the guidelines from foot to knee, including the knee under the compression bandage to reduce edema. The skin must be respected, and protection on the ankles, should limit the trauma and the development of a iatrogenic ulcer.

The patient has to be trained, in the choice of shoes as well as in accepting the physical exercises. Walking is recommended but appropriate shoes, adapted to multi-layer bandaging, are rare and expensive. Cost limitations are often seen.

Conclusions

Based on the literature and personal experience, we may list some explanations for this poor compliance to compression: difficulties of bandage application especially when the legs present some degree of arthritis, psychological and aesthetic resistance, refusal to wash the legs, heat and discomfort, loss of muscular strength and associated pathologies. These patients said they would prefer to take pills or to be operated on... rather than wear compression. The need to wear compressive bandages for life, the recurrence rate, the need for someone else to help, the exclusion from normal social life and the cost of the treatments are the mostly evoked reasons to interrupt the treatment.

Analysis of the effectiveness of interventions concerning the enhancement of compliance must be completed: patients should be encouraged to enhance physical activity, shoes should be adapted, pain must be controlled, education and training improved. The selection of adapted compression devices (2 layers rather than 4 layers, hosiery rather than bandages) is crucial, as well as the control of oedema and pain. Another important factor is the associated arterial insufficiency which has to be checked regularly and the compression techniques adapted accordingly. ■

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Reimbursement of Compression Therapy in Europe – An Overview

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Introduction

Chronic venous diseases such as varicosities, post-thrombotic syndrome and chronic venous insufficiency are among the most common diseases in western countries. The majority of leg ulcers are caused by problems in the veins, resulting in an accumulation of blood in the legs.

The prevalence of venous ulceration is rising with the increasing age of the population. About one percent of people in western countries will suffer from a leg ulcer at some time. An epidemiological study in Germany – the Bonn Veins Study –found a prevalence of leg ulcers of 0.2 per cent in the age group between 30-39 years, which increases to 0.8 per cent in the population between 50-59 years and 2.4 per cent between 70-79 years (1). A study among 252.000 people in London found 113 ulcerations (prevalence 0.04 per cent) (2). On average, the prevalence of venous leg ulcers does not differ between men and women (3). Venous ulceration represents the most prevalent form of hard-to-heal wounds and these problematic wounds have a significant impact on total healthcare costs. Demographic factors, including an ageing population and a rising number of obese people, are leading to a growing population of patients with associated problems such as venous, lymphatic and diabetic problems. This underlines the impact of venous ulcers on healthcare costs.

The main treatment of leg ulcers caused by venous problems is compression by bandages or stockings in order to aid venous return. There is a whole range of compression garments available. Mechanical compression therapy is also widely used with a significant growth rate.

Whilst in many healthcare systems in Europe compression therapy is reimbursed and therefore well established, in other countries costs for bandages and hosiery are not covered by health insurance**.**

In the past, a pan-European initiative was aiming to introduce an international standard for the treatment of venous leg ulcers (4). Furthermore, in the **International Compression Club** (ICC, www.icc-compressionclub.com) proposals elaborated by joint working groups of experts from the medical field and the industry will hopefully be able to provide a valuable basis for improvement of internationally accepted regulations and guidelines. Working groups consisting of medical experts and representatives of the industry are invited to plan and coordinate the following activities:

- Organise meetings in which problems of common interest to both groups can be discussed
- Develop and deliver consensus reports and recommendations
- Organise teaching courses on compression therapy
- Provide guidance on experimental and clinical trials
- Plan and coordinate effective communication and education
- Give recommendations for indications and classification of compression products.
- Different statements and guidelines have been published (see also www.icc-compressionclub.com).

Given the demographic factors of venous ulceration and the importance of patient compliance and improved healing rates - with their impact on direct healthcare costs and indirect costs (such as inability to work and patients' quality of life) - gaining reimbursement for the different treatments of compression therapy in all European healthcare systems would be a major achievement. Insufficient reimbursement of medical equipment for compression therapy can lead to inefficient therapy and low compliance of the patient (5). The problem is sharpened by the fact that chronic venous diseases are progressive, with high recurrence rates. On average, one third of patients suffer from one recurrence, another third from four relapses and more. The socio-economic impact of venous ulceration is considerable, and reimbursement in the European healthcare systems is a critical factor (6). This article aims to give an overview on the different reimbursement policies concerning compression therapy in Europe.

Germany

The German medical device market is the largest in Europe. Approximately 90 per cent of the population is insured under the Statutory Health Insurance (SHI), the so-called *Gesetzliche Krankenversicherung (GKV).* The remaining 10 per cent are covered by private insurances. Insurance payments under the SHI are mainly based on the percentage of income, divided between employee and employer.

At present Germany has about 180 sick funds, but their number will decrease due to mergers. All of these sick funds offer the same catalogue of benefits. This catalogue is defined by the Federal Joint Committee (*Gemeinsamer*

ICC Working groups and their activities (2005-2010)

Working groups	Coordinator	Meeting	Publications
Interface pressure and stiffness measurement *in vivo*	H.PARTSCH M.CLARK	Jan 27-29, 2005 Vienna, Austria	Dermatol Surg 2006;32:224-33
Education and publicity	JP.BENIGNI	June 3, 2005 Maastricht The Netherlands	Phlébologie 2006;59: 179-86
Guidelines for testing compression material	E.RABE	Sept 17, 2005 Cologne Germany	EJVES 2008 ;35 :494-500
Classification of compression bandages	H.PARTSCH M.CLARK	Oct 4, 2006 Rostock Germany	Dermatol Surg 2008;34:600-09
Indications for compression therapy	H.PARTSCH A.CORNU-THENARD	May 19, 2007 Vienna Austria Nov 24, 2007 Paris France	Int Angiol 2008;27:193-219
Effects of compression therapy, experimental proof	H.PARTSCH G.MOSTI	Sept 13, 2008 Lucca , Italy	Int Angiol In print
Clinical trials needed to evaluate compression therapy in breast cancer related lymphoedema (BCRL)	N. STOUT H.PARTSCH F. MARIANI	June 12, 2009 Ponzano, Veneto, Italy	Submitted Int Angiol
Chronic oedema needs chronic compression. How can we do better?	N.STOUT H.PARTSCH C.MOFFATT	March 26, 2010 Brighton, UK	In preparation

Bundesausschuss, GBA) – a Board with delegates from hospitals, sick funds and office-based physicians.

In Germany the provision of healthcare can be broadly separated into ambulatory and hospital sector. Outpatient treatment is mainly supplied by independent doctors´ offices under contract to the Statutory Health Insurance. Physicians who treat patients covered by the *GKV* must be registered by the regional Association of Statutory Health Insurance Physicians (*Kassenärztliche Vereinigung*).

Hospitals in Germany are grouped into three main types:

- Public hospitals (*Öffentliche Krankenhäuser*) run by local authorities
- Voluntary, non-profit making hospitals (*Freigemeinnützige Krankenhäuser*) run by churches or non-profit organisations like the German Red Cross
- Private Hospitals (*Privatkrankenhäuser*) run as free commercial enterprises

The German diagnosis-related group (G-DRG) system is fully installed in the hospitals.

Germany is considered as one of the highly developed markets in Europe in compression therapy. All commonly used bandages – like short and long stretch bandages, zinc paste bandages – are reimbursed in the outpatient setting as dressing material. Hosiery has to be listed in the *Hilfsmittelverzeichnis* – a positive list for medical equipment – which is distributed by the National Association of Statutory Health Insurance Funds (*GKV-Spitzenverband*). An application for reimbursement is required by sick funds. Within hosiery systems there are different specifications on pressure that have to be considered in order to obtain reimbursement. Physicians tend to be the key decision makers. In the outpatient setting a physician´s prescription is necessary to obtain the medical equipment covered by health insurance.

The hosiery market shows higher growth rates than bandages because of the comfort offered by these systems.

France

The French medical equipment market is the second largest in Europe after Germany. France provides a basic, universal health insurance – the Caisse Nationale d´Assurance Maladie (CNAM) – through large occupation-based funds. Within the CNAM there are four major health →

insurances: The Caisse Nationale d´Assurance Maladie des Travailleurs Salariés (CNAMTS) covers the salaried workers and their families (80 per cent of the total population); the Caisse Nationale d´Assurance Maladie des Professions Indépendantes (CANAM) covers the independent professionals; the MSA (Mutalité Sociale Agricole) agricultural workers; and there is also a Caisse for the civil servants.

Equipment for compression therapy that seeks to get reimbursed in an outpatient and home care setting has to be listed on the LPPR (Liste des produits et prestations remboursables) – a National list for medical devices, with fixed price ceilings. Admission to an existing generic group is a very quick process and the product can be marketed immediately after obtaining the CE mark. The listing of new products in the LPPR requires demonstration of clinical and health-economical benefits.

France is known as a long stretch market. Short stretch bandages are not yet reimbursed, but this is under consideration by CNEDiMTS (Commission nationale d´evaluation des dispositifs médicaux et des technologies de santé) - as a generic group. CNEDiMTS is a sub-organisation of the Haute Autorité de Santé (HAS), the French National Authority for Health, that was set up by the Government in 2004. Its activities range from assessment of drugs, medical devices and procedures, to publication of guidelines, accreditation of healthcare organisations, and certification of doctors. All of these decisions are based on scientific expertise. CNEDiMTS is responsible for the evaluation of medical devices and decides whether a product should be reimbursed or not.

In France there are three general categories of hospitals: the public hospitals, which account for 65 per cent of hospital beds; the private, non-profit hospitals; and the profit-making hospitals. In the inpatient setting compression garments are usually included in the Groupes Homogènes de Séjour (GHS), the French DRG-system.

UK

In England, Wales, Scotland and Northern Ireland healthcare is generally provided through the National Health Service (NHS). Established in 1948, the object of the NHS was to provide a "comprehensive health service to improve the physical and mental health of the people through the prevention, diagnosis and treatment of illness" (NHS Act 1946). The NHS is mostly funded from general taxation, including a proportion from National Insurance payments. It is organized into Trusts ('Primary Care Trusts'), which administer healthcare within a geographic region. Procurement Hubs are groups of Trusts and there are currently approximately 10 throughout the country, made up of several hospitals geographically, but not always. Each Trust can have 3 or 4 Hubs making decisions about products used, but some Trusts can work outside of the Hub's guidelines. The Contract for the supply of goods comes under the NHS Supply Chain.

Primary care services are provided by general practitioners (GPs), dentists, pharmacists and opticians. The majority of these providers are independent contractors. There are about 32,000 GPs in England and their number is slowly increasing. Hospitals across the UK are mostly public. There are also private hospitals which mainly provide treatment to people who are privately insured or who pay for their treatment.

The market for compression therapy is well developed in the UK. The relevant reimbursement mechanism for medical equipment for compression therapy is the UK Drug Tariff, a monthly publication of products that can be prescribed and are paid for by the NHS. The Drug Tariff can be seen as a 'positive list' for medical devices. Products included in the Drug Tariff are considered appropriate for use in the community or with patients at home, and can be prescribed by GPs or nurse prescribers. In order to be listed on the Drug Tariff, an application has to be made to the Department of Health (DOH). A new product for compression therapy usually fits into an existing category in the Drug Tariff. If this is not the case, the product has to prove an additional benefit that outweighs any additional costs for the NHS. Currently bandages, multi-layer compression bandages, hosiery and garments used as part of mechanical compression are listed on the Drug Tariff. Hospitals are not bound by the Drug Tariff; they are free to draw up their own lists of compression products.

Other European markets

In **Italy** equipment for compression therapy is usually integrated into the hospital or local authority budget. In outpatient care, bandages or hosiery are only reimbursed in certain regions. In **Spain** bandages and hosiery are not covered in the outpatient setting by the National Health Service. In **Scandinavia,** generally bandages are reimbursed, but hosiery and hosiery systems are not completely covered by the public health services. Short stretch bandages are preferably used in Scandinavia. The **Swedish** healthcare system is funded by the government and is decentralized in municipalities. Sweden has an ageing population, with one of the world´s largest percentage of old people. The government therefore shows a high awareness of diseases such as chronic venous ulcers and is looking for ways to increase the efficiency of care for older people. The reimbursement policies in the **Benelux-countries** differ very much. The **Belgian** healthcare system reimburses hosiery only under certain conditions and in special indications. Not all of the short and long stretch bandages are covered. In **the Netherlands**, short stretch bandages are the preferred choice, but reimbursement in the community depends on prior approval of the health insurance. Usually all kinds of short and long stretch bandages and hosiery are reimbursed. There is a high awareness on the impact of chronic diseases and there are different approaches, such as the DBC-programs to manage them. In **Luxembourg**, sick funds cover the reimbursement of bandages, if the products are pre-approved with a tariff rate fixed by negotiation. In **Austria** and **Switzerland**, reimbursement systems for compression therapy are well developed. All kinds of static compression can be found on the Austrian 'positive list' for medical equipment, the *Tarif für Heilbehelfe und Hilfsmittel*. The same applies for Switzerland, where short and long stretch bandages are listed on the relevant *Mittel- und Gegenstandsliste (MiGeL)* and therefore are covered by the obligatory health insurance.

Conclusion

There are many differences in the reimbursement policies for compression therapy of venous ulcers, which lead to totally different therapy regimens. Reimbursement mechanisms for compression therapy are highly complex in