POSITION
DOCUMENT

Understanding **compression therapy**

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Tel: +44(0)20 7561 5400 E-mail: info@mepltd.co.uk

EUROPEAN WOUND MANAGEMENT ASSOCIATION
Secretariat: PO BOX 864, London SE1 8TT, UK
Tel: +44 (0)20 7848 3496 www.ewma.org

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Understanding compression therapy

CJ Moffatt

The potential impact of compression therapy on ulcer healing has been highlighted in numerous studies across the world during the last decade. There can be few healthcare interventions that can claim such dramatic effects on outcome. Patients report improvements in pain, mobility and general quality of life as a consequence of their ulcer healing. It is therefore a salutary finding in producing this position document, that we are far from being able to establish pan-European standards for compression therapy.

The physiological basis for compression therapy is, however, well established. Partsch, in describing the mechanisms behind compression, shows how effective materials directly impact on venous, arterial and lymphatic function and on the inflammatory processes such as white cell entrapment associated with ulceration. He highlights the potential differences between individual compression systems when used in practice and the need to apply appropriate levels of compression. Technological advances in the last decade concerning elastomers have led to sophisticated developments in bandage and hosiery production. Materials are now being developed that overcome some of the traditional problems associated with elastic bandages. New and creative approaches in this area are encouraging.

An understanding of Laplace's Law and the inverse relationship between the radius of a patient's limb and the pressure applied is important in bringing the science of bandaging to the art of compression. However, despite many attempts to measure the sub-bandage pressure, the evidence would suggest that this is often misleading. Clark, in the second article, describes the limitations of the current standards in use and their variations across countries. Europe now requires the development of a new standard. We must look for an effective method of classifying bandages, perhaps similar to that being developed for compression hosiery.

While in many countries in Europe compression is well established, in other countries the reimbursement systems do not cover the bandages and hosiery materials, with many patients being treated with dressings alone. Such a system must be challenged if we are to move wound care forward. The issues of reimbursement are complex and resistance to placing products into the systems are often based on a misplaced belief that this will escalate the cost of care. In many countries there are few strategies to monitor the costs for the numerous patients with ulceration and the real cost to the healthcare systems remains hidden. Franks and Posnett discuss the importance of treatments being both clinically and cost-effective where budgets are constrained and offer a method for evaluating the cost-effectiveness of a systematic treatment approach using high compression. Part of the strategic mission of EWMA is to fight for equal standards of practice across the whole of Europe. Gaining reimbursement for compression would be a major breakthrough that we must strive to achieve.

The need for clear clinical guidelines has prompted the development of a recommended treatment pathway by the International Leg Ulcer Advisory Board. In the final paper, Marston and Vowden discuss the scientific basis of the pathway and the important clinical issues underpinning it. The literature is clear that compression is more effective than no compression and that high compression is more effective than low compression. With the development of new bandage systems and large randomised controlled trials of current regimens, the picture concerning the differences between them should become clearer in the next few years. Compression, however, is only one part of effective care provision. The pathway stresses the importance of correct assessment, particularly the identification of arterial disease, and the role of the multidisciplinary team in ensuring safe practice. For compression therapy to reach its true potential it is important that patient care is well delivered within effective, multidisciplinary services.

We hope this document will stimulate an international debate which will allow for the reclassification and a furtherance of the art and science of compression therapy across Europe.

Professor and Co-director, Centre for Research and Implementation of Clinical Practice, Thames Valley University, London, UK. Immediate Past President, EWMA.

POSITION DOCUMENT

Understanding the pathophysiological effects of compression

H Partsch

INTRODUCTION

Compression has been used for many centuries in the treatment of oedema and other venous and lymphatic disorders of the lower limb, but the exact mechanisms of action remain poorly understood. This paper considers the physiological and biochemical effects of compression.

COMPRESSION

If an oncotic pressure gradient exists across a semi-permeable membrane, such as a capillary wall, water is drawn across the barrier until the concentrations on both sides are equal. (Oncotic pressure is the *osmotic pressure* created by protein colloids in plasma.) The relationship between these factors is summarised in Starling's equation[1].

The amount of lymph formed depends upon the permeability of the capillary wall (filtration coefficient) and the gradient of hydrostatic and oncotic pressure between blood and tissue. The hydrostatic pressure difference causes filtration, while the oncotic pressure difference causes reabsorption (Figure 1).

Oedema

Oedema, the accumulation of fluid in extra-vascular tissue, occurs as a result of complex interactions involving the permeability of capillary walls and the hydrostatic and oncotic pressure gradients that exist between the blood vessels and surrounding tissue.

Starling's equation suggests that the application of external compression will counteract the loss of capillary fluid by increasing local tissue pressure and reinforce reabsorption by squeezing fluid into the veins and lymph vessels. This in turn will help to resolve oedema (Figure 1). Various causes of oedema are identified in Table 1.

Depending upon the amount of pressure applied, a compression bandage may influence the internal volume of veins, arteries and lymph vessels. Structures near the surface of the skin are compressed more than the deep vessels. This is because the compressive force is partly dissipated by compression of the surrounding tissues.

Nuclear medical investigations have shown that compression removes more water than protein from the tissue, increasing oncotic tissue pressure. This results in a rapid reaccumulation of oedematous fluid if compression is not sustained[2].

STARLING'S EQUATION

$F=c(Pc-Pt)-(\pi c-\pi t)$

F represents net filtration force (which is the origin of lymph)
c is the filtration coefficient
Pc is capillary blood pressure
Pt is tissue pressure
πc is capillary oncotic pressure
πt is tissue oncotic pressure

Table 1 | **Causes of oedema**

Physiology	Possible cause	Effect
↑ Capillary permeability (c)	Cellulitis, arthritis, hormonal cyclic oedema	Inflammatory oedema, 'idiopathic oedema'
↑ Venous (capillary) pressure (Pc)	Heart failure, venous insufficiency, dependency syndrome	Cardiac, venous oedema
↑ Oncotic tissue pressure (πt)	Failure of lymph drainage	Lymphoedema
↓ Oncotic capillary pressure (πc)	Hypoalbuminaemia, nephrotic syndrome, hepatic failure	Hypoproteinaemic oedema

Effects of compression

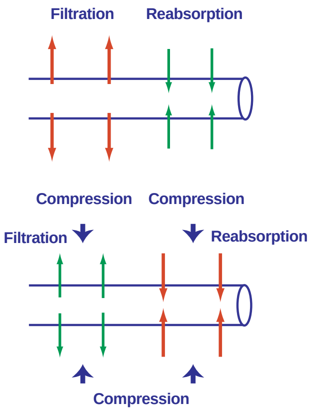
Venous system

In a standing individual blood flows slowly through the veins. The venous pressure, which equals the weight of the blood column between the foot and right atrium, is about 80-100 mmHg. During walking, however, blood flow is accelerated by the combined action of the calf muscle pump and the foot pump, which in patients with competent valves, decreases the volume of venous blood in the foot and reduces venous pressure to about 10-20 mmHg.

If the valves in the large veins become incompetent due to primary degeneration or post-thrombotic damage, blood will oscillate up and down in those segments lacking functional valves.

Professor of Dermatology, University of Vienna, Department of Dermatology, Vienna, Austria.

Figure 1 | **Compression works against filtration and encourages reabsorption**



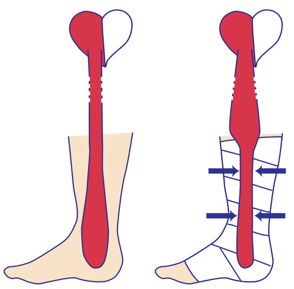
The resulting retrograde (backward) flow in the veins of the lower leg (venous reflux) leads to a reduced fall in venous pressure during walking (ambulatory venous hypertension). This causes fluid loss into the tissues and the formation of oedema. Compression of veins with incompetent valves produces an increase in orthograde (towards the heart) flow and a reduction in venous reflux.

The application of adequate levels of compression reduces the diameter of major veins as demonstrated by phlebography and Duplex ultrasound[3]. This has the effect of reducing local blood volume[4], by redistributing blood towards central parts of the body. As this can lead to an increase in the preload of the heart and affect cardiac output by about 5%[5] (Figure 2), bilateral bandaging of the thighs and lower legs should be avoided in patients with borderline cardiac function.

Reducing the diameter of major blood vessels will have the secondary effect of increasing flow velocity, provided the arterial flow remains unchanged. The clinical significance of these effects depends upon the relationship between the intravenous hydrostatic pressure and the degree of external compression applied. In a supine (lying down) individual, pressures in excess of about 10 mmHg over the calf are sufficient to reduce venous stasis, a major factor in thrombus formation, by producing a marked decrease in blood volume in the lower legs, accompanied by a corresponding increase in blood velocity. Pressures in excess of 30 mmHg do not result in a further increase in blood velocity in the large veins or the microcirculation as at this pressure the vessels are maximally emptied and venous volume cannot be reduced any further[6].

In the upright position, the pressure in the lower leg fluctuates during walking, between 20-100 mmHg, and therefore much higher levels of compression (e.g. 40-50 mmHg) are required to exert a marked effect upon blood flow.

Figure 2 | **Compression of the leg veins leads to a shift in blood volume with an increase in the preload of the heart**



Arterial circulation

Although it is accepted that compression should never be allowed to impede arterial inflow, there is currently no convincing clinical evidence to indicate what levels of compression may safely be applied to a limb, particularly if there is a risk of arterial impairment.

A systolic ankle pressure below 50-80 mmHg is commonly regarded as a contradiction for high compression therapy, as is an ankle-brachial pressure index (ABPI) of less than 0.8. Intermittent pneumatic compression systems that exert pressures of 30-80 mmHg aid venous return, reduce oedema and may even help to increase arterial flow (by a type of reactive hyperaemic response)[7].

Lymphatic system

The function of the lymphatic system is to remove fluid from the interstitial tissues and return it to the venous system. In patients with venous insufficiency, isotopic lymphography shows that prefascial lymphatic drainage is intact or even increased. Subfascial lymph transport is reduced or absent in patients with deep vein thrombosis and deep venous incompetence due to a post-thrombotic syndrome[8].

Short-stretch compression bandages and walking exercises can improve the diminished subfascial lymph transport, but prefascial lymph transport may be decreased due to the reduction of filtration[8]. The morphological changes of the lymphatics in lipodermatosclerotic skin, such as fragmentation and extravasation of the contrast medium (dermal back-flow), can be normalised with long-term compression[9].

The dramatic reduction of oedema by compression therapy can be explained by the reduction of lymphatic fluid in the tissue, rather than by an improvement of lymphatic transport[10].

KEY POINTS

1. Compression is the most important component in the conservative treatment of venous leg ulcers and lymphoedema.
2. Doppler assessment should always be used before applying compression with frequent reassessment to ensure adequate arterial flow in the limb.
3. For ambulant patients with venous insufficiency, high levels of compression (e.g. 40-50 mmHg) are required to produce beneficial haemodynamic effects.
4. Impaired lymphatic drainage, secondary to severe chronic venous insufficiency, may be improved by compression.
5. Sustained compression is neccessary to prevent refilling.

Microcirculation

Ambulatory venous hypertension in patients with chronic venous insufficiency is the trigger for functional alterations in the endothelium. These alterations are complex and only partially understood. One possibility is that neutrophils become activated, adhere to the endothelial cells and, mediated by the surface exposure of adhesion molecules, produce endothelial injury by releasing cytokines, oxygen free radicals, proteolytic enzymes and platelet activating factors[11]. Dermal tissue fibrosis (lipodermatosclerosis) is associated with increased transforming growth factor (TGF)-beta(1) gene expression[12]; the loss of tissue compliance caused by the fibrosis can lead to reduced skin perfusion and ulceration[13]. Capillary microthrombosis also contributes to tissue necrosis[14].

Compression accelerates blood flow in the microcirculation, favours white cell detachment from the endothelium and prevents further adhesion[15]. Capillary filtration is also reduced and reabsorption is increased due to enhanced tissue pressure[14]. In lipodermatosclerotic areas where skin perfusion may be reduced due to the strain associated with high tissue pressure[13], the use of compression therapy can increase this gradient and improve blood flow. This leads to softened skin[16].

Effects on mediators involved in the local inflammatory response may explain both the immediate pain relief that occurs with good compression and subsequent ulcer healing. It has recently been demonstrated, for example, that compression therapy is able to reduce elevated levels of vascular endothelial growth factor and tumour necrosis factor (alpha) in patients with venous ulcers and that this reduction of serum cytokine levels parallels ulcer healing[17]. The influence of compression on the tissue injury caused by free radicals, including nitric oxide, requires further investigation[18].

CONCLUSION

The application of external compression initiates a variety of complex physiological and biochemical effects involving the venous, arterial and lymphatic systems. Provided that the level of compression does not adversely affect arterial flow and the right application technique and materials are used, the effects of compression can be dramatic, reducing oedema and pain while promoting healing of ulcers caused by venous insufficiency.

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Compression bandages: principles and definitions

M Clark

INTRODUCTION

The degree of compression produced by any bandage system over a period of time is determined by complex interactions between four principle factors – the physical structure and elastomeric properties of the bandage, the size and shape of the limb to which it is applied, the skill and technique of the bandager and the nature of any physical activity undertaken by the patient. This paper describes the mechanisms by which compression is achieved and maintained, and discusses some of the practical problems involved in measuring sub-bandage pressure.

DETERMINING SUB-BANDAGE PRESSURE

Laplace's Law

The pressure generated by a bandage immediately following application is determined principally by the tension in the fabric, the number of layers applied, and the degree of curvature of the limb. The relationship between these factors is governed by Laplace's Law (see Box). The use of this law to calculate or predict sub-bandage pressure has been described by Thomas[1], although this remains a controversial issue[2].

Bandage performance

Tension

The *tension* in a bandage is determined initially by the amount of force applied to the fabric during application. The ability of a bandage to *sustain* a particular degree of tension (and therefore sub-bandage pressure) is determined by its elastomeric properties, and these in turn are a function of the composition of the yarns and the method of construction.

LAPLACE'S LAW

$P \propto T/R$

P represents pressure
T is tension
R is radius
$\propto$ is proportional

Applied pressure is *directly proportional* to the tension in a bandage but *inversely proportional* to the radius of curvature of the limb to which it is applied (**P** increases with **T** but **P** decreases as **R** increases)

Extensibility

The ability of a bandage to increase in length in response to an applied force is described as its *extensibility* (ability to stretch) and it has become common practice across Europe to use terms such as **short-stretch** (minimally extensible, inelastic, passive) and **long-stretch** (highly extensible, elastic, active) to describe this aspect of a bandage's performance.

At some point, the physical structure of a bandage will prevent further stretching once a certain degree of extension is achieved. This condition is called 'lock-out'. Stemmer and colleagues[3] suggested that short-stretch bandages should lock-out at up to 70% extension (and ideally at 30 to 40% extension), with long-stretch bandages only locking out at over 140% extension. Unfortunately, they did not suggest what tension should be applied to the bandages in order to achieve these levels of extension, since different bandages may achieve similar extensions when very different extension forces are applied[4]. Without some form of 'reference' tension, definitions such as long- or short-stretch are relatively meaningless and it is preferable to use the terms elastic or inelastic.

With elastic bandages a small change in extension (as might occur during walking) will result in minor fluctuations in sub-bandage pressure. These bandages are also able to accommodate changes in limb circumference, as occurs when oedema is reduced, with minimal effects on sub-bandage pressure. Conversely, with inelastic bandages large changes in sub-bandage pressure may result from minor changes in calf geometry. These bandages may produce high compression during walking, but low resting pressures (see Box).

INELASTIC/ELASTIC BANDAGES

Inelastic bandages produce a low resting pressure and high pressure on moving (i.e. create peak pressures)

Elastic bandages produce sustained compression with minor variations during walking

Power

The amount of force required to cause a specific increase in the length of an elastic bandage is an indicator of the bandage's *power*[5]; this characteristic determines the amount of pressure a bandage will produce at a predetermined extension.

Elasticity

The *elasticity* of a bandage determines its ability to return to its original (unstretched) length as the tension is reduced.

Senior Research Fellow, Wound Healing Research Unit, University of Wales College of Medicine, Cardiff, UK.

Table 1 | **Comparison of British and German bandage pressures**

Group RAL-GZ	Type BS 7505	Level of compression	Pressure British standard (mmHg)	Pressure German standard (mmHg)
1	3A	Light	Up to 20	18.4-21.2
2	3B	Light	21-30	25.1-32.1
3	3C	Moderate	31-40	36.4-46.5
4	3D	High	41-60	>59

STANDARDS FOR BANDAGES

Currently there are no international or European standards relating to the performance of compression bandages. An on-line search of 20 European national standards bodies, conducted in December 2002, identified three national standards related to bandages used to apply limb compression, two of which, British Standard (BS) 7505:1995[6] and RAL-GZ 387 (Germany)[7], will be used to illustrate the lack of European agreement on the classification of compression bandage systems. The third standard, from Switzerland, dates back to 1975.

The standards set out test methods for establishing the different aspects of the performance of non-adhesive, fabric-based compression bandages. Of note is that different test methods are used in different countries across Europe.

BOX 1. Sub-bandage pressure measurement

1. **Pressure sensors**
   Large diameter sensors tend to provide an average value of pressure applied over a large surface area and so do not report peak pressures. Inflexible sensors may record artificially high pressures given their inability to conform to the surface of the leg (point loading of the sensor).
2. **Site of sensor application**
   A sensor placed over a soft tissue (calf) may return lower pressure readings than a similar sensor placed over a hard site (ankle).
3. **Method of application**
   The application technique (figure-of-eight or spiral), the number of layers applied and the degree of overlap between layers will affect the pressure applied to the leg.
4. **Position of limb**
   Pressures are higher when standing and significantly altered during walking[11].

British standard

Bandages are classified within the standard into one of six categories. Type 1 refers to retention, lightweight, elastic bandages. Type 2 are support bandages (inelastic, short-stretch) and type 3A to 3D are compression bandages (elastic, long-stretch). The four classes of compression bandage are defined according to their ability to apply a specified sub-bandage pressure to a known ankle circumference (23 cm) where the bandage is applied with a 50% overlap between successive layers.

German standard

The German standard also classifies compression bandages into four groups. However the thresholds used in the BS and German standards differ (see Table 1). This may be due to differences in the required level of pressure and the use of different test methods. This highlights a need for wider European agreement on the classification of compression bandages[8] and the introduction of a standard similar to that in preparation for compression hosiery[9].

Achieving adequate pressure

On a normal leg the circumference of the ankle is generally substantially smaller than that of the calf, and it follows from Laplace's Law that if a bandage is applied with constant tension and overlap, the pressures achieved at the gaiter and the calf will be lower than those applied at the ankle. As the circumference of the leg progressively increases, a compression gradient is produced with the highest pressure on the most distal part of the limb (i.e. the ankle). The consistent formation of this ideal pressure gradient has been difficult to demonstrate practically[10]. The failure to demonstrate graduated compression may reflect poor operator technique, the practical problems of maintaining constant tension throughout the bandage during the application process and poor measurement technique. Factors affecting the measurement of sub-bandage pressure are listed in Box 1.

Problem solving

Some of the practical problems associated with bandage application have been addressed by manufacturers who have included various visual guides to help operators achieve the required tension within the bandage. Advances in textile technology may also help to reduce both inter- and intra-bandager variability. One very promising concept is the development of an elastomeric yarn which enables a bandage to achieve relatively constant sub-bandage pressures regardless of minor variations in extension[12].

CONCLUSION

Compression of the lower leg aids the healing of venous leg ulcers. Much is made of sub-bandage pressures in the presentation and evaluation of compression bandages – the values cited (for example 40 mmHg at the ankle) are typically given as single values with no apparent variation within and between subjects. In reality, sub-bandage pressures are greatly influenced by several factors including posture, locomotion and bandage application techniques.

The current standards classify individual products, but do not define the ways in which these bandages work clinically. In addition, simplistic descriptions of short-stretch (inelastic) and long-stretch (elastic) bandages fail to take account of the huge variations within these two groups and, more importantly, the development of multi-layer compression systems that combine materials with different performance characteristics.

Multi-layer bandage development is based upon the fact that multiple layers of weak elastic bandages can be used in combination to achieve optimum compression without the inherent risk of using 'high power' elastic bandages capable of excessive pressure. Multi-layer bandages are complex with some incorporating both elastic and inelastic materials, which provide advantages of both systems: the elastic element provides sustained pressure and the inelastic element provides high pressures during walking and low resting pressures.

At the heart of any new classification must be the ability to translate the technical details about systems into a clinical decision. Optimal levels of compression and best methods of application remain to be determined across Europe, perhaps within the framework of developing a European-wide standard for the testing and classification of bandage systems.

KEY POINTS

1. Characteristics of extensibility, power and elasticity affect the amount of pressure a bandage will apply and how long it will be sustained.
2. The current classification system refers to individual bandages and does not adequately reflect the physiological effects of multi-layer bandaging systems.
3. A European-wide standard for the testing and classification of bandage systems is required.

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POSITION DOCUMENT

Cost-effectiveness of compression therapy

PJ Franks[1] J Posnett[2]

INTRODUCTION

A recent systematic review of the literature on compression therapy for venous leg ulcers concluded that treatment with compression improves healing compared with no compression and that high, multi-layer compression is more effective than low compression or single-layer compression[1]. The most clinically effective treatment, however, is not always the most cost-effective. This article looks at the meaning of cost-effectiveness in relation to the treatment of patients with a venous leg ulcer.

COST-EFFECTIVENESS

Cost-effectiveness is about ensuring that available resources are used in the most efficient way to improve the health-related quality of life of patients as a whole. When budgets are constrained, it may be more efficient to treat 30 patients with a less effective therapy than to treat 25 patients with the best. The choice of treatment will depend on the balance between the additional costs involved in implementing one option and the extent of the additional benefits generated (see Box) (Figure 1).

The Cochrane review on compression in venous ulceration concluded that there is insufficient evidence in the literature to draw conclusions about the relative cost-effectiveness of different treatment regimens[1]. In the absence of evidence from published studies, it is necessary to use a modelling approach to illustrate the principles involved.

There are a number of methods for assessing cost in relation to the outcomes of treatment including: *cost minimisation* (if outcomes are identical the least cost option is selected); *cost utility analysis* (in which outcomes are measured by the value placed by patients on alternative health states, such as living with an infected ulcer); *cost-effectiveness analysis* (in which outcomes are measured in clinical terms, such as time to heal a wound) and *cost benefit analysis* (in which outcomes are valued in money terms)[2]. A cost-effectiveness approach has been chosen because it is the most relevant, given available information.

Comparing systematic treatment with usual care

First, for the purposes of this analysis, two treatment options were compared, that of a systematic treatment regimen using high compression bandaging (4-layer) for all patients as appropriate (**option A**), against the usual care provided by nurses in the community (**option B**). With usual care there is no systematic approach to the delivery or use of high compression. The next stage was to estimate expected outcomes and costs for the two groups of patients treated over a period of at least 52 weeks. The time period is important as differences between treatment costs and outcomes usually depend on the time at which the difference is measured. Fifty-two weeks is chosen as it corresponds to an annual budgetary cycle and is meaningful to decision-makers.

In this example the viewpoint of the analysis is the health services (UK) and costs included are those that impact directly on healthcare providers. When further information is available it may be appropriate to adopt a societal perspective that includes costs falling on patients, their families and other private and public sector organisations.

Information has been abstracted from published clinical audits and randomised clinical trials of treatment regimens published during the 1990s and cited in Medline. 'Usual' care refers to evidence where the costs and outcomes relate to treatment provided by nurses prior to the introduction of a systematic approach to care. Key costs include frequency of care, site of care delivery and use of wound care products including bandages, dressings and topical agents. The studies chosen provide evidence of both clinical effectiveness and appropriate cost data on the same patients[3-7]. Readers may wish to examine the original articles for definitions and descriptions of usual care.

Expected outcomes

The study by Simon *et al*[3] reports on a baseline comparison of outcomes in two health authorities in the UK in 1993 and a before-and-after study comparing outcomes after the introduction of community leg ulcer clinics in 1994. The 12-week healing rates (20%,

1. Professor of Health Sciences and and Co-director, Centre for Research and Implementation of Clinical Practice, Thames Valley University, London, UK.
2. Professor of Health Economics, University of York, York, UK; and Head of Health Economics, Smith and Nephew Wound Management.

TREATMENT OPTIONS

Example 1:
Option A and B cost the same, but the outcomes for patients are better with option A. Option A is unambiguously more cost-effective.

Example 2:
Patient outcomes are the same with both options but option A is less costly than option C. Option A is unambiguously more cost-effective.

Example 3:
Option A costs more than option D and produces better outcomes for patients. Which option is more cost-effective is a matter of judgement.

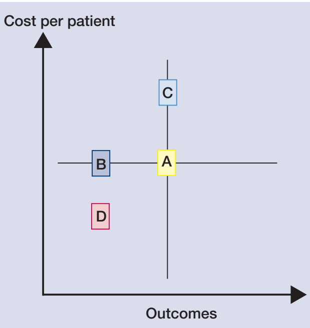

Figure 1 | **Relationship between cost and outcome**

23% and 26%) in the before-arm of this study provide an estimate of the healing rates which might be expected from the usual care provided by community nurses in the UK. The Morrell[4] and Taylor[5] studies show similar healing rates at 12 weeks for a usual care regimen (24% and 21%).

The Morrell study[4] and the before-and-after study by Simon *et al*[3] evaluate the impact of the introduction of community leg ulcer clinics (i.e. sytematic treatment regimen) and the use of high compression bandaging where appropriate. Healing rates are improved in both studies and are reasonably consistent at 12 weeks (42% Simon[3], 34% Morrell[4]). The healing rates with high compression reported in the Taylor[5], Marston[6] and Moffatt[7] studies are higher than those observed in other studies (72-75%) and this is probably a result of differences in the risk factors for healing, principally ulcer size and duration of the ulcers.

The probabilities of healing and recurrence used in the cost-effectiveness model were imputed from the 12, 24 and 52-week healing rates and annual rates of recurrence reported by Morrell *et al*[4]. The Morrell study was chosen for this illustration as it is one of very few studies that measured healing rates up to 52 weeks. In addition, the healing rates with high compression are quite conservative relative to other studies; this means that our estimate of the relative cost-effectiveness of compression will also be conservative.

Weekly costs of treatment

The two main determinants of the weekly costs of treatment are the setting of care and the frequency of dressing changes. The care setting is important: providing care in a specialist outpatient clinic is more costly than a home visit by a community nurse, which in turn is more costly than a visit to a practice nurse[8]. In order to abstract from the impact of care setting on costs and to focus on the cost impact of treatment alone, the cost-effectiveness model assumes patients in both groups are treated by a community nurse at home (Table 1).

Table 1 | **Weekly cost (unhealed)**

Dressing changes	Systematic care with high compression (%)	Usual care (%)
Nurse time	€ 24 (60.0)	€ 24 (80.0)
Dressings/bandages	€ 13 (32.5)	€ 3 (10.0)
Other costs	€ 3 (7.5)	€ 3 (10.0)
Total cost per week	€ 40	€ 30
Frequency (per week)	1.1	2.2
Total cost per week	€ 44	€ 66

NOTE ON COSTS

1. £1 = 1.5 euros (€)
2. Usual care = based on 2000 prices reported in Simon study[3]
3. High compression bandaging (4-layer) = cost of Profore®[9]
4. Nurse time = average costs of a community nurse visit (including travel time)[8]
5. Usual care dressing change frequency = based on Morrell study[4] 2.2 (2.4 Freak[10] and Simon[3]). High compression = based on Morrell study[4] 1.07 (1.01 Simon[3])

Results

The cost-effectiveness model was run for a cohort of 100 patients over 52 weeks, using a Markov (decision) model. The results are shown in Table 2.

Patient outcomes: The model predicts the number of first ulcers healed and the number of recurrences associated with treatment for both groups. The predictions of the model are the same as the results reported in the Morrell study[4].

Costs: The average annual cost per patient and the average cost per first ulcer healed are both lower using a systematic treatment approach. The average cost per healed ulcer is higher than the cost per patient. This is because not all ulcers are healed within the 52-week period. More than one patient needs to be treated to achieve one healed ulcer.

KEY POINTS

1. Current evidence suggests that high compression is the single most effective means of healing venous ulcers.
2. Where the most effective treatment is also the most expensive, other factors such as additional benefits need to be quantified.
3. Using leg ulcer healing as a key clinical outcome, systematic treatment with high compression is shown to be a cost-effective method of treating patients with venous leg ulceration.
4. There is a clear need for a global perspective on the relative costs of high compression therapy in the management of patients with a venous leg ulcer.

Table 2 | **Expected costs and outcomes**

	Systematic care with high compression (option A)	Usual care* (option B)
First ulcers healed		
12 weeks	34%	24%
24 weeks	58%	42%
52 weeks	71%	60%
Median time to heal	19-20 weeks	35-36 weeks
Mean time to heal (patients who heal)	15.9 weeks	19.2 weeks
Recurrences (within 52 weeks)	17 (24%)	13 (22%)
Average cost per patient	€ 1,205	€ 2,135
Cost per first ulcer healed (excluding recurrences)	€ 1,697	€ 3,558

*as defined by Morrell et al[4]

Discussion

This illustration shows that, based on the assumptions used in this example, option A *dominates* option B: outcomes are better and costs are lower. Despite the fact that the compression bandage (4-layer) is four times more expensive than the typical dressings used in a usual care regimen, the cost per week is lower with a systematic approach using high compression because of the lower frequency of dressing changes. Even if the effectiveness of the two treatment options is the same, a systematic regimen using high compression (option A) is more cost-effective due to its lower weekly cost. With option A more patients are expected to respond to treatment and fewer remain unhealed after 52 weeks of treatment. This would suggest that a systematic approach using high compression (4-layer) is unambiguously more cost-effective than usual care (option B) in the treatment of venous leg ulcers.

The implications for efficiency are straightforward: with the same annual budget (€ 2,135) it would be possible to treat 100 patients with option B or 177 patients with option A. Alternatively, it would be possible to treat 100 patients with option A at a cost that is 44% lower.

CONCLUSION

In the past, decisions on reimbursement have been made principally on the basis of clinical evidence alone. With the demand for higher efficiency in using scarce resources there is likely to be an ever greater demand for evidence of cost-effectiveness before treatments are reimbursed. There is a clear need to provide more evidence on different treatment modalities, and for evidence from other countries and healthcare systems to provide a global perspective on the relative cost-effectiveness of systematic use of high compression and other therapies used in the management of patients with chronic venous ulceration.

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Compression therapy: a guide to safe practice

W Marston[1], K Vowden[2]

INTRODUCTION

Compression has been successfully applied to the management of leg ulceration since the time of Hippocrates[1]. As yet, however, there is little international agreement on the optimal mode of compression. Recently, the International Leg Ulcer Advisory Board was commissioned to provide guidance on the use of various treatment techniques for leg ulcer management. The result of this collaboration was the development of a recommended treatment pathway, which highlights the central role of compression in the treatment of venous leg ulceration[2] (Figure 1). This pathway is based on a combination of Cochrane systematic reviews, published guidelines and a review of approximately 150 published papers. Expert opinion was used to address issues where no reliable research data were available. In this paper, the treatment pathway will be discussed and the rationale behind the recommendations explored.

RECOMMENDED TREATMENT PATHWAY

Patient presents with suspected venous leg ulcer

↓

Non-invasive diagnostics
- Ankle-brachial pressure index (ABPI)
- Confirmation of venous disease
- Investigations to exclude other disorders

Assessment

Assessment is the key to effective leg ulcer treatment. Chronic venous insufficiency, diabetic complications and arterial insufficiency, when taken together, are responsible for over 90% of leg ulcers. It has been reported that patients with venous leg ulcers often have other complex pathologies, which may impact on treatment[3]. A detailed patient history provides clues as to the differential diagnosis, and physical examination is important to evaluate the size and characteristics of the wound and should highlight any associated medical conditions. The process of assessing a patient with lower limb ulceration is set out in a number of publications and features widely in the European and UK guidelines[4-6]. This should also include an evaluation of the patient's social circumstances as these may impact on both care and healing[7].

Risk

Failure to recognise arterial disease will result in the unsafe application of high compression therapy. Arterial perfusion should be evaluated using the hand-held Doppler to calculate the ankle-brachial pressure index (ABPI)[8]. Training and experience increases the accuracy of this assessment[9]. Pedal pulses should also be palpated, although this alone is an inadequate method of assessment[10]. Opinion would suggest that an ABPI <0.8 is usually taken to indicate that the patient is unsuitable for high compression bandaging. Evidence for the choice of 0.8 is lacking, yet most expert practitioners use this as a guide for the safe application of high compression[11]. However, an ABPI >0.8 does not always indicate that high compression bandaging can be undertaken safely and other factors may need to be considered before applying compression.

Factors to be considered before applying compression
Skin condition – delicate friable skin can be damaged by high levels of pressure
Shape of the limb – the sub-bandage pressure and the pressure gradient will be altered by the limb shape in accordance with Laplace's Law. Skin overlying exposed bony prominences may be subject to pressure damage
Presence of neuropathy – the absence of a protective response increases the risk of sub-bandage pressure damage
Presence of cardiac failure – rapid fluid shifts can be dangerous as it increases the preload of the heart

The ABPI may not always be reliable, particularly in patients with diabetes where vascular calcification can prevent arterial compression and falsely elevate arterial systolic pressure and therefore the ABPI. In these patients, Doppler waveforms and toe pressure analysis have been found to be more reliable[12]. Other modalities that may be useful include transcutaneous PO_2 and laser Doppler measurement of skin perfusion pressure[13,14]. Arterial perfusion should be re-evaluated on a regular basis in all patients receiving

1. Assistant Professor of Surgery, Medical Director, University of North Carolina Wound Management Clinic, University of North Carolina School of Medicine, Chapel Hill, North Carolina, USA. 2. Nurse Consultant (Acute and Chronic Wounds), Bradford Royal Infirmary, Bradford, UK.

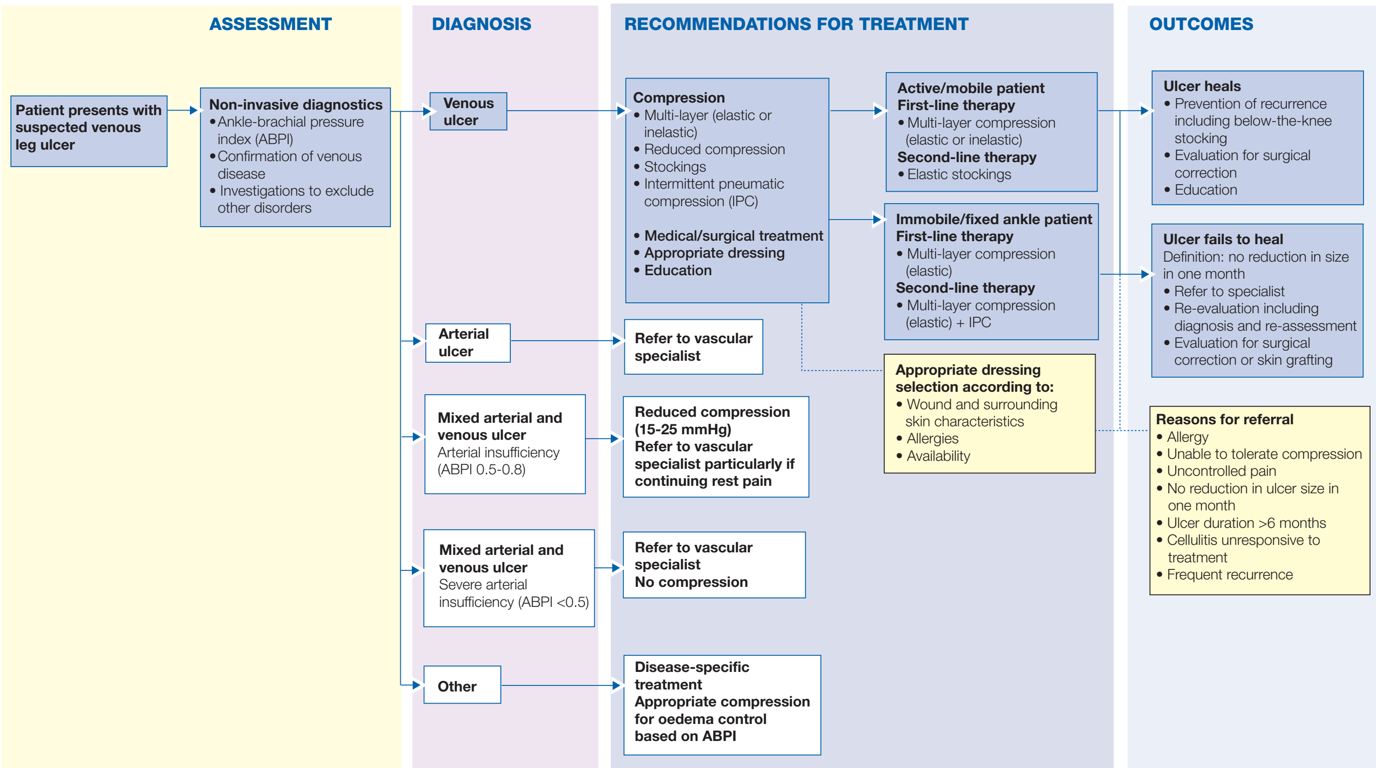

Figure 1 | **A recommended treatment pathway developed by the Leg Ulcer Advisory Board for the use of compression therapy in venous leg ulcers**

compression therapy, in particular in the elderly, in whom arterial disease is more common and may progress more rapidly[15].

The recommended treatment pathway also emphasises the importance of confirming the presence of venous disease. Factors other than chronic venous insufficiency, such as congestive heart failure, renal insufficiency, and morbid obesity may be responsible for limb oedema and chronic ulceration. The presence of venous disease may be confirmed using venous Duplex ultrasound or plethysmography[16,17].

Diagnosis

Following assessment, a leg ulcer can be assigned as follows:

- **Uncomplicated venous ulceration** – an ulcer occurring in the presence of venous disease in a limb with an ABPI >0.8 and no other significant medical diseases that would prevent the use of high compression therapy
- **Complicated venous ulceration** – an ulcer occurring in the presence of venous disease in a limb with an ABPI <0.8 or with other significant medical diseases that would prevent the use of high compression bandages or may complicate management. This includes:
  – **Mixed arterial and venous ulcer** (moderate arterial insufficiency with an ABPI 0.5-0.8). In a normotensive individual an ABPI 0.5 equates to an ankle systolic pressure of 65-75 mmHg and at such pressures high compression bandaging is potentially unsafe
  – **Mixed arterial and venous ulcer** (severe arterial insufficiency with an ABPI<0.5)
- **Arterial ulceration**
- **Other causes of ulceration**.

International Leg Ulcer Advisory Board: C Allegra (Italy); V Falanga (USA); M Fleur (Belgium); K Harding (UK); M Jünger (Germany); C Lindholm (Sweden); W Marston (USA); S Meaume (France); C Moffatt (UK); HAM Neuman (The Netherlands); H Partsch (Austria); T Phillips (USA); V Ruckley (UK); RG Sibbald (Canada); M Stacey (Australia); JE Torra i Bou (Spain); W Vanscheidt (Germany).

UNCOMPLICATED VENOUS ULCERS
Compression systems

High compression elastic bandages

These elastic, highly extensible (long-stretch) bandages expand or contract to accommodate changes in leg geometry during walking with the result that pressure changes over the calf are fairly small. They also sustain applied pressures for extended periods, even when the patient is at rest.

High compression inelastic bandages

These inelastic, minimally extensible (short-stretch) cotton bandages, when firmly applied, cannot accommodate changes in limb circumference. As a result, the pressures beneath such bandages tend to increase during the walking cycle as the calf muscle attempts to expand against the relatively rigid and inextensible fabric covering. The bandage therefore reinforces or supports the action of the calf muscle pump[18].

These bandages tend to have lower residual or resting pressures than more elastic bandages, making them inappropriate for use in immobile patients[19]. However, this may make them safer when the arterial supply is moderately impaired. They also require more frequent replacement[20] as they do not 'follow in' as the oedema is reduced and the leg dimensions decrease.

It is suggested that such bandages have a significant effect on deep venous haemodynamics when compared with elastic compression stockings, which exert their primary effect on the superficial venous system. Inelastic bandages may therefore be more effective in patients with extensive deep vein reflux (*see page 3*).

Multi-layer bandaging

There are a variety of multi-layer systems available. They all tend to have 3-4 layers and include either elastic or inelastic compression bandages, cohesive/adhesive bandages, crepe bandages and/or padding layers. The components in each system are different and have different extensibilities, powers and elasticities. It is possible that the success of elastic multi-layer compression systems is due to the fact that these generally contain a combination of bandages. The elastic bandage provides sustained compression and the cohesive/adhesive inelastic bandage offers rigidity and enhances the calf muscle pump function. The concept of multi-layer is that pressure is applied in layers, giving an accumulation of pressure.

Dynamic compression

The role of dynamic compression or intermittent pneumatic compression (IPC) in the management of lower limb venous ulcer disease has been reviewed[21]. Although much of the medical literature relates to the use of IPC in the prevention of deep vein thrombosis, there is some evidence that improvements in venous return due to the use of IPC may facilitate healing of venous leg ulcers. Eight small studies have been undertaken, which conclude that IPC may be of benefit, particularly when used in conjunction with compression bandaging, but as yet there is no statistically significant evidence for its routine use[22,23]. Theoretical analysis of the benefits of IPC, however, do suggest that it may be advantageous in the immobile patient with a slow or non-healing ulcer[21].

Recommended treatment options

Cullum *et al* performed an extensive literature search yielding 22 trials evaluating compression techniques[24]. From this it was concluded that these trials supported the use of compression therapy, with higher healing rates compared to no compression. High compression (ankle compression 35-45 mmHg) was more effective than low (reduced) compression (ankle compression 15-25 mmHg), and elastic or inelastic multi-layer systems were more effective than single-layer compression. There was no evidence of differences between hosiery, Unna's boot (paste bandage with either an elastic or inelastic overlay), inelastic and elastic multi-layer high compression bandaging[24].

To date, there appear to be few studies that have effectively compared the results obtained with elastic multi-layer and inelastic multi-layer high compression[25].

Based on the results of these randomised clinical trials, expert opinion and patient-related factors, the treatment pathway recommends a preference for multi-layer high compression systems for venous leg ulcers. In order to optimise care, the International Leg Ulcer Advisory Board has based decisions on both the physiological effects of bandaging on mobile and immobile patients and the differences in outcome between these two groups (i.e. immobile patients in whom healing is often difficult to achieve[26]).

Active/mobile patient
First-line therapy
- Multi-layer compression (elastic or inelastic)

Second-line therapy
- Elastic stockings

Immobile/fixed ankle patient
First-line therapy
- Multi-layer compression (elastic)

Second-line therapy
- Multi-layer compression (elastic) + IPC

Active and mobile patients

For active patients, either elastic or inelastic multi-layer compression is recommended. For patients who prefer the self-care option, elastic compression hosiery can be used as an alternative, particularly in those with smaller ulcers who do not need a bulky primary dressing.

Immobile patients

Elastic multi-layer compression is recommended for immobile patients or those with a fixed ankle joint. Compression with inelastic bandages is not recommended as these bandages cannot perform properly if the calf muscle pump is weak or ineffective as they will fail to generate adequate levels of compression. IPC may be used as an adjunct to elastic multi-layer compression when the ulcer is not healing as expected with compression bandaging alone, although the supporting evidence for this is limited[21,23].

Choosing an ideal compression system

In putting together this document, which draws upon current evidence and expert opinion, a number of criteria are proposed that should be considered as benchmarks for the ideal compression system in patients with uncomplicated venous ulcers.

Benchmarks for an ideal compression system
Clinical effectiveness – evidence-based treatment
Sustained compression – ability to provide and maintain clinically effective levels of compression for at least one week during walking and at rest
Enhances calf muscle pump function
Non-allergenic – account needs to be taken of known and likely allergens (e.g. latex hypersensitivity)
Ease of application and ease of training
Conformable and comfortable (non-slip)
Durable

Appropriate dressing selection according to:
- Wound and surrounding skin characteristics
- Allergies
- Availability

Appropriate dressing selection

A Cochrane systematic review recommends that for the majority of venous ulcers, a simple non-adherent, absorbent dressing offers sufficient ulcer protection under the compression system[24]. However, clinicians must choose an appropriate dressing according to the characteristics of the wound and surrounding skin, taking into account issues such as exudate and pain.

Reasons for referral
- Allergy
- Unable to tolerate compression
- Uncontrolled pain
- No reduction in ulcer size in one month
- Ulcer duration >6 months
- Cellulitis unresponsive to treatment
- Frequent recurrence

Other treatment considerations

In patients who fail to progress with high compression bandaging, who have venous ulcers complicated by co-existing arterial disease (ABPI<0.8), or who develop complications such as cellulitis, allergy, uncontrolled pain or who fail to tolerate compression therapy, referral to a specialist is necessary for further assessment and management.

MIXED ARTERIAL AND VENOUS ULCERS

For patients with an ABPI <0.5, compression therapy is not indicated and referral to a vascular specialist is recommended. Many of these patients may benefit from either arterial surgery or interventional radiology.

If the ulcer is classified as mixed, the ABPI is 0.5-0.8, and there is access to expert bandagers and teams with immediate access to vascular services, the patient may be treated with reduced compression of 15-25 mmHg. This has been proved to be an effective method of care[27,28]. An inelastic, short-stretch system may also be used which has a lower resting pressure, although this form of compression is less effective in the immobile patient.

Ischaemic rest pain is an absolute contraindication for compression therapy and an indication for urgent referral to a vascular specialist.

OTHER CAUSES

Other conditions such as rheumatoid arthritis, diabetes, renal failure, anaemia, infection, oedema, autoimmune disorders, pyoderma gangrenousum and malignancy are less common causes of leg ulceration. These patients require disease-specific treatments; compression, providing the ABPI is adequate, may also have a major part to play in the management of oedema in these conditions.

REASSESSMENT

The effectiveness of treatment should be evaluated continually by the multidisciplinary team in order to maximise the healing potential. The degree of improvement at four weeks has been related to eventual ulcer healing[29,30]. If the wound shows progress, with a measurable decrease in size at this time, it is reasonable to continue the initial therapy. However, if no measurable progress has been made, or there is a change in the patient's underlying medical status, a complete re-assessment should be performed. This should include reassessment of the venous and arterial systems and the appearance of the ulcer. Where indicated, bacterial culture and biopsy should be taken.

A reassessment of the patient's lifestyle and suitability of the chosen therapy should be undertaken. This may result in the use of an alternate form of compression or referral to a specialist for the consideration of venous surgery, or for patients with a reduced ABPI, arterial investigation.

Adjunctive treatments

Those patients with ulcers that show slow progress in the first 3-4 weeks of treatment or that fail to heal may benefit from the addition of adjunctive therapies to accelerate healing once other correctable causes of delayed healing have been investigated. It is, however, beyond the scope of this article to discuss these in detail, although it is worth mentioning that treatment with oxypentifylline has been shown to improve ulcer healing[31].

Factors affecting outcome

Delayed healing of venous leg ulcers

Much work is still needed to identify the clinical, social and psychological effects of compression on healing. Several studies have evaluated risk factors associated with delayed healing of venous leg ulcers treated with compression therapy[32,33]. Using multivariate analysis, Franks *et al*[7] identified three major factors that can delay ulcer healing: ulcer size, ulcer pre-treatment duration and limb mobility. Margolis *et al*[34] also examined factors affecting healing and suggested a simple scoring system to predict ulcer healing. While some authors propose a role for popliteal vein reflux as an independent risk factor[35-37], others such as Guest[38] suggest that this is not an important factor in delayed ulcer healing.

It has also been suggested that socio-economic factors, through an association with general health, nutritional status and adherence to treatment, may adversely affect healing rates[39]. The study by Franks *et al*[7] showed an association between social factors (social class, central heating, being male and being single) and venous ulcer healing, although further investigation is required to understand the precise mechanisms of these associations.

Ulcer heals
- Prevention of recurrence including below-the-knee stocking
- Evaluation for surgical correction
- Education

Ulcer fails to heal
Definition: no reduction in size in one month
- Refer to specialist
- Re-evaluation including diagnosis and re-assessment
- Evaluation for surgical correction or skin grafting

Patient participation with treatment

It is important for practitioners to encourage patients to participate actively in their treatment. This may improve concordance and aid healing[40]. The use of education and a holistic approach to care is important, as is an effective interaction between the healthcare professional and the patient if best outcomes are to be achieved. Adherence with treatment is also dependent upon patient motivation, which can be affected by factors such as social isolation or treatment discomfort[41]. Pain management is an often underestimated aspect of leg ulcer management. Effective symptom control either with dressings or analgesia can improve quality of life and patient tolerance of compression therapy[42].

Preventing recurrence

Unfortunately ulcer recurrence is common[43-45] with many patients experiencing multiple episodes of ulceration[46]. Moffatt and Dorman[47] identified factors that lead to re-ulceration. These include a history of a deep vein thrombosis, previous ulcer size and arterial hypertension. The mainstay of preventative treatment is hosiery[48] providing compression of 35-45 mmHg at the ankle. For patients who find it difficult to apply their garments, a lower level of compression (25-35 mmHg) or a combination of low compression hosiery may be used. Alternatives include the use of long-term elastic or inelastic bandaging. Sustained use of these techniques to prevent recurrent oedema results in a lower incidence of ulcer recurrence[49]. The higher the level of compression the patient can tolerate the lower the incidence of recurrence[50]. This does, however, depend on the regular use and replacement of prescribed hosiery.

The role of surgery in both the healing and prevention of venous leg ulceration is yet to be established; results published to date would suggest that surgery reduces ulcer recurrence[51,52] although further work, including randomised controlled studies, is required.

CONCLUSION

Multi-layer high compression bandaging has been shown unequivocally to provide a safe and highly effective treatment for the majority of patients with uncomplicated lower limb venous ulceration. Healing rates of up to 70% at 12 weeks can be obtained and when combined with a programme to prevent ulcer recurrence can dramatically improve patients' quality of life and reduce the burden of venous ulcer disease on healthcare systems.

Further work is needed to validate the benchmarking criteria used to define the ideal compression system proposed in this document. This will be helped by the development of an international classification system which is required to standardise terminology and ensure that the physical attributes of bandages are reflected in a common language.

The recommended treatment pathway developed by the International Leg Ulcer Advisory Board highlights the association between accurate assessment, detailed diagnosis and effective compression therapy in the management of uncomplicated venous leg ulcers. Using the recommended treatment pathway described, healthcare professionals can, by working together, develop their practice and ensure the highest standards of care for patients with lower leg ulceration.

KEY POINTS

1. High compression therapy is the cornerstone of management of venous leg ulcers.
2. The recommended treatment pathway highlights the importance of effective compression therapy, as well the need for accurate assessment and detailed diagnosis.
3. In patients with uncomplicated venous leg ulcers, decisions about which compression system to use should be based on whether the patient is mobile or immobile.
4. Criteria for an ideal compression system have been proposed and require validation.
5. To prevent ulcer recurrence patients require life-long compression therapy.
6. Patient-related and social factors, which may include treatment costs, must be taken into consideration when recommending compression therapy to achieve the best healing rates.

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